

Reason for report:
EARNINGS

ARDELYX, INC.

2Q EPS: Low Cash Burn & Milestone Payment from AZN

• **Bottom Line:** This morning ARDX reported 2Q'14 net income of ~\$3.8m vs. our est of -\$2.7m. The increase was attributed to the recognition of licensing revenue related to a 1x milestone payment from AZN (MP). In the press release the company provided updates on 1) the receipt of a \$25m milestone from AZN for the initiation of a Ph. 2b trial investigating tenapanor in ESRD-Pi 2) reiterated timelines for topline Ph. 2 data for its lead tenapanor programs 3) net proceeds from the company's recent IPO of ~\$61m which further boosted ARDX's cash balance to ~\$118m. We remain OP with a \$32/ shr price target.

• **No major pipeline updates; mgmt reiterated key dates for tenapanor programs.** Mgmt expects top line data from its Ph. 2b program for IBS-C in 4Q'14 & data from its Ph. 2b ESRD-Pi in 1H'15. ARDX is partnered with AZN for tenapanor and AZN has agreed to fully fund tenapanor's development. ARDX is eligible for up to ~\$200m in development milestones and tiered royalties (in teens) once approved.

• **Tenapanor targets kidney disease indications representing a significant market opportunity with many unmet needs.** Approx. ~300K dialysis patients in the US are taking phosphate binders and we expect this population to increase due to: 1) increase in obesity/ diabetes – 2 causes of end stage renal disease [ESRD]; 2) aging population. The US market in '13 for phosphate binders was approximately ~\$1 billion (net sales). There are significant unmet needs in this market. Current marketed products have many unwanted side effects such as: 1) GI issues; 2) hypercalcemia leading to vascular calcification; 3) pill burden – patients are required to take ~9-10 phosphate binders a day. We expect tenapanor to gain approx ~30% share and forecast risk adj. (probability of success [POS]: 35%) peak sales of ~\$148m by '30. ARDX also intends to develop tenapanor for chronic kidney disease (CKD) stage 3/4 pts (~2m pts in the US) and has blockbuster pot'l; we est risk adj. (POS: 25%) peak sales of ~\$660m in '30.

• **Cash burn was in line with our ests; recent IPO should provide ARDX enough runway to hit key milestones.** ARDX currently has ~\$118m in cash; total opex was ~\$6.4m vs our est. of ~\$7.7m and with a continued low burn rate and non-dilutive cash flow from the AZN deal – we expect ARDX to have enough resources to reach key milestones and provide investors upside over the next 1-2 yrs.

• **Changes to our model:** We updated our model to reflect 1) an increase in licensing revenue based on AZN milestone payments for FY'14 & 2) an updated share count.

Key Stats: (NASDAQ:ARDX)

S&P 600 Health Care Index:	1,286.06
Price:	\$12.36
Price Target:	\$32.00
Methodology:	Sum-of-the-parts DCF analysis
52 Week High:	\$21.60
52 Week Low:	\$12.13
Shares Outstanding (mil):	20.3
Market Capitalization (mil):	\$250.9
Book Value/Share:	\$0.00
Cash Per Share:	\$5.81
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	6.5A	8.8A	33.0	(0.23)A	0.18A	(0.08)	(0.05)	(0.11)	NM
2014E - Old	8.6A	5.0	5.5	5.0	24.0	(0.23)A	(0.20)	(0.15)	(0.15)	(0.72)	NM
2015E - New	--	--	--	--	50.0	--	--	--	--	(0.02)	NM
2015E - Old	--	--	--	--	50.0	--	--	--	--	(0.03)	NM
2016E - New	--	--	--	--	60.0	--	--	--	--	0.40	30.9x
2016E - Old	--	--	--	--	60.0	--	--	--	--	0.51	NM

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 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	91	23
Old	29	24	50	60	60	91	23
Difference	-	9.00	-	-	-	-	-
Total EPS Forecasts 2014-19E							
	2013	2014E	2015E	2016E	2017E	2018E	2019E
New	(0.65)	(0.11)	(0.02)	0.40	0.42	1.42	0.29
Old	(0.65)	(0.72)	(0.03)	0.51	0.53	1.81	0.37
Difference	-	0.61	0.01	(0.11)	(0.12)	(0.39)	(0.08)
Diluted share count 2014-19E							
	2013	2014E	2015E	2016E	2017E	2018E	2019E
New	10	20	23	23	26	27	27
Old	10	16	18	18	21	21	22
Difference	-	4	5	5	6	6	6

