

Reason for report:  
**EARNINGS**

## ARDELYX, INC.

### 4Q Update: Cash Burn in Line & CKD Data in 2Q; Remain OP

• **Bottom Line:** ARDX reported 4Q'14 financial results including cash burn of ~\$4m, in line with our estimate of ~\$3.8m. On the CC, mgmt provided updates on: (1) tenapanor -- Ph.2 data in chronic kidney disease (CKD) are still expected in 2Q'15; (2) ARDX plans to host an R&D day in mid-2015 to showcase the company's progress on its pre-clinical platforms; and (3) mgmt reiterated AZN (MP) will decide on the future development plans for tenapanor after the CKD trial reads out and AZN can view the totality of the data. ARDX ended the year with approximately ~\$107m in cash. We remain OP with a \$32/shr price target.

• **Heading into CKD Ph.2 data readout, we expect flexible dosing to help mitigate SEs.** Following tenapanor's Ph.2b ESRD-Pi top-line data that included higher-than-expected rates of diarrhea in the higher dose arms, we believe investors will be paying close attention to the GI side effect (SE) rates seen in the upcoming CKD trial. We expect to see lower rates of diarrhea mainly due to the fact that the CKD trial will employ a more flexible dosing regimen -- the trial is a dose escalating trial allowing pts to be titrated up/down from the starting dose of 15mg BID to as low as 5mg BID and as high as 30mg BID based on a patient's tolerability. The Ph.2 ESRD-Pi trial was a fixed dose study and contributed to the high rates of diarrhea seen at the 30mg dose. Future studies for ESRD-Pi will allow for dose escalation/de-escalation which we believe will help mitigate GI side effects while maintaining tenapanor's efficacy.

• **AZN expected to update on development plans after getting add'l data in 2Q.** On the CC, mgmt did not provide any update on when a potential decision would be made on the future of the three tenapanor programs. Mgmt remains bullish on all the programs and we expect once the CKD data is released in 2Q, AZN will consider the totality of the data from the trials to determine the next steps. ARDX is entitled to milestones of ~\$10m -- \$25m on the initiation of any clinical program(s) AZN plans to move forward with.

• **ARDX to hold an investor day to showcase its pre-clinical development engine.** Mgmt noted it plans to hold an investor R&D day in mid-2015 to provide more information on ARDX's pre-clinical programs. While a date has not been set, the company plans to provide more detailed updates on its proprietary pipeline focused in GI, cardio-renal, and metabolic diseases. ARDX has disclosed unpartnered programs for IBS-D, hyperkalemia and fluid overload indications, which we view as high value markets with significant unmet needs.

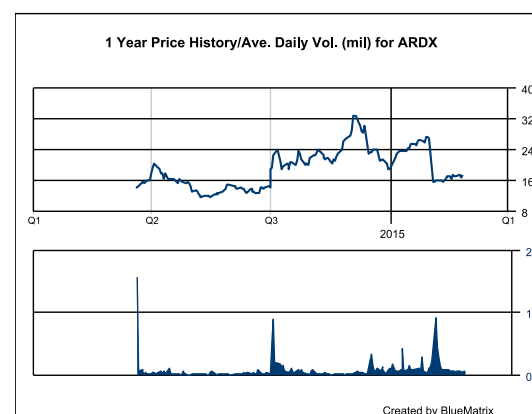
• **Changes to our model.** We updated our model to reflect: (1) a ~\$10m milestone payment in 3Q'15 (vs. 2Q'15 previously) as we assume AZN moves ahead with the IBS-C Ph.3 trial prior to the start of the end-stage renal disease (ESRD)/CKD trial, and (2) share count of the qtr.

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	8.7	9.3	20.3	11.7	50.0	( 0.18)	( 0.16)	0.36	( 0.14)	( 0.11)	NM
2015E - Old	8.7	19.3	10.3	11.7	50.0	( 0.17)	0.30	( 0.10)	( 0.20)	( 0.12)	NM
2016E - New	--	--	--	--	60.0	--	--	--	--	0.43	40.2x
2016E - Old	--	--	--	--	60.0	--	--	--	--	0.45	NM

