Ardelyx Reports Second Quarter 2018 Financial Results and Recent Highlights

August 7, 2018

Operating Runway Extended to Mid-2020
Preparing to Submit NDA for Tenapanor in IBS-C in Early Q4 2018
Conference Call to be Held Today at 4:30 p.m. ET

FREMONT, Calif., Aug. 7, 2018 /PRNewswire/ -- Ardelyx, Inc. (NASDAQ: ARDX), today reported business highlights and financial results for the second quarter ended June 30, 2018.

"Our focus during the first half of 2018 has been on execution as we work to bring to market first-in-class medicines for renal diseases," said Mike Raab, president and chief executive officer of Ardelyx. "The PHREEDOM Trial, our second Phase 3 study for tenapanor for hyperphosphatemia, is underway and we are on track for data in 2019. If positive, tenapanor could be the first small molecule drug on the market for hyperphosphatemia in dialysis patients with a new, innovative mechanism. We have also advanced our RDX013 program for hyperkalemia and continue to make progress toward initiating clinical development in 2019. Before those important events, we plan to submit our first NDA for tenapanor for IBS-C early in the fourth quarter of this year, a landmark milestone for Ardelyx. With a healthy balance sheet, we are well positioned to achieve both our near and longer-term objectives."

Business and Pipeline Updates

- **On Track to Submit NDA for Tenapanor for IBS-C:** Following the successful completion of the Phase 3 T3MPO program in late 2017, Ardelyx remains 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) early in the fourth quarter of 2018. Ardelyx currently plans to pursue one or more strategic relationships to efficiently bring tenapanor to patients with IBS-C in the United States.
- **Data Presented at Digestive Disease Week:** In June 2018, Ardelyx presented its positive, Phase 3 T3MPO-2 trial results for tenapanor for the treatment of IBS-C in an oral presentation. In addition, Ardelyx presented preclinical data from the company's APECCS platform demonstrating tenapanor'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; and preclinical data from the RDX-011 NHE3 program showing normalization of GI transit in models of opioid-induced constipation, multiple sclerosis and cystic fibrosis.
- **Operating Runway Extended to Mid-2020:** In the second quarter of 2018, Ardelyx raised a net $103.1 million in capital, after all fees and costs, following a successful underwritten public offering of 14,375,000 shares of its common stock, including full exercise of the option for overallotment, and execution of a $50 million senior secured term loan facility with Solar Capital Ltd. and the Life Sciences Group at Bridge Bank, a division of Western Alliance Bank. The capital raised through these activities extends the company's runway to mid-2020, based on its current operating plan.

Second Quarter 2018 Financial Results

- **Cash Position**: As of June 30, 2018, Ardelyx had total capital resources including cash, cash equivalents and short-term investments of $212.7 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 $16.1 million for the three months ended June 30, 2018, a decrease of $4.5 million, or 22 percent, compared to $20.6 million for the three months ended June 30, 2017. The decrease consisted of a $2.4 million decrease in the company's external program costs primarily related to the discontinuation of the RDX7675 program and reduction of activities related to the RDX8940 program, partially offset by an increase in expense due to the start of the company's second tenapanor hyperphosphatemia Phase 3 clinical trial. The $4.5 million decrease further included a $2.1 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 $6.1 million for the three months ended June 30, 2018, an increase of $0.3 million, or 5 percent, compared to $5.8 million for the three months ended June 30, 2017. The increase was primarily due to increases 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 quarter ended June 30, 2018, was $22.3 million compared to a net loss of $25.7 million for the quarter ended June 30, 2017.

Conference Call Information

The company will host a conference call today, August 7, 2018, at 4:30 p.m. ET. To participate in the conference call, please dial (855) 296-9612 (toll-free) or (920) 663-6277 (toll) and reference call ID number 1592643. A webcast of the call can be accessed by visiting the Investor section of the Ardelyx website at ir.ardelyx.com. A replay of the webcast will be available on the Ardelyx website for 60 days following the call.

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 early in the fourth quarter of 2018. To efficiently bring its treatments to market, Ardelyx is pursuing 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, Ardelyx's expected timing for the filing of its NDA for tenapanor for the treatment of hyperphosphatemia, Ardelyx's expected timing for the commencement of clinical development for its RDX013 program, 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 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 August 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)

	June 30, 2018	December 31, 2017
	(Unaudited)	(1)
Assets		
Cash and cash equivalents	$ 91,751	$ 75,383
Short-term investments	120,980	58,593
Accounts receivable	30	10,796
Unbilled license revenue	5,000	—
Property and equipment, net	6,689	8,032
Prepaid and other assets	4,086	5,099
Total Assets	$ 228,536	$ 157,903
Liabilities and stockholders' equity		
Accounts payable and other current liabilities	$ 14,609	$ 17,871
Uncharged license fees	1,000	—
Loan payable, long term	48,836	—
Other long-term liabilities	677	720
Stockholders' equity	163,414	139,312
Total liabilities and stockholders' equity	$ 228,536	$ 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 June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
	(Unaudited)	(Unaudited)	(Unaudited)	(Unaudited)
Revenue:				
Licensing revenue	$ —	$ —	$ 2,320	$ —
Other revenue	30	—	30	—
Total revenues	30	—	2,350	—
Cost of revenue	—	—	464	—
Gross Profit	30	—	1,886	—
Operating expenses:				
Research and development	$ 16,046	$ 20,572	$ 29,396	$ 42,960
General and administrative	6,138	5,846	12,329	11,892
Total operating expenses	22,184	26,418	41,725	54,852
Loss from operations	(22,154)	(26,418)	(39,839)	(54,852)
Other (expense) income	(135)	697	535	1,123
Provision for income taxes	(2)	—	(6)	—
Net loss	$ (22,291)	$ (25,721)	$ (39,310)	$ (53,729)
Net loss per common share, basic & diluted	$ (0.42)	$ (0.54)	$ (0.78)	$ (1.13)
Shares used in computing net loss per share, basic and diluted	52,824,483	47,403,243	50,206,470	47,373,404

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