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): March 2, 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 March 2, 2023, Ardelyx, Inc. (the "Company") announced its financial results for the quarter and year ended December 31, 2022. The Company also announced that as of February 28, 2023, it had an unaudited cash, cash equivalents and short-term investments balance of $121.0 million. 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: March 2, 2023

ARDELYX, INC.

By: /s/ Justin Renz

Justin Renz
Chief Financial and Operations Officer

Exhibit 99.1

Ardelyx Reports Fourth Quarter and Full Year 2022 Financial Results and Provides Business Update

Continued successful launch of IBSRELA, ending FY 2022 with $15.6 million in net product sales

Resubmission of XPHOZAH New Drug Application expected in early-Q2 2023

Company ends Q4 with approximately $123.9 million in cash and investments

Conference call scheduled for 4:30 PM Eastern Time

WALTHAM, Mass., March 2, 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 fourth quarter and full year ended December 31, 2022 and provided a business update.

“2022 was a remarkable year for Ardelyx, having met significant milestones that demonstrate our deep and profound commitment to bringing our novel mechanism products to patients in need. In April, we began the process of launching our first therapy, IBSRELA, for adult patients with irritable bowel syndrome with constipation and we are demonstrating significant, quarter-over-quarter prescription growth. In addition, after the positive outcome of our appeal process for XPHOZAH, and a productive Type A meeting with the Food and Drug Administration in February 2023, we believe we are now on the path to launching another important medicine in the second half of the year for patients on dialysis,” said Mike Raab, president and chief executive officer of Ardelyx. “Our efforts, our commitment to patients and our tenacity have positioned us well in 2023 as we continue to build growth and momentum for IBSRELA, execute on our plans for a successful launch of XPHOZAH, if approved, and create opportunities to expand our business to support the next phase of the company’s growth. As evidenced by our continued success with IBSRELA, we are well on our way to realizing our mission to discover, develop and commercialize novel mechanism products for patients with unmet medical needs. We are pleased with our progress and excited about the opportunity to reach even more patients in the future.”

Recent Business Highlights

IBSRELA® (tenapanor) finishes 2022 with $15.6 million in net product sales, $8.7 million in Q4 2022

In March 2022, Ardelyx launched IBSRELA (tenapanor) for the treatment of irritable bowel syndrome with constipation (IBS-C) in the United States. The targeted commercial launch is focused on high-writing physicians and the patients who experience persistent symptoms, despite treatment with a prescription therapy for IBS-C. Ardelyx has seen consistent month-over-month growth trends in both new and refill prescriptions, supported by data from the independent research firm Spherix which reported in December that 60% of surveyed gastroenterologists had adopted IBSRELA with 32% of non-prescribers intending to adopt within three months.

XPHOZAH® (tenapanor) prepares for New Drug Application (NDA) resubmission in early Q2 2023

In February, Ardelyx participated in a Type A meeting with members of the U.S. Food and Drug Administration's (FDA) Division of Cardiology and Nephrology (DCN) to discuss resubmission of the NDA for XPHOZAH for the control of serum phosphorus in patients with chronic kidney disease (CKD) on dialysis. The meeting was very productive and provided Ardelyx with information required to complete its NDA resubmission. The company currently intends to submit the NDA early in the second quarter of 2023. Ardelyx is preparing to launch XPHOZAH, if approved, in the second half of 2023.

The resubmission of the NDA follows two significant developments for XPHOZAH that happened in the fourth quarter of 2022, providing a path to bring XPHOZAH to patients following a prolonged appeal process to the Complete Response Letter the company received in July 2021. In November, the Cardiovascular and Renal Drugs Advisory Committee voted nine to four that the benefits of treatment with XPHOZAH outweigh its risks for the control of serum phosphorus in adults with CKD on dialysis when administered as a monotherapy, and voted ten to two, with one abstention, that the benefits of treatment with XPHOZAH in combination with phosphate binder treatment outweigh its risks. Following the favorable outcome of the Advisory Committee meeting, in December, the FDA's Office of New Drugs granted the appeal for XPHOZAH and directed the DCN to work with Ardelyx to develop an appropriate label.