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

### Key Stats: (NASDAQ:ARDX)

<b>S&amp;P 600 Health Care Index:</b>	<b>1,567.22</b>
<b>Price:</b>	<b>\$17.30</b>
Price Target:	\$32.00
Methodology:	Sum-of-the-parts DCF analysis, 15% discount rate
52 Week High:	\$35.48
52 Week Low:	\$11.37
Shares Outstanding (mil):	18.5
Market Capitalization (mil):	\$320.1
Book Value/Share:	\$0.00
Cash Per Share:	\$5.80
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 \$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-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							
	2014	2015E	2016E	2017E	2018E	2019E	2020E
New	32	50	60	60	90	19	36
Old	33	50	60	60	90	19	36
Difference	(1.38)	-	-	-	-	-	-
Total EPS Forecasts 2014-20E							
	2014	2015E	2016E	2017E	2018E	2019E	2020E
New	(0.31)	(0.11)	0.43	0.45	1.51	0.21	0.73
Old	(0.17)	(0.12)	0.45	0.47	1.56	0.21	0.75
Difference	(0.15)	0.00	(0.01)	(0.01)	(0.05)	(0.01)	(0.02)
Diluted share count 2014-19E							
	2014	2015E	2016E	2017E	2018E	2019E	2020E
New	10	21	22	24	25	25	26
Old	18	21	21	24	24	25	25
Difference	(8)	1	1	1	1	1	1

Source: Leerink Partners, Company Information

## 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 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	1Q14	2Q14	3Q14	4Q14	2014	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	8	3.2	6.5	4.8	3.9	18	1.2	1.3	1.3	1.2	5	-	-	-	-	-	-	-	-	na
Collaborative development revenue	21	5.3	2.6	2.8	2.5	13	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>29</b>	<b>8.6</b>	<b>9.1</b>	<b>7.6</b>	<b>6.3</b>	<b>32</b>	<b>8.7</b>	<b>9.3</b>	<b>20.3</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	nm	50%	-79%	88%	132%	49%	24%	
COGS	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	na
% of sales	0%	na	na	na	na	0%	na	na	na	na	0%	0%	0%	0%	0%	0%	0%	0%	0%	na
Gross Income	28.9	8.6	9.1	7.6	6.3	31.6	8.7	9.3	20.3	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%	
Discovery research	7.7	2.4	2.6	2.5	5.3	12.7	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	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	na
AZN collaboration dev expense	20.3	5.3	2.6	3.2	2.1	13.2	8.6	8.8	8.6	9.0	35.0	35.0	35.0	35.0	-	-	-	-	-	na
Total R&D	28.1	7.6	5.2	5.7	7.4	25.9	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	nm	89%	57%	75%	117%	82%	125%	121%	54%	97%	89%	74%	72%	48%	41%	22%	9%	6%	5%	
G&A	3.7	1.4	1.2	1.8	2.9	7.3	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	13%	na	na	na	na	23%	na	na	na	na	14%	12%	12%	8%	39%	21%	9%	6%	5%	
Selling & Marketing	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	na
Total operating expenses	31.8	9.0	6.4	7.5	10.3	33.2	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>(2.9)</b>	<b>(0.5)</b>	<b>2.8</b>	<b>0.1</b>	<b>(3.9)</b>	<b>(1.6)</b>	<b>(3.6)</b>	<b>(3.1)</b>	<b>8.0</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	nm	na	na	na	na	-5%	na	na	na	na	-3%	13%	16%	44%	20%	57%	82%	88%	90%	
<b>Net financial expense</b>	<b>(3.6)</b>	<b>(2.6)</b>	<b>1.0</b>	<b>(0)</b>	<b>0.0</b>	<b>(1.6)</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>(6.4)</b>	<b>(3.1)</b>	<b>3.8</b>	<b>0.1</b>	<b>(3.9)</b>	<b>(3.1)</b>	<b>(3.8)</b>	<b>(3.3)</b>	<b>7.8</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	18.4%	46.4%	31.7%	64.7%	85.7%	91.1%	93.5%	
Taxes (benefit)	0.1	-	-	-	0.1	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%	10.0%	15.0%	20.0%	25.0%	30.0%	35.0%	
<b>Net Income/(loss) (MM)</b>	<b>(7)</b>	<b>(3.1)</b>	<b>3.8</b>	<b>0.1</b>	<b>(4.0)</b>	<b>(3.2)</b>	<b>(3.8)</b>	<b>(3.3)</b>	<b>7.8</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	41%	NM	NM	NM	NM	-36%	NM	NM	nm	15.6%	18.4%	41.7%	26.9%	51.8%	64.3%	63.8%	60.7%	
<b>Diluted EPS</b>	<b>(\$5.82)</b>	<b>(\$0.23)</b>	<b>\$0.18</b>	<b>\$0.00</b>	<b>(\$0.21)</b>	<b>(\$0.31)</b>	<b>(\$0.18)</b>	<b>(\$0.16)</b>	<b>\$0.36</b>	<b>(\$0.14)</b>	<b>(\$0.11)</b>	<b>\$0.43</b>	<b>\$0.45</b>	<b>\$1.51</b>	<b>\$0.21</b>	<b>\$0.73</b>	<b>\$2.05</b>	<b>\$2.96</b>	<b>\$3.42</b>	<b>49%</b>
Y/Y	NM					NM					NM	NM	5%	234%	-86%	254%	182%	45%	15%	
Weighted Avg Diluted Shares (MM)	1.1	13.3	20.3	19.1	18.5	10.2	21.1	21.3	21.4	21.2	21.2	21.7	24.5	25.0	25.5	26.0	26.5	27.0	27.6	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

