



## Ardelyx Reports First Quarter 2021 Financial Results and Recent Business Highlights

May 6, 2021

FREMONT, Calif. and WALTHAM, Mass., May 6, 2021 /PRNewswire/ -- Ardelyx, Inc. (Nasdaq: ARDX), a biopharmaceutical company focused on developing innovative first-in-class medicines to improve treatment for people with kidney and cardiorenal diseases, today reported business highlights and financial results for the first quarter ended March 31, 2021.



"We continue to prepare for the potential approval and launch of tenapanor following the recent extension of our PDUFA date to July 29, 2021," said Mike Raab, president and chief executive officer of Ardelyx. "We remain confident in the comprehensive data included in our New Drug Application and believe tenapanor represents an attractive alternative to currently available therapies to control serum phosphorus in CKD patients on dialysis. To that end, we are committed to working with the FDA through the completion of its review of our NDA and look forward to the possibility of making a significant impact in the lives of patients."

### Recent Business and Pipeline Updates

- Prescription Drug User Fee Act (PDUFA) date for tenapanor for the control of serum phosphorus in adult patients with chronic kidney disease (CKD) on dialysis was extended by three months to July 29, 2021.
- Received a \$5 million milestone payment in April 2021 from the company's collaboration partner, Kyowa Kirin Co., Ltd. (KKC) following KKC's initiation of four Phase 3 clinical studies of tenapanor for hyperphosphatemia patients on dialysis in Japan.
- Appointed industry veteran, Muna Bhanji, R.Ph., to the company's board of directors.
- Presented two posters: 1) the mechanistic understanding of phosphate absorption and 2) continuing education needs of clinicians managing hyperphosphatemia, at the National Kidney Foundation 2021 Spring Clinical Meeting.
- Presented poster titled: A Long-Term, Open Label Study to Evaluate the Ability of Tenapanor Alone or in Combination with Sevelamer to Achieve Normal Serum Phosphorus in Patients with CKD on Dialysis (NORMALIZE) at the ISN World Congress of Nephrology 2021.

### First Quarter 2021 Financial Results

- **Cash Position:** As of March 31, 2021, Ardelyx had total cash, cash equivalents and short-term investments of \$178.2 million, as compared to total cash, cash equivalents and short-term investments of \$188.6 million as of December 31, 2021.
- **Revenue:** The company generated \$6.6 million in revenue, which primarily represents a \$5.0 million milestone from KKC following its initiation of four Phase 3 clinical studies of tenapanor for hyperphosphatemia patients on dialysis in Japan.
- **R&D Expenses:** Research and development expenses were \$20.5 million for the three months ended March 31, 2021, an increase of \$4.6 million, or 29 percent, compared to \$15.8 million for the three months ended March 31, 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 \$17.1 million for the three months ended March 31, 2021, an increase of \$10.0 million, or 140 percent, compared to \$7.1 million for the three months ended March 31, 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 prepares for the anticipated U.S. launch of tenapanor for the control of serum phosphorus in CKD patients on dialysis.
- **Net Loss:** Net loss for the quarter ended March 31, 2021 was \$33.2 million, as compared to \$22.4 million for the quarter ended March 31, 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 advancing tenapanor, a novel product candidate to control serum phosphorus in adult patients with CKD on dialysis, for which the company's NDA is currently under review by the FDA. 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<sup>®</sup> (tenapanor) on September 12, 2020. 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 statements regarding the potential for tenapanor to be approved for marketing by the FDA for the control of serum phosphorus in chronic kidney disease patients on dialysis. 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, the uncertainties associated with 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 May 6, 2021, and its future current and periodic reports to be filed with the Securities and Exchange Commission.

**Ardelyx, Inc.**  
**Condensed Balance Sheets**  
(In thousands)

	<b>March 31, 2021</b>	<b>December 31, 2020</b>
	<b>(Unaudited)</b>	<b>(1)</b>
<b>Assets</b>		
Cash and cash equivalents	\$ 84,070	\$ 91,032
Investments	94,142	97,566
Accounts receivable	5,783	—
Property and equipment, net	2,292	1,936
Right-of-use assets	1,667	2,274
Prepaid and other assets	22,339	8,754
<b>Total assets</b>	<b>\$ 210,293</b>	<b>\$ 201,562</b>
<b>Liabilities and stockholders' equity</b>		
Accounts payable	\$ 5,378	\$ 5,626
Accrued compensation and benefits	4,348	5,672
Current portion of operating lease liability	1,412	2,117
Loan payable, current portion	16,667	4,167
Deferred revenue	5,670	4,177
Accrued expenses and other liabilities	11,262	6,657
Operating lease liability, net of current portion	397	413
Loan payable, net of current portion	34,348	46,621
Stockholders' equity	130,811	126,112
<b>Total liabilities and stockholders' equity</b>	<b>\$ 210,293</b>	<b>\$ 201,562</b>

(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)

	<b>Three Months Ended March 31,</b>	
	<b>2021</b>	<b>2020</b>
<b>Revenues:</b>		
Collaborative development revenue	\$ 1,454	\$ 1,175
Product supply revenue	126	38
Licensing revenue	5,002	—
<b>Total revenues</b>	<b>6,582</b>	<b>1,213</b>
<b>Operating expenses:</b>		
Cost of revenue	1,000	—
Research and development	20,456	15,844
General and administrative	17,131	7,138
<b>Total operating expenses</b>	<b>38,587</b>	<b>22,982</b>
<b>Loss from operations</b>	<b>(32,005)</b>	<b>(21,769)</b>
Interest expense	(1,100)	(1,357)
Other income (expense), net	(49)	753
<b>Loss before provision for income taxes</b>	<b>(33,154)</b>	<b>(22,373)</b>
<b>Provision for income taxes</b>	<b>\$ 1</b>	<b>\$ —</b>
<b>Net loss</b>	<b>\$ (33,155)</b>	<b>\$ (22,373)</b>
<b>Net loss per common share, basic and diluted</b>	<b>\$ (0.34)</b>	<b>\$ (0.25)</b>
<b>Shares used in computing net loss per share - basic and diluted</b>	<b>97,179,241</b>	<b>88,880,658</b>

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SOURCE Ardelyx

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