Ardelyx Reports Second Quarter 2021 Financial Results

August 13, 2021

FREMONT, Calif. and WALTHAM, Mass., Aug. 13, 2021 /PRNewswire/ -- Ardelyx, Inc. (Nasdaq: ARDX), a biopharmaceutical company focused on the discovery, development, and commercialization of innovative first-in-class medicines to improve treatment for people with kidney and cardiorenal diseases, today reported business events and financial results for the second quarter ended June 30, 2021.

Recent Business Events

- On July 29, 2021, the company announced that the U.S. Food & Drug Administration (FDA) issued a Complete Response Letter (CRL) for the company's New Drug Application (NDA) for tenapanor for the control of serum phosphorus in adult patients with chronic kidney disease (CKD) on dialysis. The company plans to request a Type A meeting with the FDA to discuss the CRL and potential next steps to support approval of the company's NDA.
- On August 2, 2021, the company began implementing a restructuring plan to better align the company's workforce and anticipated commercial and development spend with the company's capital resources and the needs of its business following the receipt of the CRL. In connection with the restructuring, the company estimates that it will incur aggregate restructuring charges of approximately $3.4 million, which will be recorded primarily in the third quarter 2021, related to one-time termination notice and severance payments and other employee-related costs. The company expects that the workforce reduction will decrease its annual cash compensation costs by approximately $17 million.
- Separately, two presentations further highlighting promising tenapanor data were given at the European Renal Association – European Dialysis and Transplant Association (ERA-EDTA) Virtual Congress 2021.

Second Quarter 2021 Financial Results

- **Cash Position:** As of June 30, 2021, Ardelyx had total cash, cash equivalents and short-term investments of $171.8 million, as compared to total cash, cash equivalents and investments of $188.6 million as of December 31, 2020.
- **Revenue:** The company generated $1.3 million in revenue for the three months ended June 30, 2021, which primarily represents collaborative development revenue from the 2019 Research Collaboration and Option Agreement between the company and Kyowa Kirin Co., Ltd.
- **R&D Expenses**: Research and development expenses were $26.0 million for the three months ended June 30, 2021, an increase of $7.2 million, or 38 percent, compared to $18.9 million for the three months ended June 30, 2020. The increase was due primarily to clinical study costs from the advancement of the company's OPTIMIZE study which were partially offset by lower costs for the PHREEDOM clinical study, as well as higher employee-related expenses for the research and development workforce.
- **G&A Expenses:** General and administrative expenses were $20.1 million for the three months ended June 30, 2021, an increase of $13.1 million, or 186 percent, compared to $7.0 million for the three months ended June 30, 2020. The increase in general and administrative expenses was primarily due to an increase in costs associated with building and staffing the company's commercial infrastructure as it prepared for the potential regulatory approval and U.S. launch of tenapanor for the control of serum phosphorus in adult patients with CKD on dialysis.
- **Net Loss:** Net loss for the quarter ended June 30, 2021, was $45.2 million, as compared to $25.0 million for the quarter ended June 30, 2020.

About Ardelyx, Inc.

Ardelyx is focused on discovering, developing and commercializing innovative first-in-class medicines to enhance the lives of patients with kidney and cardiorenal diseases. Ardelyx is developing tenapanor, a novel product candidate to control serum phosphorus in adult patients with CKD on dialysis, which has completed three successful Phase 3 trials. Ardelyx is also advancing RDX013, a potassium secretagogue, for the potential treatment of elevated serum potassium, or hyperkalemia, a problem among certain patients with kidney and/or heart disease and has an early-stage program in metabolic acidosis, a serious electrolyte disorder in patients with CKD. 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 for the development and commercialization of tenapanor in their respective territories.

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 expectation with regard to its interactions and communications with the FDA and its plans and expectations as to the possibility of a pathway to approval of tenapanor for the control of serum phosphorus in adult patients with chronic kidney disease on dialysis, and Ardelyx's expectations regarding the costs associated with its restructuring plan and the reduction in annual cash compensation costs resulting from the workforce reduction. Such forward-looking statements involve substantial risks and uncertainties that could cause 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, whether the company will be able to address the deficiencies identified by the FDA, whether additional trials will be necessary and if so, the scope of those trials, and whether and to what extent the restructuring costs may be in excess of what Ardelyx expects. 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 13, 2021, 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, 2021 (Unaudited)	December 31, 2020 (1)
Assets		
Cash and cash equivalents	$ 86,745	$ 91,032
Investments	85,064	97,586
Property and equipment, net	2,666	1,936
Right-of-use assets	14,519	2,274
Prepaid and other assets	15,988	8,754
Total assets	$ 204,982	$ 201,562
Liabilities and stockholders' equity		
Accounts payable	$ 2,587	$ 5,626
Accrued compensation and benefits	5,939	5,672
Current portion of operating lease liability	3,184	2,117
Loan payable, current portion	36,111	4,167
Deferred revenue	4,359	4,177
Accrued expenses and other liabilities	8,552	6,657
Operating lease liability, net of current portion	11,548	413
Loan payable, net of current portion	15,133	46,621
Stockholders' equity	117,569	126,112
Total liabilities and stockholders' equity	$ 204,982	$ 201,562

(1) Derived from the audited financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2020.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Revenues:				
Collaborative development revenue	1,310	1,125	2,764	2,300
Product supply revenue	—	5	126	43
Licensing revenue	3	706	5,005	706
Total revenues	1,313	1,836	7,895	3,049
Operating expenses:				
Cost of revenue	—	141	1,000	141
Research and development	26,021	18,864	46,477	34,708
General and administrative	20,124	7,038	37,255	14,176
Total operating expenses	46,145	26,043	84,732	49,025
Loss from operations	(44,832)	(24,207)	(76,837)	(45,976)
Interest expense	(1,202)	(1,226)	(2,302)	(2,583)
Other income (expense), net	847	477	798	1,230
Loss before provision for income taxes	(45,187)	(24,956)	(78,341)	(47,329)
Provision for income taxes	$ 2	$ —	$ 3	$ —
Net loss	$ (45,189)	$ (24,956)	$ (78,344)	$ (47,329)
Net loss per common share, basic and diluted	$ (0.45)	$ (0.28)	$ (0.79)	$ (0.59)
Shares used in computing net loss per share - basic and diluted	100,040,083	89,080,046	98,617,564	88,890,353

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SOURCE Ardelyx

Kimia Keshtbod, kkeshtbod@ardelyx.com; Sylvia Wheeler, Wheelhouse Life Science Advisors, swheeler@wheelhouselsa.com; Alex Santos, Wheelhouse Life Science Advisors, asantos@wheelhouselsa.com