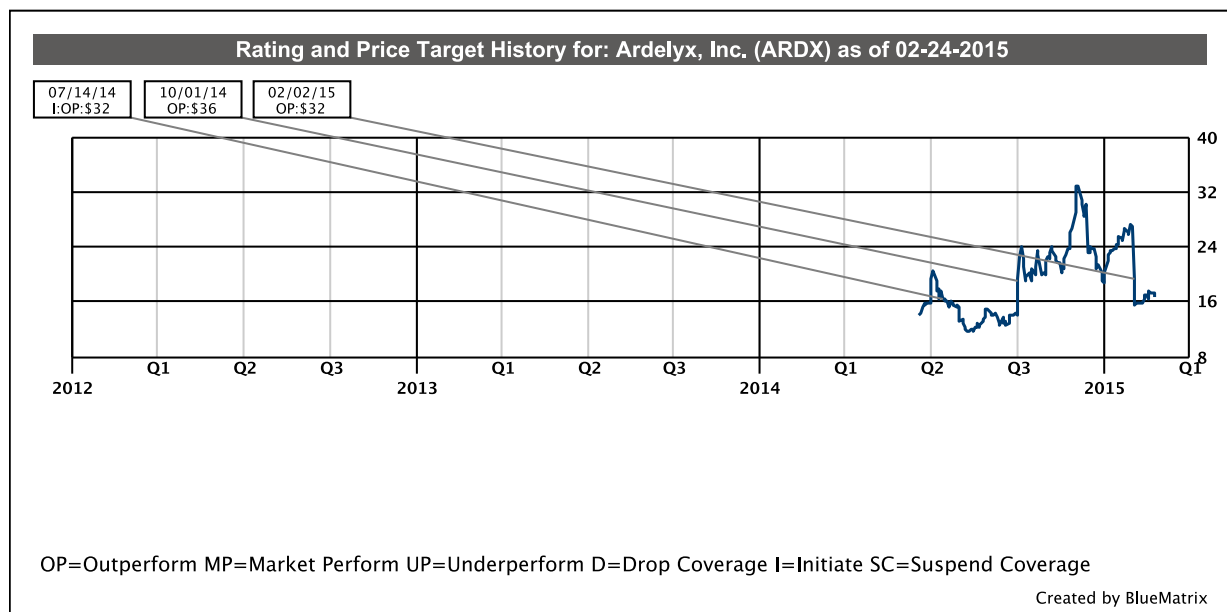
I, Jason M. Gerberry, JD, certify that the views expressed in this report accurately reflect my views and that no part of my compensation was, is, or will be directly related to the specific recommendation or views contained in this report.

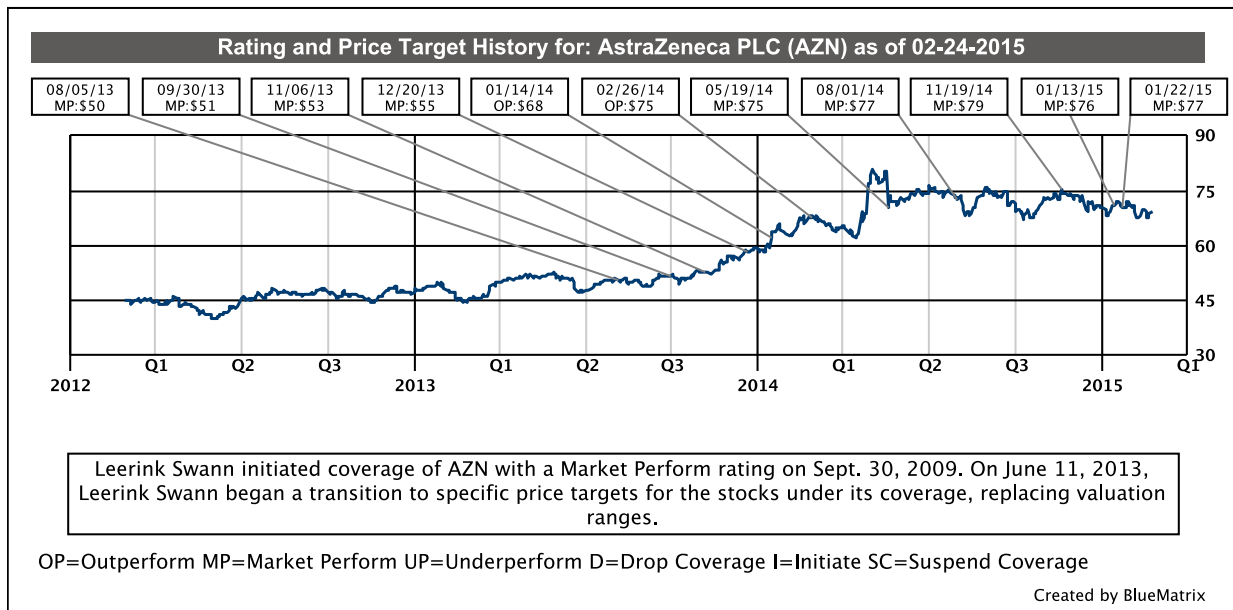
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### Risks to Valuation

