Ardelyx Reports Third Quarter 2021 Financial Results

November 12, 2021

FREMONT, Calif. and WALTHAM, Mass., Nov. 12, 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 third quarter ended September 30, 2021.

Recent Business Events

- The company presented four posters at the American Society of Nephrology Kidney Week 2021 (ASN Kidney Week), which took place virtually on November 4 – November 7, 2021, highlighting additional positive clinical observations with tenapanor, a first-in-class phosphate absorption inhibitor which has completed three successful Phase 3 clinical trials for the control of serum phosphorus in adult patients with chronic kidney disease (CKD) on dialysis. The company also shared important data focusing on the patient experience with tenapanor from the Phase 4 OPTIMIZE trial, which is designed to optimize the treatment of hyperphosphatemia in patients with CKD on dialysis.
- On November 4, 2021, the company announced that it expects to submit a Formal Dispute Resolution Request (FDRR) by the end of the fourth quarter 2021 to appeal the issuance of a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) for the company's New Drug Application (NDA) for tenapanor for the control of serum phosphorus in adult patients with CKD on dialysis.
- On October 13, 2021, the company announced the results of an End of Review Type A meeting with FDA's Division of Cardiology and Nephrology, noting that the meeting did not provide clarity regarding a reasonable path forward for the resubmission of the company's NDA for tenapanor for the control of serum phosphorus in adult patients with CKD on dialysis.
- On October 12, 2021, the company announced that it began implementing a restructuring plan to reduce operating costs and better align the company's workforce with the needs of its business following the receipt of the CRL from the FDA on July 28, 2021, and the outcome of the End of Review Type A meeting. The restructuring plan is expected to be completed in December 2021.
- On September 3, 2021, the company announced the publication of the company's long term 52-week Phase 3 PHREEDOM trial in the American Society of Nephrology Journal, Kidney 360. The publication highlights a clinically meaningful reduction in mean serum phosphorus from 7.7 mg/dL to 5.1 mg/dL at the end of the 26-week treatment period in the efficacy analysis set.

Third Quarter 2021 Financial Results

- **Cash Position:** As of September 30, 2021, Ardelyx had total cash, cash equivalents and short-term investments of $141.7 million, as compared to total cash, cash equivalents and investments of $188.6 million as of December 31, 2020.
- **Revenue:** The company generated $1.2 million in revenue for the three months ended September 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 $23.7 million for the three months ended September 30, 2021, an increase of $11.5 million, or 94 percent, compared to $12.2 million for the three months ended September 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. Research and development employee-related expenses included $1.2 million in severance payments and other employee-related costs associated with a restructuring implemented in August 2021.
- **G&A Expenses:** General and administrative expenses were $19.7 million for the three months ended September 30, 2021, an increase of $12.1 million, or 158 percent, compared to $7.6 million for the three months ended September 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. General and administrative employee-related expenses included $2.4 million in severance payments and other employee-related costs associated with a restructuring implemented in August 2021.
- **Net Loss:** Net loss for the quarter ended September 30, 2021, was $43.6 million, compared to $18.1 million for the quarter ended September 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 to submit a Formal Dispute Resolution Request to appeal the FDA's issuance of a CRL for its NDA for tenapanor for the control of serum phosphorus in CKD patients on dialysis, and the expected timing thereof, and Ardelyx's expectations regarding the timing of the completion of the restructuring that it began implementing in October 2021. 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, uncertainties associated with the NDA process, and the Formal Dispute Resolution process, as well as uncertainties associated with restructuring efforts. 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. 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 November 12, 2021, and its future current and periodic reports to be filed with the Securities and Exchange Commission.

Ardelyx, Inc.
Condensed Balance Sheets
(In thousands)

	September 30, 2021 (Unaudited)	December 31, 2020 (1)
Assets		
Cash and cash equivalents	$ 75,288	$ 91,032
Investments	66,363	97,566
Accounts receivable	287	—
Property and equipment, net	2,651	1,936
Right-of-use assets	13,580	2,274
Prepaid and other assets	12,679	8,754
Total assets	$ 170,848	$ 201,562
Liabilities and stockholders' equity		
Accounts payable	$ 4,263	$ 5,626
Accrued compensation and benefits	4,770	5,672
Current portion of operating lease liability	3,391	2,117
Loan payable, current portion	44,444	4,167
Deferred revenue	3,474	4,177
Accrued expenses and other liabilities	11,373	6,657
Operating lease liability, net of current portion	10,669	413
Loan payable, net of current portion	7,032	46,621
Stockholders' equity	81,432	126,112
Total liabilities and stockholders' equity	$ 170,848	$ 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 September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Revenues:				
Collaborative development revenue	$ 886	$ 1,356	$ 3,650	$ 3,656
Product supply revenue	285	1,357	411	1,400
Licensing revenue	2	—	5,007	706
Total revenues	1,173	2,713	9,068	5,762
Operating expenses:				
Cost of revenue	—	—	1,000	141
Research and development	23,695	12,240	70,172	46,948
General and administrative	19,714	7,634	56,969	21,810

Total operating expenses	43,409	19,874	128,141	68,899
Loss from operations	(42,236)	(17,161)	(119,073)	(63,137)
Interest expense	(1,216)	(1,202)	(3,518)	(3,785)
Other (expense) income, net	(134)	255	664	1,485
Loss before provision for income taxes	(43,586)	(18,108)	$ (121,927)	$ (65,437)
Provision for income taxes	1	—	4	—
Net loss	$ (43,587)	$ (18,108)	$ (121,931)	$ (65,437)
Net loss per common share, basic and diluted	$ (0.42)	$ (0.20)	$ (1.21)	$ (0.73)
Shares used in computing net loss per share - basic and diluted	104,144,606	89,365,798	100,480,156	89,109,772

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SOURCE Ardelyx

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