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# Ardelyx Inc. (ARDX)

# Q2:14 Earnings, Multiple Near-Term Catalysts Ahead, Reiterate OUTPERFORM

- ARDX reported Q2 net income of \$3.8M and ended the quarter with \$117.8M in cash, boosted by net proceeds of \$61M from its June 19 IPO. Because development for its lead programs are being funded by partners, we forecast little to no cash burn for ARDX going forward.
- ARDX received a \$25M milestone payment from partner AstraZeneca in May, triggered by the start of a Phase IIb trial of tenapanor in hyperphosphatemia in ESRD patients on hemodialysis. Tenapanor is also currently being evaluated in Phase II trials for CKD and IBS-C.
- We expect near-term catalysts to focus investor interest. Data from all three Phase II tenapanor trials is expected in 2014/2015: data from the IBS-C study is expected in Q4:14, and data from the hyperphosphatemia and CKD studies are expected in H1:15 and H2:15, respectively.
- We expect clinical success for tenapanor. We believe tenapanor's dual inhibition of sodium and phosphorus uptake and the subsequent reduction in water absorption will produce a clinical benefit in patients suffering from excessive levels of phosphorus and sodium in serum. The diversion of minerals and water into the stool should also aid in the treatment of constipation-related symptoms. Considering that the financial risk for its programs has been assumed by partners and the large market size of the indications its drugs are targeting, we believe ARDX has a very attractive risk/reward ratio.
- Reiterate OUTPERFORM rating and \$31 price target. Our price target of \$31 is derived by applying a 6 multiple to ARDX's share of 2022 tenapanor sales in the US, added to a 15 multiple of the royalty ARDX is expected to receive in 2022 for ex-US sales of tenapanor.

Risks to the achievement of our price target include clinical or regulatory failure for tenapanor and failure to achieve sales or earnings estimates.

**FYE Dec** 2014E 2015E 2013A REV ACTUAL CURR. PREV. CONS. CURR. PREV. CONS. Q1 Mar 8.6A N/AA 12.0E 15.3E \$14.3E 9.2A 14.0E 17.3E 25.6E Q2 Jun 9.1A 11.2A Q3 Sep 8.4E 11.5E 9.7E 20.6E 23.8E 19.2E Q4 Dec 8.5E 11.8E 9.8E 22.6E 25.8E 33.2E Year\* 28.9A 34.6E 43.0E \$37.3E 69.2E 82.2E 78.3E Change 19% 100% 0E

	2013A		2014E			2015E	
EPS	ACTUAL	CURR.	PREV.	CONS.	CURR.	PREV.	CONS.
Q1 Mar		(\$2.44)A			\$0.24E	\$0.21E	\$0.10E
Q2 Jun		\$0.20A	\$3.86A	(\$0.00)A	\$0.23E	\$0.14E	\$0.64E
Q3 Sep		\$0.13E	\$0.11E	\$0.02E	\$0.27E	\$0.25E	\$0.09E
Q4 Dec		\$0.12E	\$0.10E	\$0.01E	\$0.23E	\$0.21E	\$0.78E
Year*	(\$5.82)A	\$0.52E	\$1.06E	(\$0.35)E	\$0.97E	\$0.81E	\$1.42E
P/E							
Change		109%			87%		

Consensus estimates are from Thomson First Call.

August 8, 2014

Price

\$12.03

Rating

# **OUTPERFORM**

# 12-Month Price Target **\$31**

David M. Nierengarten, Ph.D. (415) 274-6862 david.nierengarten@wedbush.com

Dilip Joseph (415) 273-7308 dilip.joseph@wedbush.com

Liana Moussatos, Ph.D. (415) 263-6626 liana.moussatos@wedbush.com

Company Information	
Shares Outst (M)	18.3
Market Cap (M)	\$220.6
52-Wk Range	\$12.13 - \$21.60
Book Value/sh	\$N/A
Cash/sh	\$6.43
Enterprise Value (M)	\$102.8
LT Debt/Cap %	0.0
Cash Burn (M)	\$0.0

### **Company Description**

Ardelyx Inc. is developing small-molecule drugs for the treatment of cardio-renal, GI and metabolic diseases. Its lead product candidate, tenapanor, is in three ongoing Phase II trials for ESRD, CKD and IBS-C.



