Ardelyx Inc. (ARDX)

4Q14 Earnings, Oversold Shares Provides Attractive Entry Point, Reiterate OUTPERFORM

- **ARDX reported a $4.0M net loss ($0.21 EPS) for 4Q, and held $107M in cash at YE14.** Earnings came in below our expectation of a profit of $0.09; consensus was $0.02. We expect ARDX to return to profitability in 1Q15 as the winding down of the Ph 2 clinical program for tenapanor reduces R&D spend.
- **We expect data from the diabetic nephropathy study in 2Q15 to better quantify what the actual diarrhea rates are with tenapanor.** The randomized double-blind Ph 2a study is evaluating the safety and PD of 5-60 mg tenapanor in 154 CKD patients with type 2 diabetes and albuminuria. The primary endpoint is reduction in albuminuria from baseline to week 12 as measured by UACR (urine albumin to creatinine ratio); secondary endpoints include additional markers related to kidney function like estimated glomerular filtration rate (eGFR). Importantly, the weekly stool frequency will also be measured, which should provide insight into what the actual increase in bowel movements (BM) is with tenapanor use. Note that stool frequency was not measured in the Ph 2b ESRD study; instead, patient reports of diarrhea were used to determine diarrhea rates. Given that constipation is common in ESRD patients, an increase in BM while on tenapanor could have been interpreted by patients to be diarrhea even while the frequency of BMs remained within normal range (3-21 BM/week). The CKD study will also allow for dose titration: the starting dose is set at 15mg BID, and patients can escalate to 30 or 60 mg or titrate down to the 5mg dose. We believe the more flexible dosing used in the CKD study is a closer approximation of the real-world usage of tenapanor, and expect the data to provide color on the actual real world safety of tenapanor.
- **We maintain that there is a path forward in ESRD.**
- **Our investment thesis on ARDX remains intact.** We believe that after accounting for the titratability of tenapanor, its clean safety record in regards to nausea/vomiting, and its lowered pill burden and ease of use (no need to take it with meals), tenapanor is an improvement over currently available therapies for hyperphosphatemia. With ARDX currently trading near what we believe the IBS-C indication alone is worth (~$15/share), we view the shares as providing investors with a near-free call option on the renal program.
- **Reiterate OP rating and $31 price target.** Our PT 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.

FYE Dec	2013A	2014A			2015E		
REV	ACTUAL	CURR.	PREV.	CONS.	CURR.	PREV.	CONS.
Q1 Mar	--	8.6A		N/AA	10.6E	12.1E	$18.0E
Q2 Jun	--	9.1A		9.1A	10.6E	14.1E	15.8E
Q3 Sep	--	7.6A		7.6A	17.1E	20.7E	15.2E
Q4 Dec	--	6.3A	8.6A	9.6A	19.1E	22.7E	25.0E
Year*	**28.9A**	**31.6A**	**33.9A**	**$35.2A**	**57.4E**	**69.5E**	**73.9E**
Change	--	9%			81%		
	2013A	2014A			2015E		
EPS	ACTUAL	CURR.	PREV.	CONS.	CURR.	PREV.	CONS.
Q1 Mar	--	($2.44)A		--	$0.15E	$0.20E	$0.43E
Q2 Jun	--	$0.20A		$0.18A	$0.13E	$0.19E	$0.19E
Q3 Sep	--	$0.00A		$0.00A	$0.30E	$0.36E	$0.10E
Q4 Dec	--	($0.21)A	$0.09A	$0.02A	$0.23E	$0.20E	$0.49E
Year*	**($5.82)A**	**($0.31)A**	**$0.23A**	**$0.10A**	**$0.80E**	**$0.95E**	**$1.61E**
P/E	--	--			--		
Change	--	95%			356%		

Consensus estimates are from Thomson First Call. * *Numbers may not add up due to rounding.*

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Price
$17.30

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

Company Information

Shares Outst (M)	18.5
Market Cap (M)	$319.6
52-Wk Range	$11.37 - $35.48
Book Value/sh	$3.44
Cash/sh	$5.81
Enterprise Value (M)	$212.3
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

Risks to the achievement of our price target include clinical failure for tenapanor, the risk that AstraZeneca chooses to withdraw from the tenapanor collaboration, regulatory failure for tenapanor, and failure to achieve sales or earnings estimates.

