Ardelyx Inc. (ARDX)

ARDX Regains Rights to Tenapanor and Related Compounds; Raises $77.8M; Trimming Price Target to $19 From $22, Reiterate OUTPERFORM

- **ARDX announced today that it has regained the development and commercialization rights for tenapanor from AstraZeneca (AZN, not covered).** ARDX will pay AZN $15M upfront, as well as $10M in R&D and transfer facilitation costs. In addition, ARDX will pay 10% royalties of tenapanor net sales, and 20% of non-royalty payments (if received). Total amounts paid to AZN would not exceed $90M, exclusive of the $10M R&D/transfer payment and a $10M payment for Ph 3 trial material and drug product inventory.
- **As expected, ARDX plans to begin its Ph 3 study of tenapanor in Q4:15 in IBS-C, pending an end of Phase 2 meeting with the FDA later this month.** We expect success in this trial, given the impressive efficacy and safety demonstrated in the Ph 2b study, comparable with the Ph 3 results for leading approved IBS-C therapy, Linzess. On the call, management indicated they expect tenapanor Ph 3 development in IBS-C to cost $60-85M.
- **In addition, the company will initiate a dose-finding Ph 2b of tenapanor for the treatment of hyperphosphatemia in dialysis patients in Q4:15.**
- **Given the substantial salesforce needed to market an IBS-C drug, we are modeling for ARDX to license tenapanor after pivotal data, retaining a 25% royalty rate for IBS-C.** In ESRD, we are modeling for ARDX to retain a 50% royalty rate on US sales of tenapanor, and 25% for the ROW.
- **ARDX also announced clinical development of its in-house developed and wholly-owned program RDX022 will begin mid:15.**
- **ARDX also announced today it has raised $77.8M in a private placement to further the clinical development of tenapanor and its wholly-owned RDX022 program, selling approximately 7.24 million shares of the common stock and warrants to purchase approximately 2.17 million shares.** After payments to AZN, and recognition of previous, we estimate ARDX has ~$140M on hand.
- **Reiterate OUTPERFORM and reducing price target to $19.** Our price target is derived from applying a 6 and 15 multiple to ARDX's share of 2022E tenapanor US sales and ex-US royalty.

FYE Dec	2014A	2015E			2016E		
REV	ACTUAL	CURR.	PREV.	CONS.	CURR.	PREV.	CONS.
Q1 Mar	8.6A	5.9A		$5.9A	3.5E	29.2E	17.6E
Q2 Jun	9.1A	44.3E	10.1E	8.4E	3.5E	29.6E	17.8E
Q3 Sep	7.6A	0.0E	16.7E	14.4E	3.5E	30.0E	30.6E
Q4 Dec	6.3A	0.0E	18.7E	21.5E	3.5E	30.4E	39.8E
Year*	**31.6A**	**50.2E**	**51.3E**	**50.1E**	**14.0E**	**119.2E**	**92.9E**
Change	9%	59%			--		
	2014A	2015E			2016E		
EPS	ACTUAL	CURR.	PREV.	CONS.	CURR.	PREV.	CONS.
Q1 Mar	($2.44)A	($0.19)A		($0.19)A	($0.68)E	$0.61E	$0.18E
Q2 Jun	$0.20A	$0.45E	$0.12E	$0.17E	($0.76)E	$0.35E	$0.03E
Q3 Sep	$0.00A	($0.22)E	$0.28E	$0.12E	($0.86)E	$0.27E	$0.64E
Q4 Dec	($0.21)A	($0.74)E	$0.21E	$0.37E	($0.82)E	$0.17E	$0.22E
Year*	**($0.31)A**	**($0.65)E**	**$0.43E**	**$0.54E**	**($2.75)E**	**$1.39E**	**$1.34E**
P/E	--	--			--		
Change	95%	-107%			--		

