



March 4, 2016

Ardelyx Reports Fourth Quarter and Full-Year 2015 Financial Results

Three Late-Stage Clinical Trials for Tenapanor Initiated in 4Q2015 RDX022 PD Study Results Support Pivotal Phase 3 Clinical Trial Plans for Hyperkalemia in 2H2016 Conference Call and Webcast Today at 8:00 a.m. ET

FREMONT, Calif., March 4, 2016 /PRNewswire/ -- Ardelyx, Inc. (NASDAQ: ARDX), a clinical-stage biopharmaceutical company focused on gastrointestinal and cardio-renal diseases, today announced financial results for the fourth quarter and full-year ended December 31, 2015.



"2015 was an exceptional year for Ardelyx, highlighted by the advancement of our clinical programs and other corporate achievements," said Mike Raab, President and Chief Executive Officer of Ardelyx. "We regained worldwide rights to our lead product candidate, tenapanor, from AstraZeneca, and accelerated its development in multiple indications. We initiated two Phase 3 clinical trials for tenapanor in IBS-C and a second Phase 2b clinical trial for tenapanor in hyperphosphatemia. We also completed a study evaluating the pharmacodynamic activity of RDX022 in hyperkalemia, the positive results of which support our plan to initiate a pivotal Phase 3 clinical trial in the second half of 2016. We remain committed to advancing our late-stage assets and rounding out our pipeline with the development of promising preclinical assets such as RDX009, for which we intend to file an IND in the second half of 2016."

Recent Clinical & Corporate Developments

- | In December, Ardelyx initiated the second of two planned Phase 3 clinical trials evaluating tenapanor for the treatment of constipation-predominant irritable bowel syndrome (IBS-C). The trial's endpoints are similar to those of the first Phase 3 clinical trial, which was initiated in October, including a 12-week primary endpoint. Additionally, the study will evaluate tenapanor versus placebo at 13 of 26 weeks along with an open-label extension.
- | In December, the Company also commenced a second Phase 2b clinical trial evaluating dosing regimens of tenapanor in end-stage renal disease (ESRD) patients with hyperphosphatemia.
- | In October, Ardelyx initiated an open-label clinical study evaluating the pharmacodynamic (PD) activity of RDX022 in 60 healthy adult volunteers. Positive results from the PD study (announced in January 2016) demonstrated RDX022's ability to bind potassium effectively in the gastrointestinal tract. In this study, RDX022 was generally well-tolerated at all doses administered up to 27.5 g/day. These findings support Ardelyx's plans to proceed with a Phase 3 clinical program. Ardelyx is pursuing regulatory approval for RDX022 using the 505(b)(2) regulatory pathway.
- | Ardelyx further strengthened its senior leadership team with the appointment in January 2016 of Paul Korner, MD, MBA, as Executive Vice President and Chief Medical Officer.
- | In January 2016, Ardelyx raised net proceeds of approximately \$80.4 million in an underwritten follow-on public offering of its common stock.

Upcoming Clinical Milestones

- | Results from the second Phase 2b clinical trial evaluating tenapanor for the treatment of hyperphosphatemia in ESRD patients are expected in the second half of 2016
- | Initiation of a pivotal Phase 3 clinical trial to evaluate RDX022 for the treatment of hyperkalemia is currently planned in the second half of 2016
- | Planned IND submission in the second half of 2016 for RDX009, a TGR5 agonist that stimulates local secretion of GLP-1 and GLP-2 in the gastrointestinal tract
- | Results from two Phase 3 clinical trials evaluating tenapanor for the treatment of IBS-C are expected in 2017

Fourth Quarter and Year Ended December 31, 2015 Financial Results

Net loss for the year ended December 31, 2015 was \$29.6 million, or \$1.29 per basic and diluted share, compared to a net

loss of \$3.2 million, or \$0.31 per basic and diluted share for the year ended December 31, 2014. Net loss for the fourth quarter of 2015 was \$17.0 million, or \$0.65 per basic and diluted share, compared to a net loss of \$4.0 million, or \$0.21 per basic and diluted share for the fourth quarter of 2014.

