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Ardelyx Reports Clinical Progress and Fourth Quarter and Full Year 2016 Financial Results

Announced Positive Data From Phase 3 Trial of Tenapanor in Hyperphosphatemia; Company Plans to Initiate Second Phase 3 Trial Mid-Year 2017
Phase 3 T3MPO-1 and T3MPO-2 Trials in IBS-C on Track to Readout By Mid-and End-of-Year 2017

FREMONT, Calif., Feb. 17, 2017 /PRNewswire/ -- Ardelyx, Inc. (NASDAQ: ARDX), a clinical-stage biopharmaceutical company focused on cardiorenal and gastrointestinal (GI) diseases, today reported recent company progress and financial results for the fourth quarter and full year ended December 31, 2016.

"We're very proud of what we achieved in 2016 and have continued to build on that momentum in 2017, with a number of additional important milestones ahead of us," said Mike Raab, president and chief executive officer of Ardelyx. "The positive data we reported from our first Phase 3 clinical trial of tenapanor for hyperphosphatemia provides a terrific start to 2017, and we plan to begin our second Phase 3 trial for tenapanor for hyperphosphatemia by mid-year. We also plan to report Phase 3 results from our T3MPO-1 and T3MPO-2 trials of tenapanor in IBS-C by mid-year and the end of the year, respectively. These milestones are significant and, if positive, will drive us down our path of becoming an independent, fully integrated and revenue generating biotechnology company in the next several years, while bringing meaningful new medicines to the millions of patients who are underserved by current treatment options."

Recent and 2016 Highlights

- Earlier this week, Ardelyx reported positive results from its Phase 3 trial evaluating tenapanor for the treatment of hyperphosphatemia in patients with end-stage renal disease (ESRD) who are on dialysis. The trial met its primary endpoint, demonstrating a statistically significant difference in change in serum phosphorus between the pooled tenapanor-treated patients and placebo-treated patients from the end of the eight-week treatment period to the end of the four-week randomized withdrawal period, in the responder population. Additionally, the responder population had a substantial mean reduction in serum phosphorus from baseline to the end of the eight-week treatment period. Notably, patients treated with tenapanor experienced a favorable safety and GI tolerability profile.
- In December 2016, Ardelyx initiated both a Phase 3 clinical trial and an onset-of-action clinical trial with RDX7675 for the treatment of patients with hyperkalemia. Data announced in January 2016 demonstrating clinically relevant fecal potassium binding in a pharmacodynamic study in healthy volunteers supported the initiation of the Phase 3 study. The company also announced in August 2016 that the United States Patent and Trademark Office issued a Notice of Allowance for its composition of matter patent for RDX7675. This patent has now issued, providing key intellectual property protection through 2035.
- Ardelyx strengthened its leadership team in 2016 with the appointments of Reg Seeto, MDDS, to chief operating officer, and Paul Korner, M.D., MBA to chief medical officer.

Fourth Quarter and Full Year 2016 Financial Results

- **Cash Position:** As of December 31, 2016, Ardelyx had total capital resources including cash, cash equivalents and short-term investments of $200.8 million compared to total capital resources including cash, cash equivalents of $107.0 million as of December 31, 2015.
- **R&D Expenses:** Research and development expense for the year ended December 31, 2016 increased to $94.2 million from $39.9 million for the year ended December 31, 2015. The increase of $54.3 million was primarily due to the advancement of our late stage clinical product candidates including an increase in personnel, facility and other costs, primarily related to increased research and development headcount, along with the following preclinical, clinical and manufacturing activities:
  - **Gastrointestinal portfolio:** increased activities associated with tenapanor in our GI portfolio, including the commencement of T3MPO-1, T3MPO-2 and T3MPO-3 to evaluate tenapanor to treat IBS-C, as well as clinical

manufacturing and process development activities associated with tenapanor and RDX8940;
- **Cardiorenal portfolio**: increased activities related to tenapanor in our cardiorenal portfolio, including the Phase 3 clinical trial to evaluate tenapanor for hyperphosphatemia in ESRD patients on dialysis, as well as clinical manufacturing activities associated with RDX7675.

