Ardelyx Reports Fourth Quarter and Full Year 2024 Financial Results and Provides Business Update

February 20, 2025

Company achieved significant commercial progress in 2024, finishing with total revenue of $333.6 million, including $319.2 million in U.S. Net Product Sales

Company reaffirms combined peak sales of IBSRELA and XPHOZAH of $1.75 Billion

Company ended FY 2024 with $250.1 million in cash, cash equivalents and investments

Conference call scheduled for 8:00 AM Eastern Time

WALTHAM, Mass., Feb. 20, 2025 (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, 2024, and provided a business update.

“Ardelyx enters 2025 in a position of strength, evidenced by significant year-over-year revenue growth for IBSRELA in 2024 and a strong first full year of XPHOZAH commercialization, driven by consistently high levels of commercial excellence, meaningful long-term potential for our existing commercial products and a strong cash position to support future growth opportunities,” said Mike Raab, president and chief executive officer of Ardelyx. “We are focused on our key priorities to grow IBSRELA, execute the XPHOZAH strategy, build a pipeline of important medicines, continue to deliver a strong financial performance, and, most importantly, achieve our mission of bringing novel therapies to patients with unmet medical needs.”

IBSRELA® (tenapanor) finishes 2024 with $158.3 million in net product sales revenue
U.S. net product sales revenue for IBSRELA in 2024 was $158.3 million, including $53.8 million in net product sales revenue in the fourth quarter, approximately 32% growth compared to the third quarter of 2024. Ardelyx currently expects full year 2025 U.S. net product sales revenue for IBSRELA to be between $240 and $250 million. Ardelyx continues to expect IBSRELA to achieve greater than ten percent market share at peak and generate more than $1 billion in annual U.S. net product sales revenue before patent term expiration.

XPHOZAH® (tenapanor) records $160.9 million net product sales revenue in first full year of commercialization
U.S. net product sales revenue for the first full calendar year of commercialization of XPHOZAH was $160.9 million, including $57.2 million in net product sales revenue during the fourth quarter of 2024. At peak, Ardelyx currently expects XPHOZAH to achieve $750 million in annual U.S. net product sales revenue before patent term expiration.

Other Corporate Developments
The company recently released its 2024 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.

Full Year 2024 Financial Results

- **Cash Position:** As of December 31, 2024, the company had total cash, cash equivalents and short-term investments of $250.1 million, compared to total cash, cash equivalents and short-term investments of $184.3 million as of December 31, 2023. During the quarter ended December 31, 2024, the company drew $49.7 million in net proceeds under its term loan with SLR Investment Corp.
- **Revenue:** Total revenue for the year ended December 31, 2024, was $333.6 million, compared to $124.5 million in total revenue in 2023, driven by increases in net product sales revenue.
    - IBSRELA U.S. net product sales revenue was $158.3 million, compared to $80.1 million in 2023.
    - XPHOZAH U.S. net product sales revenue was $160.9 million, compared to $2.5 million in 2023.
    - Product supply revenue was $11.6 million, compared to $6.1 million in 2023.
    - Licensing revenue was $78 thousand, compared to $35.8 million in 2023. 2023 licensing revenue included $30.0 million in payments from Kyowa Kirin following the approval of tenapanor for hyperphosphatemia in Japan, as well as $5.0 million in 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.
    - Non-cash royalty revenue related to the sale of future royalties was $2.7 million with no comparable revenue during the same period of 2023.
- **R&D Expenses:** Research and development expenses were $52.3 million for the year ended December 31, 2024, compared to $35.5 million for the year ended December 31, 2023, primarily related to increased medical engagement with the scientific communities in the areas of gastroenterology and nephrology and pediatric clinical trials.
- **SG&A Expenses:** Selling, general and administrative expenses were $258.7 million for the year ended December 31, 2024 compared to $134.4 million for the year ended December 31, 2023. The increase in selling, general and administrative expenses was primarily due to increased costs associated with the company’s field-based sales team expansion for IBSRELA and the launch of XPHOZAH.
- **Net Loss:** Net loss for the year ended December 31, 2024, was $39.1 million, or $(0.17) per share, compared to net loss of $66.1 million, or $(0.30) per share, for the year ended December 31, 2023. The net loss for the full year 2024 included share-based compensation expense of $37.4 million and non-cash interest expense related to the sale of future royalties of

$7.1 million.

