Ardelyx Reports Third Quarter 2018 Financial Results and Recent Highlights

November 7, 2018

Tenapanor Second Registration Trial for Hyperphosphatemia Ongoing; On-Track for Data in 2019

FREMONT, Calif., Nov. 7, 2018 /PRNewswire/ -- Ardelyx, Inc. (Nasdaq: ARDX), today reported business highlights and financial results for the third quarter ended September 30, 2018.

"During our first Renal Day event, we heard strong feedback from physician, dietician and policy experts on the need for greater awareness of the health risks of hyperphosphatemia and for new treatments that are both effective and convenient for patients on dialysis. Our panelists shared enthusiasm for tenapanor, making us even more energized about its potential to become the first and only non-binder treatment for this severe and highly prevalent disorder in patients on dialysis," said Mike Raab, president and chief executive officer of Ardelyx.

"Tenapanor has a completely new mechanism for treating hyperphosphatemia and is easy to take, with just two small pills daily. In our first Phase 3 trial, tenapanor demonstrated efficacy in reducing serum phosphorus and a favorable safety profile. Additionally, preclinical data presented recently at ASN show encouraging synergy between tenapanor and sevelamer. We look forward to beginning a clinical trial soon to evaluate tenapanor in combination with either sevelamer or another approved phosphate binder, and to further advancing our second Phase 3 registration trial of tenapanor as a monotherapy for the treatment of hyperphosphatemia, with data anticipated in 2019. Positive data from these studies would affirm our belief that tenapanor has the potential to be used both as a monotherapy and combination agent with existing phosphate binders," added Mr. Raab.

Business and Pipeline Updates

- **Preclinical Data Demonstrate Synergy of Tenapanor and Sevelamer Combination:** At the American Society of Nephrology (ASN) annual meeting in October 2018, preclinical data were reported from animal models in which sevelamer, a phosphate binder and today's standard-of-care for the treatment of hyperphosphatemia, was administered at three dose levels with either tenapanor or placebo added twice daily for 11 days. Two additional groups received either tenapanor or placebo alone. Results from this preclinical study showed that the combination of tenapanor and sevelamer resulted in greater reductions in intestinal phosphate absorption than when either agent was administered alone, with a synergistic effect between the two treatments. These data support Ardelyx's plans to evaluate tenapanor in combination with phosphate binders in a planned Phase 2/3 clinical trial.
- **Company Hosted "Renal Day" Focused on Treatment Landscape of Renal Disorders:** In October 2018, Ardelyx hosted an investor event called "Renal Day," the first of an anticipated annual series of events. Panelists included Dr. Geoff Block, director of clinical research at Colorado Kidney Care; Dr. Glenn Chertow professor of medicine (nephrology) at Stanford University School of Medicine; Rory Pace, renal dietician, director of nutrition services at Satellite Healthcare; and Lauren Randall Buckley, group vice president, health policy & reimbursement strategy at Jeffrey J. Kimbell & Associates. The panelists discussed the significant need to improve hyperphosphatemia management in patients on dialysis, challenges with today's treatments, which are limited to binders, and the current market access landscape. Panelists also spoke to the important role tenapanor could play in treating hyperphosphatemia patients in the future, if approved. A replay of the event is available on the Events and Presentations page under the investor relations section of Ardelyx's website at www.ardelyx.com.
- **Tenapanor's Unique Mechanism of Action Inhibiting Paracellular Phosphate Absorption Detailed in *Science Translational Medicine*:** The novel mechanism of action for tenapanor for the treatment of hyperphosphatemia was published in the peer-reviewed journal *Science Translational Medicine*. In the paper, titled "Inhibition of sodium/hydrogen exchanger 3 in the gastrointestinal tract by tenapanor reduces paracellular phosphate permeability," Ardelyx concluded that phosphate absorption in humans occurs primarily through a dynamically regulated paracellular pathway, rather than the transcellular transport pathway. This pathway of phosphate flux is inhibited by tenapanor in a manner that appears largely specific for phosphate, whereas the overall absorption of other ions and large molecules studied, other than sodium, appears not to be affected.
- **New Drug Application for U.S. Marketing Authorization of Tenapanor for IBS-C Submitted to U.S. Food and Drug Administration:** Ardelyx submitted its New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) in September 2018 requesting U.S. marketing authorization for tenapanor for the treatment of patients with irritable bowel syndrome with constipation (IBS-C). Based on standard FDA review timelines, Ardelyx expects to receive notification of acceptance of the filing for substantive review before the end of the year.
- **Data from T3MPO-3 Long-Term Safety Trial of Tenapanor for IBS-C Showcased in Presidential Poster at ACG 2018 Annual Meeting:** In October 2018, new data from the company's long-term safety trial of tenapanor for IBS-C, the T3MPO-3 trial, were presented at the American College of Gastroenterology (ACG) 2018 Annual Meeting. Results from T3MPO-3 showed a mean compliance rate with tenapanor of approximately 98 percent. Overall, tenapanor was well-tolerated, with the most common adverse event being diarrhea (9.2%). There were limited discontinuations (2.1%), with only 1.7 percent of patients discontinuing due to diarrhea.

