Ardelyx Reports 2017 Financial Results and Appoints Industry Veteran, Jan Lundberg, Ph.D., to Board of Directors

March 14, 2018

Enrollment Underway in Second Registration Study of Tenapanor for Hyperphosphatemia
NDA for Tenapanor for IBS-C on Track for Submission in Second Half of 2018

FREMONT, Calif., March 14, 2018 /PRNewswire/ -- Ardelyx, Inc. (NASDAQ: ARDX), today reported pipeline highlights and financial results for the fourth quarter and full-year ended December 31, 2017. In addition, industry-leading research expert, Jan M. Lundberg, Ph.D., has been appointed to the company's board of directors, effective March 23, 2018.

"Jan's extensive research expertise positions him as an invaluable addition to the Ardelyx team, and we are delighted that he is joining our board. We look forward to leveraging his substantial experience, as he has been involved in the discovery, development and approval of more than 20 products," said Mike Raab, president and chief executive officer of Ardelyx. "As we look ahead, our focus is on addressing the significant need for new treatments for patients with renal diseases by developing first-in-class, small molecule medicines, as with tenapanor for hyperphosphatemia and our RDX013 program for hyperkalemia. We believe that the combination of our proprietary drug discovery platform, renal drug development capabilities and our plans for a specialized U.S. commercial approach targeting nephrologists, positions Ardelyx to meaningfully change the care of many patients, while creating value for shareholders."

Pipeline Updates

- **Second Phase 3 Clinical Trial of Tenapanor for Hyperphosphatemia Underway:** In February 2018, Ardelyx began treating patients in the Phreedom Trial, the company's second Phase 3 clinical trial of tenapanor for the treatment of hyperphosphatemia in patients with end-stage renal disease who are on dialysis. This clinical trial includes a 26-week open-label treatment period, with a 12-week placebo-controlled randomized withdrawal period followed by an additional 14-week safety extension period for a total of up to 52 weeks. An active control group, for safety analysis only and consistent with other Phase 3 registration studies for hyperphosphatemia, will receive sevelamer carbonate, open-label, for the entire 52-week study period. Topline data from this clinical trial are currently anticipated in 2019.
- **Expanding Renal Pipeline with RDX013 Program:** Ardelyx is leveraging its expertise in renal drug development to advance its early-stage RDX013 program for the potential treatment of hyperkalemia. RDX013 is a novel, small molecule program that Ardelyx believes may work by tapping into the gastrointestinal tract's natural ability to secrete potassium into the lumen of the gut to reduce serum potassium levels. This mechanism differs significantly from the potassium binders currently on or approaching the market, and, like tenapanor for hyperphosphatemia, has the potential to provide the first non-binder approach to treat hyperkalemia with the aim of improving adherence and compliance with potentially better efficacy and safety.
- **Preparing NDA Submission for Tenapanor for IBS-C:** Ardelyx has completed its T3MPO program designed to support the registration of tenapanor for the treatment of irritable bowel syndrome with constipation (IBS-C). Both the T3MPO-1 and T3MPO-2 Phase 3 clinical trials achieved their primary endpoints and demonstrated that tenapanor had a durable effect on reducing constipation and abdominal pain caused by IBS-C, in many patients treated. The favorable safety profile of tenapanor was supported by the completed T3MPO-3 long-term, safety extension study. With the completion of clinical development for this program, Ardelyx is preparing a New Drug Application for tenapanor for IBS-C, which the company currently intends to submit to the U.S. Food and Drug Administration in the second half of 2018.

"We believe that tenapanor represents a more than $1 billion market opportunity for both hyperphosphatemia and IBS-C," added Reg Seeto, MBBS, chief operating officer of Ardelyx. "For our renal pipeline, our plan is to deploy our internal expertise to bring tenapanor to the U.S. market on our own, while leveraging strategic collaborations to bring it to markets outside the U.S. For IBS-C, we intend to leverage collaborations to bring tenapanor to patients globally. Our collaborations with KHK in Japan and Fosun Pharma in China are each off to a strong start, and we look forward to evaluating additional opportunities to expand the reach of our novel products."

