
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): October 30, 2025



ARDELYX, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-36485
(Commission
File Number)

26-1303944
(IRS Employer
Identification Number)

400 FIFTH AVE., SUITE 210, WALTHAM, MASSACHUSETTS 02451
(Address of principal executive offices, including Zip Code)

Registrant's telephone number, including area code: (510) 745-1700

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.0001	ARDX	The Nasdaq Global Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition.

On October 30, 2025, Ardelyx, Inc. (the “Company”) announced its financial results for the quarter ended September 30, 2025. The full text of the press release issued in connection with the announcement is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information furnished under this Item 2.02 shall not be considered “filed” under the Securities Exchange Act of 1934, as amended, nor shall it be incorporated by reference into any future filing under the Securities Act of 1933, as amended, or under the Securities Exchange Act of 1934, as amended, unless the Company expressly sets forth in such future filing that such information is to be considered “filed” or incorporated by reference therein.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press release of Ardelyx, Inc.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: October 30, 2025

ARDELYX, INC.

By: /s/ Justin Renz
Justin Renz
Chief Financial and Operations Officer

Ardelyx Reports Third Quarter 2025 Financial Results and Provides Corporate Update

Q3 2025 product revenue of \$105.5 million reflects 15% year-over-year growth

IBSRELA® Q3 revenue of \$78.2 million reflects 92% year-over-year growth; IBSRELA guidance raised, 2025 revenue expected to be between \$270-275 million

XPHOZAH® Q3 revenue of \$27.4 million, up 9% compared to Q2 2025

Company announces pipeline program for next-generation NHE3 inhibitor; Potential application across multiple therapeutic areas

Conference call scheduled for 4:30 PM Eastern Time

WALTHAM, Mass., October 30, 2025 - 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, 2025 and provided a corporate update.

“This quarter’s results highlight the growth of our business as we advance toward year-end and position Ardelyx for an even stronger performance in 2026,” said Mike Raab, president and chief executive officer of Ardelyx. “IBSRELA continues to outperform, driven by sustained demand from IBS-C patients seeking a differentiated treatment option and by the effectiveness of our targeted commercial execution. Our strategy translated into expanded patient adoption, accelerated revenue growth and increased conviction for the long-term value of this franchise. For XPHOZAH, we are encouraged by the consistent growth, despite the dynamic market environment. The progress we are making underscores the agility and discipline of our team, as well as the strength of our commercial model. Finally, the announcement of RDX10531, our next generation NHE3 inhibitor, underscores our leadership in NHE3 inhibition and represents a pivotal step in building a pipeline of important medicines.”

Raab continued, “Our commercial success and disciplined capital allocation have created a solid financial foundation, enabling us to invest in innovation and long-term growth. Our achievements this quarter demonstrate our commitment to advancing transformative therapies, the efficiency of our execution, and our ability to deliver meaningful and sustained value to patients and shareholders.”

IBSRELA® (tenapanor) records \$78.2 million in revenue in Q3 2025

IBSRELA’s strong growth continued in the third quarter of 2025, generating \$78.2 million in U.S. revenue, a 92% increase compared to the same period of 2024 and a 20% increase compared to the second quarter of 2025. IBSRELA saw continued growth in new and total writers as well as new and refill prescriptions driven by strong commercial execution and prescription pull-through. The company expects continued growth of IBSRELA and to generate between \$270 and \$275 million in IBSRELA revenue for the full-year 2025.

XPHOZAH® (tenapanor) records \$27.4 million revenue during Q3 2025

U.S. revenue for XPHOZAH during the third quarter of 2025 was \$27.4 million, reflecting 9% growth compared to the second quarter of 2025, driven by quarter-over-quarter increases in paid demand prescriptions, total dispenses and total writers. The company expects continued growth in the fourth quarter of 2025 driven by the commercial strategy focusing on patient access, driving clinical conviction among nephrologists and supporting prescription pull-through.

Building a Pipeline of Important Medicines

During the third quarter, Ardelyx began the development of RDX10531, a next generation sodium/hydrogen exchanger 3 (NHE3) inhibitor. NHE3 is an antiporter expressed on the apical surface of the small and large intestines and is responsible for absorbing the majority of ingested sodium. The company is currently conducting activities to support an Investigational New Drug (IND) submission to the U.S. Food and Drug Administration for RDX10531 in 2026.

Other Corporate Developments

- In October, the company announced the appointment of Sue Hohenleitner as Chief Financial Officer to be effective November 4, 2025.
- In August, the company announced the appointment of Edward Conner, M.D. as Chief Medical Officer and John Bishop, Ph.D. as Chief Technical Operations Officer.
- The company had a significant presence at the 2025 Annual Scientific Meeting for the American College of Gastroenterology (ACG 2025) in Phoenix from October 24-29, 2025. The company presented three posters and sponsored a Product Theater.

