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): August 4, 2022

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 August 4, 2022, Ardelyx, Inc. (the "Company") announced its financial results for the fiscal quarter ended June 30, 2022. 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: August 4, 2022

ARDELYX, INC.

By: /s/ Robert Felsch

Robert Felsch
Senior Vice President and Chief Accounting Officer

Exhibit 99.1

Ardelyx Reports Second Quarter 2022 Financial Results and Recent Business Highlights

Conference call scheduled for 4:30 p.m. Eastern Time today

WALTHAM, Mass., Aug 4, 2022 - 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 business updates and financial results for the second quarter ended June 30, 2022.

“The second quarter marks a significant point of transition for Ardelyx as a commercial company,” said Mike Raab, president and chief executive officer of Ardelyx. “We are now three months into the launch of IBSRELA®, for the treatment of IBS-C in adults, and see that the market is responding enthusiastically to this much-needed innovative therapy. We are building strong relationships with the treating community and, across GI practices. Our sales and marketing launch efforts are raising visibility and building a foundational demand for IBSRELA. Separately, the FDA assigned a date for the advisory committee to review our NDA for XPHOZAH® for hyperphosphatemia, and we look forward to the opportunity to highlight the strong data that support XPHOZAH and its potential to make a difference in the lives of patients with chronic kidney disease on dialysis.”

Recent Business Highlights and Updates

- Spherix Global Insights, a company that publishes independent, syndicated monthly tracking research has included IBSRELA (tenapanor) as one of the key launches to follow in the GI space. Three months post-launch, Spherix reports that with respect to those GIs surveyed in its market research, two-thirds are aware of IBSRELA, 41% report use of IBSRELA, and 92% rate IBSRELA as either a substantial or moderate advance over currently available irritable bowel syndrome with constipation (IBS-C) therapies. In addition, those GIs surveyed reported that 31% of their patients may be candidates for treatment. Among those who have not yet used IBSRELA, 57% expect to use it within three months and an additional 21% expect to use within six months.
- The American Gastroenterological Association (AGA) announced their updated Clinical Practice Guideline on the “Pharmacological Management of Irritable Bowel Syndrome with Constipation.” The updated guideline includes IBSRELA in their IBS-C treatment recommendations.

- The company presented multiple posters at the Digestive Disease Week Conference (DDW 2022) in San Diego, CA on May 21-24, 2022, which included long term data demonstrating the impact of IBSRELA on abdominal pain and other abdominal symptoms; effect of IBSRELA on treatment satisfaction, degree of relief, and quality of life; and early onset of action in treating symptoms of irritable bowel syndrome with constipation.
- On June 21, 2022, the company announced that the U.S. Food and Drug Administration (FDA) informed the company that a meeting of the Cardiovascular and Renal Drugs Advisory Committee (Advisory Committee) is tentatively scheduled for November 16, 2022. As part of the Formal Dispute Resolution Request (FDRR), the Advisory Committee is being convened at the request of FDA's Office of New Drugs (OND) in order to provide input regarding the clinical meaningfulness of the phosphate lowering effect observed in the company's Phase 3 clinical program for XPHOZAH (tenapanor) for the control of serum phosphorus in adult patients with chronic kidney disease (CKD) on dialysis.
- On June 30, 2022, the company announced a $20 million financing agreement with HealthCare Royalty Partners (HealthCare Royalty) based on the sale of its future royalties and sales milestones from Kyowa Kirin Co., Ltd (Kyowa Kirin), its collaboration partner in Japan, for the commercialization of tenapanor for hyperphosphatemia. Under the agreement, the company received from HealthCare Royalty a $10 million upfront payment and is entitled to an additional $5 million following Kyowa Kirin's receipt of regulatory approval to market tenapanor for hyperphosphatemia in Japan, and $5 million in the event net sales in Japan exceed a certain target level in 2025. In return, HealthCare Royalty will receive the royalty payments and commercial sales milestones that the company may earn under the license agreement with Kyowa Kirin.

Second Quarter 2022 Financial Results

- **Cash Position:** As of June 30, 2022, the company had total cash, cash equivalents and investments of $81.0 million, as compared to total cash, cash equivalents and investments of $116.7 million as of December 31, 2021.
- **Product Sales:** Net product sales for IBSRELA were $1.6 million during the quarter ended June 30, 2022.
- **Collaboration Revenue:** The company generated $1.0 million in collaboration revenue for the quarter ended June 30, 2022, as compared to $1.3 million for the quarter ended June 30, 2021. The decrease in collaboration revenue was primarily the result of the recognition of the previously received upfront payment from the 2019 research and collaboration agreement between the company and Kyowa Kirin

that was fully earned and recognized as revenue as of December 31, 2021. The decrease in collaboration revenue was partially offset by product supply revenue related to the manufacturing and supply of tenapanor and other materials for Kyowa Kirin pursuant to the 2017 license agreement between the company and Kyowa Kirin.