We maintain that there is a path forward in ESRD. ARDX said that Astra is waiting for the CKD study to readout and will weigh the totality of data from the Ph 2 studies before deciding on the future development of tenapanor. We view the likelihood of Astra returning the rights to the program as highly unlikely, given the high responses and safety observed in the Ph 2b IBS-C study that are competitive with currently available therapies (see Fig. 1). There is a risk that Astra could choose to focus development efforts solely on IBS-C going forward, but we believe this unlikely as well, since the renal applications for tenapanor were the primary draw for Astra when they entered into the collaboration in 2012. We also believe that the current ESRD dataset is not as negative as many investors perceive. Both the 10mg and 30mg BID doses in the Ph 2b study produced a >1.5mg/dL decrease in serum phosphate levels (see Fig. 2), which is considered the approvable endpoint for treating hyperphosphatemia. However, only the 30mg dose had a high discontinuation rate due to diarrhea (32%), with the 13% discontinuation rate for the 10mg dose coming in below what has been reported in studies of Renvela (27%, although differences in trial design make a direct comparison difficult). We also note that no nausea or vomiting were observed with the 10 and 30mg BID doses of tenapanor, vs rates of ~20% with Renvela (see Fig. 3 and 4). We believe the design of any potential Ph 3 study in ESRD is likely to be more primed for success, ie. moving away from fixed dosing to allow for titration, and more accurately assessing diarrhea through stool frequency measurements.

Figure 1: Comparing Linzess to Tenapanor in IBS-C

	Linzess, oral (290ug once-daily)	Tenapanor, oral (50mg twice-daily)
Trial	Ph 3 (n=804, 401 in Linzess arm)	Ph 2b (n=371, about 93 each in placebo and 50mg arms)
Overall Responder Rate* (primary regulatory endpoint in the US and EU)	34%, vs 14% for placebo (p<0.0001)	50%, vs 24% for placebo (p<0.001)
Rates of diarrhea	20%, vs 2% for placebo	11%, vs 0% for placebo

*defined as an increase (from baseline) of at least 1 complete spontaneous bowel movement per week for at least 6/12 weeks on study and at least a 30% reduction in abdominal pain

Source: Wedbush Securities, Inc.

Figure 2: Dose-Related Decrease in Serum Phosphate Levels with Tenapanor in Ph 2b ESRD Study

Group	n	LSMean*	95% CI
1 mg BID	23	-0.47	(-1.18, 0.24)
3 mg BID	21	-1.18	(-1.93, -0.44)
10 mg BID	23	-1.70	(-2.41, -0.99)
30 mg BID	24	-1.98	(-2.67, -1.28)
3 mg QD	22	-0.56	(-1.28, 0.17)
30 mg QD	21	-1.11	(-1.85, -0.37)
Placebo	26	-0.54	(-1.21, 0.13)

*LSMean = Least square mean. Change from Baseline at End of Treatment (mg/dL)

Source: Company data

Figure 3: Discontinuation Rate in Ph 2b ESRD Study

Adverse Event Term	1 mg BID	3 mg BID	10 mg BID	30 mg BID	3 mg QD	30 mg QD	Placebo
n/group	23	21	23	25	22	21	26
Discontinuations due to AE/group**	3	3	3	9	1	7	2
Abdominal Pain				1			
Diarrhea*	2	3	3	8		6	
Nausea						1	
Vomiting						1	
Serum Calcium Decrease					1		
Hyperphosphatemia	1				1		2
Dizziness						1	
Atherosclerosis		1					

*The term "diarrhea" also includes similar changes in stool form or bowel habits
**There may be multiple reasons for a single discontinuation

Source: Company data

Figure 4: GI-Related AEs with Approved ESRD Therapies

Adverse Events*	Renvela®#	Fosrenol®**	Auryxia®
Abdominal Pain	9%	5%	
Constipation	8%		8%
Diarrhea	19%		21%
Nausea	20%	11%	11%
Vomiting	22%	9%	7%

Source: Company data

Milestones

2Q15	Data from Ph 2a study in CKD patients with Type II diabetes and albuminuria
Mid15	Updates regarding earlier stage pipeline at ARDX R&D Day
Mid15/2H15	AstraZeneca to decide on future development plans for tenapanor, and potential start of registration-studies for ESRD, CKD and IBS-C (triggers $20M milestone payment, $10M if only IBS-C indication pursued)

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.

