Ardelyx Reports Third Quarter 2022 Financial Results and Recent Business Highlights

November 3, 2022

Conference call scheduled for 4:30 p.m. Eastern Time today

WALTHAM, Mass., Nov. 3, 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 updates and financial results for the third quarter ended September 30, 2022.

"We are now a full six months into the launch of IBSRELA® and are extremely encouraged by the commercial progress we are making," said Mike Raab, president, and chief executive officer of Ardelyx. "Our efforts are reinforcing strong demand and market receptivity for our novel treatment option in the IBS-C market. We are in a unique position in the biopharmaceutical industry, demonstrating our status as an evolving, impressive growth story with many opportunities ahead. We look forward to continued commercial progress with IBSRELA and the upcoming FDA Advisory Committee meeting for XPHOZAH® on November 16, 2022."

Recent Business Highlights and Updates

- The company had a significant presence at the American College of Gastroenterology 2022 Annual Scientific Meeting (ACG 2022) in Charlotte, NC on October 21-26. The company presented two posters which included post-hoc data analyses from its Phase 3 T3MPO trials and sponsored a Product Theater titled: *An Innovative Approach to the Treatment of Adults with Irritable Bowel Syndrome with Constipation (IBS-C)* where Susan Lucak, MD, reviewed the multifactorial pathophysiology of IBS-C, the novel mechanism of action of IBSRELA, and safety and efficacy data for IBSRELA from the Phase 3 clinical development program. Finally, the company sponsored a Continuing Medical Education (CME) program titled: *Partnering with Patients, Personalizing Care for IBS-C*, where experts in the field provided education on disease pathophysiology, diagnosis and treatment of IBS-C.
- On October 31, the company announced that its collaboration partner in Japan, Kyowa Kirin Co., Ltd, submitted a New Drug Application (NDA) to the Japanese Ministry of Health, Labour and Welfare (MHLW) for tenapanor for the improvement of hyperphosphatemia in adult patients with chronic kidney disease (CKD) on dialysis. Based on this achievement, in the fourth quarter of 2022, Ardelyx expects to receive an aggregate of $35 million in milestone payments and payments associated with the 2022 amendment of the license agreement.
- Earlier today, the company presented two poster presentations at the American Society of Nephrology (ASN) Meeting, with a third poster presentation scheduled for November 5th. All three poster presentations highlight data from the company's three Phase 3 trials (BLOCK, AMPLIFY and PHREEDOM) in patients with hyperphosphatemia on maintenance dialysis in the U.S. Additionally, earlier today at ASN, Kyowa Kirin, presented results of two Phase 3 studies of tenapanor in a similar patient population in Japan. Kyowa Kirin made a public announcement with their results which is available here: Kyowa Kirin ASN Press Release.

Third Quarter 2022 Financial Results

- **Cash Position:** As of September 30, 2022, the company had total cash, cash equivalents and investments of $90.6 million, as compared to total cash, cash equivalents and investments of $116.7 million as of December 31, 2021.
- **Product Sales:** Net product sales for IBSRELA were $4.9 million during the quarter ended September 30, 2022.
- **Collaboration Revenue:** The company generated $0.1 million in collaboration revenue for the quarter ended September 30, 2022, as compared to $1.2 million for the quarter ended September 30, 2021. The decrease in collaboration revenue was primarily the result of the recognition of the previously received upfront payment from the 2019 research and collaboration agreement between the company and Kyowa Kirin that was fully earned and recognized as revenue as of December 31, 2021.
- **R&D Expenses**: Research and development expenses were $7.5 million for the quarter ended September 30, 2022, a decrease of $16.2 million, or 68.5%, compared to $23.7 million for the quarter ended September 30, 2021. Research and development expenses included non-cash stock compensation expense of approximately $0.5 million and $0.7 million in the quarters ended September 30, 2022, and September 30, 2021, respectively. The decrease in R&D expenses is primarily the result of lower clinical study costs as a result of the completion of the OPTIMIZE study, lower tenapanor

manufacturing expenses due to the company's capitalization of costs associated with the production of IBSRELA to inventory, and lower expenses for research following the significant reduction in the research function in the fourth quarter of 2021.

