



Ardelyx Reports First Quarter 2020 Financial Results and Recent Business Highlights

May 7, 2020

Company maintains strong balance sheet with \$223.2 million in cash, cash equivalents and short-term investments

FREMONT, Calif., May 7, 2020 /PRNewswire/ -- Ardelyx, Inc. (Nasdaq: ARDX), a specialized biopharmaceutical company focused on developing innovative first-in-class medicines to improve treatment for people with kidney and cardiovascular diseases, today reported business highlights and financial results for the first quarter ended March 31, 2020.



"During these unprecedented times, our priorities are focused on the well-being and safety of our employees, patients, and communities, while continuing on our mission to provide patients with first-in-class, disruptive medicines based on our breakthrough science," said Mike Raab, president and chief executive officer of Ardelyx. "We are fortunate that much of our clinical work has been completed, with minimal impact of the pandemic on our business, and we are on track to submit our NDA for tenapanor for the control of serum phosphorus in adult patients with CKD on dialysis by mid-year. In preparation for potential approval in mid-2021, we are laying the foundation for launch with important pre-commercial activities underway."

Recent Business and Pipeline Updates

- Initial data from NORMALIZE released in December 2019 demonstrated that of the 73 patients, treated for more than one month, 42% achieved normal phosphorus levels of less than 4.6 mg/dL and of those, 58% accomplished this with either tenapanor alone or with tenapanor in combination with only one to three sevelamer tablets per day. These early and exciting data represent a 45% improvement over current phosphate binder data from the 2019 Dialysis Outcomes and Practice Patterns Study (DOPPS), an ongoing, national prospective study of hemodialysis practice.
- Appointed industry veteran, Onaiza Cadoret-Manier to the company's board of directors.
- Our collaboration partner in Canada, Knight Therapeutics, received approval from Health Canada for IBSRELA® for the treatment of IBS-C in adults.
- Planned initiation of the OPTIMIZE clinical trial in 2020, a study to inform physicians on the integration of tenapanor into clinical practice.

Expected 2020 Milestones

- **Preparing NDA Submission for Tenapanor for the Control of Serum Phosphorus in mid-2020:** With strong data from its clinical program for tenapanor, Ardelyx is preparing a New Drug Application for tenapanor for the control of serum phosphorus in adult patients with CKD on dialysis, which the company currently intends to submit to the U.S. Food and Drug Administration in mid-2020.
- Reporting AMPLIFY and PHREEDOM Phase 3 results and NORMALIZE Phase 4 results at upcoming medical conferences.

First Quarter 2020 Financial Results

- **Cash Position:** As of March 31, 2020, Ardelyx had total cash, cash equivalents and short-term investments of \$223.2 million, as compared to total cash, cash equivalents and short-term investments of \$247.5 million as of December 31, 2019.
- **Revenue:** The company generated \$1.2 million in revenue, which primarily represents collaborative development revenue, for the quarter ended March 31, 2020.
- **R&D Expenses:** Research and development expenses were \$15.8 million for the three months ended March 31, 2020, a decrease of \$4.6 million, or 22.3 percent, compared to \$20.4 million for the three months ended March 31, 2019. The decrease was due primarily to a decrease in external R&D expenses, with a \$5.1 million decrease in tenapanor-related expenses, as well as a \$0.8 million decrease in RDX013 program-related expenses, partially offset by \$0.8 million of higher expenses attributable to research conducted under the Research Collaboration and Option Agreement entered into with Kyowa Kirin Co., Ltd., in November 2019 and general R&D expenses. Of the overall tenapanor-related decrease, approximately \$4.1 million relates to lower clinical study costs and approximately \$1.4 million relates to lower manufacturing expenses.
- **G&A Expenses:** General and administrative expenses were \$7.1 million for the three months ended March 31, 2020, an increase of \$2.0 million, or 39.5 percent, compared to \$5.1 million for the three months ended March 31, 2019. The increase in general and administrative expenses was primarily due to an increase in headcount and related personnel costs, including stock-based compensation costs related to option vesting and performance-based restricted stock units, severance expenses related to the departure of the company's former chief financial officer in March 2020, and an increase in professional services.

- **Net Loss:** Net loss for the quarter ended March 31, 2020 was \$22.4 million, as compared to \$26.1 million for the quarter ended March 31, 2019.

About Ardelyx, Inc.

Ardelyx is focused on enhancing the way people with kidney and cardiovascular diseases are treated by developing innovative first-in-class medicines. Ardelyx's pipeline includes tenapanor for the control of serum phosphorus in adult patients with CKD on dialysis, preparing for NDA filing mid-year, 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 received FDA approval of IBSRELA (tenapanor) on September 12, 2019. Ardelyx has established agreements with Kyowa Kirin Corporation in Japan, Fosun Pharma in China and Knight Therapeutics in Canada for the development and commercialization of tenapanor in the 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 Ardelyx's product candidates in treating the diseases and conditions for which they are being developed, the potential for the use of tenapanor for the control of serum phosphorus in chronic kidney disease (CKD) patients on dialysis, and Ardelyx's expectation regarding the timing of the company's submission to the FDA of a NDA for tenapanor for the control of serum phosphorus in adult CKD patients on dialysis. 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, and 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 7, 2020, and its future current and periodic reports to be filed with the Securities and Exchange Commission.

Ardelyx, Inc. Condensed Balance Sheets (In thousands)

	March 31, December 31,	
	2020	2019
	(Unaudited)	(1)
Assets		
Cash and cash equivalents	\$ 105,895	\$ 181,133
Short-term investments	117,312	66,379
Unbilled revenue	750	750
Property and equipment, net	2,968	3,436
Right-of-use assets	3,468	3,970
Prepaid and other assets	4,929	4,114
Total assets	<u>\$ 235,322</u>	<u>\$ 259,782</u>
Liabilities and stockholders' equity		
Accounts payable	\$ 1,012	\$ 2,187
Accrued compensation and benefits	1,951	4,453
Current portion of operating lease liability	2,715	2,608
Loan payable, current portion	7,437	1,183
Deferred revenue	3,366	4,541
Accrued expenses and other liabilities	6,936	7,248
Operating lease liability, net of current portion	1,355	2,076
Loan payable, net of current portion	42,793	48,831
Stockholders' equity	167,757	186,655
Total liabilities and stockholders' equity	<u>\$ 235,322</u>	<u>\$ 259,782</u>

(1) Derived from the audited financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2019.

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

	Three Months Ended March 31,	
	2020	2019
	(Unaudited)	(Unaudited)
Revenues:		
Collaborative development revenue	\$ 1,175	\$ —
Other revenue	38	—
Total revenues	<u>1,213</u>	<u>—</u>
Operating expenses:		
Research and development	15,844	20,381
General and administrative	7,138	5,117
Total operating expenses	<u>22,982</u>	<u>25,498</u>
Loss from operations	(21,769)	(25,498)
Interest expense	(1,357)	(1,434)

Other income, net	753	790
Loss before provision for income taxes	(22,373)	(26,142)
Provision for income taxes	—	2
Net loss	<u>\$ (22,373)</u>	<u>\$ (26,144)</u>
Net loss per common share, basic and diluted	<u>\$ (0.25)</u>	<u>\$ (0.42)</u>
Shares used in computing net loss per share - basic and diluted	<u>88,880,658</u>	<u>62,546,295</u>
Comprehensive loss:		
Net loss	(22,373)	(26,144)
Unrealized (losses) gains on available-for-sale securities	(64)	50
Comprehensive loss	<u>\$ (22,437)</u>	<u>\$ (26,094)</u>

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SOURCE Ardelyx

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