Ardelyx Reports Second Quarter 2019 Financial Results and Recent Business Highlights

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AMPLIFY clinical trial to read out 3Q19
PHREEDOM clinical trial to read out 4Q19

FREMONT, Calif., Aug. 9, 2019 /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 second quarter ended June 30, 2019.

"We are excited for a catalyst-rich second half of 2019 with planned completion of the final stages of development for tenapanor before we seek approval for its use in treating hyperphosphatemia in end-stage renal disease patients on dialysis," said Mike Raab, president and chief executive officer of Ardelyx. "There continues to be a high unmet need for novel hyperphosphatemia treatments to help ESRD patients achieve phosphorus goals. If positive, the results from our ongoing second Phase 3 clinical trial, PHREEDOM, investigating tenapanor as monotherapy, will allow us to file our NDA next year. If approved, tenapanor will provide patients and health care providers with a novel, first-in-class and much more patient-friendly approach to managing phosphorus levels in dialysis patients. We look forward to announcing results for PHREEDOM in the fourth quarter of this year, and announcing results for AMPLIFY, our ongoing Phase 3 clinical trial evaluating tenapanor's use in combination with phosphate binders in the third quarter of this year."

Remaining Expected 2019 Milestones

- Results from the PHREEDOM clinical trial, the company's second Phase 3 clinical trial evaluating tenapanor as a monotherapy treatment for hyperphosphatemia in patients with end-stage renal disease (ESRD) who are on dialysis, are currently expected to be announced in the fourth quarter of 2019.
- Results from the AMPLIFY clinical trial, the company's Phase 3 clinical trial evaluating tenapanor's efficacy in combination with phosphate binders, are currently expected to be announced in the third quarter of 2019.
- The company's New Drug Application for U.S. marketing authorization of tenapanor for patients with IBS-C has a target action date under the Prescription Drug User Fee Act (PDUFA) of September 12, 2019.

Second Quarter 2019 Financial Results

- Cash Position: As of June 30, 2019, Ardelyx had total capital resources including cash, cash equivalents and short-term investments of $123.9 million compared to total capital resources including cash, cash equivalents and short-term investments of $168.1 million as of December 31, 2018.
- R&D Expenses: Research and development expenses were $19.4 million for the three months ended June 30, 2019, an increase of $3.4 million, or 21 percent, compared to $16.0 million for the three months ended June 30, 2018. The increase included a $7.5 million increase in expense primarily related to the Company's manufacturing of tenapanor, the continued clinical development of tenapanor for the treatment of hyperphosphatemia in ESRD patients on dialysis and the Company's hyperkalemia program, RDX013, partially offset by an out-of-period adjustment that reduced clinical trial expenses by $4.1 million related to the tenapanor clinical trials.
- G&A Expenses: General and administrative expenses were $5.4 million for the three months ended June 30, 2019, a decrease of $0.7 million, or 12 percent, compared to $6.1 million for the three months ended June 30, 2018. The decrease was primarily related to a decrease in professional services and a reduction in stock-based compensation costs partially offset by an increase in headcount and related personnel costs.
- Net Loss: Net loss for the three months ended June 30, 2019 was $25.5 million, or $0.41 per share, compared to a net loss of $22.3 million, or $0.42 per share, for the three months ended June 30, 2018.

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 Kirin (formerly known as 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 for the treatment of hyperphosphatemia, Ardelyx's expected timing for receipt and announcement of data from its ongoing Phase 3 clinical trials of tenapanor for the treatment of hyperphosphatemia in ESRD patients, and Ardelyx's expected timing for filing of its NDA for tenapanor for hyperphosphatemia. 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 August 9, 2019, and its future current and periodic reports to be filed with the Securities and Exchange Commission.

Ardelyx, Inc.
Condensed Balance Sheets
(In thousands)

	June 30, 2019	December 31, 2018
	(Unaudited)	(1)
Assets		
Cash and cash equivalents	$ 89,626	$ 78,768
Short-term investments	34,315	89,321
Accounts receivable	17	85
Unbilled license revenue	—	5,000
Property and equipment, net	4,469	5,611
Right-of-use assets	4,919	—
Prepaid and other assets	4,634	4,547
Total assets	$ 137,980	$ 183,332
Liabilities and stockholders' equity		
Accounts payable and other current liabilities	$ 14,015	$ 16,728
Uncharged license fees	—	1,000
Current portion of operating lease liability	2,318	—
Operating lease liability, net of current portion	3,433	—
Loan payable, long term	49,597	49,209
Other long-term liabilities	—	582
Stockholders' equity	68,617	115,813
Total liabilities and stockholders' equity	$ 137,980	$ 183,332

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
	(Unaudited)	(Unaudited)	(Unaudited)	(Unaudited)
Revenue:				
Licensing revenue	$ —	$ —	$ —	$ 2,320
Other revenue	18	30	18	30
Total revenues	18	30	18	2,350
Cost of revenue	—	—	—	464
Gross Profit	18	30	18	1,886
Operating expenses:				
Research and development	$ 19,475	$ 16,046	$ 39,856	$ 29,396
General and administrative	5,371	6,138	10,488	12,329
Total operating expenses	24,846	22,184	50,344	41,725
Loss from operations	(24,828)	(22,154)	(50,326)	(39,839)
Other (expense) income	(639)	(135)	(1,283)	535
Provision for income taxes	—	(2)	(2)	(6)
Net loss	$(25,467)	$(22,291)	$(51,611)	$(39,310)
Net loss per common share, basic & diluted	$(0.41)	$(0.42)	$(0.82)	$(0.78)
Shares used in computing net loss per share, basic and diluted	62,651,863	52,824,483	62,599,371	50,206,470

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