ARDELYX, INC.
Form 8-K
June 22, 2016

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): June 22, 2016

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)**

34175 Ardenwood Blvd., Suite 200

Fremont, CA 94555

(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))

Item 8.01 Other Events.

On June 22, 2016, Ardelyx, Inc. (the Company) announced updates to two of the Company s ongoing development programs.

Tenapanor for the Treatment of Hyperphosphatemia for ESRD Patients on Dialysis

The Company announced that, based on the outcome of a meeting with the U.S. Food and Drug Administration (FDA) regarding tenapanor for the treatment of hyperphosphatemia in end-stage renal disease (ESRD) patients on dialysis, the Company s ongoing Phase 2b hyperphospatemia trial may serve as the first of two registration trials to support the registration of tenanapor for the treatment of hyperphosphatemia in ESRD patients on dialysis. Based on the FDA s feedback, the Company has elected to change the primary endpoint to use the results of the placebo-controlled randomized withdrawal portion of the trial as the primary endpoint, and the Company has submitted a new statistical analysis plan to the FDA to reflect this change. Additionally, the Company is increasing the number of patients to be enrolled in the trial to further strengthen the trial and maintain a power of ninety percent (90%). With these changes, the Company currently expects that results from the ongoing clinical trial, previously expected in the second half of 2016, to be reported in the first quarter of 2017.

RDX227675 for the Treatment of Hyperkalemia

Separately, the Company also announced that it has recently received positive results from its once-daily dosing arm of the RDX227675 pharmacodynamic study in healthy adult volunteers, leading the Company to determine that that once- or twice-daily dosing will be the most appropriate dosing regimens for further development and evaluation in the treatment of hyperkalemia in its upcoming trials. Following these results, the Company has decided to accelerate the commencement of a previously planned Phase 2b trial designed to evaluate the rate of onset of action of RDX227675 along with safety and efficacy in patients with chronic kidney disease with or without heart failure. The Company currently expects to commence this Phase 2b clinical trial in the fourth quarter of 2016 and results from this trial are expected to be available in the first half of 2017. The Phase 2b clinical trial is not expected to affect the timing or design of the previously announced Phase 3 clinical trial for RDX227675, which is still expected to be initiated in the fourth quarter of 2016.

Statements made in this Current Report on Form 8-K, other than statements of historical fact, are forward-looking statements within the meaning of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, including, for example, statements relating to the potential for tenapanor in treating hyperphosphatemia in ESRD patients on dialysis,, the expected timing of the results of the on-going clinical trial evaluating tenapanor for the treatment of hyperphosphatemia in ESRD patients on dialysis, the potential for the ongoing clinical trial evaluating tenapanor for the treatment of hyperphosphatemia in ESRD patients on dialysis to serve as the first of two well-controlled clinical trials to support registration, the potential for RDX227675 in treating hyperkalemia in CKD kidney and heart disease patients, the expected timing of the initiation of the Phase 2b and Phase 3 clinical trials evaluating RDX227675 in treating hyperkalemia in CKD patients and the expected timing of the results of the Phase 2b trial. Forward-looking statements are subject to a number of known and unknown risks and uncertainties that might cause actual results to differ materially from those expressed or implied by such statements. For example, there can be no assurances with respect to the commencement, pace of enrollment, completion or success of clinical trials; and there can be no assurances that Ardelyx will pursue further activities with respect to the clinical development of tenapanor or RDX227675. These and other risk factors are set forth in the Company s annual report on Form 10-K for the fiscal year ended December 31, 2015 and subsequent SEC filings, including the Company s Quarterly Reports on Form 10-Q and Current Reports on Form 8-K filed with the Securities and Exchange Commission. Ardelyx disclaims any intention or duty to update any forward-looking statement made in this Current Report on Form 8-K.

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: June 22, 2016

ARDELYX, INC.

By: /s/ Mark Kaufmann
Mark Kaufmann
Chief Financial Officer