Third Quarter 2025 Financial Results

- **Cash Position:** As of September 30, 2025, the company had total cash, cash equivalents and short-term investments of \$242.7 million, as compared to total cash, cash equivalents and short-term investments of \$250.1 million as of December 31, 2024 and \$238.5 million as of June 30, 2025.
- **Revenues:** Total revenue for the quarter ended September 30, 2025 was \$110.3 million, compared to \$98.2 million in total revenue during the quarter ended September 30, 2024, primarily reflecting increased IBSRELA revenue, offset by a decline in XPHOZAH revenue.
 - IBSRELA revenue was \$78.2 million, compared to \$40.6 million during the same period of 2024.
 - XPHOZAH revenue was \$27.4 million, compared to \$51.5 million during the same period of 2024. The year-over-year decline in revenue is due to the loss of Part D coverage for Medicare patients following the transition of oral only therapies into the Medicare End-Stage Renal Disease Prospective Payment System on January 1, 2025.
 - No product supply revenue was recorded in the current quarter, compared to \$5.3 million during the same period of 2024.
 - Licensing revenue was \$25 thousand, compared to \$20 thousand during the same period of 2024.
 - Non-cash royalty and milestone revenue related to the sale of future royalties and commercialization milestones was \$4.8 million, compared to \$0.8 million during the same period of 2024. The current period includes a \$3.4 million commercialization milestone from our partner in Japan, Kyowa Kirin Corp.
- **R&D Expenses:** Research and development expenses were \$18.1 million for the quarter ended September 30, 2025, compared to \$15.3 million for the quarter ended September 30, 2024. The increase primarily reflects expenses related to life cycle management. R&D expenses include engagement with scientific communities and pipeline expansion activities, such as the development of RDX10531.
- **SG&A Expenses:** Selling, general and administrative expenses were \$83.6 million for the quarter ended September 30, 2025, an increase compared to \$65.0 million for the quarter ended September 30, 2024 and consistent with SG&A expenses reported during the second quarter of 2025.
- **Net Loss:** Net loss for the quarter ended September 30, 2025 was \$1.0 million, or \$(0.00) per share, compared to net loss of \$0.8 million, or \$(0.00) per share, for the quarter ended September 30, 2024. The net loss for the third quarter of 2025 included non-cash revenue of \$4.8 million, share-based compensation expense of \$12.7 million and non-cash interest expense related to the sale of future royalties of \$2.2 million.

Conference Call Details

The company will host a conference call today, October 30, 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://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 $\geq 2\%$ 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. The company is developing RDX10531, a next-generation NHE3 inhibitor with potential application across multiple therapeutic areas. 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 net product sales revenue for IBSRELA for the full year 2025; and the potential for RDX10531 to have broad application across multiple therapeutic areas. 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 October 30, 2025, and its future current and periodic reports to be filed with the Securities and Exchange Commission.

Investor and Media Contacts:

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Ardelyx, Inc.
Condensed Balance Sheets
(in thousands)

	September 30, 2025	December 31, 2024
	(Unaudited)	(1)
Assets		
Cash and cash equivalents	\$ 42,715	\$ 64,932
Short-term investments	199,990	185,168
Accounts receivable	76,610	57,705
Prepaid commercial manufacturing	8,051	16,378
Inventory	129,358	91,184
Property and equipment, net	2,069	1,495
Right-of-use assets	5,152	2,380
Prepaid and other assets	22,225	16,512
Total assets	<u>\$ 486,170</u>	<u>\$ 435,754</u>
Liabilities and stockholders' equity		
Accounts payable	\$ 18,390	\$ 16,000
Accrued compensation and benefits	15,056	14,940
Current portion of operating lease liability	1,435	1,562
Deferred revenue	20,280	17,918
Accrued expenses and other liabilities	45,965	35,665
Long-term debt	202,138	150,853
Deferred royalty obligation related to the sale of future royalties	28,626	25,527
Total stockholders' equity	154,280	173,289
Total liabilities and stockholders' equity	<u>\$ 486,170</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 September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Revenues				
Product sales, net				
IBSRELA	\$ 78,158	\$ 40,638	\$ 187,606	\$ 104,444
XPHOZAH	27,357	51,452	75,800	103,749
Total product sales, net	105,515	92,090	263,406	208,193
Product supply revenue	—	5,322	6,439	7,461
Licensing revenue	25	20	5,065	56
Non-cash royalty revenue related to the sale of future royalties	4,789	809	7,195	1,776
Total revenues	110,329	98,241	282,105	217,486
Cost of goods sold				
Cost of product sales	2,662	1,715	8,247	4,133
Other cost of revenue	1,320	14,013	20,441	28,159
Total cost of goods sold	3,982	15,728	28,688	32,292
Operating expenses				
Research and development	18,067	15,310	48,671	38,651
Selling, general and administrative	83,612	64,970	250,822	182,618
Total operating expenses	101,679	80,280	299,493	221,269
Income (loss) from operations	4,668	2,233	(46,076)	(36,075)
Interest expense	(5,796)	(3,357)	(14,343)	(9,039)
Non-cash interest expense related to the sale of future royalties	(2,188)	(1,924)	(6,478)	(5,202)
Other income, net	2,449	2,282	6,667	6,766
Loss before provision for income taxes	(867)	(766)	(60,230)	(43,550)
Provision for income taxes	102	43	962	231
Net loss	\$ (969)	\$ (809)	\$ (61,192)	\$ (43,781)
Net loss per share of common stock - basic and diluted	\$ (0.00)	\$ (0.00)	\$ (0.25)	\$ (0.19)
Shares used in computing net loss per share - basic and diluted	241,908,407	235,911,399	240,165,744	234,516,305