Ardelyx Reports Fourth Quarter and Full Year 2021 Financial Results and Recent Highlights

February 28, 2022

Company Advancing Toward Launch of IBSRELA® in April 2022
Conference Call scheduled for 4:30 PM Eastern Time

WALTHAM, Mass., Feb. 28, 2022 /PRNewswire/ -- Ardelyx, Inc. (Nasdaq: ARDX), a biopharmaceutical company founded with a mission to discover, develop and commercialize innovative first-in-class medicines that meet significant unmet medical needs, today reported business events and financial results for the fourth quarter and full year ended December 31, 2021.

"With a tumultuous 2021 behind us, Ardelyx is positioned to be a biopharma standout in 2022 with our evolution to a commercial stage company with our April launch of IBSRELA for the treatment of irritable bowel syndrome with constipation (IBS-C) in adults," said Mike Raab, president and chief executive officer of Ardelyx. "This year we become a revenue-generating company commercializing a novel mechanism treatment we developed, with a clear line of sight to breakeven and, ultimately, profitability for the product, which we believe will create significant shareholder value. I want to recognize the entire Ardelyx team whose dedication over the years has brought us to this critical inflection point. Every single team member has an unyielding commitment to patients that fuels our mission to bring to market a diverse pipeline of drug candidates and provide the company optionality. We are very excited to see our first drug enter the market and improve the lives of patients with IBS-C."

Recent Business Events

- The company plans to launch IBSRELA (tenapanor), the company's FDA approved treatment for irritable bowel syndrome with constipation (IBS-C) in adults, in April of 2022.
- The company's collaboration partner, Kyowa Kirin Co. Ltd., (KKC) announced positive Phase 3 results of tenapanor for hyperphosphatemia in patients on hemodialysis in Japan and plans to file for approval in the second half of 2022 with potential regulatory approval in the second half of 2023.
- On February 4, 2022, the company received an Appeal Denied Letter ("ADL") from the Office of Cardiology, Hematology, Endocrinology and Nephrology ("OCHEN") of the U.S. Food and Drug Administration (the "FDA") in response to its Formal Dispute Resolution Request ("FDRR") submitted in early December 2021. In February 2022, the company submitted an appeal of the ADL to the Office of New Drugs ("OND"), Center for Drug Evaluation and Research. If accepted for consideration, the company expects a decision on the appeal to the OND in April 2022.
- On February 24, 2022, the company announced it is paying off the remainder of $25.0 million in principal plus interest outstanding under the Loan and Security agreement entered into among the company, Solar Capital Ltd. and Western Alliance Bank in May 2018, and has entered into a new term loan with SLR Investment Corp. for $27.5 million, which provides for two years of interest only payments, and an option for an additional $22.5 million in term loan debt if the company receives FDA approval for XPHOZAH® (tenapanor) by December 31, 2022, and meets certain net revenue criteria and other conditions. This further extends the company's cash position in support of the IBSRELA launch.

Full Year 2021 Financial Results

- **Cash Position:** As of December 31, 2021, we had total cash, cash equivalents and short-term investments of $116.7 million, as compared to total cash, cash equivalents and investments of $188.6 million as of December 31, 2020.
- **Revenue:** We generated $10.1 million in revenue for the year ended December 31, 2021, an increase of $2.5 million, or 33 percent, compared to $7.6 million for the year ended December 31, 2020. The increase in our revenue was primarily the result of a $5.0 million development milestone which we earned in 2021 upon the initiation by KKC of Phase 3 clinical studies in Japan to evaluate tenapanor for hyperphosphatemia.
- **R&D Expenses**: Research and development expenses were $91.1 million for the year ended December 31, 2021, an increase of $26.1 million, or 40 percent, compared to $65.1 million for the year ended December 31, 2020. The increase in our R&D expenses is primarily the result of tenapanor manufacturing costs as well as clinical study costs from the advancement of our OPTIMIZE study which were partially offset by lower costs for the PHREEDOM Phase 3 clinical study, which concluded in the second quarter of 2020. Research and development expenses included $2.7 million in severance payments and other employee-related costs associated with restructuring.
- **G&A Expenses:** General and administrative expenses were $72.3 million for the year ended December 31, 2021, an increase of $39.2 million, or 118 percent, compared to $33.2 million for the year ended December 31, 2020. The increase

in general and administrative expenses was primarily due to an increase in costs associated with preparations for the commercial launch of tenapanor. General and administrative employee-related expenses included $3.5 million in severance payments and other employee-related costs associated with restructuring.

- **Net Loss:** Net loss for the year ended December 31, 2021, was $158.2 million, compared to $94.3 million for the year ended December 31, 2020.

Conference Call Details

The company will host a conference call today, February 28, 2022, at 4:30 PM ET to discuss today's announcement. To participate in the conference call, please call (855) 296-9612 (toll-free) or (920) 663-6277 (toll) and reference call ID number 2790368. A webcast of the call can also be accessed by visiting the Investor page of the company's website www.ardelyx.com and will be available on the website for 30 days following the call.

IMPORTANT SAFETY INFORMATION

WARNING: RISK OF SERIOUS DEHYDRATION IN PEDIATRIC PATIENTS

IBSRELA is contraindicated in patients less than 6 years of age; in nonclinical studies in young juvenile rats administration of tenapanor caused deaths presumed to be due to dehydration. Avoid use of IBSRELA in patients 6 years to less than 12 years of age. The safety and effectiveness of IBSRELA have not been established in patients less than 18 years of age.

