Ardelyx Reports Third Quarter 2024 Financial Results and Provides Business Update

October 31, 2024

IBSRELA generates $40.6 million in net product sales revenue; Company expects full year 2024 IBSRELA net sales revenue to be between $145 and $150 million

XPHOZAH generates $51.5 million in net product sales revenue

Company ends Q3 with approximately $190 million in cash, cash equivalents and investments

Conference call scheduled for 4:30 PM Eastern Time

WALTHAM, Mass., Oct. 31, 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 third quarter ended September 30, 2024 and provided a business update.

"The continued strong performance of Ardelyx reported during the third quarter demonstrates our ability to execute and deliver on our goals, to focus on serving the patient and to build towards the future," said Mike Raab, president and chief executive officer of Ardelyx. "IBSRELA continues to deliver consistent quarter-over-quarter growth driven by strong fundamentals: an attractive safety and efficacy profile, expanding awareness among healthcare prescribers, a streamlined path to access and, importantly, positive experiences among treated patients. In addition, the unmet need among dialysis patients for another option to help achieve and maintain target phosphorus levels is clear, demonstrated by the continued strong demand and growth for XPHOZAH. We remain committed to ensuring that this well-tolerated, effective and differentiated medicine remains available to patients, despite CMS' planned change in Medicare Part D reimbursement in early-January 2025, and we are confident that we have made decisions that will best support our efforts to protect patient access to XPHOZAH. Finally, we continue to thoughtfully strengthen our balance sheet, providing us with capital to invest as we look to expand our business."

IBSRELA® (tenapanor) records $40.6 million in net product sales revenue in Q3 2024
U.S. net product sales revenue for IBSRELA during the third quarter of 2024 was $40.6 million, showing approximately 15% quarter-over-quarter growth compared to the second quarter of 2024, and significant growth compared to the $22.3 million in net product sales revenue the company reported during the third quarter of 2023. The strong Q3 2024 performance reflects the continued growing demand for IBSRELA, demonstrated by increases in new and refill prescriptions as well as growth in new and repeat writing healthcare providers.

Ardelyx currently expects full-year 2024 U.S. net product sales revenue for IBSRELA to be between $145.0 and $150.0 million.

XPHOZAH® (tenapanor) launch progresses, records $51.5 million net product sales revenue during Q3 2024
A strong XPHOZAH launch continues, with the company reporting $51.5 million in net product sales revenue during the third quarter of 2024, approximately 39% quarter-over-quarter growth compared to the second quarter of 2024. The Q3 2024 performance reinforces the significant unmet need among dialysis patients with hyperphosphatemia.

Other Corporate Developments

- Today, the company announced that it amended its February 2022 loan agreement with investment affiliates managed by SLR Capital Partners (SLR). The company drew $50 million at SOFR plus 4.02% in October 2024, added the opportunity to draw an additional $50 million at the same interest rate, and extended the interest-only period for existing and new tranches funded under the instrument to July 1, 2028.
- The company had a significant presence at the 2024 Annual Scientific Meeting for the American College of Gastroenterology (ACG 2024) in Philadelphia from October 25-30, 2024. The company presented two posters featuring data from the 2024 IBS in America supplemental survey, sponsored by the company in collaboration with Health Union, which was conducted to better understand the symptoms and impact of IBS-C on the overall health and quality of life among patients.
- The company had a significant presence at the 2024 Annual American Society of Nephrology Kidney Week in San Diego from October 23-27, 2024. The company presented two posters covering additional data for XPHOZAH.
- In October, the company announced the publication of a review article exploring the patient burden and therapeutic landscape of IBS-C in the U.S. in *Clinical and Experimental Gastroenterology.* The article is available online and can be found here.
- In August, the company announced the appointment of experienced biopharma executive, Eric Foster, as Chief Commercial Officer.
- In July, the company announced the publication of two plain language summaries from XPHOZAH clinical trials in *Current Medical Research and Opinion*.

Third Quarter 2024 Financial Results

- *Cash Position*: As of September 30, 2024, the company had total cash, cash equivalents and short-term investments of $190.4 million, as compared to total cash, cash equivalents and short-term investments of $184.3 million as of December 31, 2023. In October, the company drew $49.7 million in net proceeds under its term loan with SLR Investment Corp.

- *Revenue*: Total revenue for the quarter ended September 30, 2024 was $98.2 million, compared to $56.4 million in total

revenue during the quarter ended September 30, 2023, driven by increases in net product sales.
  - IBSRELA U.S. net product sales revenue was $40.6 million, compared to $22.3 million during the same period of 2023.
  - XPHOZAH U.S. net product sales revenue was $51.5 million, with no comparable revenue during the same period of 2023.
  - Product supply revenue was $5.3 million, compared to $2.1 million during the same period of 2023.
  - Licensing revenue was $20 thousand, compared to $32 million during the same period of 2023 related to $30 million milestone and license agreement amendment payments from Kyowa Kirin following the approval of tenapanor for hyperphosphatemia in Japan, as well as a $2.0 million milestone payment from Fosun Pharma following the acceptance of the NDA for tenapanor for hyperphosphatemia in China.
  - Non-cash royalty revenue related to the sale of future royalties was $0.8 million, with no comparable revenue during the same period of 2023.

