
**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): February 4, 2022



ARDELYX, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-36485
(Commission
File Number)

26-1303944
(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.

Item 8.01 Other Events.

On February 4, 2022, the Company received an Appeal Denied Letter (“ADL”) from the Office of Cardiology, Hematology, Endocrinology and Nephrology (“OCHEN”) of the U.S. Food and Drug Administration (the “FDA”) in response to its Formal Dispute Resolution Request (“FDRR”) submitted in early December 2021, and following its submission on January 7, 2022, of additional clarifying data requested by OCHEN. The Company intends to appeal the ADL to the Office of New Drugs (“OND”), Center for Drug Evaluation and Research. If accepted for consideration, the Company expects a decision on the appeal to the OND in April 2022.

The Company submitted the FDRR in response to the Complete Response Letter (“CRL”) the Company received on July 28, 2021, regarding its New Drug Application (“NDA”) for the control of serum phosphorus in chronic kidney disease patients on dialysis. The FDRR was focused on demonstrating that the data submitted in the NDA supported the clinical significance of the treatment effect of tenapanor. The CRL noted that in order for the NDA to be approved, the Company needs to conduct an additional adequate and well-controlled trial demonstrating a clinically relevant treatment effect on serum phosphorus or an effect on the clinical outcome thought to be caused by hyperphosphatemia in CKD patients on dialysis. The ADL provided the Company a potential additional path forward involving the resubmission of the NDA (without conducting an additional trial) with a number of new analyses of each of the Company’s Phase 3 clinical trials; an assessment of tenapanor’s benefits and risks; and a proposal of how to label tenapanor for prescribers.

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: February 9, 2022

ARDELYX, INC.

By: /s/ Justin Renz

Justin Renz

Chief Financial Officer