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): September 3, 2019

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))

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 September 3, 2019, Ardelyx, Inc. (the "Company" or "Ardelyx"), a specialized biopharmaceutical company focused on developing first-in-class medicines to improve treatment for people with cardiorenal diseases, reported positive results from AMPLIFY, a pivotal Phase 3 study of tenapanor in combination with phosphate binders in patients with chronic kidney disease ("CKD") on dialysis whose hyperphosphatemia was not previously controlled with binders alone. The AMPLIFY study met the primary endpoint and all key secondary endpoints, including demonstrating a statistically significant (p=0.0004) reduction in serum phosphorus levels for patients treated with tenapanor and phosphate binders compared to phosphate binders alone. Tenapanor is an investigational, first-in-class, small molecule, non-binder, phosphate absorption inhibitor being developed to treat hyperphosphatemia in patients with CKD on dialysis.

Key Study Results

For the primary endpoint, patients treated in the tenapanor arm (tenapanor in combination with phosphate binders, n=116) had a statistically significant (p=0.0004) mean reduction in serum phosphorus from baseline to the end of the four-week treatment period of 0.84 mg/dL, as compared to those treated in the binder arm (placebo in combination with phosphate binders, n=119) who had a mean reduction of 0.19 mg/dL. Patients in the tenapanor arm had statistically significant decreases in serum phosphorus during all four weeks ranging from 0.84 to 1.21 mg/dL (p-values≤0.0004). During the treatment period, up to 49.1% of patients in the tenapanor arm achieved a serum phosphorus of <5.5 mg/dL which was statistically significant compared with up to 23.5% in the binder arm (p-values£0.0097). There was a statistically significant 22% to 24% reduction (p-values£0.0027) in FGF23 levels in the tenapanor arm as compared to the binder arm. Elevated levels of FGF23 are associated with an increased risk of major cardiovascular events.

Tenapanor was well tolerated. Only 4.3% of patients in the tenapanor arm discontinued treatment compared to 2.5% in the binder arm. The single adverse event with a placebo-adjusted rate greater than 3% was loose stools/diarrhea at 36%, where most incidents were reported within the first five days of treatment, were transient in nature and the median time to resolution was four days after onset. Notably, only 2.6% of patients in the tenapanor arm discontinued treatment due to loose stools/diarrhea, as compared to 0.8% in the binder arm. There were no serious adverse events related to tenapanor.

About AMPLIFY

AMPLIFY, a double-blind, placebo-controlled, randomized study, enrolled a total of 236 patients with CKD on dialysis, who despite a stable phosphate binder regimen, had a serum phosphorus level greater than or equal to 5.5 mg/dL and less than or equal to 10.0 mg/dL at screening. After a run-in of two to four weeks, patients were randomized 1:1 to receive tenapanor or placebo twice daily while continuing their established phosphate binder regimen. Baseline serum phosphorus at randomization was at a mean level of 6.8 mg/dL. Tenapanor was initiated at a starting dose of 30 mg twice daily with tenapanor dose adjustments allowed based on serum phosphorus level and gastrointestinal tolerability.

The primary endpoint of the study was the comparison of the change from baseline in serum phosphorus levels at week four between the tenapanor and binder arms. The key secondary endpoints included a comparison of the proportion of patients achieving a serum phosphorus level below 5.5 mg/dL at week four and relative change from baseline in FGF23 levels between the tenapanor and binder arms at week four.

About Tenapanor for Hyperphosphatemia

Tenapanor, discovered and developed by Ardelyx, is a first-in-class, proprietary, oral, medicine in late-stage clinical development for the control of serum phosphorus in patients with CKD on dialysis. Tenapanor has a unique mechanism of action and acts locally in the gut to inhibit the sodium hydrogen exchanger 3 (NHE3). This results in the tightening of the epithelial cell junctions, thereby significantly reducing paracellular uptake of phosphate, the primary pathway of phosphate absorption. In addition, if approved, tenapanor will be easier than phosphate binders for patients to take with a regimen of just one small pill, taken twice daily. The Company previously reported results from its first Phase 3 monotherapy study with tenapanor in CKD patients on dialysis, reporting that the primary endpoint was met (p=0.01) and that 50% of patients (n=164) experienced a mean serum phosphorus reduction of 2.56 mg/dL.

About Hyperphosphatemia

Hyperphosphatemia is a serious condition resulting in an abnormally elevated level of phosphorus in the blood that is estimated to affect more than 745,000 dialysis patients in major developed countries. The kidney is the organ responsible for regulating phosphorus levels, but when kidney function is significantly impaired, phosphorus is not adequately eliminated from the body. As a result, hyperphosphatemia is a common condition among people with CKD and especially those on dialysis. Despite treatment with phosphate binders (the only approved therapy for hyperphosphatemia), approximately 70% of CKD patients on dialysis continue to experience elevated phosphorus levels over time (Spherix RealWorld Dynamix, Dialysis 2018). Phosphorus levels greater than 5.5 mg/dL have been shown to be an independent risk factor for cardiovascular morbidity and mortality in dialysis patients (Block 2004), and common treatment goals are to manage serum phosphorus levels to <5.5mg/dL.

About Fibroblast Growth Factor 23 (FGF23)

FGF23 is a protein in humans that is responsible for phosphate and vitamin D metabolism. Prospective clinical studies have demonstrated a linear association between elevated levels of FGF23 and a greater risk of major cardiovascular events and mortality. FGF23 is independently associated with greater left ventricular mass and greater prevalence of left ventricular hypertrophy (Amaral 2012).

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 potential for the Company's product candidates in treating the diseases and conditions for which they are being developed; the Company's future development plans for tenapanor and other product candidates and the expected timing thereof. 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, the uncertainties inherent in research and the clinical development process, including the regulatory approval process. 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 Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (the "SEC") on August 9, 2019, and its future current and periodic reports to be filed with the SEC.

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: September 3, 2019

ARDELYX, INC.

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