Source: Leerink Partners LLC estimates, company filings

VALUATION

Our ~\$32/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	3Q14E	4Q14E	2014E	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	-	-	-	-	-	-	-	-	-	-	2	5	7	10	12	11	14%
Total tenapanor royalties	-	-	-	-	-	-	-	-	-	-	6	23	50	90	118	137	29%
Licensing revenue	3	8	3.2	6.5	2.0	3.3	15	5	-	-	-	-	-	-	-	-	na
Collaborative development revenue	2	21	5.3	2.6	4.5	5.6	18	35	35	35	35	-	-	-	-	-	na
AZN milestones	-	-	-	-	-	-	-	10	25	25	50	-	-	-	-	-	na
Total Revenue (MM)	5	29	8.6	9.1	6.5	8.8	33	50	60	60	91	23	50	90	118	137	29%
% y/y growth	na	na	na	na	na	na	na	na	na	nm	51%	-75%	123%	80%	31%	16%	
COGS	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	na
% of sales	0	0%	na	na	na	na	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	na
Gross Income	5.4	28.9	8.6	9.1	6.5	8.8	33.0	50.0	60	60	91	23	50	90	118	137	29%
% of net sales	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	2.4	2.1	9.4	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	4.5	5.6	18.0	35	35	35	35	-	-	-	-	-	na
Total R&D	10.2	28.1	7.6	5.2	6.9	7.7	27.4	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%	106%	87%	83%	89%	74%	72%	47%	35%	16%	9%	7%	6%	
G&A	4.0	3.7	1.4	1.2	1.3	1.3	5.2	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	16%	14%	12%	12%	8%	33%	15%	8%	6%	5%	
Selling & Marketing	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	na
Total operating expenses	14.2	31.8	9.0	6.4	8.2	9.0	32.6	51.5	52.0	50.5	50.5	15.5	15.5	15.5	15.5	15.5	0%
Operating (loss)/gain	(8.8)	(2.9)	(0.5)	2.8	(1.7)	(0.2)	0.4	(1.5)	8.0	9.5	40.4	7.1	34.8	74.9	102.9	121.9	50%
% of sales	-163%	nm	na	na	na	na	1%	-3%	13%	16%	44%	31%	69%	83%	87%	89%	
Net financial expense	(1.0)	(3.6)	(2.6)	1.0	-	(1.0)	(2.6)	1.0	1.3	1.5	2.1	2.3	2.6	3.4	4.3	5.3	13%
Pre-tax Income	(9.8)	(6.4)	(3.1)	3.8	(1.7)	(1.2)	(2.2)	(0.5)	9.3	11.0	42.5	9.3	37.4	78.3	107.3	127.2	45%
% Pre-tax Margin	nm	nm	nm	nm	nm	nm	nm	nm	nm	18.4%	46.8%	41.4%	74.4%	86.6%	90.6%	92.6%	
Taxes (benefit)	-	0.1	-	-	-	-	-	-	-	-	4.3	1.4	7.5	19.6	32.2	44.5	64%
% 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%	
Net Income/(loss) (MM)	(10)	(7)	(3.1)	3.8	(1.7)	(1.2)	(2.2)	(1)	9	11	38	8	30	59	75	83	40%
% of net sales	NM	NM	N/M	41%	N/M	N/M	NM	nm	15.6%	18.4%	42.1%	35.2%	59.6%	65.0%	63.4%	60.2%	
Diluted EPS	(\$1.26)	(\$0.65)	(\$0.23)	\$0.18	(\$0.08)	(\$0.05)	(\$0.11)	(\$0.02)	\$0.40	\$0.42	\$1.42	\$0.29	\$1.07	\$2.06	\$2.58	\$2.78	38%
Y/Y	NM	NM					NM	NM	NM	5%	240%	-80%	270%	92%	25%	8%	
Weighted Avg Diluted Shares (MM)	7.8	10.2	13.3	20.3	22.0	24.0	19.9	22.9	23.3	26.4	26.9	27.4	28.0	28.6	29.1	29.7	1%
% growth	NM	31%					96%	15%	2%	13%	2%	2%	2%	2%	2%	2%	

