Ardelyx Reports Third Quarter 2017 Operating Results and Clinical Progress

November 7, 2017

FREMONT, Calif., Nov. 7, 2017 /PRNewswire/ -- Ardelyx, Inc. (NASDAQ: ARDX), today provided an update on its clinical programs and reported financial results for the third quarter ended September 30, 2017.

"2017 has been a landmark year for Ardelyx, with three statistically significant Phase 3 trial readouts for tenapanor – two for IBS-C and one for hyperphosphatemia," said Mike Raab, chief executive officer of Ardelyx. "For IBS-C patients, tenapanor could offer a completely new mechanism of action with a demonstrated best-in-class response rate, as seen in our T3MPO-2 study. For patients with hyperphosphatemia, tenapanor could be the first-ever non-binder treatment, potentially relieving the significant pill burden associated with binders. In order to maximize its therapeutic opportunity across both indications, we plan to leverage collaborations as part of our strategy of efficiently bringing tenapanor to patients as quickly as possible. As we head into 2018, we are closer to realizing the significant potential that minimally systemic, non-absorbed medicines could have for patients, which is the vision on which Ardelyx was founded."

Clinical Program Updates

Tenapanor for IBS-C

- **T3MPO-2 Phase 3 Trial in IBS-C Hits Statistical Significance for All Primary and Secondary Endpoints** - In October, Ardelyxannounced positive results from the company's second Phase 3 registration study of tenapanor for the treatment of patients with irritable bowel syndrome with constipation (IBS-C). The study hit statistical significance for the primary endpoint and all secondary endpoints evaluated for the topline results and demonstrated the ability to normalize bowel movements. Tenapanor was well-tolerated in the study, consistent with previous studies.
- **T3MPO-1 Phase 3 Data Highlighted in Oral Presentation at ACG Annual Meeting:** At the American College of Gastroenterology (ACG) Annual Meeting in October, Bill Chey, M.D., a principal investigator in the T3MPO clinical program, presented detailed data from Ardelyx's first positive Phase 3 registration study, T3MPO-1, evaluating tenapanor for the treatment of people with IBS-C, which were originally announced in May 2017.
- **T3MPO-3 Long-term Safety Study Fully Enrolled; Preparing for NDA:**Ardelyx's long-term safety study of tenapanor for IBS-C, T3MPO-3, is fully enrolled and on track to conclude by the end of 2017. With the completion of T3MPO-3, Ardelyx expects to have all data necessary to file a New Drug Application (NDA) with the U.S. Food and Drug Administration (FDA) in the second half of 2018, seeking marketing authorization for tenapanor in IBS-C.
- **Tenapanor Pain Mechanism Spotlighted at ACG Annual Meeting:** Also at the ACG meeting, Ardelyx and collaborators from Johns Hopkins University School of Medicinereported preclinical data showing that tenapanor works to reduce abdominal pain caused by IBS-C through the inhibition of TRPV-1 dependent signaling.

Tenapanor for Hyperphosphatemia

- **Second Phase 3 Study of Tenapanor for Hyperphosphatemia:** In an effort to optimize the potential for clinical and regulatory success in its second Phase 3 trial, and based on learnings from the first successful Phase 3 study, Ardelyx sought feedback on the study protocol from the FDA. Ardelyx is awaiting feedback from FDA, and pending the agency's response is ready to begin enrollment in this Phase 3 clinical trial.
- **Data from First Phase 3 Study Highlighted at ASN Annual Meeting:** Last week, Ardelyx presented detailed positive efficacy and safety data from the company's first Phase 3 study of tenapanor for the treatment of hyperphosphatemia at the American Society of Nephrology (ASN) Annual Meeting. The data were originally announced in February 2017.

RDX7675 for Hyperkalemia

- **Onset-of-Action Study:** Ardelyx anticipates providing an update from its onset-of-action study for RDX7675 for the treatment of hyperkalemia by the end of 2017.

Third Quarter 2017 Financial Results

- **Cash Position:** As of September 30, 2017, Ardelyx had total capital resources including cash, cash equivalents and short-term investments of $129.3 million compared to total capital resources including cash, cash equivalents and short-term investments of $200.8 million as of December 31, 2016.
- **R&D Expenses:** Research and development expenses were $15.4 million for the three months ended September 30, 2017, a decrease of $9.5 million, or 38 percent, compared to $24.9 million for the three months ended September 30, 2016. The decrease consisted of a net $10.2 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, as well as a decrease in clinical and process development activities. This was offset by an increase of $0.7 million in internal program costs, primarily due to increases in salaries and stock-based compensation costs prior to a corporate restructuring announced in August 2017, as well as severance costs associated with the corporate restructuring.
- **G&A Expenses:** General and administrative expenses were $5.8 million for the three months ended September 30, 2017, an increase of $1.5 million, or 35 percent, compared to $4.3 million for the three months ended September 30, 2016. The increase was primarily due to increases in salaries and related costs, including stock-based compensation and facilities costs, due to an increase in headcount and an expansion of facilities in the second half of 2016, increased legal fees, principally related to patent applications, and severance costs.
- **Net Loss:** Net loss for the quarter ended September 30, 2017, was $20.7 million compared to a net loss of $29.0 million for the quarter ended September 30, 2016.

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 portfolios 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, the company's TGR5 agonist. For more information, please visit http://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 tenapanor and RDX7675 and the expected timing thereof; Ardelyx's ability to establish collaborations in the future; and Ardelyx's expectations regarding the filing of an NDA with the FDA seeking marketing authorization for tenapanor for the treatment of IBS-C. 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 Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on November 7, 2017, and its future current and periodic reports to be filed with the Securities and Exchange Commission.

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

	September 30, 2017 (Unaudited)	December 31, 2016 (1)
Assets		
Cash and cash equivalents	$ 59,454	$ 74,598
Short-term investments	69,834	126,225
Property and equipment, net	8,622	8,991
Prepaid and other assets	5,195	3,317
Total Assets	$ 143,105	$ 213,131
Liabilities and stockholders' equity		
Accounts payable and other current liabilities	$ 15,727	$ 19,201
Long-term liabilities	741	779
Stockholders' equity	126,637	193,151
Total liabilities and stockholders' equity	$ 143,105	$ 213,131

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017 (Unaudited)	2016 (Unaudited)	2017 (Unaudited)	2016 (Unaudited)
Operating expenses:				
Research and development	$ 15,365	$ 24,863	$ 58,325	$ 67,951
General and administrative	5,860	4,337	17,752	13,469
Total operating expenses	21,225	29,200	76,077	81,420
Loss from operations	(21,225)	(29,200)	(76,077)	(81,420)
Other income	501	169	1,624	307
Provision for income taxes	—	—	—	—
Net loss	$ (20,724)	$ (29,031)	$ (74,453)	$ (81,113)
Net loss per common share, basic & diluted	$ (0.44)	$ (0.65)	$ (1.57)	$ (2.15)
Shares used in computing net loss per share, basic and diluted	47,464,310	44,935,126	47,404,039	37,706,045

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