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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

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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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**Leerink Partners LLC Equity Research**


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<b>Director of Equity Research</b>	<b>John L. Sullivan, CFA</b>	(617) 918-4875	john.sullivan@leerink.com
<b>Associate Director of Research</b>	<b>Alice C. Avanian, CFA</b>	(617) 918-4544	alice.avanian@leerink.com
<b>Healthcare Strategy</b>	<b>John L. Sullivan, CFA</b>	(617) 918-4875	john.sullivan@leerink.com
	<b>Alice C. Avanian, CFA</b>	(617) 918-4544	alice.avanian@leerink.com
<b>Biotechnology</b>	<b>Howard Liang, Ph.D.</b>	(617) 918-4857	howard.liang@leerink.com
	<b>Joseph P. Schwartz</b>	(617) 918-4575	joseph.schwartz@leerink.com
	<b>Michael Schmidt, Ph.D.</b>	(617) 918-4588	michael.schmidt@leerink.com
	<b>Gena Wang, Ph.D., CFA</b>	(212) 277-6073	gena.wang@leerink.com
	<b>Paul Matteis</b>	(617) 918-4585	paul.matteis@leerink.com
	Jonathan Chang, Ph.D.	(617) 918-4015	jonathan.chang@leerink.com
	Richard Goss	(617) 918-4059	richard.goss@leerink.com
<b>Life Science Tools and Diagnostics</b>	<b>Dan Leonard</b>	(212) 277-6116	dan.leonard@leerink.com
	Justin Bowers, CFA	(212) 277-6066	justin.bowers@leerink.com
<b>Pharmaceuticals/Major</b>	<b>Seamus Fernandez</b>	(617) 918-4011	seamus.fernandez@leerink.com
	Aneesh Kapur	(617) 918-4576	aneesh.kapur@leerink.com
<b>Specialty Pharmaceuticals</b>	<b>Jason M. Gerberry, JD</b>	(617) 918-4549	jason.gerberry@leerink.com
	Derek C. Archila	(617) 918-4851	derek.archila@leerink.com
<b>Medical Devices, Cardiology &amp; Orthopedics</b>	<b>Danielle Antalffy</b>	(212) 277-6044	danielle.antalffy@leerink.com
	Puneet Souda	(212) 277-6091	puneet.souda@leerink.com
	<b>Richard Newitter</b>	(212) 277-6088	richard.newitter@leerink.com
	Ravi Misra	(212) 277-6049	ravi.misra@leerink.com
<b>Healthcare Services</b>	<b>Ana Gupte, Ph.D.</b>	(212) 277-6040	ana.gupte@leerink.com
<b>Healthcare Technology &amp; Distribution</b>	<b>David Larsen, CFA</b>	(617) 918-4502	david.larsen@leerink.com
	Christopher Abbott	(617) 918-4010	chris.abbott@leerink.com
<b>Digital Health</b>	<b>Steven Wardell</b>	(617) 918-4097	steven.wardell@leerink.com
<b>Sr. Editor/Supervisory Analyst</b>	<b>Mary Ellen Eagan, CFA</b>	(617) 918-4837	maryellen.eagan@leerink.com
<b>Supervisory Analysts</b>	Robert Egan		bob.egan@leerink.com
	Amy N. Sonne		amy.sonne@leerink.com
<b>Editorial</b>	Cristina Diaz-Dickson	(617) 918-4548	cristina.diaz-dickson@leerink.com
<b>Research Associate</b>	Carmen Augustine	(212) 277-6012	carmen.augustine@leerink.com

**New York**  
299 Park Avenue, 21<sup>st</sup> floor  
New York, NY 10171  
(888) 778-1653

**Boston**  
**One Federal Street, 37<sup>th</sup> Floor**  
**Boston, MA 02110**  
**(800) 808-7525**

**San Francisco**  
201 Spear Street, 16<sup>th</sup> Floor  
San Francisco, CA 94105  
(800) 778-1164