- **SG&A Expenses:** Selling, general and administrative expenses were $18.7 million for the quarter ended September 30, 2022, a decrease of $1.0 million, or 5.3%, compared to $19.7 million for the quarter ended September 30, 2021. Selling, general and administrative expenses included non-cash stock compensation expense of approximately $1.4 million and $1.5 million in the quarters ended September 30, 2022, and September 30, 2021, respectively. The decrease in selling, general and administrative expenses was primarily due to a reduction in ongoing and one-time costs as a result of the restructuring action carried out during the third quarter of 2021, offset by increased costs associated with the continuing commercial launch of IBSRELA during the third quarter of 2022.
- **Net Loss:** Net loss for the quarter ended September 30, 2022 was $22.9 million, or $(0.14) per share, compared to $43.6 million, or $(0.42) per share, for the quarter ended September 30, 2021.

Conference Call Details

The company will host a conference call today, November 3, 2022, at 4:30 p.m. ET to review its financial results and provide a business overview. To participate in the conference call, please dial (866) 374-5140 (domestic) or (404) 400-0571 (international) and enter the pin 79680409#. Live audio of the conference call will be simultaneously webcast and will be available under the Investors section of the company's website at www.ardelyx.com. The webcast will be archived and available for replay 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 distension (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's first approved product, IBSRELA® (tenapanor) is available in the United States and Canada. Ardelyx is developing XPHOZAH® (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 has a Phase 2 potassium lowering compound, RDX013, for the potential treatment of elevated serum potassium, or hyperkalemia, a problem among certain patients with kidney and/or heart disease and 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 the potential commercial and other opportunities for the company, and Ardelyx's current expectation of the date of the Advisory Committee meeting to be convened to provide input regarding the clinical meaningfulness of the phosphate lowering effect observed in the Phase 3 clinical program for XPHOZAH. 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 commercialization of drugs, and uncertainties regarding the FDA regulatory 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 November 3, 2022, 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, 2022 (Unaudited)	December 31, 2021 (1)
Assets		
Cash and cash equivalents	$ 61,628	$ 72,428
Investments	28,995	44,261
Accounts receivable	5,208	502
	1,250	
Inventory, current portion		—
Property and equipment, net	1,294	2,362
Right-of-use assets	10,182	12,752
Prepaid commercial manufacturing	16,145	9,406
Prepaid and other assets	19,970	8,202
Total assets	$ 144,672	$ 149,913
Liabilities and stockholders' equity		
Accounts payable	$ 3,113	$ 4,277
Accrued compensation and benefits	7,165	5,422
Current portion of operating lease liability	3,791	3,492
Current portion of long-term debt	26,541	32,264
Deferred revenue	12,563	4,727
Accrued expenses and other liabilities	7,338	7,366
Operating lease liability, net of current portion	6,878	9,748
Deferred royalty obligation related to the sale of future royalties	10,422	—
Stockholders' equity	66,861	82,617
Total liabilities and stockholders' equity	$ 144,672	$ 149,913

(1) Derived from the audited financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2021.

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,	
	2022	2021	2022	2021
Revenues:				
Product sales, net	$ 4,885	$ —	$ 6,899	$ —
Product supply revenue	92	285	1,058	411
Licensing revenue	9	2	23	5,007
Collaborative development revenue	—	886	—	3,650
Total revenues	4,986	1,173	7,980	9,068
Operating expenses:				
Cost of revenue	732	—	955	1,000
Research and development	7,467	23,695	26,059	70,172
Selling, general and administrative	18,667	19,714	56,868	56,969
Total operating expenses	26,866	43,409	83,882	128,141
Loss from operations	(21,880)	(42,236)	(75,902)	(119,073)
Interest expense	(886)	(1,216)	(2,409)	(3,518)

Non-cash interest expense related to the sale of future royalties	(831)	—	(841)	—
Other income (expense), net	704	(134)	1,258	664
Loss before provision for income taxes	(22,893)	(43,586)	(77,894)	(121,927)
Provision for income taxes	—	1	8	4
Net loss	$ (22,893)	$ (43,587)	$ (77,902)	$ (121,931)
Net loss per common share, basic and diluted	$ (0.14)	$ (0.42)	$ (0.53)	$ (1.21)
Shares used in computing net loss per share - basic and diluted	165,104,789	104,144,606	147,319,818	100,480,156

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SOURCE Ardelyx

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