Corporate Updates

- **Industry Veteran Jan M. Lundberg, Ph.D.Appointed to Board of Directors**: Dr. Lundberg brings more than 22 years of experience in biopharma and significant research strength to the board. He currently serves as executive vice president, science and technology, and president, Lilly Research Laboratories at Eli Lilly where he has been instrumental in the submissions and approvals of 10 new products over the last five years. Before Lilly, he was global head of discovery research at AstraZeneca, where he played a key role in numerous drug candidate nominations, development projects and marketed-product support, as well as in-licensing, partnering and acquisitions. Prior to AstraZeneca, he served as the head of preclinical research at Astra AB. Dr. Lundberg was also the co-founder of Aerocrine AB, a biotech diagnostic company with exhaled nitric oxide as an allergic asthma breath test. He earned a BSM equivalent in medicine from the University of Gothenburg in Sweden and a Ph.D. in pharmacology from Karolinska Institute in Stockholm, Sweden.
- **Fosun Pharma Agreement Brings Tenapanor to China for Cardiorenal Diseases and IBS-C:** A license agreement with Shanghai Fosun Pharmaceutical Industrial Development Company Limited (Fosun Pharma), signed in December 2017, provides Fosun Pharma with the exclusive rights to develop and commercialize tenapanor in China for the treatment of patients with hyperphosphatemia related to chronic kidney disease, as well as patients with IBS-C. Under the terms of the agreement, Ardelyx received an upfront payment of $12 million and is eligible to receive additional milestones of up to $113 million, as well as tiered royalties on net sales ranging from the mid-teens to 20 percent.
- **Kyowa Hakko Kirin Agreement Brings Tenapanor to Japan for Cardiorenal Diseases:** A license agreement with Kyowa Hakko Kirin Co., Ltd. (KHK), signed in November 2017, provides KHK exclusive rights to develop and commercialize tenapanor for the treatment of cardiorenal diseases, including hyperphosphatemia, in Japan. Under the terms of the license agreement, Ardelyx received a $30 million upfront payment and is eligible to receive up to approximately $130 million in development and commercialization milestones based upon currency exchange rates as of the effective date of the license agreement, as well as high-teen royalties on net sales throughout the term of the agreement.

Full Year 2017 Financial Results

- **Cash Position:** As of December 31, 2017, Ardelyx had total capital resources comprising cash, cash equivalents and short-term investments of $134.0 million compared to total capital resources comprising cash, cash equivalents and short-term investments of $200.8 million as of December 31, 2016.
- **Revenue:** Licensing revenue for the year ended December 31, 2017 was $42.0 million, related to the recognition of revenue from upfront license payments under Ardelyx's agreements with KHK and Fosun Pharma. The company generated no license revenue for the year ended December 31, 2016.
- **Cost of Revenue:** Cost of revenue for the year ended December 31, 2017 was $8.4 million, representing license payments due to AstraZeneca in accordance with the company's termination agreement entered into with AstraZeneca in June 2015. The company generated no revenue for the year ended December 31, 2016 and therefore had no cost of revenue.
- **R&D Expenses:** Research and development expenses were $75.5 million for the year ended December 31, 2017, a decrease of $18.7 million, or 20 percent, compared to $94.2 million for the year ended December 31, 2016. The decrease consisted of a net $23.8 million decrease in external program costs, primarily due to a decrease in expenses incurred for clinical development activities related to the completion of some of the company's Phase 3 clinical trials for tenapanor. This was offset by an increase of $5.1 million in internal program costs, primarily due to salaries and related costs, including stock-based compensation, facilities-related costs, principally related to supporting the growth of our development team and severance costs relating to a reduction in the workforce in the third quarter 2017.
- **G&A Expenses:** General and administrative expenses were $23.2 million for the year ended December 31, 2017, an increase of $4.5 million, or 24 percent, compared to $18.7 million for the year ended December 31, 2016. The increase was primarily due to increases in salaries and related costs, including stock-based compensation and facilities costs including depreciation expense, due to an increase in headcount and expansion of facilities in late 2016, increased legal fees, and severance costs due to the refocusing of resources towards late-stage programs and subsequent reduction in the workforce in the third quarter of 2017, offset by reductions in certain professional services.
- **Net Loss:** Net loss for the year ended December 31, 2017, was $64.3 million compared to a net loss of $112.4 million for the year ended December 31, 2016.

