
**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 1, 2014

ARDELYX, INC.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-36485
(Commission
File Number)

26-1303944
(IRS Employer
Identification Number)

34175 Ardenwood Blvd.
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))
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Item 7.01 Regulation FD Disclosure.

On October 1, 2014, Ardelyx, Inc. (the “Company”) issued a press release reporting results from its Phase 2b clinical trial evaluating tenapanor in patients with constipation-predominant irritable bowel syndrome (“IBS-C”).

The Company will host an investor conference call and webcast at 8:00 a.m. ET on Wednesday, October 1, 2014 to discuss the Phase 2b results. The live webcast and a replay may be accessed by visiting the Company’s website at <http://ir.ardelyx.com/>.

Conference call information is as follows: (855) 296-9612 (U.S.) or (920) 663-6277 (international). Conference ID number is 13895374.

Representatives of the Company intend to present the information in the slides attached hereto as Exhibit 99.1, which is being furnished herewith under this Item 7.01.

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 by reference 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 1, 2014, the Company announced positive results from its Phase 2b clinical trial evaluating tenapanor, a minimally-absorbed inhibitor of the intestinal sodium transporter NHE3, in patients with IBS-C. Results from this study demonstrated statistically significant and clinically meaningful improvement in IBS-C symptoms for tenapanor-treated patients compared to patients receiving placebo. At the 50 mg dose, the study met its primary efficacy endpoint of an increase in the complete spontaneous bowel movement (“CSBM”) responder rate.

The clinical trial was a Phase 2b, randomized, double blind, placebo-controlled, multi-center study to evaluate the safety and efficacy of three dose levels of tenapanor in 371 subjects with IBS-C as defined by the Rome III criteria and who had active disease as determined during a two-week screening period. Subjects who qualified and who were randomized into the study received 5, 20, or 50 mg of tenapanor or placebo twice daily for 12 consecutive weeks. At the end of this treatment period, subjects were followed for an additional 4 weeks. The primary endpoint, overall CSBM responder rate, was achieved in 60.7 percent of patients receiving tenapanor 50 mg twice daily versus 33.7 percent receiving placebo ($p < 0.001$). A responder was defined as a patient who had an increase of greater than or equal to one CSBM from baseline during 6 out of 12 weeks. The results are reported on an intent-to-treat basis.

The overall responder rate, or dual composite endpoint percent, was achieved in 50 percent of patients receiving tenapanor 50 mg twice daily versus 23.6 percent receiving placebo ($p < 0.001$). An overall responder was defined as a patient who was an overall CSBM responder and who experienced at least a 30 percent decrease in abdominal pain from baseline in the same week for 6 of 12 weeks. In addition, of those patients who were administered 50 mg twice daily, over 65 percent responded that they were ‘quite satisfied’ or ‘very satisfied’ with tenapanor versus about 38 percent with placebo, a result that was statistically significant.

Most secondary endpoints measured also demonstrated significant improvements for patients receiving 50 mg tenapanor twice daily compared to placebo-treated patients. A dose response relationship among all doses was observed in the primary endpoint, as well as in most secondary endpoints, although statistical significance was not achieved at the 5 mg or 20 mg doses. Additionally, the activity of tenapanor was maintained throughout the entire 12-week treatment period.

Tenapanor was well-tolerated in these patients, and the safety results were consistent with those observed in previous tenapanor trials. The most common adverse events at 50 mg twice daily (greater than or equal to 5 percent) that occurred more frequently in tenapanor-treated patients compared to placebo-treated patients were diarrhea at 11.2 percent vs. 0 percent, and urinary tract infections at 5.6 percent vs. 4.4 percent. Overall rates of discontinuation due to adverse events were 4.5 percent for the tenapanor-treated patients (50 mg twice daily) and 3.3 percent for the placebo-treated patients. Based on the analysis of plasma samples tested as part of the study, the minimally systemic nature of tenapanor was confirmed. The findings of the clinical study are expected to be presented in an appropriate peer-reviewed forum.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
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 1, 2014

ARDELYX, INC.

