Ardelyx Reports First Quarter 2018 Financial Results and Recent Business Highlights

May 8, 2018

On Track to Submit NDA for Tenapanor in IBS-C in Second Half of 2018
Enrollment Underway in Second Registration Study of Tenapanor for Hyperphosphatemia

FREMONT, Calif., May 8, 2018 /PRNewswire/ -- Ardelyx, Inc. (NASDAQ: ARDX), today reported business highlights and financial results for the first quarter ended March 31, 2018.

"The first quarter of 2018 has been about execution for Ardelyx," said Mike Raab, president and chief executive officer of Ardelyx. "We are focused on enrolling our second Phase 3 study for tenapanor for hyperphosphatemia and investigating the potential of our RDX013 program for the treatment of hyperkalemia. In addition, our team is preparing the NDA submission for tenapanor for IBS-C, which, when submitted, will be a landmark milestone for our company. We now have three strategic collaborations in place that will enable us to bring tenapanor to patients in geographies outside of the U.S., positioning us to be able to meaningfully impact the care of many patients."

Recent Business and Pipeline Updates

- **On Track to Submit NDA for Tenapanor for IBS-C in 2H 2018:** Following the successful completion of the T3MPO program in late 2017, Ardelyx is on-track to submit a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for tenapanor for irritable bowel syndrome with constipation (IBS-C) in the second half of 2018. The Phase 3 T3MPO program was designed to support the registration of tenapanor for the treatment of IBS-C.
- **Patient Enrollment Underway in Second Phase 3 Clinical Trial of Tenapanor for Hyperphosphatemia:** 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 open-label 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, open-label, for the entire 52-week study period. Ardelyx currently expects to report topline data from this clinical trial in 2019.
- **Knight Therapeutics Agreement Brings Tenapanor for IBS-C and Hyperphosphatemia to Canada:** A license agreement with Knight Therapeutics, Inc. (Knight), signed in March 2018, provides Knight with exclusive rights to commercialize tenapanor in Canada for the treatment of IBS-C and hyperphosphatemia. Under the terms of the agreement, Ardelyx is eligible to receive up to CAD 25 million in total payments, including an upfront payment and development and sales milestones, as well as double-digit tiered royalties on net sales. Knight will have the exclusive rights to market and sell tenapanor in Canada.

Upcoming Digestive Disease Week Presentations

Ardelyx has been selected to give an oral presentation of its Phase 3 T3MPO-2 trial results for tenapanor for the treatment of IBS-C in the clinical sciences late-breaking plenary session. The company is also presenting three posters. Ardelyx will present preclinical data from the company's APECCS platform demonstrating tenpanor's pain mechanism, preclinical data from its RDX-023 FXR agonist program showing reduction in steatosis, inflammation and fibrosis in three mouse models of NASH, as well as preclinical data from the RDX-011 NHE3 program showing normalization of GI transit in models of opioid-induced constipation, multiple sclerosis and cystic fibrosis. Digestive Disease Week is being held June 2-5, 2018 in Washington D.C.

First Quarter 2018 Financial Results

- **Cash Position**: As of March 31, 2018, Ardelyx had total capital resources including cash, cash equivalents and short-term investments of $127.4 million compared to total capital resources including cash, cash equivalents and short-term investments of $134.0 million as of December 31, 2017.
- **Revenue**: Licensing revenue for the quarter ended March 31, 2018 was $2.3 million, related to the recognition of revenue from licensing activities. The company generated no license revenue for the quarter ended March 31, 2017.
- **Cost of Revenue**: Cost of revenue for the quarter ended March 31, 2018 was $0.5 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 quarter ended March 31, 2017 and therefore had no cost of revenue.
- **R&D Expenses**: Research and development expenses were $13.4 million for the three months ended March 31, 2018, a decrease of $9.0 million, or 40 percent, compared to $22.4 million for the three months ended March 31, 2017. The decrease consisted of a $7.0 million decrease in external program costs primarily related 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, offset partially by an increase from the start of the company's hyperphosphatemia Phase 3 study, discontinuation of the RDX7675 program and reduction of activities associated with the company's RDX8940 program. The $9.0 million decrease further included a $2.0 million decrease in internal program costs, primarily due to a decrease in salaries and related costs, including stock-based compensation costs, resulting from a reduction in work force during the third quarter of 2017.
- **G&A Expenses**: General and administrative expenses were $6.2 million for the three months ended March 31, 2018, an increase of $0.2 million, or 2 percent, compared to $6.0 million for the three months ended March 31, 2017, remaining relatively flat. The increase was primarily due to increases in stock-based compensation expense, partially offset by a reduction in salaries and related costs due to reduction in work force during the third quarter of 2017.
- **Net Loss**: Net loss for the quarter ended March 31, 2018, was $17.0 million compared to a net loss of $28.0 million for the quarter ended March 31, 2017.

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 outside the U.S., with 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; Ardelyx's expected timing for the filing of its NDA for tenapanor for the treatment of IBS-C, Ardelyx's expected timing to report 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 Knight Therapeutics 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.
Condensed Consolidated Balance Sheets
(In thousands)

	March 31, 2018 (Unaudited)	December 31, 2017 (1)
Assets		
Cash and cash equivalents	$ 67,745	$ 75,383
Short-term investments	59,704	58,593
Accounts receivable	—	10,796
Unbilled license revenue	5,000	—
Property and equipment, net	7,358	8,032
Prepaid and other assets	3,030	5,099
Total assets	$ 142,837	$ 157,903
Liabilities and stockholders' equity		
Accounts payable and other current liabilities	$ 12,162	$ 17,871
Uncharged license fees	1,000	—
Long-term liabilities	699	720
Stockholders' equity	128,976	139,312
Total liabilities and stockholders' equity	$ 142,837	$ 157,903

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

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

	Three Months Ended March 31,	
	2018 (Unaudited)	2017 (Unaudited)
Revenue:		
Licensing revenue	$ 2,320	$ —
Cost of revenue	464	—
Gross profit	1,856	—
Operating expenses:		
Research and development	$ 13,350	$ 22,387
General and administrative	6,191	6,047
Total operating expenses	19,541	28,434
Loss from operations	(17,685)	(28,434)
Other income	670	426
Provision for income taxes	(4)	—
Net loss	$ (17,019)	$ (28,008)
Net loss per common share, basic & diluted	$ (0.36)	$ (0.59)
Shares used in computing net loss per share, basic and diluted	47,559,366	47,343,234

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