Figure 5: Valuation Table

Product	Indication	Forecasted 2022 Sales	ARDX Share*	Multiple/Discount	Value per Share
Tenapanor	ESRD	$255M (US)	50%	6x / 35%	$6.15
		$251M (Europe/Japan)	12%	15x / 35%	
	Stage 3b/4 CKD	$522M (US)	50%	6x / 35%	$9.50
		$174M (Europe/Japan)	12%	15x / 35%	
	IBS-C	$823M (US)	50%	6x / 35%	$15.27
		$306M (Europe/Japan)	12%	15x / 35%	
				Total	$30.93

** we assume ARDX exercises US co-promotion option*

Source: Wedbush Securities, Inc.

Financial Model

2/25/2015
Ticker: (ARDX:Nasdaq)
Ardelyx, Inc

Wedbush PacGrow Life Sciences
David M. Nierengarten, Ph.D.
415-274-6862

	Q1	Q2	Q3	Q4	2014	Q1	Q2	Q3	Q4	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E
Revenues:																	
US Product Sales	$0	$0	$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	$0	$0	$5,482	$26,086	$52,235	$87,696
Licensing and other revenue	$3,236	$6,507	$4,767	$3,884	$18,394	$8,109	$8,109	$11,680	$11,680	$39,578	$84,720	$52,284	$52,284	$66,000	$66,000	$42,000	$42,000
Collaborative development revenue	$5,314	$2,630	$2,831	$2,454	$13,229	$2,454	$2,454	$5,454	$7,454	$17,816	$36,438	$44,290	$50,010	$54,132	$58,594	$63,424	$68,653
Total Revenues	**8,550**	**9,137**	**7,598**	**6,338**	**31,623**	**10,563**	**10,563**	**17,134**	**19,134**	**57,394**	**121,158**	**96,574**	**112,558**	**245,365**	**428,177**	**675,411**	**998,473**
Cost and Expenses:																	
Cost of Sales	0	0	0	0	0	0	0	0	0	0	0	0	1,026	11,975	27,750	51,775	80,012
R&D	7,637	5,183	5,694	7,386	25,900	5,387	5,563	8,749	11,947	31,646	73,121	119,194	152,628	183,685	222,152	269,913	329,339
SG&A	1,377	1,203	1,823	2,884	7,287	3,057	3,240	3,435	3,641	13,373	16,884	21,315	29,476	71,882	111,318	171,382	241,975
Total Operating Expenses	**9,014**	**6,386**	**7,517**	**10,270**	**33,187**	**8,444**	**8,803**	**12,184**	**15,588**	**45,019**	**90,004**	**140,509**	**183,130**	**267,542**	**361,220**	**493,069**	**651,327**
Operating Income (Loss)	(464)	2,751	81	(3,932)	(1,564)	2,119	1,760	4,950	3,546	12,375	31,154	(43,935)	(70,573)	(22,177)	66,957	182,342	347,146
Net Interest Income (Expense)	(4)	(8)	(7)	29	10	805	825	846	885	3,361	4,441	4,811	7,157	5,359	5,309	7,715	12,105
Other non-operating Income (Expense)	(2,603)	1,010	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Income Before Income Taxes	(3,071)	3,753	74	(3,903)	(1,554)	2,924	2,585	5,795	4,431	15,736	35,594	(39,124)	(63,416)	(16,818)	72,266	190,056	359,252
Provision for Income Taxes	0	0	0	67	67	155	137	307	235	834	8,801	0	0	223	3,830	57,325	125,738
Net Income (Loss)	(3,071)	3,753	74	(3,970)	(1,621)	2,769	2,448	5,488	4,196	14,902	26,793	(39,124)	(63,416)	(17,041)	68,436	132,731	233,514
GAAP EPS	**(2.44)**	**0.20**	**0.00**	**(0.21)**	**(0.31)**	**0.15**	**0.13**	**0.30**	**0.23**	**0.80**	**1.43**	**(1.72)**	**(2.77)**	**(0.74)**	**2.97**	**5.73**	**10.03**
Weighted Basic Shares Outstanding	1,256	2,611	18,374	18,474	10,248	18,499	18,524	18,549	18,574	18,574	18,674	22,774	22,874	22,974	23,074	23,174	23,274
Cash Burn	0	0	(5,773)	(1,995)	0	0	0	0	0	0	0	(24,188)	(60,713)	(27,870)	0	0	0
Cash Balance	33,221	117,814	112,044	107,286	107,286	110,022	112,746	118,029	121,805	121,805	147,838	238,969	178,257	150,387	199,983	302,156	498,903

Source: Wedbush Securities Inc.

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.