About Ardelyx, Inc.
Ardelyx is focused on enhancing the way people with renal diseases are treated by developing first-in-class medicines. Ardelyx's renal pipeline includes the Phase 3 development of tenapanor for the treatment of hyperphosphatemia in people with end-stage renal disease who are on dialysis and RDX013, a potassium secretagogue program for the potential treatment of high potassium, or hyperkalemia, a problem among certain patients with kidney and/or heart disease. In addition, Ardelyx has completed Phase 3 development of tenapanor for the treatment of irritable bowel syndrome with constipation and anticipates submitting a New Drug Application to the U.S. Food and Drug Administration for this indication in the second half of 2018. To efficiently bring its treatments to market, Ardelyx is pursing strategic collaborations in the U.S. and other countries, with established agreements with KHK in Japan and Fosun Pharma in China. 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 expected timing for the filing of its NDA for tenapanor for the treatment of IBS-C, Ardelyx's expected timing to receive topline data for its second Phase 3 clinical trial of tenapanor for the treatment of hyperphosphatemia in patients with end-stage renal disease who are on dialysis, the potential for Ardelyx to receive milestone and royalty payments from Shanghai Fosun Pharmaceutical Industrial Development and Kyowa Hakko Kirin Co., Ltd and Ardelyx's ability to establish collaborations in the future. 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, including the regulatory approval process. 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 filed with the Securities and Exchange Commission on March 14, 2018, 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, 2017 (Unaudited)	December 31, 2016 (1)
Assets		
Cash and cash equivalents	$ 75,383	$ 74,598
Short-term investments	58,593	126,225
Accounts receivable	10,796	—
Property and equipment, net	8,032	8,991
Prepaid and other assets	5,099	3,317
Total Assets	$ 157,903	$ 213,131
Liabilities and stockholders' equity		
Accounts payable and other current liabilities	$ 17,871	$ 19,201
Long-term liabilities	720	779
Stockholders' equity	139,312	193,151
Total liabilities and stockholders' equity	$ 157,903	$ 213,131

(1) Derived from the audited financial statements included on Form 10-K for the year ended December 31, 2016.

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

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2017 (Unaudited)	2016 (Unaudited)	2017 (Unaudited)	2016 (1)
Revenue:				
Licensing revenue	$ 42,000	$ —	$ 42,000	$ —
Cost of revenue	8,400	—	8,400	—
Gross profit	33,600	—	33,600	—
Operating expenses:				
Research and development	17,159	26,210	75,484	94,161

General and administrative	5,479	5,266	23,231	18,734
Total operating expenses	22,638	31,476	98,715	112,895
Income (loss) from operations	10,962	(31,476)	(65,115)	(112,895)
Other income, net	331	200	1,955	508
Provision for income taxes	(1,179)	—	(1,179)	—
Net income (loss)	$ 10,114	$ (31,276)	$ (64,339)	$ (112,387)
Net income (loss) per common share, basic	$ 0.21	$ (0.66)	$ (1.36)	$ (2.80)
Shares used in computing net income (loss) per share - basic	47,528,183	47,303,494	47,435,331	40,118,522
Net income (loss) per common share, diluted	$ 0.21	$ (0.66)	$ (1.36)	$ (2.80)
Shares used in computing net income (loss) per share - diluted	48,724,123	47,303,494	47,435,331	40,118,522

(1) Derived from the audited financial statements included on Form 10-K for the year ended December 31, 2016.

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