Ardelyx Reports Fourth Quarter and Full Year 2023 Financial Results and Provides Business Update

February 22, 2024

Strong commercial performance of IBSRELA continues, ending FY 2023 with $80.1 million in net product sales revenue; 2024 net product sales revenue currently expected to be between $140.0 to $150.0 million

XPHOZAH launch off to a strong start, ending FY 2023 with $2.5 million in net product sales revenue

Company ends FY 2023 with $184.3 million in cash and investments

Conference call scheduled for 4:30 PM Eastern Time

WALTHAM, Mass., Feb. 22, 2024 (GLOBE NEWSWIRE) -- 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 financial results for the fourth quarter and full year ended December 31, 2023 and provided a business update.

“Ardelyx enters 2024 with tremendous commercial and operational momentum. We finished 2023 with a strong revenue performance as both IBSRELA and XPHOZAH launches continue to exceed expectations. We will look to significantly expand our position within their respective markets in 2024,” said Mike Raab, president and chief executive officer of Ardelyx. “We have two first-in-class therapies with strong clinical profiles where patients continue to have unmet treatment needs. We will focus on executing our commercial approach, which has proven to be effective, increasing our investment in IBSRELA to help more patients and increase market share, while simultaneously advancing the launch of XPHOZAH. We are well-capitalized, we are working to establish a track record of delivering consistent results, and we believe we have opportunities for additional value creation in 2024.”

IBSRELA® (tenapanor) finishes 2023 with $80.1 million in net product sales revenue, $28.1 million in Q4 2023
U.S. net product sales revenue for the first full calendar year of commercialization of IBSRELA was $80.1 million. During the fourth quarter of 2023, IBSRELA U.S. net product sales revenue was $28.1 million, reflecting 26% growth compared to the third quarter of 2023. In January, Ardelyx announced that it expects IBSRELA to achieve greater than 10 percent share of the prescription irritable bowel syndrome with constipation (IBS-C) market at peak and generate more than $1.0 billion in annual U.S. net product sales revenue before patent term expiration. In 2024, the company will continue to invest to support future realization of the potential for IBSRELA, including the expansion of the IBSRELA sales team, additional promotional programming and omnichannel digital capabilities, increased sampling availability, and expanded support provided by the ArdelyxAssist™ patient services program.

Ardelyx currently expects full-year 2024 U.S. net product sales revenue for IBSRELA to be between $140.0 and $150.0 million.

XPHOZAH® (tenapanor) launched in November 2023, records $2.5 million net product sales revenue during Q4 2023
Following approval by the U.S. Food and Drug Administration (FDA) of XPHOZAH in October 2023 and launch in November 2023, Ardelyx has seen a strong initial response from the nephrology community. U.S. net product sales revenue in the fourth quarter of 2023 were $2.5 million.

Today, the company announced the planned initiation of a long-term, prospective, observational cohort study designed to collect real-world evidence for XPHOZAH. The objective of the study is to evaluate the impact of an XPHOZAH-based regimen (XBR) in a real-world setting, in patients with hyperphosphatemia on maintenance dialysis who were not controlled on binder therapy. The study will follow patients in the United States for a period of up to three years.

Other Corporate Developments

- The company recently released its 2023 Environmental, Social and Governance (ESG) report, demonstrating the company’s commitment and progress towards initiatives and best practices that build a more equitable and sustainable organization. The report is available on the company’s website.
- Kyowa Kirin Co., Ltd. announced that tenapanor, marketed as PHOZEVEL®, will be available to patients in Japan as of February 20, 2024. In September 2023, Ardelyx and Kyowa Kirin announced that PHOZEVEL received approval from the Japanese Ministry of Health, Labour and Welfare for the New Drug Application for tenapanor for the improvement of hyperphosphatemia in adult patients with chronic kidney disease (CKD) on dialysis.
- In January, the company hosted a Key Opinion Leader Discussion regarding the IBS-C treatment landscape with Philip Schoenfeld, M.D., MS Ed, MSc, Chief (Emeritus) of the Gastroenterology Section at the John D. Dingell VA Medical Center in Detroit, Mich. The event webcast is archived on the company’s website.
- In November, the company announced that XPHOZAH has been granted Orphan Drug Designation by the U.S. FDA for the treatment of pediatric hyperphosphatemia.
- The company had a significant presence at the American Society of Nephrology Kidney Week 2023 meeting in Philadelphia from November 1-5, 2023. The company presented four posters providing additional data highlighting the safety and efficacy of XPHOZAH. In addition, the company’s commercial partner in Japan, Kyowa Kirin, presented two posters. The company also sponsored an Exhibitor Spotlight titled “A New Paradigm: Rethinking Hyperphosphatemia Management,” where Arnold Silva, M.D., Ph.D., director of Home and Peritoneal Dialysis Programs at the Boise Kidney & Hypertension Institute, and David Spiegel, M.D., vice president of nephrology at Ardelyx, led a discussion on important

clinical considerations in managing CKD patients with hyperphosphatemia.

