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): May 12, 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))

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 May 12, 2017, Ardelyx, Inc. (the "Company") announced topline results from the T3MPO-1 trial, the first of two Phase 3 trials evaluating tenapanor for the treatment of patients with irritable bowel syndrome with constipation ("IBS-C"). Tenapanor is the Company's investigational, minimally systemic, small-molecule NHE3 inhibitor. The T3MPO-1 trial achieved statistical significance for the primary endpoint and seven of eight secondary endpoints. The primary endpoint, the combined responder rate for six of 12 weeks, showed that a greater proportion of tenapanor-treated patients compared to placebo-treated patients (27.0% vs 18.7%, p=0.02) had at least a 30 percent reduction in abdominal pain and an increase of one or more complete spontaneous bowel movements ("CSBMs") in the same week for at least six of the 12 weeks of the treatment period. Tenapanor was well-tolerated, consistent with the experience across previous clinical trials.

T3MPO-1 was a 12-week double-blind, placebo-controlled, multi-center, randomized trial with a four-week, randomized withdrawal period conducted in a total of 610 patients meeting the ROME III criteria for the diagnosis of IBS-C. Patients were randomized one to one to receive either 50 mg tenapanor (n=309) or placebo (n=301) twice-daily. The trial included a two-week screening period, during which patients with active disease, based on bowel movement frequency and abdominal pain score recorded in a daily phone diary, were randomized into the trial.

During the two-week screening period, the baseline mean weekly CSBMs were 0.2 and the mean abdominal pain score was 6.3 (on a 0 - 10 scale where 0 is no pain and 10 is very severe).

Key data are as follows:

Table 1

6 of 12 Treatment Week Results	Tenapanor	Placebo	P value
Combined responder (primary endpoint) (abdominal pain and CSBM responder)	27.0%	18.7%	p=0.02
CSBM responder (increase ≥ 1 CSBM from baseline)	33.9%	29.4%	p=0.27
Abdominal pain responder (≥ 30% abdominal pain reduction)	44.0%	33.1%	p=0.008

Table 2

9 of 12 Treatment Week Results	Tenapanor	Placebo	P value
Combined responder (abdominal pain and CSBM responder)	13.7%	3.3%	p<0.001
CSBM responder (increase ≥ 1 CSBM from baseline)	16.9%	5.0%	p<0.001
Abdominal pain responder (≥ 30% abdominal pain reduction)	30.3%	19.4%	p=0.003

Table 3

Durable Overall Responder Rate Results (9 of 12 and ≥3 of last 4 Treatment Weeks)	Tenapanor	Placebo	P value
Combined responder (abdominal pain and CSBM responder)	13.0%	3.3%	p<0.001
CSBM responder (increase ≥ 1 CSBM from baseline)	16.0%	4.7%	p<0.001
Abdominal pain responder (≥ 30% abdominal pain reduction)	29.3%	19.4%	p=0.006

Tenapanor was well-tolerated, consistent with the experience across previous clinical trials. The only adverse events observed in more than two percent of patients treated with tenapanor, as compared with placebo, were diarrhea (14.6% vs 1.7%) and nausea (2.6% vs 1.7%). Discontinuations due to diarrhea were 5.9 percent for the tenapanor-treated patients, compared to 0.6 percent for the placebo group, based on the preliminary results.

A second Phase 3 trial, T3MPO-2, a 26-week study evaluating tenapanor for the treatment of patients with IBS-C is ongoing with data expected early in the fourth quarter of 2017. Patients who have completed T3MPO-1 and T3MPO-2 are eligible to enter T3MPO-3, the Company's open-label, long-term safety trial where patients can continue to receive tenapanor for up to one year. T3MPO-3 is expected to conclude in late 2017.

T3MPO-1 Primary and Key Secondary Endpoint Definitions

- Combined responder rate (6/12 week): A six of 12 week combined responder is a CSBM responder and an abdominal pain responder during the same week for six of 12 weeks.
- CSBM responder rate (6/12 week): A six of 12 week CSBM responder is a patient that has an increase of at least one CSBM from baseline during a week for six of 12 weeks.
- Abdominal pain responder rate (6/12 week): A six of 12 week abdominal pain responder is a patient that has at least a 30 percent decrease in abdominal pain during a week for six of 12 weeks.
- Combined responder rate (9/12 week): A nine of 12 week combined responder is a nine of 12 week CSBM responder and an abdominal pain responder during the same week for nine of 12 weeks.
- CSBM responder rate (9/12 week): A nine of 12 week CSBM responder is a patient that has an increase of at least one CSBM from baseline and at least three CSBMs during a week for nine of 12 weeks.
- Abdominal pain responder rate (9/12 week): A nine of 12-week abdominal pain responder is a patient that has at least a 30 percent decrease in abdominal pain during a week for nine of 12 weeks.
- Durable responder rates (9/12 week): All three durable responder endpoints – combined responder rate, CSBM responder rate and abdominal pain responder rate – are identical to the nine of 12 week responder endpoints, except the response must also occur in three of the last four treatment period weeks.

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: May 12, 2017

ARDELYX, INC.

By: /s/ Elizabeth Grammer
Elizabeth Grammer
Senior Vice President and General Counsel