Source: Leerink Partners, LLC estimates and company reports

Disclosures Appendix

Analyst Certification

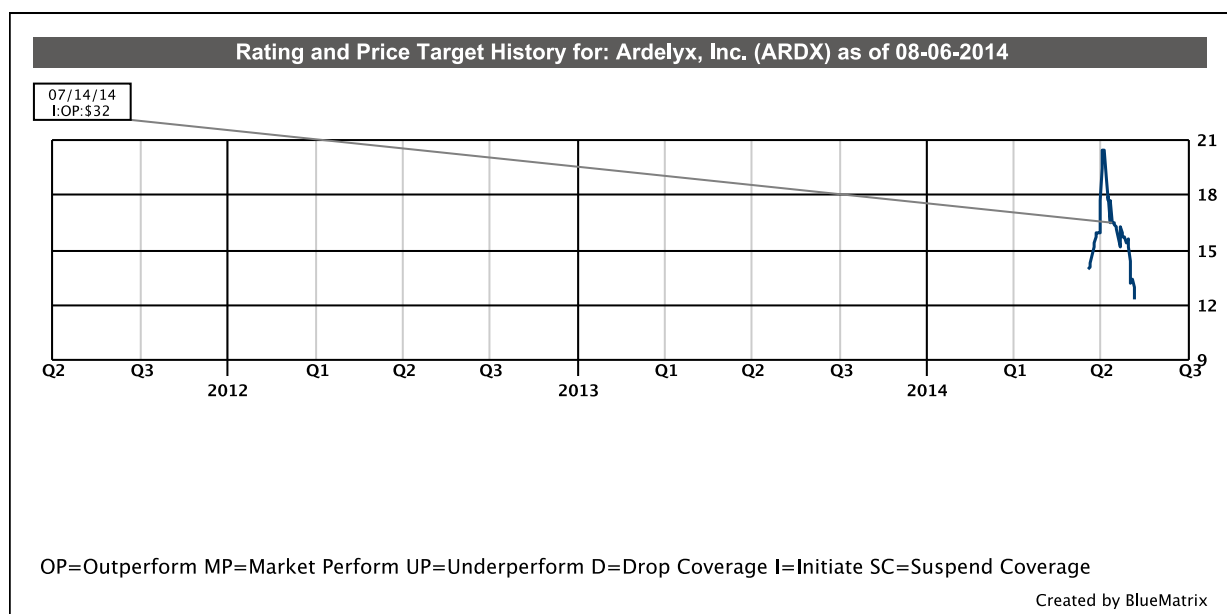
I, Jason M. Gerberry, JD, certify that the views expressed in this report accurately reflect my views and that no part of my compensation was, is, or will be directly related to the specific recommendation or views contained in this report.