Source: Thomson Reuters

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<sup>\*</sup> Numbers may not add up due to rounding.



#### **Investment Thesis**

Ardelyx (NASDAQ:ARDX) is a clinical-stage company focused on developing small-molecule drugs that act locally within the gastrointestinal (GI) tract for the treatment of cardio-renal, GI and metabolic disorders. Its lead drug candidate, tenapanor, is an oral, non-absorbed inhibitor of NHE3, a sodium transporter expressed in the GI tract. Tenapanor is being developed to treat hyperphosphatemia in end-stage renal disease (ESRD) and late-stage chronic kidney disease (CKD), as well as constipation predominant irritable bowel syndrome (IBS-C). Clinical studies have demonstrated tenapanor's ability to reduce the absorption of dietary sodium and phosphorus and to increase the frequency of bowel movements, key factors in reducing the progression of kidney disease and alleviating the symptoms of IBS-C. AstraZeneca has licensed worldwide rights to tenapanor, while Ardelyx is eligible for milestones and royalties and retains US co-promotion rights.

### **Upcoming Milestones**

Q4:14 Data from Phase 2b trial to treat IBS-C

H1:15 Data from Phase 2b trial to treat hyperphosphatemia in ESRD patients

H2:15 Data from a Phase 2a trial to treat late-stage CKD

H2:15 Potential start of pivotal Phase 3 trial(s) of tenapanor in hyperphosphatemia

H2:15 Potential start of Phase 2b trial of tenapanor to treat CKD

#### **Financial Model**

8/7/2014

Ticker: (ARDX:Nasdaq)

Ardelyx, Inc

#### Wedbush PacGrow Life Sciences

David M. Nierengarten, Ph.D.

415-274-6862

415-274-6862															
	2012	2013	Q1	Q2	Q3	Q4	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E
Revenues:															
US Product Sales	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$10,264	\$119,751	\$277,496	\$517,752	\$800,125
ex-US royalties	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$5,482	\$26,086	\$52,235	\$87,696
Licensing and other revenue	\$3,182	\$8,063	\$3,236	\$6,507	\$5,609	\$5,609	\$20,961	\$39,578	\$84,720	\$52,284	\$52,284	\$66,000	\$66,000	\$42,000	\$42,000
Collaborative development revenue	\$2,228	\$20,865	\$5,314	\$2,630	\$2,762	\$2,900	\$13,605	\$29,598	\$51,289	\$62,342	\$70,392	\$76,195	\$82,475	\$89,274	\$96,633
Total Revenues	5,410	28,928	8,550	9,137	8,371	8,509	34,566	69,176	136,009	114,626	132,940	267,428	452,058	701,261	1,026,454
Cost and Expenses:					_	_	_	_							
Cost of Sales	0	0	0	0	0	0	0	0	0	0	1,026	11,975	,	51,775	80,012
R&D	10,184	28,093	7,637	5,183	5,372	5,666	23,858	43,428	87,971			205,748		295,762	357,320
SG&A	4,031	3,700	1,377	1,203	1,275		5,207	6,268					94,813	154,877	225,470
Total Operating Expenses	14,215	31,793	9,014	6,386	6,647	7,018	29,065	49,696	95,885	147,235	189,215	273,100	368,596	502,415	662,803
Operating Income (Loss)	(8,805)	(2,865)	(464)	2,751	1,724	1,491	5,501	19,480	40,124	(32,610)	(56,275)	(5,672)	83,461	198,846	363,651
Net Interest Income (Expense)	(30)	(52)	(4)	(8)	884	909	1,781	3,893	5,046	5,688	5,876	4,541	4,991	7,286	11,948
Other non-operating Income (Expense)	(950)	(3,506)	(2,603)	1,010	0	0	0	0	0	0	0	0	0	0	0
Income Before Income Taxes	(9,785)	(6,423)	(3,071)	3,753	2,607	2,400	7,282	23,374	45,170	(26,922)	(50,399)	(1,132)	88,452	206,132	375,599
Provision for Income Taxes	0	141	0	0	138	127	265	5,477	15,810	0	0	595	14,690	72,146	131,460
Net Income (Loss)	(9,785)	(6,564)	(3,071)	3,753	2,469	2,273	7,017	17,897	29,361	(26,922)	(50,399)	(1,726)	73,762	133,986	244,139
GAAP EPS	(11.32)	(5.82)	(2.44)	0.20	0.13	0.12	0.52	0.97	1.58	(1.37)	(2.55)	(0.09)	3.70	6.69	12.12
Total Shares Outstanding	864	1,128	1,256	18,336	18,336	18,336	18,336	18,436	18,536	19,636	19,736	19,836	19,936	20,036	20,136
Cash Burn	0	0	0	0	0	0	0	0	0	(10,736)	_	(12,729)	0	0	0
Cash Balance	32,903	34,435	33,221	117,814	121,263	123,204	123,204	140,720	169,156	195,620	147,740	135,011	189,952	293,411	500,829