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

EXHIBIT INDEX

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ARDELYX®

IBS-C Phase 2b Results

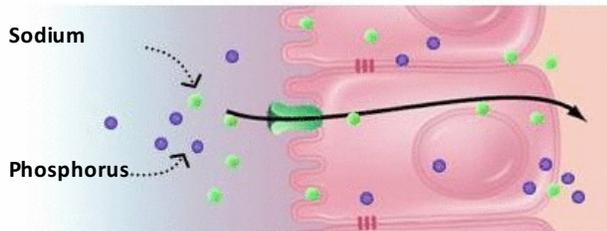
October 2014

Tenapanor Reduces Sodium and Phosphorus Absorption



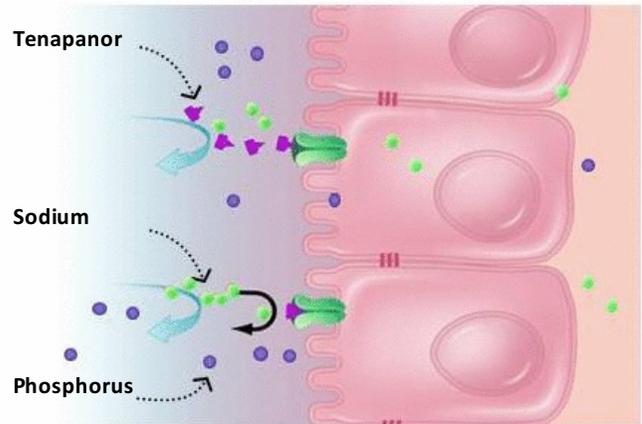
WITHOUT TENAPANOR

Dietary Sodium/Phosphorus Passes Into Circulation



WITH TENAPANOR

Diverts Sodium/Phosphorus from Circulation



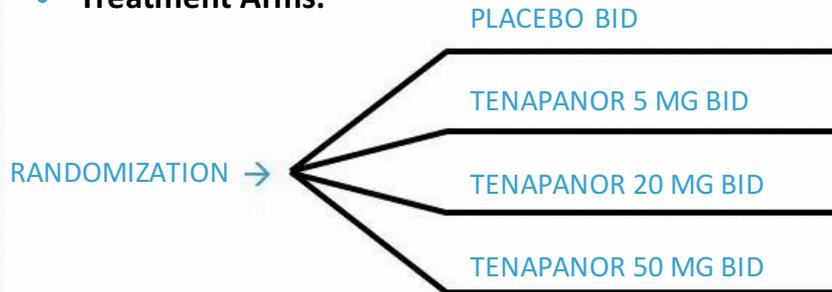
Tenapanor is a non-systemic small molecule inhibitor of NHE3, a sodium transporter present on the epithelia of the GI tract

Local Activity in the Gut

IBS-C Phase 2b Protocol



- **Design:** Double-blind, placebo-controlled, randomized 1:1:1:1 into three treatment arms, 1 placebo arm (approximately 93 patients/group) for a total of 371 patients; 12 weeks treatment, 4 weeks follow-up
- **Primary Endpoint:** Percent complete spontaneous bowel movement (CSBM)* responders (patient needs to have an increase of at least one CSBM from baseline for 6 of the 12 treatment weeks)
- **Secondary Endpoints:** Overall Responder Rate, Abdominal Pain and Abdominal and IBS-C Symptoms
- **Treatment Arms:**



*CSBM defined as a bowel movement that feels complete and is not aided by the use of any other medication, like a laxative

- Trial met primary efficacy endpoint: complete spontaneous bowel movement (CSBM) responder [60.7% in tenapanor 50 mg bid group vs. 33.7% placebo; $p < 0.001$]
- The overall responder rate for the dual composite endpoint (CSBM responder and abdominal pain responder in 6 of 12 weeks) was higher in the tenapanor 50 mg bid group compared to the placebo group [50.0% vs. 23.6% placebo; $p < 0.001$]
- This dual composite endpoint is the primary regulatory endpoint in Europe and US (EMA draft guidance 2013, FDA guidance 2012)



