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): May 5, 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 May 5, 2022, Ardelyx, Inc. (the "Company") announced its financial results for the fiscal quarter ended March 31, 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: May 5, 2022

ARDELYX, INC.

By: /s/ Robert Felsch
Robert Felsch
Senior Vice President and Chief Accounting Officer

Exhibit 99.1

Ardelyx Reports First Quarter 2022 Financial Results and Recent Business Highlights

Conference Call Scheduled for 4:30 PM Eastern Time Today

WALTHAM, Mass., May 5, 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 provided a business update and reported financial results for the first quarter ended March 31, 2022.

“Ardelyx is off to a great start in 2022, with the commercial launch of IBSRELA®, our first-in-class, novel therapy for the treatment of IBS-C in adults,” said Mike Raab, president and chief executive officer of Ardelyx. “Initial channel stocking began in late March, the sales force is mobilized across the country, and early response to the product as a new treatment option has been positive. In parallel, we continue to persist in our pursuit of FDA approval for XPHOZAH®, our first-in-class, phosphate absorption inhibitor, and received notification from the FDA that an advisory committee meeting will be convened to get further input from experts, augmented with clinicians familiar with the clinical management of hyperphosphatemia.”

Recent Business Highlights

- On April 4, 2022, the company announced the launch of IBSRELA (tenapanor), the first and only NHE3 inhibitor for the treatment of irritable bowel syndrome with constipation (IBS-C) in adults. IBSRELA is the first FDA-approved product for Ardelyx. Commercial efforts are focused on the 9,000 HCPs who account for 50% of the prescriptions of IBS-C indicated products, with broad-based distribution, a targeted specialty sales force, and omnichannel tactics. Marketing messages center on the multifactorial pathophysiology of IBS-C, and the role novel mechanism IBSRELA can play to address important medical unmet needs.
- The company presented multiple presentations at the National Kidney Foundation 2022 Spring Clinical Meetings, in Boston, MA on April 6-10, 2022, covering additional positive clinical observations of XPHOZAH an investigational, first-in-class, phosphate absorption inhibitor for the control of serum phosphorus in adult patients with chronic kidney disease (CKD) on dialysis.

- On April 11, 2022, the company announced it reached an agreement with its Japanese collaboration partner, Kyowa Kirin Co. Ltd., to amend the license agreement, originally executed in 2017. Under the amendment, in consideration for a reduction in the royalty rate due Ardelyx upon net sales in Japan, Kyowa Kirin has agreed to pay Ardelyx consideration of up to an additional U.S. $40 million payable in two tranches. The first payment is due following Kyowa Kirin's filing with the Japanese Ministry of Health, Labour and Welfare (MHLW) of its application for marketing approval for tenapanor and the second payment is due following MHLW’s approval to market tenapanor for hyperphosphatemia in Japan. Kyowa Kirin is finalizing its Phase 3 clinical program for tenapanor for hyperphosphatemia and has disclosed its current expectation to file for approval with MHLW in the second half of 2022 and its current expectation that it will receive a decision from MHLW regarding its application in the second half of 2023. The royalty rate will be reduced from the high teens to low double digits for a two-year period of time following the first commercial sale in Japan, and then to mid-single digits for the remainder of the royalty term.
- On April 25, 2022, the company announced that the Office of New Drugs (OND), Center for Drug Evaluation and Research (CDER) of the U.S. Food and Drug Administration (FDA), has provided an interim response to Ardelyx’s second level of appeal of the Complete Response Letter (CRL) received on July 28, 2021, for XPHOZAH. The OND noted that additional input from the Cardiovascular and Renal Drug Advisory Committee augmented with expert clinicians would be valuable in further considering the clinical meaningfulness of the phosphate lowering effect demonstrated in Ardelyx’s Phase 3 clinical program for XPHOZAH.

First Quarter 2022 Financial Results

- **Cash Position:** As of March 31, 2022, we had total cash, cash equivalents and investments of $89.7 million, as compared to total cash, cash equivalents and investments of $116.7 million as of December 31, 2021.
- **Product Sales:** We recognized our first commercial product sales, net for IBSRELA during March 2022 in the amount of $0.5 million.
- **Collaboration Revenue:** We generated $18 thousand in collaboration revenue for the quarter ended March 31, 2022, as compared to $6.6 million for the quarter ended March 31, 2021. The decrease in our collaboration revenue was primarily the result of a $5.0 million development milestone which we earned in 2021, as well as recognition of the previously received upfront payment from the KKC 2019 research and collaboration agreement that was fully earned and recognized as revenue as of December 31, 2021.