Full Year 2023 Financial Results

- **Cash Position:** As of December 31, 2023, the company had total cash, cash equivalents and short-term investments of $184.3 million, compared to total cash, cash equivalents and short-term investments of $123.9 million as of December 31, 2022. During the quarter ended December 31, 2023, the company drew $22.4 million in net proceeds under its term loan with SLR Investment Corp. Subsequent to December 31, in January 2024, the company received a $3.0 million milestone payment from Fosun Pharma following the U.S. approval of XPHOZAH.
- **Revenues:** Total revenues for the year ended December 31, 2023 were $124.5 million, compared to $52.2 million in total revenues in 2022, reflecting increased net product sales, licensing revenues and product supply revenue. U.S. net product sales revenue for IBSRELA was $80.1 million, compared to $15.6 million in 2022. U.S. net product sales revenue in 2023 for XPHOZAH was $2.5 million following its commercial launch in November 2023. Licensing revenue was $35.8 million in the year, including $30.0 million in milestone and license agreement amendment payments from Kyowa Kirin following the approval of tenapanor for hyperphosphatemia in Japan, as well as $5.0 million in milestone payments from Fosun Pharma related to the acceptance of the New Drug Application for tenapanor for the control of serum phosphorus in adult patients with CKD on dialysis in China and the FDA approval of XPHOZAH in the U.S. Product supply revenue was $6.1 million, compared to product supply revenue of $1.5 million in 2022.
- **R&D Expenses:** Research and development expenses were $35.5 million for the year ended December 31, 2023, compared to $35.2 million for the year ended December 31, 2022.
- **SG&A Expenses:** Selling, general and administrative expenses were $134.4 million for the year ended December 31, 2023, an increase of $57.8 million compared to $76.6 million for the year ended December 31, 2022. The increase in selling, general and administrative expenses was primarily due to increased costs associated with the ongoing commercialization of IBSRELA and commercial activities to prepare for and launch XPHOZAH.
- **Net Loss:** Net loss for the year ended December 31, 2023, was $66.1 million, or $(0.30) per share, compared to net loss of $67.2 million, or $(0.42) per share, for the year ended December 31, 2022. The net loss for the full year 2023 included share-based compensation expense of $13.5 million, non-cash interest expense related to the sale of future royalties of $3.9 million and a non-cash impairment of a lease right of use asset of $0.4 million.

Conference Call Details

The company will host a conference call today, February 22, 2024, at 4:30 PM ET to discuss today's announcement. To participate in the conference call, please dial (844) 481-2838 (domestic) or (412) 317-1858 (international) and ask to be joined into the Ardelyx call. 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 (IBSRELA)

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.

IMPORTANT SAFETY INFORMATION (XPHOZAH)
CONTRAINDICATIONS
XPHOZAH is contraindicated in:

- Pediatric patients under 6 years of age
- Patients with known or suspected mechanical gastrointestinal obstruction

WARNINGS AND PRECAUTIONS
Diarrhea
Patients may experience severe diarrhea. Treatment with XPHOZAH should be discontinued in patients who develop severe diarrhea.

MOST COMMON ADVERSE REACTIONS
Diarrhea, which occurred in 43-53% of patients, was the only adverse reaction reported in at least 5% of XPHOZAH-treated patients with CKD on dialysis across trials. The majority of diarrhea events in the XPHOZAH-treated patients were reported to be mild-to-moderate in severity and resolved over time, or with dose reduction. Diarrhea was typically reported soon after initiation but could occur at any time during treatment with XPHOZAH. Severe diarrhea was reported in 5% of XPHOZAH-treated patients in these trials.

INDICATION
XPHOZAH (tenapanor), 30 mg BID, is indicated to reduce serum phosphorus in adults with chronic kidney disease (CKD) on dialysis as add-on therapy in patients who have an inadequate response to phosphate binders or who are intolerant of any dose of phosphate binder therapy.