- Dose response relationship was observed in the primary endpoint, as well as in most other secondary endpoints, although statistical significance was not achieved at the 5 mg or 20 mg doses; activity of tenapanor was maintained throughout entire 12-week treatment period
- Adequate relief of IBS symptoms was statistically significant ($p=0.002$) for tenapanor 50 mg bid (63.1%) versus placebo (39.3%) at the endpoint week (week 12 or last valid week)
- Based on the treatment satisfaction patient scale questionnaire, more subjects receiving 50 mg bid responded that they were “quite satisfied” or “very satisfied” with tenapanor versus placebo [65% vs. 38% placebo; $p<0.001$]



- Tenapanor well-tolerated across all treatment arms, and there were no serious drug-related adverse events.
- The most common adverse events at 50 mg bid ($\geq 5\%$) that occurred more frequently in tenapanor-treated patients compared to placebo-treated patients were diarrhea 11.2 percent vs. 0 percent and urinary tract infections 5.6 percent vs. 4.4 percent
- Based on the analysis of plasma samples tested as part of the study, the minimally systemic nature of tenapanor was confirmed





GI Disorder:
Constipation and
Abdominal Pain

IBS-C MARKET

- Approximately 1.4% of the US population, or 4.4 million individuals, have IBS-C.
- About one million patients have been diagnosed

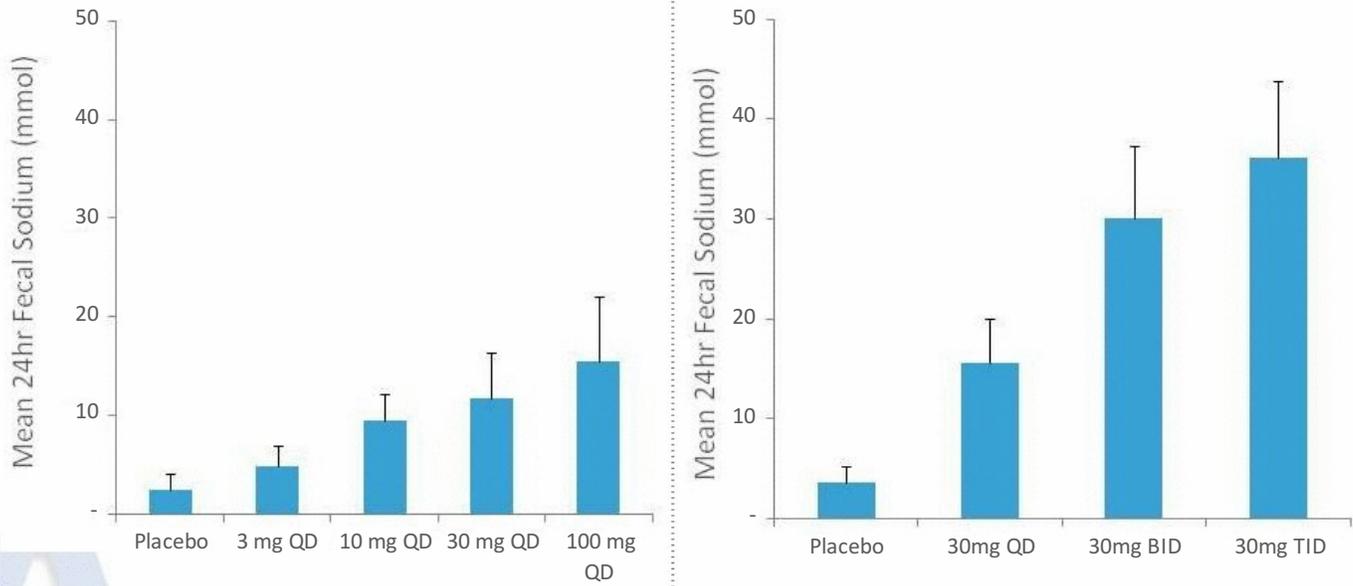
LIMITATIONS OF CURRENT TREATMENTS

- OTC Drugs Inexpensive but Not Very Effective in Moderate to Severe Cases
- Amitiza® and Linzess® Fall Short:
 - Achieve Endpoint in Only 7% to 20% of Patients
 - Side Effects (e.g., Nausea and Diarrhea, respectively)
- Medical Need for Improved Therapies with Better Efficacy, Excellent Safety and Tolerability