Total revenue is comprised of licensing revenue and collaborative development revenue. Licensing revenue increased to \$21.6 million for the year ended December 31, 2015 from \$18.4 million for the year ended December 31, 2014. The increase primarily reflects the impact of the recognition of the remaining deferred revenue balance related to the AstraZeneca license agreement of \$43.1 million during the three months ended June 30, 2015, which was recognized as a result of the termination of the license agreement with AstraZeneca in June 2015. This amount was primarily offset by an aggregate of \$25.0 million in upfront payments made to AstraZeneca in connection with the termination of the AstraZeneca agreement. Licensing revenue for the fourth quarter of 2015 decreased to zero from \$3.9 million for the fourth quarter of 2014 because of the termination of the AstraZeneca agreement in June 2015.

Collaborative development revenue is comprised of development expenses that were reimbursable to Ardelyx by AstraZeneca. Collaborative development revenue for the year ended December 31, 2015 decreased to \$2.4 million from \$13.2 million for the year ended December 31, 2014. Collaborative development revenue for the fourth quarter of 2015 decreased to zero from \$2.5 million for the fourth quarter of 2014. The decrease in both the full year and fourth quarter was attributable to the termination of the AstraZeneca agreement in June 2015.

Research and development expense for the year ended December 31, 2015 increased to \$39.9 million from \$25.9 million for the year ended December 31, 2014. The change was primarily due to the \$7.3 million in expenses incurred for the tenapanor clinical trial material purchased from AstraZeneca as well as an increase of \$6.7 million in expenses incurred for clinical development activities associated with tenapanor and RDX022, and manufacturing process development for RDX022. Research and development expense for the fourth quarter of 2015 increased to \$12.8 million from \$7.4 million for the fourth quarter of 2014. The increase was driven by an increase of \$5.4 million in expenses incurred primarily for clinical development activities associated with tenapanor and RDX022, and manufacturing process development for RDX022.

General and administrative expense was \$13.5 million for the year ended December 31, 2015 compared to \$7.3 million for the year ended December 31, 2014. General and administrative expense was \$4.1 million for the fourth quarter of 2015 as compared to \$2.9 million for fourth quarter of 2014. The increase in both the full year and the fourth quarter was primarily due to an increase in professional services fees, personnel and public company costs.

Cash and cash equivalents were \$107.0 million as of December 31, 2015 compared with \$107.3 million as of December 31, 2014 primarily as a result of the private placement completed in June 2015 that yielded approximately \$74.3 million in net proceeds, offset by \$3.5 million of capital equipment purchases and \$71.8 million in cash required for operating activities including the \$25.0 million paid to AstraZeneca in connection with the termination of the license agreement in June 2015.

On January 13, 2016, we completed the sale and issuance of an aggregate of 8,625,000 shares of our Common Stock in an underwritten public offering. We received net proceeds from the offering of approximately \$80.4 million, after deducting the Underwriters' discounts and commissions and estimated offering expenses payable by us.

Conference Call & Webcast Information

Ardelyx management will host a live conference call and webcast today at 8:00 a.m. ET to discuss the financial results for the fourth quarter and year ended December 31, 2015. The live webcast and a replay may be accessed by visiting the Investor Relations section of the Ardelyx website at ir.ardelyx.com.

Please connect to the Company's website at least 15 minutes prior to the live webcast to ensure adequate time for any software download that may be needed to access the webcast. Alternatively, please call 1-855-296-9612 (US) or 920-663-6277 (International) to listen to the live conference call. The conference ID number for the live call is 58231765. Please dial in approximately 10 minutes prior to the call. An archived webcast replay will be available on the Company's website until March 18, 2016.

About Ardelyx, Inc.

Ardelyx is a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of innovative, minimally-systemic, small molecule therapeutics that work exclusively in the gastrointestinal tract to treat gastrointestinal and cardio-renal diseases. Ardelyx has developed a proprietary drug discovery and design platform enabling it, in a rapid and cost-efficient manner, to discover and design novel drug candidates. Utilizing this platform, Ardelyx has discovered and designed tenapanor, which it is evaluating for the treatment of constipation-predominant irritable bowel syndrome, or IBS-C, and management of hyperphosphatemia in patients with end stage renal disease. In addition to tenapanor, Ardelyx is developing RDX022, a non-absorbed polymer for the treatment of hyperkalemia, or high potassium, in kidney and heart disease patients. Ardelyx is also advancing several research programs focused in

gastrointestinal and cardio-renal diseases. Ardelyx is located in Fremont, California. For more information, please visit Ardelyx's website at www.ardelyx.com.