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

June 3, 2015

Price
$14.37

Rating
OUTPERFORM

12-Month Price Target
$19 **(from $22)**

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Company Information

Shares Outst (M)	25.9
Market Cap (M)	$371.8
52-Wk Range	$7.95 - $35.48
Book Value/sh	$3.11
Cash/sh	$5.38
Enterprise Value (M)	$232.6
LT Debt/Cap %	0.0
Cash Burn (M)	$63.9

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

- **In addition, the company will initiate a dose-finding Ph 2b of tenapanor for the treatment of hyperphosphatemia in dialysis patients in Q4:15.** Recall, tenapanor met its primary endpoint in its previous Ph 2b ESRD trial, demonstrating statistically significant reductions in serum phosphate levels from baseline, but diarrhea rates were higher than in the IBS-C trial (although appeared manageable at lower doses that remained effective).

- **ARDX also announced clinical development of its in-house developed and wholly-owned program RDX022 will begin mid:15.** RDX022 is a non-absorbed polystyrene sulfonate polymer, being developed to treat elevated potassium (hyperkalemia), in patients with chronic kidney disease (CKD) and heart failure. Its improved chemical and physical properties, as well as formulation improvements, may allow for dosing advantages over polymers currently available, or in development. Previous FDA findings of the reference drug product will allow ARDX to pursue a faster approval for RDX022 through a 505b(2) regulatory pathway. Given its stage, however, we do not currently incorporate potential future revenues into our valuation at this time.

- **Further details regarding ARDX's clinical development plans for tenapanor and RDX022 will be disclosed at the company's R&D day, which will be held in New York on July 14th.**

Risks to the achievement of our price target include clinical or regulatory failure for tenapanor, inability to find a licensing partner for tenapanor, and failure to achieve sales or earnings estimates.

Milestones

July 14 ARDX R&D day
mid:15 Early clinical trials for RDX022 for treatment of hyperkalemia patients
Q4:15 Begin Ph 3 trial of tenapanor in IBS-C
2H:16 Begin Ph 3 trial of RDX022 for treatment of hyperkalemia patients

Source: Company data, Wedbush Securities, Inc.

6/3/2015
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	$12,470	$73,877	$137,350	$252,799	$345,819
ex-US royalties	$0	$0	$0	$0	$0	$0	$0	$0	$3,233	$37,190	$113,720	$239,551	$357,815
Licensing and other revenue	$18,394	$3,884	$43,143	$0	$0	$47,027	$14,000	$164,000	$54,000	$54,000	$54,000	$54,000	$54,000
Collaborative development revenue	$13,229	$1,999	$1,199	$0	$0	$3,198	$0	$0	$0	$0	$0	$0	$0
Total Revenues	**31,623**	**5,883**	**44,342**	**0**	**0**	**50,225**	**14,000**	**164,000**	**69,703**	**165,067**	**305,070**	**546,350**	**757,634**
Cost and Expenses:													
Cost of Sales	0	0	0	0	0	0	0	0	924	4,696	6,687	9,991	12,728
R&D	25,900	6,198	29,308	3,295	16,493	55,294	84,683	114,904	125,118	129,553	163,558	206,488	260,687
SG&A	7,287	3,175	3,366	3,567	3,781	13,889	17,535	22,138	30,258	53,796	58,772	67,031	73,873
Total Operating Expenses	**33,187**	**9,373**	**32,674**	**6,863**	**20,274**	**69,184**	**102,218**	**137,041**	**156,300**	**188,045**	**229,017**	**283,510**	**347,287**
Operating Income (Loss)	(1,564)	(3,490)	11,669	(6,863)	(20,274)	(18,958)	(88,218)	26,959	(86,597)	(22,978)	76,053	262,840	410,346
Net Interest Income (Expense)	10	(12)	737	1,044	1,006	2,775	2,998	2,884	4,048	3,657	3,892	8,173	15,869
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)	12,406	(5,819)	(19,268)	(16,183)	(85,220)	29,843	(82,549)	(19,322)	79,945	271,012	426,215
Provision for Income Taxes	67	0	658	0	0	658	0	6,133	0	210	4,237	39,753	149,175
Net Income (Loss)	(1,621)	(3,502)	11,749	(5,819)	(19,268)	(16,840)	(85,220)	23,711	(82,549)	(19,532)	75,708	231,259	277,040
GAAP EPS	**(0.31)**	**(0.19)**	**0.45**	**(0.22)**	**(0.74)**	**(0.65)**	**(2.75)**	**0.76**	**(2.41)**	**(0.57)**	**2.20**	**6.70**	**8.00**
Weighted Basic Shares Outstanding	10,248	18,607	25,872	25,897	25,922	25,922	31,022	31,122	34,222	34,322	34,422	34,522	34,622
Cash Burn	0	(9,264)	(31,979)	(4,976)	(17,653)	(63,872)	(78,386)	0	(81,747)	(25,899)	0	0	0
Cash Balance	107,286	98,318	139,159	134,182	116,529	116,529	126,494	155,512	126,775	100,876	170,538	388,097	655,781

