ARDELYX, INC.

FORM 8-K
(Current report filing)

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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 15, 2017

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 February 15, 2017, Ardelyx, Inc. (the "Company") announced positive results from a Phase 3 clinical trial (the "Trial") evaluating the efficacy and safety of tenapanor for the treatment of hyperphosphatemia in patients with end-stage renal disease ("ESRD") who are on dialysis. Tenapanor is a first-in-class, proprietary, oral, experimental medication in late-stage clinical development. The Trial met its primary endpoint and was generally well-tolerated.

The Trial was a two part study, with an eight-week randomized treatment period, followed by a four-week placebo-controlled randomized withdrawal period. The Company enrolled a total of 219 ESRD patients with hyperphosphatemia who are on dialysis. The enrolled patients were randomized evenly into three arms, in which all groups received tenapanor for eight weeks. Tenapanor was administered at fixed doses of 3 mg or 10 mg twice-daily and in a dose-titration arm starting at 30 mg twice-daily with the option to down-titrate once a week during the first four weeks to 20, 15, 10 and 3 mg twice-daily, based on gastrointestinal ("GI") tolerability. After the end of the eight-week treatment period, patients were re-randomized 1:1 to either remain on their current tenapanor dose or switch to placebo for a four-week, placebo-controlled, randomized withdrawal period.

The primary endpoint of the Trial is the difference in change in serum phosphorus between the pooled tenapanor-treated patients and placebo-treated patients from the end of the eight-week treatment period to the end of the four-week randomized withdrawal period, in the responder population. The responder population, which was reviewed by the U.S. Food and Drug Administration, is defined as patients who demonstrate a greater than or equal to 1.2 mg/dL decrease in serum phosphorus from baseline during the initial eight-week treatment period. Tolerability endpoints included stool consistency as measured by the Bristol Stool Form Scale ("BSFS") and frequency.

The responder population (n=80 out of 164) had a mean reduction in serum phosphorus from baseline to the end of the eight-week treatment period of 2.56 mg/dL, with a reduction of up to 5.7 mg/dL. 33% of patients in the responder population had a reduction in serum phosphorus of greater than 3 mg/dL. The Trial demonstrated a statistically significant difference in serum phosphorus levels from the end of the eight-week treatment period to the end of the four-week randomized withdrawal period between the tenapanor-treated group and the placebo-treated group in the responder patient population (mean -1.01 mg/dL, median of -1.3 mg/dL) and met its primary endpoint (95% confidence interval, -1.44, -0.21, LSmean -0.82 mg/dL, p=0.01). Tenapanor was well-tolerated in the Trial. Only 7.8% of patients discontinued treatment due to GI side effects. In the eight-week treatment period, the only adverse event that affected more than 5% of patients treated with tenapanor was diarrhea (39%), a patient-reported side effect of loosened stool or increased frequency in bowel movements regardless of magnitude. In the four-week randomized withdrawal period, there was a diarrhea rate of 1.2% for patients treated with tenapanor compared with 2.4% on placebo. Treatment discontinuations due to diarrhea for patients treated with tenapanor was 7.8% (n=17). There were no discontinuations due to diarrhea in the randomized withdrawal period. In order to fully assess GI tolerability, patients used an eDiary to record the frequency of daily bowel habits, as well as stool form using the BSFS. During the eight-week treatment period, there was a 0.4 per day increase in bowel movement frequency from baseline, and during the four-week randomized withdrawal period, there was a 0.29 per day increase as compared to placebo. Bowel movement frequency was within the normal range in all groups.

During the eight-week treatment period, there was a 0.87 point increase in BSFS from a baseline score of 4.2, out of a maximum of seven, where seven is liquid stool. During the four-week randomized withdrawal period, there was a 0.7 point difference in BSFS between placebo (4.4) and tenapanor treatment (5.1).

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 15, 2017

ARDELYX, INC.

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