

Ardelyx Inc. (ARDX)

Q1:15 EPS; Well Capitalized Ahead of Key Partnership Decision for Tenapanor

- ARDX reported Q1:15 EPS of \$(0.19), below our estimate of \$0.15 and consensus of \$0.01, due to a decrease in received collaboration revenues related to tenapanor development activities. The company ended Q1 with \$98.3M in cash and equivalents.
- Following the recent completion of the Ph 2a study of tenapanor in CKD, as well as two Ph 2b studies in IBS-C and ESRD, ARDX is currently awaiting partner Astra-Zeneca's decision on whether to retain worldwide rights to tenapanor. ARDX remains poised to continue development of tenapanor in IBS-C and ESRD should Astra decide to return the rights, and remains well capitalized to do so. The company is scheduled to meet with the FDA in June regarding study design for Ph 3 endpoint for IBS-C, with the Ph 3 study to begin Q4:15.
- Recall, tenapanor met the primary endpoint in its Ph 2b IBS-C trial, comparing favorably with leading approved IBS-C therapy Linzess on measures of both efficacy and safety. Notably, the diarrhea rate for tenapanor in this trial was 11.2% at the 50 mg dose (vs. 1% of placebo patients), compared to 11-18% for Linzess in its Ph 2b study (vs. 0% of placebo patients).
- Tenapanor also met its primary endpoint in its Ph 2b ESRD trial, demonstrating statistically significant reductions in serum phosphate levels from baseline in ESRD patients with hyperphosphatemia.
- Positive takeaways from the CKD trial.
- Although uncertainty remains regarding the rights of tenapanor, we regard ARDX shares as having limited downside risk at current levels. Whilst maintaining that we see a path forward in ESRD, we note our belief that tenapanor is worth ~\$15 a share in IBS-C alone, an indication in which tenapanor compared favorably to a leading therapy on both safety and efficacy.
- Reiterate OUTPERFORM and our PT of \$22. Our PT is derived by applying a 6 and 15 multiple to ARDX's share of 2022 tenapanor US sales and ex-US royalty.

May 12, 2015

Price
\$9.06

Rating
OUTPERFORM

12-Month Price Target
\$22

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Company Information

Shares Outst (M)	18.6
Market Cap (M)	\$168.6
52-Wk Range	\$7.95 - \$35.48
Book Value/sh	\$3.26
Cash/sh	\$5.28
Enterprise Value (M)	\$70.3
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

FYE Dec	2014A	2015E			2016E		
REV	ACTUAL	CURR.	PREV.	CONS.	CURR.	PREV.	CONS.
Q1 Mar	8.6A	5.9A	10.6A	\$10.9A	29.2E	29.6E	21.8E
Q2 Jun	9.1A	10.1E	10.6E	11.3E	29.6E	30.1E	32.4E
Q3 Sep	7.6A	16.7E	17.1E	24.0E	30.0E	30.5E	35.6E
Q4 Dec	6.3A	18.7E	19.1E	23.8E	30.4E	31.0E	66.8E
Year*	31.6A	51.3E	57.4E	70.0E	119.2E	121.2E	101.8E
Change	9%	62%			--		
EPS	2014A	2015E			2016E		
	ACTUAL	CURR.	PREV.	CONS.	CURR.	PREV.	CONS.
Q1 Mar	(\$2.44)A	(\$0.19)A	\$0.15A	\$0.01A	\$0.61E	\$0.62E	\$0.32E
Q2 Jun	\$0.20A	\$0.12E	\$0.13E	\$0.18E	\$0.35E	\$0.36E	\$0.76E
Q3 Sep	\$0.00A	\$0.28E	\$0.29E	\$0.90E	\$0.27E		\$0.84E
Q4 Dec	(\$0.21)A	\$0.21E	\$0.22E	\$0.49E	\$0.17E	\$0.18E	\$1.30E
Year*	(\$0.31)A	\$0.43E	\$0.80E	\$1.53E	\$1.39E	\$1.43E	\$1.34E
P/E	--	--			--		
Change	95%	238%			--		

Consensus estimates are from Thomson First Call.

* Numbers may not add up due to rounding.

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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.

- **Tenapanor also met its primary endpoint in its Ph 2b ESRD trial, demonstrating statistically significant reductions in serum phosphate levels from baseline in ESRD patients with hyperphosphatemia.** Although diarrhea rates were higher than in the IBS-C trial (likely due to the different underlying pathophysiologies), the discontinuation rate due to AEs at the effective dose of 10 mg BID was similar to placebo (13% vs. 8%, difference of one patient), indicating the diarrhea was likely manageable. Note, the reported trial discontinuation rates for currently-approved phosphate binders Renvela and Auryxia were 27% and 21%, respectively, vs. active control groups of 10% and 14%.
- **Positive takeaways from the CKD trial.** Despite missing the primary endpoint in its recent Ph 2a study in stage 3 CKD patients with Type II diabetes and albuminuria, tenapanor-treated patients had reduced phosphate absorption, increased bowel movement frequency and softer stools, supporting further development in IBS-C and ESRD patients. Although diarrhea was self-reported in two-thirds of patients, no other safety signals were observed, distinguishing tenapanor from Renvela and Auryxia, which are associated with increased rates of nausea and vomiting.

