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 31, 2023

ARDELYX, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-36485**	**26-1303944**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(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. o

Item 2.02 Results of Operations and Financial Condition.

On October 31, 2023, Ardelyx, Inc. (the "Company") announced its financial results for the quarter ended September 30, 2023. 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).

SIGNATURES

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 31, 2023

ARDELYX, INC.

By: /s/ Justin Renz

Justin Renz
Chief Financial and Operations Officer

Exhibit 99.1

Ardelyx Reports Third Quarter 2023 Financial Results and Updates 2023 U.S. IBSRELA® Net Sales Revenue Guidance

Continued successful launch of IBSRELA, with Q3 net sales revenue of $22.3 million; Company currently expects 2023 full year IBSRELA U.S. net sales revenue to be $76 to $78 million

XPHOZAH® launch underway following October 17, 2023 FDA approval

Company ends Q3 with $165.1 million in cash, cash equivalents and short-term investments

Conference call scheduled for 8:00 AM Eastern Time

WALTHAM, Mass., October 31, 2023 - 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, 2023 and provided a business update.

“Ardelyx is effectively advancing on all fronts with clear focus, evidenced by the continued strong performance of IBSRELA as well as the approval and commercial launch of XPHOZAH,” said Mike Raab, president and chief executive officer. “Demonstrating consistent, quarter-over-quarter growth of IBSRELA prescriptions during the third quarter, we achieved a 22 percent increase in net sales revenue. We continue to see an increase in new and repeat writers, as well as new and refill prescriptions increasing from established writers at a steady, meaningful trajectory. We have raised our full year U.S. net sales revenue guidance for IBSRELA, reflecting the important benefit this product is offering to patients. In addition, on October 17, we received our long sought after FDA approval of XPHOZAH. Our team is in the field, and launch is underway. We anticipate having product in channel in early November.”

IBSRELA® (tenapanor) growth continued with $22.3 million in U.S. net sales revenue in Q3 2023

Revenue for Ardelyx’s first commercialized product, IBSRELA, continued a persistent growth pattern. Driven by increased demand for IBSRELA, the company reported net sales revenue of $22.3 million in the third quarter, 22 percent quarter-over-quarter growth compared to the second quarter of 2023.

XPHOZAH® (tenapanor) received FDA approval on Oct. 17, 2023

On October 17, 2023, Ardelyx announced that the U.S. Food and Drug Administration (FDA) approved XPHOZAH 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. Following approval, the company began commercial launch activities as well as final supply and distribution activities. The company currently expects to have XPHOZAH available in early November.

Other Corporate Developments

- On October 17, the company announced that it amended its February 2022 loan agreement with investment affiliates managed by SLR Capital Partners (SLR). The amendment includes access to an additional $50 million in committed debt financing, and at Ardelyx’s election and subject to SLR credit approval, may be further increased by an additional $50 million. The interest-only period for existing and new tranches funded under the instrument has been extended to December 31, 2026, following the company’s decision to draw the second tranche of $22.5 million in October.

- In September, the company announced that its collaboration partner in Japan, Kyowa Kirin Co., Ltd. (TSE: 4151, Kyowa Kirin), received approval from the Japanese Ministry of Health, Labour and Welfare for the New Drug Application (NDA) for tenapanor for the improvement of hyperphosphatemia in adult patients with CKD on dialysis. As a result of the approval, in October, Ardelyx received an aggregate of $30 million from Kyowa Kirin in milestone payments and payments under the 2022 amendment to the license agreement between Ardelyx and Kyowa Kirin as well as a $5 million payment under the terms of its agreement with HealthCare Royalty Partners.
- In late-October, Ardelyx's partner in China, Shanghai Fosun Pharmaceutical Industrial Development Co. Ltd. (Fosun Pharma), received approval from the Hong Kong Department of Health for the marketing application for IBSRELA for the treatment of irritable bowel syndrome (IBS-C) in adults. The company also earned a $3.0 milestone payment from Fosun Pharma following the U.S. FDA approval of XPHOZAH, which is expected to be received in the fourth quarter.
- Ardelyx announced the publication of results from its T3MPO-3 long-term open-label safety trial of IBSRELA for IBS-C in the Journal of Neurogastroenterology and Motility (JNM). The paper, titled "Long-term safety of tenapanor in patients with irritable bowel syndrome with constipation in the T3MPO-3 study," can be accessible at the online edition of the publication here.
- Ardelyx presented two posters covering additional positive clinical observations of IBSRELA at the 2023 North American Society for Pediatric Gastroenterology, Hepatology and Nutrition Annual Meeting, which took place in San Diego, California from October 4-7, 2023.
- The company had a significant presence at the 2023 Annual Scientific Meeting for the American College of Gastroenterology (ACG 2023) in Vancouver, Canada from October 20-25, 2023. The company presented two posters and an oral presentation covering additional positive observations of IBSRELA. One poster, "Tenapanor Can Improve Abdominal Symptoms Independent of Changes in Bowel Movement Frequency in Adult Patients with IBS-C" authored by Darren Brenner, M.D., Anthony Lembo, M.D., Yang Yang, Ph.D. and David Rosenbaum, Ph.D., received a President's Award distinction for high quality, novel, unique and interesting research. The company also sponsored a Product Theater titled "Discover a Different Mechanism of Action to Treat Adults with IBS-C: A Case Based Discussion," where Kavita Kongara, M.D. Director of Motility services at Northside Hospital in Atlanta, Ga. and Kimberley Orleck, PA-C, MPH, RD, director of APPs at the Atlanta Gastroenterology Associates, United Digestive led a discussion on important clinical considerations in managing adult patients with IBS-C.

