ARDELYX, INC.
Form 8-K
October 11, 2017

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): October 11, 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 7.01 Regulation FD Disclosure.

Attached hereto as Exhibit 99.1 is a corporate presentation of Ardelyx, Inc. (the Company) incorporated by reference herein.

The information furnished under this Item 7.01 shall not be considered filed under the Securities Exchange Act of 1934, as amended, nor shall it be incorporated 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 October 11, 2017, the Company announced positive results from T3MPO-2, its second Phase 3 study of tenapanor for irritable bowel syndrome with constipation (IBS-C). The study hit statistical significance for the primary endpoint and all secondary endpoints evaluated for the topline results and demonstrated the ability to normalize bowel movements. 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 (36.5% vs. 23.7%, p<0.001) had at least a 30 percent reduction in abdominal pain and an increase of one or more complete spontaneous bowel movements (CSBM) in the same week for at least six of the 12 weeks of the treatment period. In addition, tenapanor achieved statistical significance for the CSBM and abdominal pain responder rates in the six of 12 and nine of 12-treatment weeks, with a consistent response across the 26 weeks of the study. Tenapanor was well-tolerated in treated patients.

T3MPO-2 is a 26-week, double-blind, placebo-controlled, multi-center, randomized trial. The trial was conducted in a total of 593 patients meeting the ROME III criteria for the diagnosis of IBS-C. Patients were randomized one-to-one to receive either 50 mg of tenapanor (n=293) or placebo (n=300) 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 scores were well-balanced between the tenapanor and placebo groups. The mean weekly CSBMs were 0.11 and the mean abdominal pain score was 6.26 (on a 0 - 10 scale where 0 was no pain and 10 was 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)	36.5%	23.7%	p<0.001
CSBM responder (increase ³ 1 CSBM from baseline)	47.4%	33.3%	p<0.001
Abdominal pain responder (³ 30% abdominal pain reduction)	49.8%	38.3%	p=0.004

Table 2

9 of 12 Treatment Week Results	Tenapanor	Placebo	P value
Combined responder (abdominal pain and CSBM responder)	18.4%	5.3%	p<0.001
CSBM responder (increase ³ 1 CSBM from baseline and ³3 CSBM/week)	22.2%	6.0%	p<0.001
Abdominal pain responder (³ 30% abdominal pain reduction)	35.8%	26.7%	p=0.015

Table 3

Durable Responder Results (9 of 12 and ³3 of last 4 treatment weeks)	**Tenapanor**	**Placebo**	**P value**
Combined responder (abdominal pain and CSBM responder)	18.1%	5.0%	p<0.001
CSBM responder (increase ³ 1 CSBM from baseline and ³3 CSBM/week)	21.2%	5.7%	p<0.001
Abdominal pain responder (³ 30% abdominal pain reduction)	34.8%	26.7%	p=0.028

Tenapanor was well-tolerated, consistent with the experience across previous clinical trials. The only adverse events observed in greater than two percent of patients in the tenapanor-treated group that were also greater than placebo were diarrhea (16.0% vs. 3.7%), flatulence (3.1% vs. 1.0%), nasopharyngitis (4.4% vs. 3.7%) and abdominal distension (3.4% vs. 0.3%). The placebo adjusted discontinuation rate due to diarrhea was 5.8 percent.

Based on positive results from two, positive Phase 3 trials, the Company is on track to submit a New Drug Application (NDA) to the U.S. Food and Drug Administration for tenapanor for the treatment of IBS-C in the second half of 2018. Final, detailed results from the study are expected to be presented at a medical meeting in 2018.

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 and the results of the trial will be included in the NDA submission for tenapanor for the treatment of patients with IBS-C.

T3MPO-2 Primary and Secondary Endpoint Definitions

Primary Endpoint:

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.

Secondary Endpoints:

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 from baseline 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. Normal bowel function is characterized by at least three bowel movements a week up to three bowel movements a day.

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 from baseline 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.

Item 9.01 Financial Statements and Exhibits.
(d) Exhibits.

Exhibit No.	**Description**
99.1	Corporate presentation of Ardelyx, Inc.

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: October 11, 2017

ARDELYX, INC.

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