Milestones

June 2015 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)

Source: Company data, Wedbush Securities

5/12/2015
Ticker: (ARDX:Nasdaq)
Ardelyx, Inc

Wedbush PacGrow Life Sciences
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	2014	Q1A	Q2E	Q3E	Q4E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E
Revenues:													
US Product Sales	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$10,264	\$98,034	\$200,943	\$368,058	\$539,003
ex-US royalties	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$5,482	\$23,062	\$41,596	\$66,850
Licensing and other revenue	\$18,394	\$3,884	\$8,109	\$11,680	\$11,680	\$35,353	\$84,720	\$52,284	\$52,284	\$66,000	\$66,000	\$42,000	\$42,000
Collaborative development revenue	\$13,229	\$1,999	\$1,999	\$4,999	\$6,999	\$15,996	\$34,477	\$41,907	\$47,318	\$51,219	\$55,441	\$60,011	\$64,958
Total Revenues	31,623	5,883	10,108	16,679	18,679	51,349	119,197	94,191	109,866	220,734	345,445	511,666	712,811
Cost and Expenses:													
Cost of Sales	0	0	0	0	0	0	0	0	1,026	9,803	20,094	36,806	53,900
R&D	25,900	6,198	5,108	8,294	11,492	31,092	71,160	116,810	149,937	180,772	218,999	266,499	325,644
SG&A	7,287	3,175	3,366	3,567	3,781	13,889	17,535	22,138	30,514	67,651	93,378	135,157	177,893
Total Operating Expenses	33,187	9,373	8,473	11,862	15,273	44,981	88,695	138,948	181,477	258,226	332,471	438,462	557,438
Operating Income (Loss)	(1,564)	(3,490)	1,635	4,817	3,406	6,368	30,502	(44,757)	(71,611)	(37,492)	12,974	73,204	155,373
Net Interest Income (Expense)	10	(12)	737	787	826	2,338	4,153	4,488	6,791	4,902	4,071	4,753	7,262
Other non-operating Income (Expense)	0	0	0	0	0	0	0	0	0	0	0	0	0
Income Before Income Taxes	(1,554)	(3,502)	2,372	5,605	4,231	8,706	34,655	(40,270)	(64,820)	(32,590)	17,045	77,956	162,636
Provision for Income Taxes	67	0	126	297	224	647	8,536	0	0	0	997	4,132	47,159
Net Income (Loss)	(1,621)	(3,502)	2,246	5,308	4,007	8,059	26,118	(40,270)	(64,820)	(32,590)	16,048	73,825	115,477
GAAP EPS	(0.31)	(0.19)	0.12	0.28	0.21	0.43	1.39	(1.76)	(2.82)	(1.41)	0.69	3.17	4.94
Weighted Basic Shares Outstanding	10,248	18,607	18,632	18,657	18,682	18,682	18,782	22,882	22,982	23,082	23,182	23,282	23,382
Cash Burn	0	(4,728)	0	0	0	0	0	(25,520)	(62,129)	(40,350)	0	0	0
Cash Balance	107,286	98,318	104,966	110,078	113,676	113,676	138,589	228,389	166,260	125,911	130,976	184,969	280,196

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.

Analyst Certification

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Neutral: 43%	Neutral: 3%
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Company	Disclosure
Ardelyx Inc.	1,3,4,5

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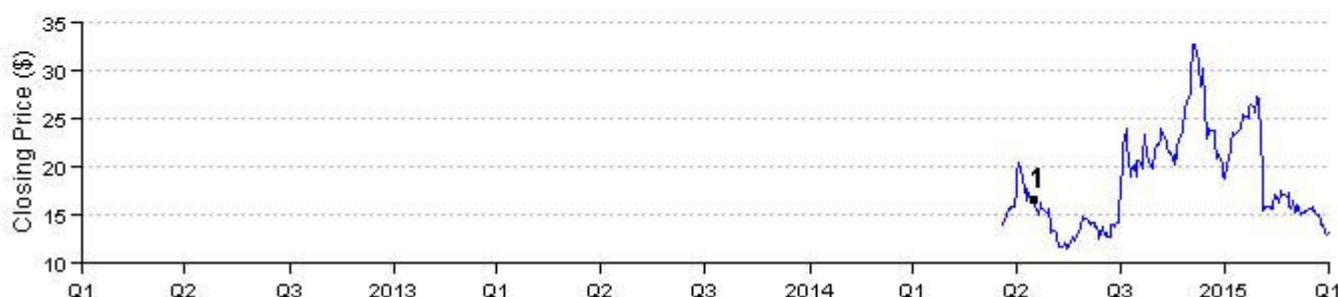
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ARDX

1) 07/14/14
OUTPERFORM \$31



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