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): April 25, 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 8.01 Other Events

Ardelyx, Inc. (the "Company") a biopharmaceutical company founded with a mission to discover, develop and commercialize innovative first-in-class medicines that meet significant unmet medical needs, today 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 the Company'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 in general, and specifically, from experts, including expert clinicians, would be valuable in further considering the clinical meaningfulness of the phosphate lowering effect observed in the Company's phase 3 clinical program for XPHOZAH. Accordingly, the OND intends to direct the Division of Cardiology and Nephrology to bring the XPHOZAH New Drug Application (NDA) to the Cardiovascular and Renal Drugs Advisory Committee, and to provide a response to the Company's appeal within thirty (30) days after the conclusion of the Advisory Committee meeting. The Company is seeking approval for XPHOZAH for the control of serum phosphorus in adult patients with chronic kidney disease (CKD) on dialysis.

In addition, the Company is reporting that it has completed its data analyses of the Phase 2 dose ranging clinical trial for RDX013 evaluating the safety and efficacy of its potassium secretagogue for the treatment of hyperkalemia, or elevated potassium, in chronic kidney disease patients who are not on dialysis. While the results of the study demonstrated an acceptable safety and tolerability profile for RDX013 and supported proof of concept in its ability to lower serum potassium levels, with statistically significant reductions compared to placebo after eight days of treatment, the study did not meet its primary endpoint of significantly reducing serum potassium levels compared to placebo after four weeks of treatment. The Company currently expects that the next steps for the program will be to evaluate a new formulation that potentially enhances subject compliance and the efficacy of RDX013 in an additional Phase 2 clinical study at such time as the Company has determined its available resources support conducting such an additional clinical study after prioritization of the Company's launch of IBSRELA® and preparations for the Advisory Committee for XPHOZAH.

Forward Looking Statements

To the extent that statements contained in this Current Report on Form 8-K are not descriptions of historical facts regarding the Company, 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 the Company's expectations regarding an additional Phase 2 dose ranging clinical study. Such forward-looking statements involve substantial risks and uncertainties that could cause the development of the Company's product candidates or the Company'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 regarding available resources. The Company 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 the Company's business in general, please refer to the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission (the "SEC") on February 28, 2022, and its future current and periodic reports to be filed with the SEC.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
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: April 25, 2022

ARDELYX, INC.

By: /s/ Justin Renz

Justin Renz
Chief Financial Officer