Third Quarter 2023 Financial Results

- **Cash Position:** As of September 30, 2023, the company had total cash, cash equivalents and short-term investments of $165.1 million, compared to total cash, cash equivalents and short-term investments of $123.9 million as of December 31, 2022. During the quarter ended September 30, 2023, the company received gross proceeds of $58.4 million for the sale of 13.8 million shares of the company's common stock under the company's sales agreement with Jefferies LLC deemed to be "at-the-market offerings." Subsequent to September 30, in October 2023, the company received $30.0 million from Kyowa Kirin, $5.0 million from Healthcare Royalty Partners and drew $22.5 million from SLR Capital. The company also currently expects a $3 million milestone payment from Fosun Pharma following the U.S. approval of XPHOZAH. As of October 30, 2023, Ardelyx's total cash, cash equivalents and short-term investments was approximately $218.1 million (unaudited).

- **Revenues:** Total revenues for the quarter ended September 30, 2023 were $56.4 million, compared to $5.0 million in total revenues in the third quarter of 2022, reflecting increased IBSRELA sales, product supply and licensing revenues. U.S. net product sales for IBSRELA were $22.3 million, compared to $4.9 million during the same period of 2022. Licensing revenue was $32.0 million in the quarter, reflecting $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. Product supply revenue was $2.1 million, compared to product supply revenue of $92,000 in the same quarter of 2022.
- **R&D Expenses**: Research and development expenses were $8.6 million for the quarter ended September 30, 2023, compared to $7.5 million for the quarter ended September 30, 2022. R&D expenses increased over the prior year primarily as a result clinical trial and pharmacovigilance activities related to IBSRELA.
- **SG&A Expenses:** Selling, general and administrative expenses were $32.7 million for the quarter ended September 30, 2023, an increase of $14.0 million compared to $18.7 million for the quarter ended September 30, 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 the launch of XPHOZAH.
- **Net Income (Loss):** Net income for the quarter ended September 30, 2023 was $6.6 million, or $0.03 per share, compared to net loss of $22.9 million, or $(0.14) per share, for the quarter ended September 30, 2022.

Financial Guidance

Ardelyx currently expects full-year 2023 U.S. net product revenue for IBSRELA to be between $76.0 and $78.0 million.

Conference Call Details

The company will host a conference call today, October 31, 2023, at 8:00 AM ET to discuss these results. 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, Inc.

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 has received approval for 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 adoption, Ardelyx’s current expectation of timing for the commercial launch of XPHOZAH; the timing and receipt of the milestone payment from Fosun Pharma that was earned upon the U.S. FDA approval of XPHOZAH; and projected net product revenue for IBSRELA for full year 2023. 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, 2023, 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, 2023 (Unaudited)	December 31, 2022 (1)
Assets		
Cash and cash equivalents	$ 33,767	$ 96,140
Investments	131,313	27,769
Accounts receivable	43,263	7,733
Prepaid commercial manufacturing	17,176	13,567
Inventory, current	8,524	3,282
Inventory, non-current	38,974	25,064
Property and equipment, net	1,116	1,223
Right-of-use assets	6,523	9,295
Prepaid and other assets	8,723	5,993
Total assets	$ 289,379	$ 190,066
Liabilities and stockholders' equity		
Accounts payable	$ 7,736	$ 10,859
Accrued compensation and benefits	8,357	7,548
Current portion of operating lease liability	4,321	3,894
Current portion of long-term debt	—	26,711
Deferred revenue	14,362	13,236
Accrued expenses and other liabilities	19,213	12,380
Operating lease liability, net of current portion	2,887	5,855
Long-term debt, net of current portion	27,229	—
Deferred royalty obligation related to the sale of future royalties	14,113	11,254
Stockholders' equity	191,161	98,329
Total liabilities and stockholders' equity	$ 289,379	$ 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 September 30,		Nine Months Ended September 30,	
	2023	**2022**	**2023**	**2022**
Revenues:				
Product sales, net	$ 22,285	$ 4,885	$ 51,949	$ 6,899
Product supply revenue	2,092	92	5,354	1,058
Licensing revenue	32,014	9	32,790	23
Total revenues	56,391	4,986	90,093	7,980
Cost of goods sold:				
Cost of sales	644	230	1,508	287
Other cost of revenue	7,048	502	11,210	668
Total cost of goods sold	7,692	732	12,718	955
Operating expenses:				
Research and development	8,637	7,467	26,012	26,059
Selling, general and administrative	32,664	18,667	86,653	56,868
Total operating expenses	41,301	26,134	112,665	82,927
Income (loss) from operations	7,398	(21,880)	(35,290)	(75,902)
Interest expense	(1,107)	(886)	(3,210)	(2,409)
Non-cash interest expense related to the sale of future royalties	(922)	(831)	(2,859)	(841)
Other income, net	1,460	704	4,308	1,258
Income (loss) before provision for income taxes	6,829	(22,893)	(37,051)	(77,894)
Provision for income taxes	200	—	214	8
Net income (loss)	$ 6,629	$ (22,893)	$ (37,265)	$ (77,902)
Net income (loss) per share of common stock - basic and diluted	$ 0.03	$ (0.14)	$ (0.17)	$ (0.53)
Shares used in computing net income (loss) per share - basic	222,782,229	165,104,789	214,976,555	147,319,818
Shares used in computing net income (loss) per share - diluted	227,894,335	165,104,789	214,976,555	147,319,818