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Company	Disclosure
Ardelyx Inc.	1,3,4,5

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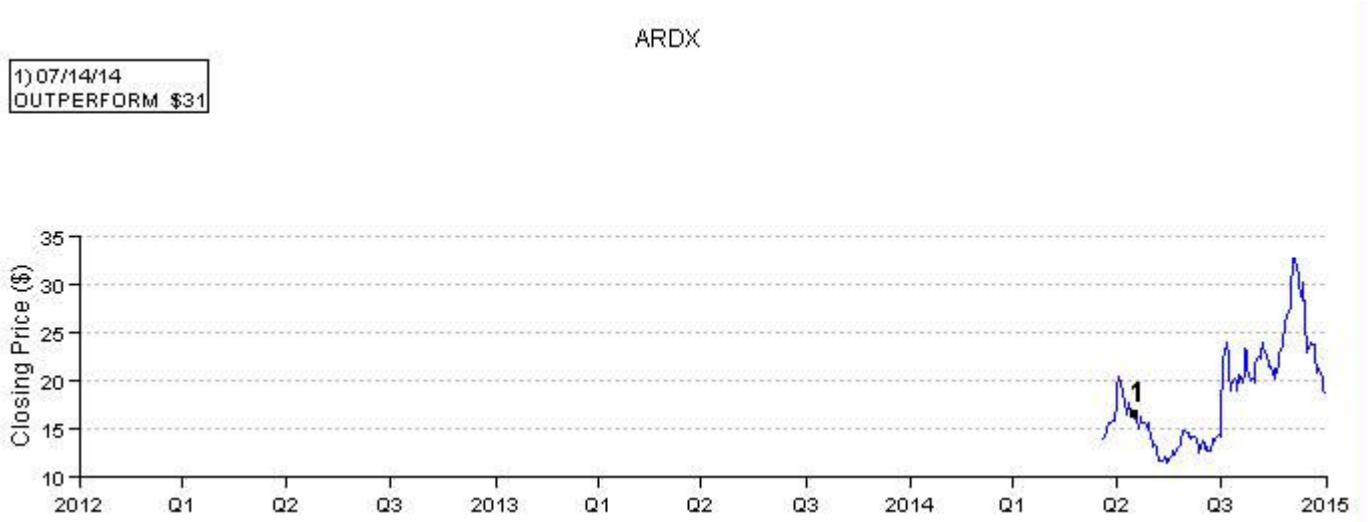

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RESEARCH DEPT. * (213) 688-4505 * www.wedbush.com
EQUITY TRADING Los Angeles (213) 688-4470 / (800) 421-0178 * EQUITY SALES Los Angeles (800) 444-8076
CORPORATE HEADQUARTERS (213) 688-8000

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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

Healthy Lifestyles
Phil Terpolilli (212) 833-1367

Leisure
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Colin Radke (213) 688-6624

Specialty Retail: Hardlines
Seth Basham, CFA (212) 938-9954
John Garrett, CFA (213) 688-4523

Specialty Retail: Softlines
Morry Brown, CFA (213) 688-4311
Taryn Kuida (213) 688-4505

RETAIL CHANNEL CHECKING GROUP

Lupine Skelly (505) 417-5427

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Environmental Services / Building Products
Al Kaschalk (213) 688-4539

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James Kim (213) 688-4380

TECHNOLOGY, INTERNET, MEDIA & SOCIAL MEDIA

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Scott Thompson (212) 938-9933

Communications and Application Software
Shyam Patil, CFA (213) 688-8062
Andy Cheng (213) 688-4548

Enterprise Software
Steve Koenig (415) 274-6801

Entertainment: Retail
Michael Pachter (213) 688-4474
Alicia Reese (212) 938-9927
Nick McKay (213) 688-4343

Entertainment: Software
Michael Pachter (213) 688-4474
Nick McKay (213) 688-4343

Financial Technology
Gil B. Luria (213) 688-4501
Aaron Turner (213) 688-4429

Internet: Media and Gaming
Michael Pachter (213) 688-4474
Nick McKay (213) 688-4343
Alicia Reese (212) 938-9927

Internet: Social Media, Advertising & Technology
Shyam Patil, CFA (213) 688-8062
Andy Cheng (213) 688-4548

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Alicia Reese (212) 938-9927
Nick McKay (213) 688-4343

Semiconductors
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Ryan Jue, CFA (415) 263-6669

LIFE SCIENCES AND HEALTH CARE

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

Heather Behanna, Ph.D. (415) 274-6874

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