- *R&D Expenses*: Research and development expenses were $15.3 million for the quarter ended September 30, 2024, compared to $8.6 million for the quarter ended September 30, 2023, primarily related to increased medical engagement with the scientific communities in the areas of gastroenterology and nephrology and pediatric clinical trials.

- *SG&A Expense*s: Selling, general and administrative expenses were $65.0 million for the quarter ended September 30, 2024, an increase of $32.3 million compared to $32.7 million for the quarter ended September 30, 2023. The increase in selling, general and administrative expenses was related to increased costs associated with the ongoing commercialization of IBSRELA and XPHOZAH, primarily the expansion of the IBSRELA field-based team which was completed during the third quarter of 2024.

- *Net Loss*: Net loss for the quarter ended September 30, 2024 was $0.8 million, or $(0.00) per share, compared to net income of $6.6 million, or $0.03 per share, for the quarter ended September 30, 2023. The $0.8 million net loss for the third quarter of 2024 included share-based compensation expense of $9.1 million and non-cash interest expense related to the sale of future royalties of $1.9 million.

Conference Call Details
The company will host a conference call today, October 31, 2024, at 4:30 PM ET to discuss today's announcement. To participate in the conference call, please dial (877) 346-6112 (domestic) or (848) 280-6350 (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, https://ir.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). 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 current expectation regarding opportunities for continued IBSRELA and XPHOZAH adoption; projected U.S. net product sales revenue for IBSRELA for full year 2024; the company's ability to execute and deliver on its goals and expand its business; and the company's ability to protect patient access to 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 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 Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on October 31, 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)

	September 30, 2024 (Unaudited)	December 31, 2023 (1)
Assets		
Cash and cash equivalents	$ 47,429	$ 21,470
Investments	142,973	162,829
Accounts receivable	53,195	22,031
Prepaid commercial manufacturing	16,663	18,925
Prepaid commercial manufacturing, non-current	—	4,235
Inventory, current	11,378	12,448
Inventory, non-current	73,780	37,039
Property and equipment, net	1,028	1,009
Right-of-use assets	3,625	5,589
Prepaid and other assets	17,792	12,004
Total assets	$ 367,863	$ 297,579
Liabilities and stockholders' equity		
Accounts payable	$ 15,824	$ 11,138
Accrued compensation and benefits	11,541	12,597
Current portion of operating lease liability	2,567	4,435
Deferred revenue	20,042	15,826
Accrued expenses and other liabilities	33,295	15,041

Operating lease liability, net of current portion	1,218	1,725
Long-term debt	100,707	49,822
Deferred royalty obligation related to the sale of future royalties	24,372	20,179
Stockholders' equity	158,297	166,816
Total liabilities and stockholders' equity	$ 367,863	$ 297,579

(1) Derived from the audited financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2023.

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,	
	2024	**2023**	**2024**	**2023**
Revenues:				
Product sales, net:				
IBSRELA	$ 40,638	$ 22,285	$ 104,444	$ 51,949
XPHOZAH	51,452	—	103,749	—
Total product sales, net	92,090	22,285	208,193	51,949
Product supply revenue	5,322	2,092	7,461	5,354
Licensing revenue	20	32,014	56	32,790
Non-cash royalty revenue related to the sale of future royalties	809	—	1,776	—
Total revenues	98,241	56,391	217,486	90,093
Cost of goods sold:				
Cost of product sales	1,715	644	4,133	1,508
Other cost of revenue	14,013	7,048	28,159	11,210
Total cost of goods sold	15,728	7,692	32,292	12,718
Operating expenses:				
Research and development	15,310	8,637	38,651	26,012
Selling, general and administrative	64,970	32,664	182,618	86,653
Total operating expenses	80,280	41,301	221,269	112,665
Income (loss) from operations	2,233	7,398	(36,075)	(35,290)
Interest expense	(3,357)	(1,107)	(9,039)	(3,210)
Non-cash interest expense related to the sale of future royalties	(1,924)	(922)	(5,202)	(2,859)
Other income, net	2,282	1,460	6,766	4,308
Income (loss) before provision for income taxes	(766)	6,829	(43,550)	(37,051)
Provision for income taxes	43	200	231	214
Net income (loss)	$ (809)	$ 6,629	$ (43,781)	$ (37,265)
Net income (loss) per share of common stock - basic and diluted	$ (0.00)	$ 0.03	$ (0.19)	$ (0.17)
Shares used in computing net income (loss) per share - basic	235,911,399	222,782,229	234,516,305	214,976,555
Shares used in computing net (loss) income per share - diluted	235,911,399	227,894,335	234,516,305	214,976,555

Source: Ardelyx, Inc.