Ardelyx Reports Fourth Quarter and Full Year 2019 Financial Results and Recent Highlights

March 6, 2020

FREMONT, Calif., March 6, 2020 /PRNewswire/ -- Ardelyx, Inc. (Nasdaq: ARDX), a specialized 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, 2019.

"2019 was a year of significant progress at Ardelyx. We successfully hit all of our key milestones bringing us closer to submitting a New Drug Application to the FDA for tenapanor for the control of serum phosphorus in adult patients with CKD on dialysis in mid-2020 and potentially providing this first in class agent to patients in need," said Mike Raab, president and chief executive officer of Ardelyx. "We enter 2020 well-positioned with data from three successful Phase 3 trials for tenapanor in hyperphosphatemia, key ex-U.S. partnerships and two years of cash on hand to prepare for U.S. commercialization of our novel therapy."

Key Accomplishments in 2019

- Published positive Phase 3 results of tenapanor for the treatment of hyperphosphatemia in the *Journal of the American Society of Nephrology*.
- Appointed renowned nephrologist, Geoffery A. Block, M.D., to the company's board of directors.
- Began the process of building a highly talented and experienced cardiorenal commercial team.
- Announced positive, statistically significant results from the Phase 3 AMPLIFY study evaluating tenapanor in dialysis patients who have uncontrolled hyperphosphatemia despite phosphate binder treatment.
- Received FDA approval for IBSRELA® (tenapanor). The company continues to seek a strategic partner to market IBSRELA in the United States.
- Expanded collaborative partnership with Kyowa Kirin Co., Ltd (KKC) with a new research agreement and a $20.0 million equity investment in Ardelyx under a Stock Purchase Agreement.
- Announced positive topline results from the PHREEDOM study evaluating tenapanor as a monotherapy for the control of serum phosphorus in patients with chronic kidney disease (CKD) on dialysis. The PHREEDOM study met its primary endpoint demonstrating a statistically significant difference in least square (LS) mean serum phosphorus change (-1.4 mg/dL, $p<0.0001$), as compared to placebo.
- Raised approximately $135 million, net of underwriting discounts and commissions, following a successful underwritten public offering of 23,000,000 shares of common stock to support commercial launch preparation for tenapanor for the control of serum phosphorus in patients with CKD on dialysis. The capital raised in the fourth quarter of 2019 extends the company's cash runway into early 2022, based on its current operating plan.
- Initiated the Phase 4 NORMALIZE study and announced initial results demonstrating that a significant number of patients achieved normal serum phosphorus levels with tenapanor alone or with tenapanor and only one to three sevelamer tablets a day.

On-Track to Submit NDA for Tenapanor for the Control of Serum Phosphorus in mid-2020: Ardelyx is on-track to submit a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for tenapanor for the control of serum phosphorus in mid-2020.

Full Year 2019 Financial Results

- **Cash Position**: As of December 31, 2019, Ardelyx had total capital resources including cash, cash equivalents and short-term investments of $247.5 million compared to total capital resources including cash, cash equivalents and short-term investments of $168.1 million as of December 31, 2018.
- **Revenue and Cost of Revenue:** Total revenues were $5.3 million for the year ended December 31, 2019 related to the company's ex-U.S. collaboration partnerships, and cost of revenues was $0.6 million related to payments due to AstraZeneca in accordance with the company's termination agreement entered into with AstraZeneca in June 2015 compared to total revenues of $2.6 million and cost of revenues of $0.5 million for the year ended December 31, 2018.
- **R&D Expenses:** Research and development expenses were $71.7 million for the year ended December 31, 2019, an increase of $2.3 million, or 3%, compared to $69.4 million for the year ended December 31, 2018. The increase consisted of a $3.7 million increase in our internal program costs and a $1.4 million decrease in our external program costs. The increase in our internal costs of $3.7 million was primarily due to an increase in headcount and related personnel costs and an increase in stock-based compensation expenses. The decrease in our external program costs of $1.4 million included a $4.6 million decrease in expenses primarily related to manufacturing of tenapanor and regulatory expenses related to our IBS-C NDA in 2018, partially offset by $2.5 million increase in clinical development expenses related to our RDX013 program and a $0.7 million increase primarily related to our tenapanor clinical trial expenses that includes an

out-of-period adjustment recorded during the second quarter of 2019 that reduced clinical trial expenses by $3.6 million related to our tenapanor clinical trials.