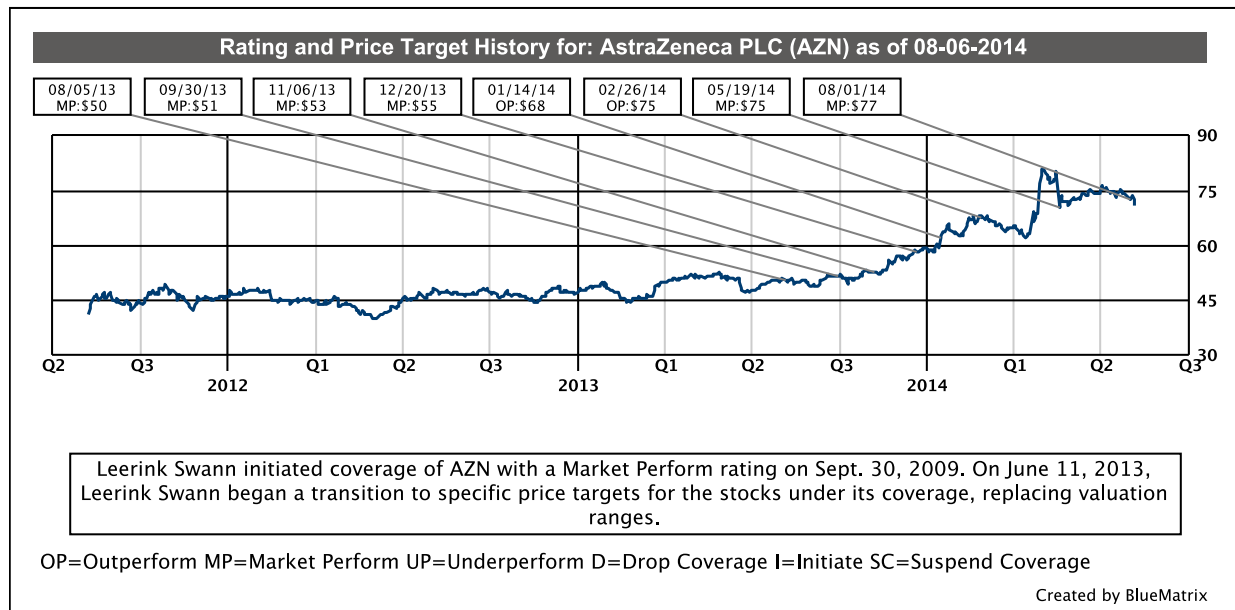
Valuation

Our ~\$32/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

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 06/30/14				
Rating	Count	Percent	IB Serv./Past 12 Mos.	
			Count	Percent
BUY [OP]	138	69.00	50	36.20
HOLD [MP]	62	31.00	2	3.20
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.

Like all Firm employees, analysts receive compensation that is impacted by, among other factors, overall firm profitability, which includes revenues from, among other business units, Institutional Equities, and Investment Banking. Analysts, however, are not compensated for a specific investment banking services transaction.

MEDACorp is a network of healthcare professionals, attorneys, physicians, key opinion leaders and other specialists accessed by Leerink and it provides information used by its analysts in preparing research.

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.

©2014 Leerink Partners LLC. All rights reserved. This document may not be reproduced or circulated without our written authority.

Leerink Partners LLC Equity Research

Director of Equity Research	John L. Sullivan, CFA	(617) 918-4875	john.sullivan@leerink.com
Associate Director of Research	Alice C. Avanian, CFA	(617) 918-4544	alice.avanian@leerink.com
Healthcare Strategy	John L. Sullivan, CFA	(617) 918-4875	john.sullivan@leerink.com
	Alice C. Avanian, CFA	(617) 918-4544	alice.avanian@leerink.com
Biotechnology	Howard Liang, Ph.D.	(617) 918-4857	howard.liang@leerink.com
	Joseph P. Schwartz	(617) 918-4575	joseph.schwartz@leerink.com
	Michael Schmidt, Ph.D.	(617) 918-4588	michael.schmidt@leerink.com
	Gena Wang, Ph.D., CFA	(212) 277-6073	gena.wang@leerink.com
	Jonathan Chang, Ph.D.	(617) 918-4015	jonathan.chang@leerink.com
	Paul Matteis	(617) 918-4585	paul.matteis@leerink.com
	Richard Goss	(617) 918-4059	richard.goss@leerink.com
Life Science Tools and Diagnostics	Dan Leonard	(212) 277-6116	dan.leonard@leerink.com
	Justin Bowers, CFA	(212) 277-6066	justin.bowers@leerink.com
Pharmaceuticals/Major	Seamus Fernandez	(617) 918-4011	seamus.fernandez@leerink.com
	Ario Arabi	(617) 918-4568	ario.arabi@leerink.com
	Aneesh Kapur	(617) 918-4576	aneesh.kapur@leerink.com
Specialty Pharmaceuticals	Jason M. Gerberry, JD	(617) 918-4549	jason.gerberry@leerink.com
Medical Devices, Cardiology & Orthopedics	Danielle Antalffy	(212) 277-6044	danielle.antalffy@leerink.com
	Puneet Souda	(212) 277-6091	puneet.souda@leerink.com
	Richard Newitter	(212) 277-6088	richard.newitter@leerink.com
	Ravi Misra	(212) 277-6049	ravi.misra@leerink.com
Healthcare Services	Ana Gupte, Ph.D.	(212) 277-6040	ana.gupte@leerink.com
Healthcare Technology & Distribution	David Larsen, CFA	(617) 918-4502	david.larsen@leerink.com
	Christopher Abbott	(617) 918-4010	chris.abbott@leerink.com
Sr. Editor/Supervisory Analyst	Mary Ellen Eagan, CFA	(617) 918-4837	maryellen.eagan@leerink.com
Supervisory Analysts	Robert Egan		bob.egan@leerink.com
	Amy N. Sonne		amy.sonne@leerink.com
Editorial	Cristina Diaz-Dickson	(617) 918-4548	cristina.diaz-dickson@leerink.com
Research Assistant	Carmen Augustine	(212) 277-6012	carmen.augustine@leerink.com

New York
299 Park Avenue, 21st floor
New York, NY 10171
(888) 778-1653

Boston
One Federal Street, 37th Floor
Boston, MA 02110
(800) 808-7525

San Francisco
201 Spear Street, 16th Floor
San Francisco, CA 94105
(800) 778-1164