### Analyst Biography

David Nierengarten, Ph.D.

David is an Analyst covering stocks in the Biotechnology/Biopharmaceuticals/BioDefense sector. His prior sell-side research experience at Robert W. Baird & Co. covered biotechnology companies of all market capitalizations, with a focus on oncology and rare diseases.

David received his B.S. (Biochemistry) from the University of Wisconsin-Madison and Ph.D. (Molecular and Cell Biology) from the University of California-Berkeley.

David's Edge: David's early stage venture capital investing experience gives him a balanced perspective on developmental-stage biotechnology companies and their ultimate risk/reward potential. His experience on the other side of that equation in a clinical-stage, venture backed biotechnology company provides him with insights into corporate operations. The combination of experiences creates a focus on value creation in this event-driven space.

#### **Analyst Certification**

I, David M. Nierengarten, Ph.D., Dilip Joseph, Liana Moussatos, Ph.D., certify that the views expressed in this report accurately reflect my personal opinion and that I have not and will not, directly or indirectly, receive compensation or other payments in connection with my specific recommendations or views contained in this report.

Disclosure information regarding historical ratings and price targets is available at http://www.wedbush.com/ResearchDisclosure/DisclosureQ214.pdf

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Outperform: Expect the total return of the stock to outperform relative to the median total return of the analyst's (or the analyst's team) coverage universe over the next 6-12 months.

Neutral: Expect the total return of the stock to perform in-line with the median total return of the analyst's (or the analyst's team) coverage universe over the next 6-12 months.

Underperform: Expect the total return of the stock to underperform relative to the median total return of the analyst's (or the analyst's team) coverage universe over the next 6-12 months.

The Investment Ratings are based on the expected performance of a stock (based on anticipated total return to price target) relative to the other stocks in the analyst's coverage universe (or the analyst's team coverage).\*

Rating Distribution (as of July 30, 2014)	Investment Banking Relationships (as of June 30, 2014)
Outperform:54%	Outperform:25%
Neutral: 42%	Neutral: 1%
Underperform: 4%	Underperform: 0%

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# Wedbush Equity Research Disclosures as of August 8, 2014

ſ	Company	Disclosure
	Ardelyx Inc.	1,3,5,7

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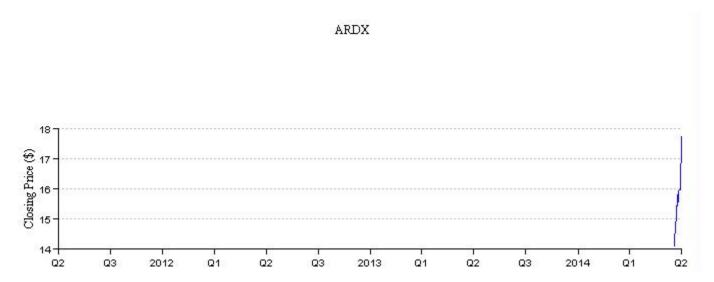
David M. Nierengarten, Ph.D. (415) 274-6862



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- 12. The analyst maintains Contingent Value Rights that enables him/her to receive payments of cash upon the company's meeting certain clinical and regulatory milestones.

