Ardelyx Reports Fourth Quarter and Full Year 2020 Financial Results and Recent Highlights

March 8, 2021

Company well positioned for PDUFA date of April 29, 2021 and the potential launch of tenapanor

FREMONT, Calif. and WALTHAM, Mass., March 8, 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 fourth quarter and full year ended December 31, 2020.

"The stage is set for an exciting year for Ardelyx in 2021" said Mike Raab, president and chief executive officer at Ardelyx. "With our PDUFA date of April 29 rapidly approaching, we are well positioned and well prepared to commercialize tenapanor upon potential FDA approval of the first and only phosphate absorption inhibitor for the control of serum phosphorus. In addition, we continue to make great progress in developing our pipeline of novel therapeutics and in building the organization for success. Our dedication and hard work over the years, particularly in 2020, have led to major advances in our development pipeline that we believe will offer differentiated benefits to patients."

Key Recent and 2020 Accomplishments:

- Submitted a New Drug Application (NDA) for tenapanor for the control of serum phosphorus in adult patients with chronic kidney disease (CKD) on dialysis and received acceptance from FDA and a Prescription Drug User Fee Act (PDUFA) date of April 29, 2021.
- Increased education and visibility on clinical data for tenapanor with:
  - Five posters at ASN Kidney Week 2020, three of which covered the company's AMPLIFY, PHREEDOM, and BLOCK Phase 3 clinical trial results, with the other two posters highlighting data from Phase 2 clinical trials evaluating the efficacy and safety of tenapanor in patients on hemodialysis conducted by the company's partner for tenapanor in Japan, Kyowa Kirin Co., Ltd (KKC).
  - Data analysis reported in June 2020 from ongoing NORMALIZE 18-month extension study showing that the use of tenapanor alone or in combination with sevelamer carbonate produced a significant phosphorus-lowering effect, with up to 47.4% of the 171 patients in the interim analysis achieving a normal serum phosphorus level, and of those, the majority were on tenapanor alone or tenapanor with low dose sevelamer of three or fewer sevelamer tablets per day.
- Ardelyx's collaboration partner in Japan, KKC, presented data at the European Renal Association-European Dialysis and Transplant Association annual meeting (ERA-EDTA 2020) from a Phase 2 study designed to evaluate if patients with hyperphosphatemia undergoing hemodialysis, who were switched to tenapanor, could achieve at least a 30% decrease in mean pill burden while maintaining their serum phosphorus level. The results demonstrated that tenapanor enabled a significant reduction in overall pill burden (mean reduction in phosphate binder pill usage by 80%), while maintaining serum phosphorus levels (mean serum phosphorus levels 5.2 mg/dL at baseline and 4.7 mg/dL at week 26).
- Presented safety and pharmacodynamics data from a Phase 1 clinical study with RDX013, noting that the results of the Phase 1 clinical study support the Company's decision to advance RDX013 to a Phase 2 clinical study in 2021.
- Enhanced commercial capabilities and market readiness with hiring of market access, patient services, marketing, and sales leadership teams.
- Strengthened leadership team with key appointments of Chief Commercial Officer, Susan Rodriguez, Chief Financial Officer, Justin Renz and Senior Vice President, Global Therapeutic Strategies and Patient Advocacy, Laura Williams.
- In October 2020, launched "Can We Do Better?" Disease Awareness Campaign highlighting significant challenges in current management of hyperphosphatemia, new mechanistic understanding of phosphate absorption, and Ardelyx's commitment to advancing patient care.
- In November 2020, hosted a virtual analyst day featuring German Hernandez, M.D., FASN, FACP, associate nephrologist at El Paso Kidney Specialists and clinical associate professor of medicine at Texas Tech University Health Sciences Center; Jennifer Robinson, president of Spherix Global Insights; and Douglas Paul, PharmD, Ph.D., vice president and partner at MME. The event focused on the company's proposed launch and commercialization plans in anticipation of the potential approval of tenapanor for the control of serum phosphorus in adult patients with CKD on dialysis. Additionally, the company reviewed its pipeline, including RDX013 for hyperkalemia and RDX020 for metabolic acidosis.
- From November 2020 through February 2021, Ardelyx sold 8,198,217 shares of common stock under its At-the-Market Facility with Jefferies LLC for gross proceeds before commissions of $56.7 million, which includes approximately $21.7 million in gross proceeds in the fourth quarter 2020.