For additional safety information, please see full Prescribing Information.

About Ardelyx
Ardelyx was founded with a mission to discover, develop and commercialize innovative, first-in-class medicines that meet significant unmet medical needs. Ardelyx has two commercial products approved in the United States, IBSRELA® (tenapanor) and XPHOZAH® (tenapanor) as well as early-stage pipeline candidates. Ardelyx has agreements for the development and commercialization of tenapanor outside of the U.S. Kyowa Kirin commercializes PHOZEVEL® (tenapanor) for hyperphosphatemia in Japan. A New Drug Application for tenapanor for hyperphosphatemia has been submitted in China with Fosun Pharma. Knight Therapeutics commercializes IBSRELA in Canada. For more information, please visit https://ardelyx.com/ and connect with us on X (formerly known as Twitter), LinkedIn and Facebook.

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 opportunities for continued IBSRELA and XPHOZAH adoption, the potential growth of market share in their respective markets, the potential market share for IBSRELA and annual U.S. net product sales revenue at peak; and projected U.S. net product sales revenue for IBSRELA for full year 2024. 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 development of, regulatory process for, and commercialization of drugs in the U.S. and internationally. 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 22, 2024, and its future current and periodic reports to be filed with the Securities and Exchange Commission.

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Ardelyx, Inc.
Condensed Balance Sheets
(In thousands)

	December 31, 2023 (Unaudited)	December 31, 2022 (1)
Assets		
Cash and cash equivalents	$ 21,470	$ 96,140
Investments	162,829	27,769
Accounts receivable	22,031	7,733
Prepaid commercial manufacturing	18,925	13,567
Prepaid commercial manufacturing, non-current	4,235	—
Inventory, current	12,448	3,282
Inventory, non-current	37,039	25,064
Property and equipment, net	1,009	1,223
Right-of-use assets	5,589	9,295

Prepaid and other assets	12,004	5,993
Total assets	$ 297,579	$ 190,066
Liabilities and stockholders' equity		
Accounts payable	$ 11,138	$ 10,859
Accrued compensation and benefits	12,597	7,548
Current portion of operating lease liability	4,435	3,894
Current portion of long-term debt	—	26,711
Deferred revenue	15,826	13,236
Accrued expenses and other liabilities	15,041	12,380
Operating lease liability, net of current portion	1,725	5,855
Long-term debt, net of current portion	49,822	—
Deferred royalty obligation related to the sale of future royalties	20,179	11,254
Stockholders' equity	166,816	98,329
Total liabilities and stockholders' equity	$ 297,579	$ 190,066

(1) Derived from the audited financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2022.

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,	
	2023	**2022**	**2023**	**2022**
Revenues:				
Product sales, net:				
IBSRELA	$ 28,113	$ 8,701	$ 80,062	$ 15,600
XPHOZAH	2,464	—	2,464	—
Total product sales, net	30,577	8,701	82,526	15,600
Product supply revenue	767	469	6,121	1,527
Licensing revenue	3,019	35,008	35,809	35,031
Total revenues	34,363	44,178	124,456	52,158
Cost of goods sold:				
Cost of product sales	815	279	2,323	566
Other cost of revenue	4,262	2,883	15,472	3,551
Total cost of goods sold	5,077	3,162	17,795	4,117
Operating expenses:				
Research and development	9,524	9,142	35,536	35,201
Selling, general and administrative	47,748	19,731	134,401	76,599
Total operating expenses	57,272	28,873	169,937	111,800
Loss from operations	(27,986)	12,143	(63,276)	(63,759)
Interest expense	(1,740)	(991)	(4,950)	(3,400)
Non-cash interest expense related to the sale of future royalties	(1,065)	(832)	(3,924)	(1,673)
Other income, net	2,322	375	6,630	1,633
(Loss) income before provision for income taxes	(28,469)	10,695	(65,520)	(67,199)
Provision for income taxes	333	—	547	8
Net (loss) income	$ (28,802)	$ 10,695	$ (66,067)	$ (67,207)
Net (loss) income per share of common stock - basic and diluted	$ (0.12)	$ 0.06	$ (0.30)	$ (0.42)
Shares used in computing net (loss) income per share - basic	232,253,351	192,430,121	219,331,253	158,690,083
Shares used in computing net (loss) income per share - diluted	232,253,351	193,840,751	219,331,253	158,690,083

Source: Ardelyx, Inc.