Conference Call Details
The company will host a conference call today, February 20, 2025, at 8:00 AM 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, 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). 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 expectations regarding: the long term potential for Ardelyx's existing commercial products; opportunities for continued IBSRELA growth; annual U.S. net product sales revenue at peak for IBSRELA and XPHOZAH; and the projected U.S. net product sales revenue for IBSRELA for full year 2025. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that are in some cases beyond our control, that could cause actual outcomes or results to differ materially 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 20, 2025, 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, 2024 (Unaudited)	December 31, 2023 (1)
Assets		
Cash and cash equivalents	$ 64,932	$ 21,470
Investments	185,168	162,829
Accounts receivable	57,705	22,031
Prepaid commercial manufacturing	16,378	18,925
Prepaid commercial manufacturing, non-current	—	4,235
Inventory, current	21,173	12,448
Inventory, non-current	70,011	37,039
Property and equipment, net	1,495	1,009
Right-of-use assets	2,380	5,589
Prepaid and other assets	16,512	12,004
Total assets	$ 435,754	$ 297,579
Liabilities and stockholders' equity		
Accounts payable	$ 16,000	$ 11,138
Accrued compensation and benefits	14,940	12,597
Current portion of operating lease liability	1,562	4,435
Deferred revenue	17,918	15,826
Accrued expenses and other liabilities	34,642	15,041
Operating lease liability, net of current portion	1,023	1,725
Long-term debt	150,853	49,822
Deferred royalty obligation related to the sale of future royalties	25,527	20,179
Stockholders' equity	173,289	166,816
Total liabilities and stockholders' equity	$ 435,754	$ 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 December 31,		Twelve Months Ended December 31,	
	2024	2023	2024	2023
Revenues				
Product sales, net				
IBSRELA	$ 53,842	$ 28,113	$ 158,286	$ 80,062
XPHOZAH	57,161	2,464	160,910	2,464
Total product sales, net	111,003	30,577	319,196	82,526
Product supply revenue	4,188	767	11,649	6,121
Licensing revenue	22	3,019	78	35,809
Non-cash royalty revenue related to the sale of future royalties	916	—	2,692	—
Total revenues	116,129	34,363	333,615	124,456
Cost of goods sold				

Cost of product sales	2,718	815	6,851	2,323
Other cost of revenue	15,546	4,262	43,705	15,472
Total cost of goods sold	18,264	5,077	50,556	17,795
Operating expenses				
Research and development	13,666	9,524	52,317	35,536
Selling, general and administrative	76,074	47,748	258,692	134,401
Total operating expenses	89,740	57,272	311,009	169,937
Income (loss) from operations	8,125	(27,986)	(27,950)	(63,276)
Interest expense	(3,967)	(1,740)	(13,006)	(4,950)
Non-cash interest expense related to the sale of future royalties	(1,886)	(1,065)	(7,088)	(3,924)
Other income, net	2,408	2,322	9,174	6,630
Income (loss) before provision for income taxes	4,680	(28,469)	(38,870)	(65,520)
Provision for income taxes	35	333	266	547
Net income (loss)	$ 4,645	$ (28,802)	$ (39,136)	$ (66,067)
Net income (loss) per share of common stock - basic and diluted	$ 0.02	$ (0.12)	$ (0.17)	$ (0.30)
Shares used in computing net income (loss) per share - basic	237,370,654	232,253,351	235,232,927	219,331,253
Shares used in computing net income (loss) per share - diluted	244,050,606	232,253,351	235,232,927	219,331,253

Source: Ardelyx, Inc.