



Ardelyx Reports First Quarter 2025 Financial Results and Provides Business Update

May 1, 2025

Company reports \$74.1 million in Q1 total revenue, reflecting 61% growth year-over-year

IBSRELA net product sales revenue of \$44.4 million; XPHOZAH net product sales revenue of \$23.4 million

Company ends Q1 with \$214.0 million in cash, cash equivalents and investments

Conference call scheduled for 4:30 PM Eastern Time

WALTHAM, Mass., May 01, 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 first quarter ended March 31, 2025 and provided a business update.

"Ardelyx delivered an outstanding first quarter, generating \$74 million in total revenue and advancing our key strategic priorities," said Mike Raab, president and chief executive officer of Ardelyx. "As IBSRELA enters its third full year on the market, it achieved exceptional year-over-year growth of 57%, a testament to the significant clinical value it delivers and the strength of our commercial strategy. XPHOZAH also posted strong year-over-year growth, despite ongoing disruption in the dialysis community, underscoring the high unmet need among patients and the momentum built by the team in 2024. The results affirm our confidence in XPHOZAH's long-term potential and the important and expanding impact on care for patients with chronic kidney disease on dialysis. Importantly, we continued to thoughtfully manage our operating expenses, preserving a strong balance sheet, and positioned the company for success and value creation as we execute on our mission to improve the lives of patients with serious diseases."

Raab continued, "Looking ahead to the next quarter and the remainder of 2025, we remain sharply focused on the strategic priorities fueling our momentum: accelerating commercial growth for IBSRELA, deepening the adoption and impact of XPHOZAH, building a pipeline of innovative therapies, and maintaining a disciplined financial performance. We are confident in our ability to continue delivering meaningful results for patients, healthcare providers and shareholders."

IBSRELA® (tenapanor) records \$44.4 million in net product sales revenue in Q1 2025

U.S. net product sales revenue for IBSRELA during the first quarter of 2025 was \$44.4 million, reflecting significant year-over-year growth of approximately 57%. The strong growth was driven by increases across key demand indicators, including total writers and new and refill prescriptions.

Ardelyx continues to expect full-year 2025 U.S. net product sales revenue for IBSRELA to be between \$240.0 and \$250.0 million.

XPHOZAH® (tenapanor) records \$23.4 million net product sales revenue during Q1 2025

U.S. net product sales revenue for XPHOZAH during the first quarter of 2025 was \$23.4 million, driven by strong commercial momentum and execution. Net sales revenue during this period reflects the release of \$3.8 million of prior periods' estimated product returns for XPHOZAH, based on assumptions from actual returns history and other data supporting an expectation of minimal returns. Excluding the returns reserve release, net sales revenue for XPHOZAH grew 30% compared to the first quarter of 2024.

Other Corporate Developments

- In April, the company announced the appointment of Merdad Parsey, M.D. Ph.D., to its Board of Directors
- In April, the company announced the appointment of Laura A. Williams, M.D., M.P.H., as the company's first Chief Patient Officer.
- In February, the company announced the approval of tenapanor in China for hyperphosphatemia. Ardelyx earned a \$5.0 million milestone payment from Fosun Pharma following the approval.

First Quarter 2025 Financial Results

- **Cash Position:** As of March 31, 2025, the company had total cash, cash equivalents and short-term investments of \$214.0 million, as compared to total cash, cash equivalents and short-term investments of \$250.1 million as of December 31, 2024.
- **Revenues:** Total revenue for the quarter ended March 31, 2025 was \$74.1 million, compared to \$46.0 million in total revenue during the quarter ended March 31, 2024, reflecting increased net product sales and licensing revenue.
 - IBSRELA U.S. net product sales revenue was \$44.4 million, compared to \$28.4 million during the same period of 2024.
 - XPHOZAH U.S. net product sales revenue was \$23.4 million, compared to \$15.2 million during the same period of 2024.
 - Product supply revenue was \$0.3 million, compared to \$2.1 million during the same period of 2024.
 - Licensing revenue was \$5.0 million, compared to \$17 thousand during the same period of 2024. The increase is related to a \$5.0 million milestone from Fosun Pharma following the approval of tenapanor for hyperphosphatemia in China.
 - Non-cash royalty revenue related to the sale of future royalties was \$1.0 million, compared to \$0.4 million during the same period of 2024.
- **R&D Expenses:** Research and development expenses were \$14.9 million for the quarter ended March 31, 2025, compared to \$10.6 million for the quarter ended March 31, 2024. The increase was primarily related to increased engagement with the scientific and medical communities.

