Ardelyx Reports Fourth Quarter 2018 Financial Results and Recent Highlights

March 6, 2019

Company is poised for two Phase 3 readouts in 2H 2019 for tenapanor in hyperphosphatemia

FREMONT, Calif., March 6, 2019 /PRNewswire/ -- Ardelyx, Inc. (Nasdaq: ARDX), a biopharmaceutical company focused on developing first-in-class medicines to improve treatment choices for people with cardiorenal diseases, today reported business highlights and financial results for the fourth quarter and full year ended December 31, 2018.

"Over the last year, we made significant progress towards developing our lead product candidate, tenapanor, and executing on our plan to provide patients with this first-ever, non-binder treatment option for the treatment of hyperphosphatemia for patients on dialysis," said Mike Raab, president and chief executive officer of Ardelyx. "We enter 2019 well-positioned with two years of cash on hand to deliver on our strategic goals to report results from two Phase 3 clinical trials during the second half of the year and to prepare for commercialization of our novel therapy."

Key Accomplishments in 2018

- Initiated the PHREEDOM clinical trial, the company's second Phase 3 clinical trial of tenapanor for hyperphosphatemia in patients with end-stage renal disease who are on dialysis. Topline results from this trial are expected in the fourth quarter of 2019.
- Initiated the Phase 3 AMPLIFY clinical trial, designed to evaluate expanded use of tenapanor as an adjunctive therapy to phosphate binders. Results from the AMPLIFY clinical trial are currently expected in the second half of 2019.
- Reported the unique mechanism of action for tenapanor to inhibit paracellular phosphate absorption in *Science and Translational Medicine*.
- Submitted and received acceptance of the filing of a New Drug Application for U.S. marketing authorization of tenapanor for patients with IBS-C. The target action date under the Prescription Drug User Fee Act (PDUFA) is September 12, 2019.
- Raised approximately $100 million through equity and debt financing to support further development and commercial launch preparation for tenapanor for the treatment of hyperphosphatemia.
- Received a $5 million milestone payment in February 2019 from the company's collaboration partner, Kyowa Hakko Kirin, for the initiation of a Phase 2 clinical study of tenapanor for hyperphosphatemia patients on dialysis in Japan.

Full Year 2018 Financial Results

- **Cash Position**: As of December 31, 2018, Ardelyx had total capital resources including cash, cash equivalents and short-term investments of $168.1 million compared to total capital resources including cash, cash equivalents and short-term investments of $134.0 million as of December 31, 2017.
- **Revenue and Cost of Revenue:** Total revenues were $2.6 million in the year ended December 31, 2018 related to the company's ex-U.S. collaboration partnerships, and cost of revenues was $0.5 million related to payments due to AstraZeneca in accordance with the company's termination agreement entered into with AstraZeneca in June 2015.
- **R&D Expenses:** Research and development expenses were $69.4 million for the year ended December 31, 2018, a decrease of $6.1 million, or 8%, compared to $75.5 million for the year ended December 31, 2017. The decrease consisted of a $1.1 million decrease in external program costs primarily due to discontinuation of the RDX7675 program and the reduction of activities associated with the RDX8940 program that was partially offset by an increase in expense related to the company's tenapanor programs. There was a $5.0 million decrease in internal program costs primarily due to a decrease in personnel costs, including stock-based compensation costs as a result of a reduction in force during the third quarter of 2017, and a related decrease in research and development activities.
- **G&A Expenses:** General and administrative expenses were $23.7 million for the year ended December 31, 2018, an increase of $0.5 million, or 2%, compared to $23.2 million for the year ended December 31, 2017. The increase was primarily due to an increase in professional services and stock-based compensation expense, 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 year ended December 31, 2018, was $91.3 million compared to a net loss of $64.3 million for the year ended December 31, 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 early 2021 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, or NDA, to the U.S. Food and Drug Administration, or FDA, for the treatment of patients with IBS-C which has been granted a target action date under the Prescription Drug User Fee Act (PDUFA) of September 12, 2019. 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 trials of tenapanor for the treatment of hyperphosphatemia in ESRD patients, and Ardelyx's expectations regarding the exhaustion 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, the uncertainties associated with the regulatory approval process, and the uncertainties in the drug commercialization 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 6, 2019, 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, 2018 (Unaudited)	December 31, 2017 (1)
Assets		
Cash and cash equivalents	$ 78,768	$ 75,383
Short-term investments	89,321	58,593
Accounts receivable	85	10,796
Unbilled license revenue	5,000	—
Property and equipment, net	5,611	8,032
Prepaid and other assets	4,547	5,099
Total Assets	$ 183,332	$ 157,903
Liabilities and stockholders' equity		
Accounts payable and other current liabilities	$ 16,728	$ 17,871
Uncharged license fees	1,000	—
Loan payable, long term	49,209	—
Other long-term liabilities	582	720
Stockholders' equity	115,813	139,312
Total liabilities and stockholders' equity	$ 183,332	$ 157,903

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

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

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2018 (Unaudited)	2017 (Unaudited)	2018 (Unaudited)	2017 (1)
Revenue:				
Licensing revenue	$ —	$ 42,000	$ 2,320	$ 42,000
Other revenue	85	—	287	—
Total revenues	85	42,000	2,607	42,000
Cost of revenue	—	8,400	466	8,400
Gross Profit	85	33,600	2,141	33,600
Operating expenses:				
Research and development	$ 22,036	$ 17,159	$ 69,373	$ 75,484
General and administrative	5,425	5,479	23,715	23,231
Total operating expenses	27,461	22,638	93,088	98,715
(Loss) income from operations	(27,376)	10,962	(90,947)	(65,115)
Interest expense	(1,438)	—	(3,534)	—
Other income	950	331	3,187	1,955
Benefit from (provision for) income taxes	2	(1,179)	(4)	(1,179)
Net (loss) income	$ (27,862)	$ 10,114	$ (91,298)	$ (64,339)
Net (loss) income per common share, basic	$ (0.45)	$ 0.21	$ (1.62)	$ (1.36)
Shares used in computing net (loss) income per share, basic	62,108,906	47,528,183	56,219,919	47,435,331
Net (loss) income per common share, diluted	$ (0.45)	$ 0.21	$ (1.62)	$ (1.36)
Shares used in computing net (loss) income per share, diluted	62,108,906	48,724,123	56,219,919	47,435,331

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

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