
**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 29, 2021



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)

**34175 ARDENWOOD BLVD., FREMONT, CALIFORNIA 94555
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 April 29, 2021, Ardelyx, Inc. (the “Company”) announced that, in connection with the ongoing review of the Company’s New Drug Application (NDA) for tenapanor for the control of serum phosphorus in chronic kidney disease (CKD) patients on dialysis, the U.S. Food and Drug Administration (FDA) made a recent information request that required the Company to submit additional analyses of its clinical data to help the agency better understand the clinical data in light of tenapanor’s novel mechanism of action as compared to approved therapies. In response, the Company submitted the requested analyses which constitute a major amendment to the NDA, resulting in an extension of the PDUFA date by three months to July 29, 2021. Tenapanor has a unique mechanism of action and acts locally in the gut to inhibit the sodium hydrogen exchanger 3, or NHE3. This results in the tightening of the epithelial cell junctions and reducing paracellular uptake of phosphate, the primary pathway of phosphate absorption.

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 30, 2021

ARDELYX, INC.

By: /s/ Elizabeth Grammer

Elizabeth Grammer

Chief Legal and Administrative Officer