- **G&A Expenses:** General and administrative expense was $18.7 million for the year ended December 31, 2016 compared to $13.5 million for the year ended December 31, 2015. The increase was primarily due to an increase in personnel, professional fees and market research and pre-commercialization activities.
- **Net Loss:** Net loss for the year ended December 31, 2016 was $112.4 million compared to a net loss of $29.6 million for the year ended December 31, 2015.

About Ardelyx, Inc.

Ardelyx is focused on enhancing the way patients with cardiorenal and gastrointestinal (GI) diseases are treated by using the gut as the gateway to delivering medicines that matter. The company has established unique cardiorenal and GI business units aimed at bringing new, effective medicines with distinct safety and dosing advantages to underserved patients. Ardelyx's cardiorenal portfolio includes the Phase 3 development of tenapanor for the treatment of hyperphosphatemia in people with end-stage renal disease who are on dialysis and the Phase 3 development of RDX7675 for the treatment of people with hyperkalemia. The company's GI portfolio includes the Phase 3 development of tenapanor for the treatment of people with irritable bowel syndrome with constipation (IBS-C), and RDX8940, a TGR5 agonist approaching Phase 1 development. Leveraging the company's platform and unique gut-restriction chemistry, Ardelyx intends to build a fully integrated, revenue-generating biopharmaceutical company with leading cardiorenal and GI business units. For more information, please visit www.ardelyx.com and connect with us on Twitter @Ardelyx.

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 Ardelyx's product candidates in treating the diseases and conditions for which they are being developed; Ardelyx's future development plans for its product candidates and the expected timing thereof; Ardelyx's expected timing for the receipt of results from its clinical trials evaluating its product candidates; Ardelyx's corporate goals; 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 Ardelyx's product candidates 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, and scale up 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 Quarterly Report on Form 10-K filed with the Securities and Exchange Commission on February 17, 2017, and its future current and periodic reports to be filed with the Securities and Exchange Commission.

Ardelyx, Inc.
Consolidated Condensed Balance Sheets
(In thousands)

	December 31, 2016	December 31, 2015
	(Unaudited)	(1)
Assets		
Cash and cash equivalents	$ 74,598	$ 107,004
Short-term investments	126,225	—
Property and equipment, net	8,991	4,711
Prepaid and other assets	3,317	5,231
Total Assets	$ 213,131	$ 116,946
Liabilities and stockholders' equity		
Accounts payable and accrued liabilities	$ 19,201	$ 7,723
Other liabilities	779	322
Stockholders' equity	193,151	108,901
Total liabilities and stockholders' equity	$ 213,131	$ 116,946

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

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2016	2015	2016	2015
	(Unaudited)	(Unaudited)	(Unaudited)	(1)
Revenues:				
Licensing revenue	$ —	$ —	$ —	$ 21,611
Collaborative development revenue	—	—	—	2,415
Total revenues	—	—	—	24,026
Operating expenses:				
Research and development	26,210	12,783	94,161	39,885
General and administrative	5,266	4,093	18,734	13,530
Total operating expenses	31,476	16,876	112,895	53,415
Loss from operations	(31,476)	(16,876)	(112,895)	(29,389)
Other income (expense)	200	(123)	508	(261)
Provision for income taxes	—	(1)	—	29
Net loss	$ (31,276)	$ (17,000)	$ (112,387)	$ (29,621)
Net loss per common share, basic & diluted	$ (0.66)	$ (0.65)	$ (2.80)	$ (1.29)
Weighted-average shares used in computing basic net loss per share, basic and diluted	47,303,494	25,958,716	40,118,522	22,892,640

(1) Derived from the audited financial statements included on Form 10-K for the year ended December 31, 2015.

To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/ardelyx-reports-clinical-progress-and-fourth-quarter-and-full-year-2016-financial-results-300409707.html

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