CONTRAINDICATIONS

- IBSRELA is contraindicated in patients less than 6 years of age due to the risk of serious dehydration.
- IBSRELA is contraindicated in patients with known or suspected mechanical gastrointestinal obstruction.

WARNINGS AND PRECAUTIONS

Risk of Serious Dehydration in Pediatric Patients

- IBSRELA is contraindicated in patients below 6 years of age. The safety and effectiveness of IBSRELA in patients less than 18 years of age have not been established. In young juvenile rats (less than 1 week old; approximate human age equivalent of less than 2 years of age), decreased body weight and deaths occurred, presumed to be due to dehydration, following oral administration of tenapanor. There are no data available in older juvenile rats (human age equivalent 2 years to less than 12 years).
- Avoid the use of IBSRELA in patients 6 years to less than 12 years of age. Although there are no data in older juvenile rats, given the deaths in younger rats and the lack of clinical safety and efficacy data in pediatric patients, avoid the use of IBSRELA in patients 6 years to less than 12 years of age.

Diarrhea

Diarrhea was the most common adverse reaction in two randomized, double-blind, placebo-controlled trials of IBS-C. Severe diarrhea was reported in 2.5% of IBSRELA-treated patients. If severe diarrhea occurs, suspend dosing and rehydrate patient.

MOST COMMON ADVERSE REACTIONS

The most common adverse reactions in IBSRELA-treated patients (incidence ≥2% and greater than placebo) were: diarrhea (16% vs 4% placebo), abdominal distention (3% vs <1%), flatulence (3% vs 1%) and dizziness (2% vs <1%).

INDICATION

IBSRELA (tenapanor) is indicated for the treatment of Irritable Bowel Syndrome with Constipation (IBS-C) in adults.

Please see full Prescribing Information, including Boxed Warning, for additional risk information.

About Ardelyx, Inc.

Ardelyx was founded with a mission to discover, develop and commercialize innovative first-in-class medicines that meet significant unmet medical needs. Ardelyx received approval for IBSRELA (tenapanor) with plans to launch in the second quarter of 2022. 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. 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 regarding the timing of a response from OND with respect to Ardelyx's submission of an appeal from the ADL issued by OCHEN; Ardelyx's expectations regarding the impact that the execution of a new loan and security agreement with SLR will have on Ardelyx's cash position; Ardelyx's expectations regarding the potential for breakeven and, ultimately, profitability for IBSRELA; Ardelyx's expectations regarding the impact on shareholder value that may result from the launch of IBSRELA; Ardelyx's expectations regarding the timing for filing for marketing approval for tenapanor for hyperphosphatemia in Japan by Ardelyx's collaboration partner, KKC and Ardelyx's expectations regarding the

potential timing for KKC's marketing approval in Japan. 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 Formal Dispute Resolution process with the FDA, uncertainties associated with its capital requirements to fund its operations, uncertainties in the commercialization of drugs in the United States, as well as uncertainties in the drug development and regulatory processes in Japan. 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 filed with the Securities and Exchange Commission on February 28, 2022, 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,	
	2021	2020
	(Unaudited)	(1)
Assets		
Cash and cash equivalents	$ 72,428	$ 91,032
Investments	44,261	97,566
Accounts receivable	502	—
Property and equipment, net	2,362	1,936
Right-of-use assets	12,752	2,274
Prepaid and other assets	17,608	8,754
Total assets	$ 149,913	$ 201,562
Liabilities and stockholders' equity		
Accounts payable	$ 4,277	$ 5,626
Accrued compensation and benefits	5,422	5,672
Current portion of operating lease liability	3,492	2,117
Loan payable, current portion	32,264	4,167
Deferred revenue	4,727	4,177
Accrued expenses and other liabilities	7,366	6,657
Operating lease liability, net of current portion	9,748	413
Loan payable, net of current portion	—	46,621
Stockholders' equity	82,617	126,112
Total liabilities and stockholders' equity	$ 149,913	$ 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 December 31,		Twelve Months Ended December 31,	
	2021	2020	2021	2020
Revenues:				
Collaborative development revenue	$ 527	$ 1,708	$ 4,177	$ 5,364
Product supply revenue	496	101	907	1,501
Licensing revenue	6	—	5,013	706
Total revenues	1,029	1,809	10,097	7,571
Operating expenses:				
Cost of revenue	—	4	1,000	145
Research and development	20,968	18,105	91,140	65,053
General and administrative	15,334	11,343	72,303	33,153
Total operating expenses	36,302	29,452	164,443	98,351
Loss from operations	(35,273)	(27,643)	(154,346)	(90,780)
Interest expense	(984)	(1,314)	(4,502)	(5,099)
Other income, net	23	83	687	1,568
Loss before provision for income taxes	(36,234)	(28,874)	$ (158,161)	$ (94,311)
Provision for income taxes	—	2	4	2
Net loss	$ (36,234)	$ (28,876)	$ (158,165)	$ (94,313)
Net loss per common share, basic and diluted	$ (0.31)	$ (0.32)	$ (1.52)	$ (1.05)
Shares used in computing net loss per share - basic and diluted	115,260,610	90,988,968	104,205,645	89,582,138

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SOURCE Ardelyx

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