Forward Looking Statements

To the extent that statements contained in this press release are not descriptions of historical facts regarding Ardelyx, they are forward-looking statements reflecting the current beliefs and expectations of management made pursuant to the safe harbor of the Private Securities Reform Act of 1995, including the potential for tenapanor in treating IBS-C and hyperphosphatemia in end stage renal disease patients, Ardelyx's future development plans for tenapanor and the timing thereof, the expected timing for the receipt of the results for the Phase 3 clinical trials in IBS-C, the expected timing for the receipt of the results for the Phase 2b hyperphosphatemia clinical trial, the potential for RDX022 in treating hyperkalemia in kidney and heart disease patients, Ardelyx's future development plans for RDX022 and the timing thereof, the expected timing for the initiation of the Phase 3 clinical trial for RDX022, the expected timing for the filing of an IND for RDX009, and the potential of Ardelyx's drug discovery and design platform. Such forward-looking statements involve substantial risks and uncertainties that could cause the development of tenapanor, RDX022, or Ardelyx's future results, performance or achievements to differ significantly from those expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, the uncertainties inherent in research and the clinical development process and the uncertainties in the manufacture of clinical trial material, including process development, scale up and tech transfer of manufacturing processes. Ardelyx undertakes no obligation to update or revise any forward-looking statements. For a further description of the risks and uncertainties that could cause actual results to differ from those expressed in these forward-looking statements, as well as risks relating to Ardelyx's business in general, please refer to Ardelyx's Annual Report on Form 10-K to be filed with the Securities and Exchange Commission on March 4, 2016, and its future current and periodic reports to be filed with the Securities and Exchange Commission.

Ardelyx, Inc. Condensed Balance Sheets (In thousands)

	December 31, 2015	December 31, 2014
	(Unaudited)	(1)
Assets		
Cash and cash equivalents	\$ 107,004	\$ 107,286
Accounts receivable	-	2,584
Property and equipment, net	4,711	2,131
Prepaid and other assets	5,231	1,413
Total Assets	<u>\$ 116,946</u>	<u>\$ 113,414</u>
Liabilities and stockholders' equity		
Accounts payable and accrued liabilities	\$ 7,723	\$ 5,557
Deferred license revenue	-	47,053
Other liabilities	322	122
Stockholders' equity	108,901	60,682
Total liabilities and stockholders' equity	<u>\$ 116,946</u>	<u>\$ 113,414</u>

(1) Derived from the audited financial statements included on Form 10-K for the year ended December 31, 2014.

Ardelyx, Inc. Condensed Statements of Operations and Comprehensive Loss (In thousands, except share and per share amounts)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2015	2014	2015	2014
	(Unaudited)	(Unaudited)	(Unaudited)	(1)
Revenues:				
Licensing revenue	\$ --	\$ 3,884	\$ 21,611	\$ 18,394
Collaborative development revenue	--	2,454	2,415	13,229
Total revenue	--	6,338	24,026	31,623
Operating expenses:				
Research and development	12,783	7,386	39,885	25,900

General and administrative	4,093	2,884	13,530	7,287
Total operating expenses	<u>16,876</u>	<u>10,270</u>	<u>53,415</u>	<u>33,187</u>
Loss from operations	(16,876)	(3,932)	(29,389)	(1,564)
Other (expense) income	(123)	29	(261)	(1,583)
(Provision for) benefit from income taxes	(1)	(67)	29	(67)
Net loss and comprehensive loss	<u>\$ (17,000)</u>	<u>\$ (3,970)</u>	<u>\$ (29,621)</u>	<u>\$ (3,214)</u>
Basic and diluted net loss per share	<u>\$ (0.65)</u>	<u>\$ (0.21)</u>	<u>\$ (1.29)</u>	<u>\$ (0.31)</u>
Shares used in computing basic and diluted net loss per share	<u>25,958,716</u>	<u>18,473,542</u>	<u>22,892,640</u>	<u>10,248,337</u>

(1) Derived from the audited financial statements included on Form 10-K for the year ended December 31, 2014.

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