Other Corporate Developments

- In February, the company released its first 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 society. The report is available on the company's website.
- In February, the company reported that it had amended the debt financing agreement with SLR Investment Corp. it entered into in February 2022. The senior term loan facility's March 1, 2027 maturity date is unchanged; however the interest only period for the $27.5 million that was drawn at the February 2022 closing may be extended by one year to March 31, 2025 if certain product revenue targets are achieved for the year ended 2023 or the company has received approval by the FDA for the NDA for XPHOZAH on or before November 30, 2023. In addition, the deadline to borrow an additional $22.5 million available under the facility has been extended to December 20, 2023, provided that the company has received approval by the FDA for the NDA for XPHOZAH on or before November 30, 2023 and that the company has achieved certain product revenue targets.

Full Year 2022 Financial Results

- **Cash Position:** As of December 31, 2022, the company had total cash, cash equivalents and short-term investments of $123.9 million, as compared to total cash, cash equivalents and short-term investments of $116.7 million as of December 31, 2021. As of February 28, 2023, the company had an unaudited cash, cash equivalents and short-term investments balance of $121.0 million, which included gross proceeds of $20.0 million for the sale of 7.7 million shares of the company's common stock which were sold at a weighted average sales price of approximately $2.60 per share during the period January 1, 2023 to January 12, 2023 under the company's sales agreement with Jefferies LLC, dated August 13, 2021, deemed to be "at-the-market offerings."
- **Product Sales:** Net product sales for IBSRELA were $15.6 million during the year ended December 31, 2022.
- **Collaboration Revenue:** The company generated $36.6 million in collaboration revenue for the year ended December 31,

2022, as compared to $10.1 million for the year ended December 31, 2021. The increase in collaboration revenue was primarily the result of $35.0 million in milestone payments and payments under the 2022 amendment to the license agreement between Ardelyx and Kyowa Kirin Co, Ltd (Kyowa Kirin), Ardelyx's collaboration partner in Japan, earned upon Kyowa Kirin's submission of a New Drug Application to the Japanese Ministry of Health, Labour and Welfare for tenapanor for the improvement of hyperphosphatemia in adult patients with CKD on dialysis. The company also realized increased product supply revenue in connection with its obligation to supply drug substance to Kyowa Kirin under its license agreement with Kyowa Kirin. Partially offsetting these increases was the full recognition through the end of 2021 of upfront payments associated with the Research Collaboration Agreement entered into with Kyowa Kirin.

- **R&D Expenses**: Research and development expenses were $35.2 million for the year ended December 31, 2022, a decrease of $55.9 million compared to $91.1 million for the year ended December 31, 2021. Research and development expenses included non-cash stock compensation expense of approximately $3.2 million and $4.1 million in the years ended December 31, 2022, and December 31, 2021, respectively. The decrease in R&D expenses is primarily due to lower clinical study costs as a result of the completion of the OPTIMIZE study, lower tenapanor manufacturing expenses due to the company's capitalization of costs associated with the production of IBSRELA to inventory, and lower expenses for research following the reduction in the research function in the fourth quarter of 2021.
- **SG&A Expenses:** Selling, general and administrative expenses were $76.6 million for the year ended December 31, 2022, an increase of $4.3 million compared to $72.3 million for the year ended December 31, 2021. Selling, general and administrative expenses included non-cash stock compensation expense of approximately $7.5 million and $7.9 million in the years ended December 31, 2022, and December 31, 2021, respectively. The increase in selling, general and administrative expenses was primarily due to increased costs associated with the ongoing commercial launch of IBSRELA during 2022.
- **Net Loss:** Net loss for the year ended December 31, 2022 was $67.2 million, or $(0.42) per share, compared to net loss of $158.2 million, or $(1.52) per share, for the year ended December 31, 2021.