- **R&D Expenses**: Research and development expenses were $8.9 million for the quarter ended March 31, 2022, a decrease of $11.6 million, or 56.7%, compared to $20.5 million for the quarter ended March 31, 2021. Research and development expenses included non-cash stock compensation expense of approximately $1.2 million and $1.1 million in the quarters ended March 31, 2022, and 2021, respectively. The decrease in our R&D expenses is primarily the result of lower clinical study costs from the OPTIMIZE study, lower tenapanor manufacturing expenses as we have begun to capitalize costs associated with the production of IBSRELA to inventory, and lower expenses for research following the elimination of our research function in the fourth quarter of 2021.
- **SG&A Expenses:** Selling, general and administrative expenses were $19.3 million for the quarter ended March 31, 2022, an increase of $2.2 million, or 12.9%, compared to $17.1 million for the quarter ended March 31, 2021. Selling, general and administrative expenses included non-cash stock compensation expense of approximately $2.5 million and $2.0 million in the quarters ended March 31, 2022, and 2021, respectively. The increase in selling, general and administrative expenses was primarily due to an increase in costs associated with preparations for the commercial launch of IBSRELA.
- **Net Loss:** Net loss for the quarter ended March 31, 2022 was $28.1 million, or $0.21 per share, compared to $33.2 million, or $0.34 per share, for the quarter ended March 31, 2021.

Conference Call Details

The company will host a conference call today, May 5, 2022, at 4:30 PM ET to review its financial results and provide a business overview. To participate in the conference call, please dial (866) 777-2509 (domestic) or (412) 317-5413 (international) and ask to be joined into the Ardelyx, Inc. call. A webcast of the call can also be accessed by visiting the Investor page of the company's website at 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. 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 FDA's plan to convene an Advisory Committee meeting to consider the NDA for XPHOZAH, Ardelyx's belief regarding the role that IBSRELA can play in addressing unmet medical needs in IBS-C, Ardelyx's expectation regarding the timing of Kyowa Kirin's filing for marketing approval for tenapanor for hyperphosphatemia in Japan and Ardelyx's expectations regarding the potential timing for Kyowa Kirin's marketing approval in Japan. 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 drug development process and the regulatory approval process, including uncertainties in the drug development and regulatory processes in Japan, and risks and uncertainties associated with the commercialization of drugs in the United States. 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 5, 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)

	March 31, 2022 (Unaudited)	December 31, 2021 (1)
Assets		
Cash and cash equivalents	$ 47,077	$ 72,428
Investments	42,627	44,261
Accounts receivable	4,394	502
Inventory	3,487	—
Property and equipment, net	2,045	2,362
Right-of-use assets	11,910	12,752
Prepaid and other assets	17,868	17,608
Total assets	$ 129,408	$ 149,913
Liabilities and stockholders' equity		
Accounts payable	$ 5,030	$ 4,277
Accrued compensation and benefits	6,304	5,422
Current portion of operating lease liability	3,592	3,492
Current portion of long-term debt	26,139	32,264
Deferred revenue	8,563	4,727
Accrued expenses and other liabilities	6,778	7,366
Operating lease liability, net of current portion	8,812	9,748
Stockholders' equity	64,190	82,617
Total liabilities and stockholders' equity	$ 129,408	$ 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 March 31,	
	2022	**2021**
Revenues:		
Product sales, net	$ 450	$ —
Product supply revenue	14	126
Licensing revenue	4	5,002
Collaborative development revenue	—	1,454
Total revenues	468	6,582
Operating expenses:		
Cost of revenue	85	1,000
Research and development	8,851	20,456
Selling, general and administrative	19,339	17,131
Total operating expenses	28,275	38,587
Loss from operations	(27,807)	(32,005)
Interest expense	(746)	(1,100)
Other income (expense), net	484	(49)
Loss before provision for income taxes	(28,069)	(33,154)
Provision for income taxes	2	1
Net loss	$ (28,071)	$ (33,155)
Net loss per common share, basic and diluted	$ (0.21)	$ (0.34)
Shares used in computing net loss per share - basic and diluted	130,934,795	97,179,241