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\* WS changed its rating system from (Strong Buy/Buy/Hold/Sell) to (Outperform/ Neutral/Underperform) on July 14, 2009. Please access the attached hyperlink for WS' Coverage Universe: <a href="http://www.wedbush.com/services/cmg/equities-division/research/equity-research">http://www.wedbush.com/services/cmg/equities-division/research/equity-research</a> Applicable disclosure information is also available upon request by contacting Ellen Kang in the Research Department at (213) 688-4529, by email to <a href="mailto:ellen.kang@wedbush.com">ellen.kang@wedbush.com</a>, or the Business Conduct Department at (213) 688-8090. You may also submit a written request to the following: Business Conduct Department, 1000 Wilshire Blvd., Los Angeles, CA 90017.

# **OTHER DISCLOSURES**

# RESEARCH DEPT. \* (213) 688-4505 \* www.wedbush.com

EQUITY TRADING Los Angeles (213) 688-4470 / (800) 421-0178 \* EQUITY SALES Los Angeles (800) 444-8076 CORPORATE HEADQUARTERS (213) 688-8000

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# **EQUITY RESEARCH DEPARTMENT**

(213) 688-4529

#### DIRECTOR OF RESEARCH

Mark D. Benson (213) 688-4435

#### MANAGER, RESEARCH OPERATIONS

Ellen Kang (213) 688-4529

RETAIL AND CONSUMER	RF1	ΓΔΙΙ	ΔND	CONSU	MFR
---------------------	-----	------	-----	-------	-----

**Consumer Products** 

Rommel T. Dionisio (212) 938-9934 Alicia Reese (212) 938-9927

Footwear, Apparel and Accessories

Corinna Freedman (212) 668-9876

**Healthy Lifestyles** 

Kurt M. Frederick, CFA CPA (415) 274-6822 Alicia Reese (212) 938-9927

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Nick Setyan (213) 688-4519 Colin Radke (213) 688-6624

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Joan L. Storms, CFA (213) 688-4537 John Garrett, CFA (213) 688-4523

Seth Basham, CFA (212) 938-9954

Specialty Retail: Softlines

Morry Brown (213) 688-4311 Taryn Kuida (213) 688-4505

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(213) 688-4539

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James Kim (213) 688-4380

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Steve Koenig (415) 274-6801 Kevin Ikeda (213) 688-4423

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Michael Pachter (213) 688-4474
Nick McKay (213) 688-4343
Nick Citrin (213) 688-4495

**Entertainment: Software** 

Michael Pachter (213) 688-4474
Nick McKay (213) 688-4343
Nick Citrin (213) 688-4495

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Michael Pachter (213) 688-4474 Nick McKay (213) 688-4343 Nick Citrin (213) 688-4495

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Shyam Patil, CFA (213) 688-8062 Andy Cheng (213) 688-4548

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Betsy Van Hees (415) 274-6869 Ryan Jue, CFA (415) 263-6669

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David M. Nierengarten, Ph.D. (415) 274-6862 Dilip Joseph (415) 273-7308

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Liana Moussatos, Ph.D. (415) 263-6626

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Los Angeles (213) 688-4470 / (800) 444-8076 Los Angeles

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**CORPORATE HEADQUARTERS** 

1000 Wilshire Blvd., Los Angeles, CA 90017-2465 Tel: (213) 688-8000 www.wedbush.com

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