
**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): July 13, 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 2.02 Results of Operations and Financial Condition

On July 19, 2021, Ardelyx, Inc. (the “Company”) announced that as of June 30, 2021, the Company had approximately \$171.8 million in cash, cash equivalents and short-term investments, which included \$28.2 million of net proceeds from sales of common stock under our at-the-market equity facility during the three months ended June 30, 2021. These dollar amounts are unaudited.

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 8.01 Other Events

On July 19, 2021, the Company announced that it received a letter from the U.S. Food and Drug Administration (the “FDA”) on July 13, 2021 stating that, as part of its ongoing review of the company’s New Drug Application (“NDA”) for the control of serum phosphorus in chronic kidney disease patients on dialysis, the FDA has identified deficiencies that preclude discussion of labeling and post-marketing requirements/commitments at this time. The FDA stated that this notification does not reflect a final decision on the information under review.

While the FDA has not provided specific details regarding the deficiencies, the FDA noted that a key issue is the size of the treatment effect and its clinical relevance. The Company plans to work with the FDA to learn more about the nature of the deficiencies and will seek to resolve them as quickly as possible. In April 2021, the FDA extended the PDUFA date for the NDA to July 29, 2021 as a result of the Company’s submission of additional data analyses requested by the FDA.

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: July 19, 2021

ARDELYX, INC.

By: /s/ Elizabeth Grammer

Elizabeth Grammer

Chief Legal and Administrative Officer