Full Year 2020 Financial Results

- **Cash Position**: As of December 31, 2020, Ardelyx had total capital resources including cash and investments of $188.6 million compared to $247.5 million as of December 31, 2019.
- **Revenue and Cost of Revenue:** Total revenues were $7.6 million for the year ended December 31, 2020 related to the company's ex-U.S. collaboration partnerships, and cost of revenues was $0.1 million related to payments due to AstraZeneca in accordance with the company's termination agreement entered into with AstraZeneca in June 2015 compared to total revenues of $5.3 million and cost of revenues of $0.6 million for the year ended December 31, 2019.

  R&D Expenses: Research and development expenses were $65.1 million for the year ended December 31, 2020, a decrease of $6.6 million, or 9%, compared to $71.7 million for the year ended December 31, 2019. The decrease in R&D expenses was primarily related to the winding down of expenses associated with our Phase 3 clinical program for tenapanor for the control of hyperphosphatemia, partially offset by higher expenses attributable to research expenses associated with our research collaboration and option agreement entered into with KKC in 2019.

  G&A Expenses: General and administrative expenses were $33.2 million for the year ended December 31, 2020, an increase of $8.9 million, or 37%, compared to $24.3 million for the year ended December 31, 2019. The increase was primarily due to an increase in costs associated with building and staffing our commercial infrastructure and teams as we prepare for the anticipated U.S. launch of tenapanor for the control of serum phosphorus in CKD patients on dialysis. The increase consisted of headcount and related personnel costs and an increase in external spending for disease awareness initiatives, commercial infrastructure and strategy.
- **Net Loss:** Net loss for the year ended December 31, 2020, was $94.3 million compared to a net loss of $94.9 million for the year ended December 31, 2019.

Financial Guidance

Ardelyx expects that its cash, cash equivalents and investments will be sufficient to fund the company's operations into the second half of 2022 based on its current operating plans.

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, with a PDUFA date of April 29, 2021. 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 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, the potential for the use of tenapanor as monotherapy and as part of a dual mechanism approach with tenapanor and phosphate binders for such indication, the potential for tenapanor alone or with small doses of phosphate binders to achieve normal serum phosphorus levels, Ardelyx's expected timing of the review of its NDA for tenapanor for the control of serum phosphorus, and Ardelyx's expectations regarding the exhaustion of its current capital resources. 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 and uncertainties in the drug commercialization 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 Annual Report on Form 10-K to be filed with the Securities and Exchange Commission on March 8, 2021, and its future current and periodic reports to be filed with the Securities and Exchange Commission.

Ardelyx, Inc.
Condensed Balance Sheets
(In thousands)

	December 31,	
	2020	2019
	(Unaudited)	(1)
Assets		
Cash and cash equivalents	$ 91,032	$ 181,133
Short-term investments	95,452	66,379
Unbilled revenue	-	750
Prepaid expenses and other assets	8,754	4,114
Property and equipment, net	1,936	3,436
Long-term investments	2,114	-
Right-of-use assets	2,274	3,970
Total assets	$ 201,562	$ 259,782
Liabilities and stockholders' equity		
Accounts payable	$ 5,626	$ 2,187
Accrued compensation and benefits	5,672	4,453
Current portion of operating lease liability	2,117	2,608
Loan payable, current portion	4,167	1,183
Deferred revenue	4,177	4,541
Accrued expenses and other current liabilities	6,657	7,248
Operating lease liability, net of current portion	413	2,076
Loan payable, net of current portion	46,621	48,831
Total stockholders' equity	126,112	186,655
Total liabilities and stockholders' equity	$ 201,562	$ 259,782

(1) Derived from the audited financial statements included on Form 10-K for the year ended December 31, 2019.

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

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2020	2019	2020	2019
	(Unaudited)	(Unaudited)	(Unaudited)	(1)
Revenue:				
Collaborative development revenue	$ 1,708	$ 459	$ 5,364	$ 459
Product supply revenue	101	291	1,501	322
Licensing revenue	0	1,500	706	4,500
Total revenues	1,809	2,250	7,571	5,281
Operating expenses:				
Cost of revenue	4	-	145	600
Research and development	18,105	14,241	65,053	71,677
General and administrative	11,343	6,857	33,153	24,267
Total operating expenses	29,452	21,098	98,351	96,544
Loss from operations	(27,643)	(18,848)	(90,780)	(91,263)
Interest expense	(1,314)	(1,398)	(5,099)	(5,726)
Other income, net	83	456	1,568	2,352
Provision for income taxes	(2)	-	(2)	(303)
Net loss	$ (28,876)	$ (19,790)	$ (94,313)	$ (94,940)
Net loss per common share, basic and diluted	$ (0.32)	$ (0.27)	$ (1.05)	$ (1.47)
Shares used in computing net loss per share, basic and diluted	90,988,968	69,823,746	89,582,138	64,478,066

(1) Derived from the audited financial statements included on Form 10-K for the year ended December 31, 2019.

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