Tenapanor Demonstrates Dose Level and Dose Frequency Response; Stool and Urine Sodium Correlate¹



PHASE 1 IN HEALTHY ADULT VOLUNTEERS

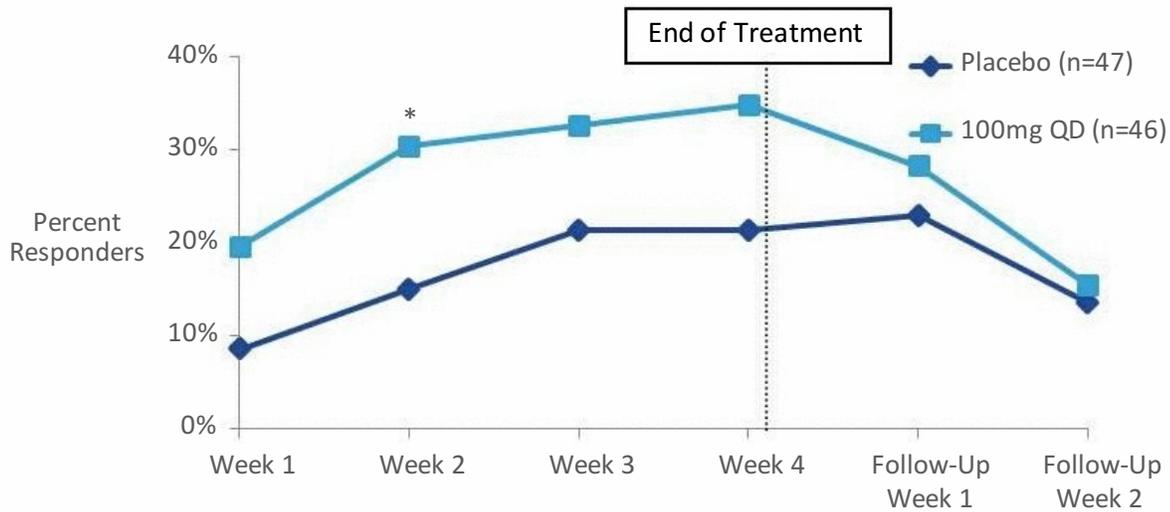


¹ RDX5791-102 published in Spencer et al Sci Transl Med 6, 227ra36 (2014) *P < 0.05 versus placebo, †P < 0.05 versus 30 mg once daily. Data are means ± SEM.

Phase 2a Had Demonstrated Activity with QD Dosing



DUAL ENDPOINT: >30% DECREASE IN WEEKLY ABDOMINAL PAIN SCORE AND >1 INCREASE IN CSBM FREQUENCY AS COMPARED TO BASELINE



Improvements in degree of bloating and abdominal pain were noted, as well as relief of IBS symptoms, severity and QOL measurements with QD dosing although the primary endpoint, change in CSBM from Baseline to Week 4, was not met in this Phase 2a study.

* p<0.05 versus placebo

Tenapanor Program – Renal Indications and IBS-C



PROGRAM	INDICATION	RESEARCH	PHASE 1	PHASE 2		STATUS
				2a	2b	
Tenapanor (NHE3 Inhibitor)	ESRD-Pi (1)					Phase 2b Data 1H:2015
	IBS-C (2)					Phase 2b Data Announced Oct 1, 2014
	CKD (3)					Phase 2a Data 2H:2015



More information about clinical trials design can be found at the following links:
 (1) ESRD-Pi: <http://clinicaltrials.gov/ct2/show/NCT02081534>
 (2) IBS-C: <http://clinicaltrials.gov/ct2/show/NCT01923428>
 (3) CKD: <http://clinicaltrials.gov/ct2/show/NCT01847092>