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
I, David M. Nierengarten, Ph.D., Dilip Joseph, Robert Driscoll, 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.

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Rating Distribution (as of March 31, 2015)	**Investment Banking Relationships (as of March 31, 2015)**
Outperform:55% Neutral: 43% Underperform: 2%	Outperform:31% Neutral: 3% Underperform: 0%

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Wedbush Equity Research Disclosures as of June 3, 2015

Company	Disclosure
Ardelyx Inc.	1,3,4,5,6,7

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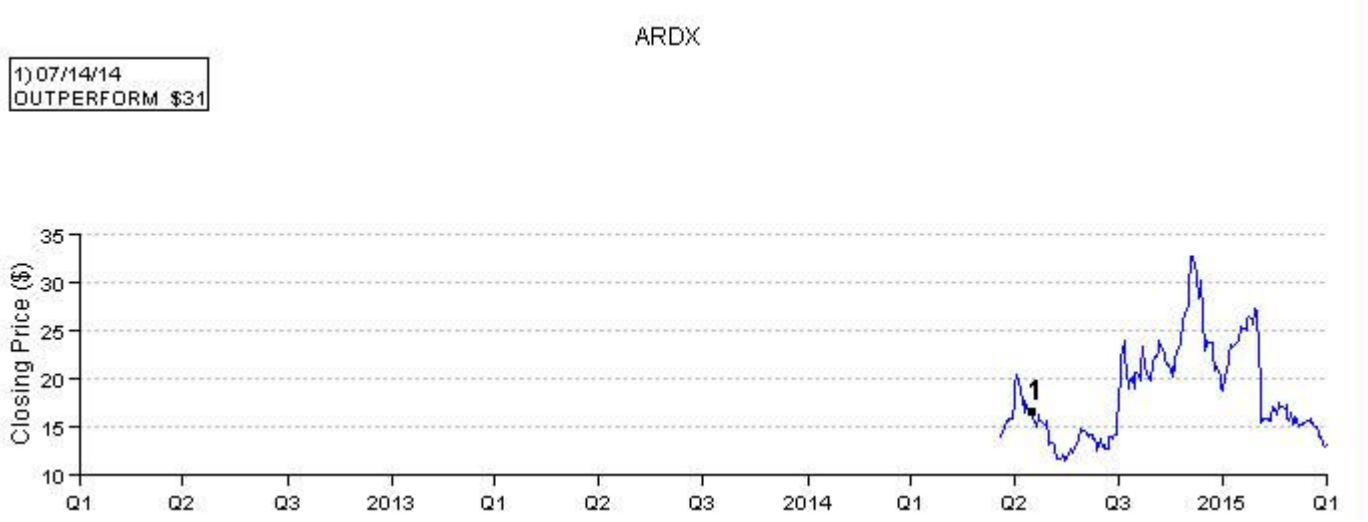

* WS changed its rating system from (Strong Buy/Buy/Hold/Sell) to (Outperform/ Neutral/Underperform) on July 14, 2009.
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