Third Quarter 2018 Financial Results

- **Cash Position**: As of September 30, 2018, Ardelyx had total capital resources including cash, cash equivalents and short-term investments of $186.4 million compared to total capital resources including cash, cash equivalents and short-term investments of $134.0 million as of December 31, 2017.
- **R&D Expenses:** Research and development expenses were $17.9 million for the three months ended September 30, 2018, an increase of $2.5 million, or 17%, compared to $15.4 million for the three months ended September 30, 2017. The increase was primarily related to our second tenapanor hyperphosphatemia Phase 3 clinical trial that was offset by a decrease related to discontinuation of the RDX7675 program, reduction of activities associated with the RDX8940 program and personnel costs, including stock-based compensation costs as a result of a reduction in force during the third quarter of 2017.
- **G&A Expenses:** General and administrative expenses were $6.0 million for the three months ended September 30, 2018, an increase of $0.1 million, or 2%, compared to $5.9 million for the three months ended September 30, 2017. The increase was primarily due to an increase in professional services partially offset by a reduction in personnel costs due to reduction in force during the third quarter of 2017.
- **Net Loss**: Net loss for the quarter ended September 30, 2018, was $24.1 million compared to a net loss of $20.7 million for the quarter ended September 30, 2017.

Financial Guidance

Ardelyx maintains its expectation that its cash, cash equivalents and short-term investments will be sufficient to fund the company's operations until at least mid-2020 based on its current operating plans.

About Ardelyx, Inc.

Ardelyx is focused on enhancing the way people with cardiorenal diseases are treated by developing first-in-class medicines. Ardelyx's cardiorenal pipeline includes the Phase 3 development of tenapanor for the treatment of hyperphosphatemia in people with end-stage renal disease (ESRD) 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 (IBS-C) and submitted a New Drug Application to the U.S. Food and Drug Administration seeking U.S. marketing approval for this indication. To efficiently bring its treatments to market, Ardelyx is pursuing strategic collaborations for tenapanor for IBS-C and hyperphosphatemia in certain territories. Ardelyx has established agreements with Kyowa Hakko Kirin in Japan, Fosun Pharma in China and Knight Therapeutics in Canada. 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, the potential for the use of tenapanor as monotherapy and in combination with phosphate binders as adjunctive therapy for the treatment of hyperphosphatemia, Ardelyx's expected timing for receipt of data from its ongoing Phase 3 clinical trial of tenapanor for the treatment of hyperphosphatemia in ESRD patients, Ardelyx's expected timing of receipt of notification from the FDA of acceptance for filing for substantive review of Ardelyx's NDA for the treatment of IBS-C, and Ardelyx's expectations regarding the sufficiency of its current capital resources. 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 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, 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)

	September 30, 2018 (Unaudited)	December 31, 2017 (1)
Assets		
Cash and cash equivalents	$ 75,015	$ 75,383
Short-term investments	111,391	58,593
Accounts receivable	167	10,796
Unbilled license revenue	5,000	—
Property and equipment, net	5,996	8,032
Prepaid and other assets	9,099	5,099
Total Assets	$ 206,668	$ 157,903
Liabilities and stockholders' equity		
Accounts payable and other current liabilities	$ 14,549	$ 17,871
Uncharged license fees	1,000	—
Loan payable, long term	49,020	—
Other long-term liabilities	651	720
Stockholders' equity	141,448	139,312
Total liabilities and stockholders' equity	$ 206,668	$ 157,903

(1)Derived from the audited financial statements included on Form 10-K for the year ended December 31, 2017.

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

	Three Months Ended September 30, 2018 (Unaudited)	2017 (Unaudited)	Nine Months Ended September 30, 2018 (Unaudited)	2017 (Unaudited)
Revenue:				
Licensing revenue	$ —	$ —	$ 2,320	$ —
Other revenue	172	—	202	—
Total revenues	172	—	2,522	—
Cost of revenue	2	—	466	—
Gross Profit	170	—	2,056	—
Operating expenses:				
Research and development	$ 17,941	$ 15,365	$ 47,337	$ 58,325
General and administrative	5,961	5,860	18,290	17,752
Total operating expenses	23,902	21,225	65,627	76,077
Loss from operations	(23,732)	(21,225)	(63,571)	(76,077)
Other (expense) income	(394)	501	141	1,624
Provision for income taxes	—	—	(6)	—
Net loss	$ (24,126)	$ (20,724)	$ (63,436)	$ (74,453)
Net loss per common share, basic & diluted	$ (0.39)	$ (0.44)	$ (1.17)	$ (1.57)
Shares used in computing net loss per share, basic and diluted	62,071,397	47,464,310	54,204,907	47,404,039

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