- **G&A Expenses:** General and administrative expenses were $24.3 million for the year ended December 31, 2019, an increase of $0.6 million, or 2%, compared to $23.7 million for the year ended December 31, 2018.
- **Net Loss:** Net loss for the year ended December 31, 2019, was $94.9 million compared to a net loss of $91.3 million for the year ended December 31, 2018.

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 early 2022 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 control of serum phosphorus in patients with CKD 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 received FDA approval of IBSRELA (tenapanor) on September 12, 2019. Ardelyx has established agreements with Kyowa Kirin in Japan, Fosun Pharma in China and Knight Therapeutics in Canada.

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 Ardelyx's expected use of proceeds from the public offering completed in December 2019, the potential for Ardelyx's products and product candidates in treating the diseases and conditions for which they are approved and being developed, the potential for the use of tenapanor as monotherapy and in combination with phosphate binders for the control of serum phosphorus, Ardelyx's ability to enter into strategic collaborations to commercialize its product candidates, and Ardelyx's expectation 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 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, 2020, and its future current and periodic reports to be filed with the Securities and Exchange Commission.

Ardelyx, Inc.
Condensed Balance Sheets
(In thousands)

	December 31, 2019	December 31, 2018
	(Unaudited)	(1)
Assets		
Cash and cash equivalents	$ 181,133	$ 78,768
Short-term investments	66,379	89,321
Accounts receivable	—	85
Unbilled revenue	750	5,000
Prepaid expenses and other assets	4,114	4,547
Property and equipment, net	3,436	5,611
Right-of-use assets	3,970	—
Total Assets	$ 259,782	$ 183,332
Liabilities and stockholders' equity		
Accounts payable	$ 2,187	$ 1,148
Accrued compensation and benefits	4,453	2,723
Uncharged license fees	—	1,000
Current portion of operating lease liability	2,608	—
Loan payable, current portion	1,183	—
Deferred revenue	4,541	—
Accrued expenses and other liabilities	7,248	13,439
Operating lease liability, net of current portion	2,076	—
Loan payable, net of current portion	48,831	49,209
Stockholders' equity	186,655	115,813
Total liabilities and stockholders' equity	$ 259,782	$ 183,332

(1)Derived from the audited financial statements included on Form 10-K for the year ended December 31, 2018.

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

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2019	2018	2019	2018
	(Unaudited)	(Unaudited)	(Unaudited)	(1)
Revenue:				
Licensing revenue	$ 1,500	$ —	$ 4,500	$ 2,320
Collaborative development revenue	459	—	459	—
Other revenue	291	85	322	287
Total revenues	2,250	85	5,281	2,607
Cost of revenue	—	—	600	466
Gross Profit	2,250	85	4,681	2,141
Operating expenses:				
Research and development	$ 14,241	$ 22,036	$ 71,677	$ 69,373
General and administrative	6,857	5,425	24,267	23,715
Total operating expenses	21,098	27,461	95,944	93,088
Loss from operations	(18,848)	(27,376)	(91,263)	(90,947)
Interest expense	(1,398)	(1,438)	(5,726)	(3,534)
Other income, net	456	950	2,352	3,187
Benefit from (provision for) income taxes	—	2	(303)	(4)
Net loss	$ (19,790)	$ (27,862)	$ (94,940)	$ (91,298)
Net loss per common share, basic and diluted	$ (0.27)	$ (0.45)	$ (1.47)	$ (1.62)
Shares used in computing net loss per share, basic and diluted	69,823,746	62,108,906	64,478,066	56,219,919

(1)Derived from the audited financial statements included on Form 10-K for the year ended December 31, 2018.

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