- **R&D Expenses**: Research and development expenses were $9.7 million for the quarter ended June 30, 2022, a decrease of $16.3 million, or 62.6%, compared to $26.0 million for the quarter ended June 30, 2021. Research and development expenses included non-cash stock compensation expense of approximately $1.0 million and $1.1 million in the quarters ended June 30, 2022, and June 30, 2021, respectively. The decrease in R&D expenses is primarily the result of lower clinical study costs from 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 elimination of the company's research function in the fourth quarter of 2021.
- **SG&A Expenses:** Selling, general and administrative expenses were $18.9 million for the quarter ended June 30, 2022, a decrease of $1.3 million, or 6.3%, compared to $20.1 million for the quarter ended June 30, 2021. Selling, general and administrative expenses included non-cash stock compensation expense of approximately $2.2 million and $2.1 million in the quarters ended June 30, 2022, and June 30, 2021, respectively. The decrease in selling, general and administrative expenses was primarily due to the timing of costs associated with preparing for and carrying out the commercial launch of IBSRELA.
- **Net Loss:** Net loss for the quarter ended June 30, 2022 was $26.9 million, or $0.19 per share, compared to $45.2 million, or $0.45 per share, for the quarter ended June 30, 2021.

Conference Call Details

The company will host a conference call today, August 4, 2022, at 4:30 p.m. ET to review its financial results and provide a business overview. To participate in the conference call via telephone, please register using this online form. Live audio of the conference call will be simultaneously webcast and will be available under the Investors section of the company's website at www.ardelyx.com. The webcast will be archived and available for replay 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 to control serum phosphorus in adult patients with CKD on dialysis, which has completed three successful Phase 3 trials. Ardelyx has a Phase 2 potassium secretagogue program, 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.

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 expectation regarding the timing of the Advisory Committee meeting to be convened to provide input regarding the clinical meaningfulness of the phosphate lowering effect observed in the Phase 3 clinical program for XPHOZAH, the potential receipt by Ardelyx of additional payments under the royalty financing agreement with HealthCare Royalty, and the potential for additional GIs to begin use of IBSRELA in the next three to six months as reported by the Spherix report. 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 FDA's regulatory process, uncertainties in the drug development and regulatory processes in Japan and uncertainties associated with the commercialization of drugs. 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 August 4, 2022, 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)

	June 30, 2022 (Unaudited)	December 31, 2021 (1)
Assets		
Cash and cash equivalents	$ 53,408	$ 72,428
Investments	27,604	44,261
Accounts receivable	5,623	502
Inventory	4,529	—
Property and equipment, net	1,541	2,362
Right-of-use assets	11,054	12,752
Prepaid commercial manufacturing	17,793	9,406
Prepaid and other assets	10,058	8,202
Total assets	$ 131,610	$ 149,913
Liabilities and stockholders' equity		
Accounts payable	$ 4,294	$ 4,277
Accrued compensation and benefits	6,405	5,422
Current portion of operating lease liability	3,691	3,492
Current portion of long-term debt	26,373	32,264
Deferred revenue	12,421	4,727
Accrued expenses and other liabilities	7,936	7,366
Operating lease liability, net of current portion	7,857	9,748
Deferred royalty obligation	9,591	—
Stockholders' equity	53,042	82,617
Total liabilities and stockholders' equity	$ 131,610	$ 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 June 30,		Six Months Ended June 30,	
	2022	**2021**	**2022**	**2021**
Revenues:				
Product sales, net	$ 1,564	$ —	$ 2,014	$ —
Product supply revenue	952	—	966	126
Licensing revenue	10	3	14	5,005
Collaborative development revenue	—	1,310	—	2,764
Total revenues	2,526	1,313	2,994	7,895
Operating expenses:				
Cost of revenue	138	—	223	1,000
Research and development	9,741	26,021	18,592	46,477
Selling, general and administrative	18,862	20,124	38,201	37,255
Total operating expenses	28,741	46,145	57,016	84,732
Loss from operations	(26,215)	(44,832)	(54,022)	(76,837)
Interest expense	(787)	(1,202)	(1,533)	(2,302)
Other income, net	70	847	554	798
Loss before provision for income taxes	(26,932)	(45,187)	(55,001)	(78,341)
Provision for income taxes	6	2	8	3
Net loss	$ (26,938)	$ (45,189)	$ (55,009)	$ (78,344)
Net loss per common share, basic and diluted	$ (0.19)	$ (0.45)	$ (0.40)	$ (0.79)
Shares used in computing net loss per share - basic and diluted	145,544,372	100,040,083	138,279,945	98,617,564