Conference Call Details

The company will host a conference call today, March 2, 2023, at 4:30 PM ET to discuss today's announcement. To participate in the conference call, please dial (877) 270-2148 (domestic) or (412) 902-6510 (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

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.

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's first approved product, IBSRELA® (tenapanor) is available in the United States and Canada. Ardelyx is developing XPHOZAH® (tenapanor), a novel product candidate for the control of serum phosphorus in adult patients with chronic kidney disease (CKD) on dialysis, which has completed three successful Phase 3 trials. Ardelyx has a Phase 2 potassium lowering compound, RDX013, for the potential treatment of elevated serum potassium, or hyperkalemia, a problem among certain patients with kidney and/or heart disease and an early-stage program in metabolic acidosis, a serious electrolyte disorder in patients with CKD. Ardelyx has established agreements with Kyowa Kirin in Japan, Fosun Pharma in China and Knight Therapeutics in Canada for the development and commercialization of tenapanor in their respective territories. For more information, please visit https://ardelyx.com/ and connect with us on 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 potential commercial opportunities and other opportunities for the

company, Ardelyx’s current expectation for both the timing of the NDA submission and potential FDA approval for XPHOZAH, and the potential extension of the interest only period for Ardelyx's senior term loan facility. 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 commercialization of drugs and uncertainties regarding the FDA regulatory process. 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 March 2, 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)

	December 31, 2022 (Unaudited)	December 31, 2021 (1)
Assets		
Cash and cash equivalents	$ 96,140	$ 72,428
Investments	27,769	44,261
Accounts receivable	7,733	502
Prepaid commercial manufacturing	13,567	9,406
Inventory, current	3,282	—
Inventory, non-current	25,064	—
Property and equipment, net	1,223	2,362
Right-of-use assets	9,295	12,752
Prepaid and other assets	5,993	8,202
Total assets	$ 190,066	$ 149,913
Liabilities and stockholders' equity		
Accounts payable	$ 10,859	$ 4,277
Accrued compensation and benefits	7,548	5,422
Current portion of operating lease liability	3,894	3,492
Current portion of long-term debt	26,711	32,264
Deferred revenue	13,236	4,727
Accrued expenses and other liabilities	12,380	7,366
Operating lease liability, net of current portion	5,855	9,748
Deferred royalty obligation related to the sale of future royalties	11,254	—
Stockholders' equity	98,329	82,617
Total liabilities and stockholders' equity	$ 190,066	$ 149,913

(1) Derived from the audited financial statements included in the Company’s Annual Report on Form 10-K for the year ended December 31, 2021.

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,	
	2022	**2021**	**2022**	**2021**
Revenues:				
Product sales, net	$ 8,701	$ —	$ 15,600	$ —
Product supply revenue	469	496	1,527	907
Licensing revenue	35,008	6	35,031	5,013
Collaborative development revenue	—	527	—	4,177
Total revenues	44,178	1,029	52,158	10,097
Operating expenses:				
Cost of revenue	3,162	—	4,117	1,000
Research and development	9,142	20,968	35,201	91,140
Selling, general and administrative	19,731	15,334	76,599	72,303
Total operating expenses	32,035	36,302	115,917	164,443
Income (loss) from operations	12,143	(35,273)	(63,759)	(154,346)
Interest expense	(991)	(984)	(3,400)	(4,502)
Non-cash interest expense related to the sale of future royalties	(832)	—	(1,673)	—
Other income, net	375	23	1,633	687
Income (loss) before provision for income taxes	10,695	(36,234)	(67,199)	(158,161)
Provision for income taxes	—	—	8	4
Net income (loss)	$ 10,695	$ (36,234)	$ (67,207)	$ (158,165)
Net income (loss) per share - basic and diluted	$ 0.06	$ (0.31)	$ (0.42)	$ (1.52)
Shares used in computing net income (loss) per share - basic	192,430,121	115,260,610	158,690,083	104,205,645
Shares used in computing net income (loss) per share - diluted	193,840,751	115,260,610	158,690,083	104,205,645