- **SG&A Expenses:** Selling, general and administrative expenses were \$83.2 million for the quarter ended March 31, 2025, compared to \$53.0 million for the quarter ended March 31, 2024. The increase was primarily related to increased costs associated with the ongoing commercialization of IBSRELA and XPHOZAH.
- **Net Loss:** Net loss for the quarter ended March 31, 2025 was \$41.1 million, or \$(0.17) per share, compared to net loss of \$26.5 million, or \$(0.11) per share, for the quarter ended March 31, 2024. The net loss for the first quarter of 2025 included share-based compensation expense of \$12.1 million and non-cash interest expense related to the sale of future royalties of \$2.1 million.

Conference Call Details

The company will host a conference call today, May 1, 2025, 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://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 $\geq 2\%$ 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 approved 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; opportunities for deepening the adoption and impact of 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 Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 1, 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)

	March 31, 2025	December 31, 2024
	(Unaudited)	(1)
Assets		
Cash and cash equivalents	\$ 30,808	\$ 64,932
Short-term investments	183,144	185,168
Accounts receivable	46,467	57,705
Prepaid commercial manufacturing	17,094	16,378
Inventory	105,875	91,184
Property and equipment, net	1,665	1,495
Right-of-use assets	3,670	2,380
Prepaid and other assets	21,471	16,512
Total assets	<u>\$ 410,194</u>	<u>\$ 435,754</u>
Liabilities and stockholders' equity		
Accounts payable	\$ 13,722	\$ 16,000
Accrued compensation and benefits	7,168	14,940
Current portion of operating lease liability	1,302	1,562
Deferred revenue	19,263	17,918
Accrued expenses and other liabilities	45,240	35,665
Long-term debt	151,301	150,853
Deferred royalty obligation related to the sale of future royalties	26,522	25,527
Total stockholders' equity	145,676	173,289
Total liabilities and stockholders' equity	<u>\$ 410,194</u>	<u>\$ 435,754</u>

(1) Derived from the audited financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2024.

Ardelyx, Inc. Condensed Statements of Operations (Unaudited) (in thousands, except share and per share amounts)

	Three Months Ended March 31,	
	2025	2024
Revenues		
Product sales, net		
IBSRELA	\$ 44,403	\$ 28,361
XPHOZAH	23,411	15,151
Total product sales, net	67,814	43,512
Product supply revenue	254	2,126
Licensing revenue	5,020	17
Non-cash royalty revenue related to the sale of future royalties	1,026	368
Total revenues	<u>74,114</u>	<u>46,023</u>
Cost of goods sold		

Cost of product sales	2,340	1,013
Other cost of revenue	9,963	6,115
Total cost of goods sold	<u>12,303</u>	<u>7,128</u>
Operating expenses		
Research and development	14,938	10,579
Selling, general and administrative	83,222	52,994
Total operating expenses	<u>98,160</u>	<u>63,573</u>
Loss from operations	(36,349)	(24,678)
Interest expense	(4,191)	(2,356)
Non-cash interest expense related to the sale of future royalties	(2,071)	(1,702)
Other income, net	2,326	2,339
Loss before provision for income taxes	<u>(40,285)</u>	<u>(26,397)</u>
Provision for income taxes	859	121
Net loss	<u>\$ (41,144)</u>	<u>\$ (26,518)</u>
Net loss per share of common stock - basic and diluted	<u>\$ (0.17)</u>	<u>\$ (0.11)</u>
Shares used in computing net loss per share - basic and diluted	<u>238,624,145</u>	<u>233,065,960</u>



Source: Ardelyx, Inc.