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

Exhibit 99.1

ARDELYX REPORTS POSITIVE T3MPO-2 PHASE 3 TRIAL RESULTS IN IBS-C

ARDELYX

OCTOBER 11, 2017

NASDAQ: ARDX

FORWARD-LOOKING STATEMENTS

To the extent that statements contained in this presentation are not descriptions of historical facts regarding Ardelyx, 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 tenapanor in treating patients with IBS-C; the commercial potential for tenapanor in treating patients with IBS-C and the potential for growth in the size of the IBS-C market. Such forward-looking statements involve substantial risks and uncertainties that could cause the development of Ardelyx's product candidates or Ardelyx'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; the uncertainties associated with the regulatory approval process; and the uncertainties in the drug commercialization process. Ardelyx 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 Ardelyx's business in general, please refer to Ardelyx's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on August 9, 2017, and its subsequent current and periodic reports filed and to be filed with the Securities and Exchange Commission.

POSITIVE T3MPO-2 RESULTS SUPPORT NDA SUBMISSION IN 2H18

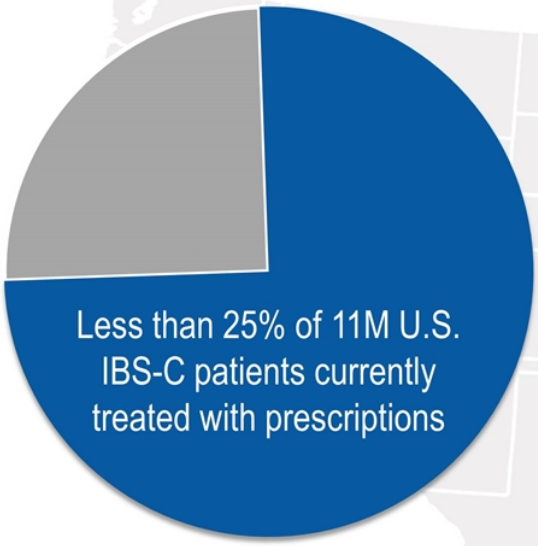
Ardelyx's Pivotal Phase 3 Study of Tenapanor for IBS-C Hits Primary and All Secondary Endpoints to Support NDA Submission in 2018

Six of 12-week combined responder rate shows clear benefit in treated patients with consistent response throughout 26 weeks

Best-in-class, nine of 12-week combined responder rate demonstrates ability to normalize patients' bowel function

FREMONT, Calif., October 11, 2017 -- Ardelyx, Inc. (NASDAQ: ARDX) today reported 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.

SIGNIFICANT AND GROWING IBS-C MARKET



GROWTH DRIVERS FOR IBS-C MARKET

- Increasing awareness of Rx treatment options
- Significant prescription growth
- Millions of untreated patients
- Sustained relief needed
- Reduction in abdominal pain needed
- Return of health-related quality of life and work productivity

THE ROLE FOR TENAPANOR

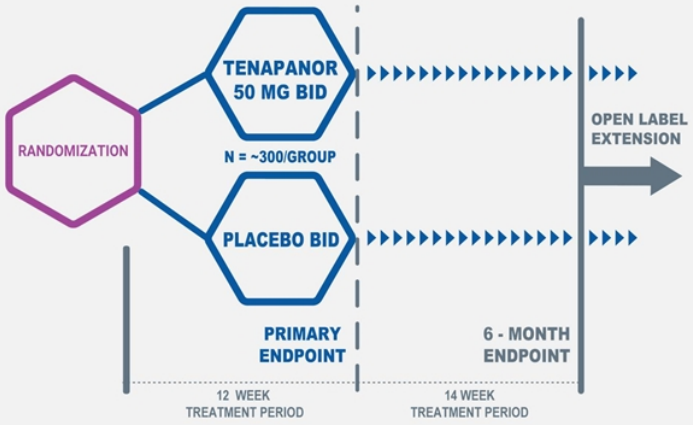
- Distinct mechanism of action
- Expanding market footprint; similar overall response rates among treatments
- Potential in CIC (15% of adults in U.S. and EU have CIC)
- Potential in opioid-induced constipation (common side effect of opioids)


T3MPO-2 PHASE 3
STUDY RESULTS
ARDELYX
NASDAQ: ARDX

T3MPO-2: STUDY DESIGN

T3MPO-2: 6-MONTH TENAPANOR IBS-C PHASE 3 TRIAL

- **Same inclusion/exclusion criteria as T3MPO-1 and Phase 2b**
- **Same 12-week treatment period primary endpoint**
- **Patients meeting Rome III criteria for diagnosis of IBS-C**
- **Active disease as measured by 2 week screening period with mean weekly CSBM < 3, SBM ≤ 5, and Ab Pain ≥ 3**



T3MPO-2: DEMOGRAPHICS

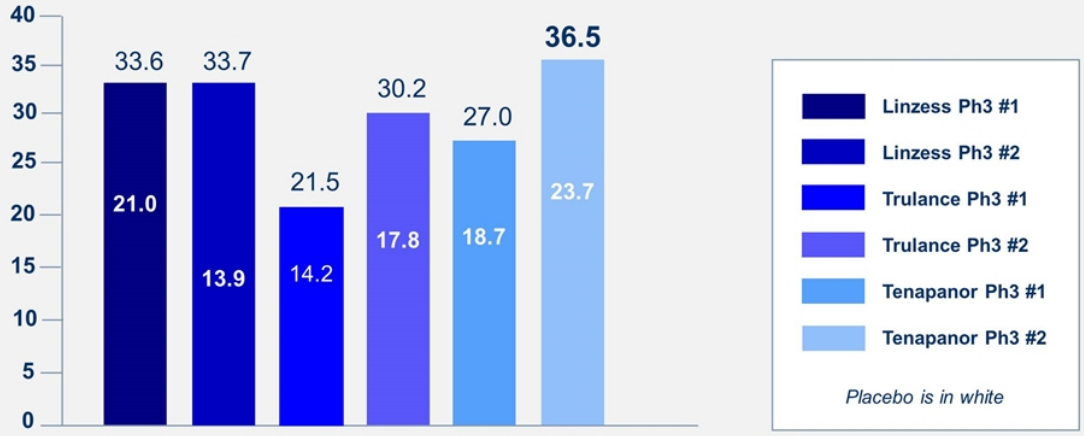
Characteristic	Tenapanor	Placebo	Overall
n	293	300	593
Age	46.1	44.8	45.4
Gender [n (%)] Male Female	 53 (18.1) 240 (81.9)	 53 (17.7) 247 (82.3)	 106 (17.9) 487 (82.1)
Race [n (%)] White Black	 185 (63.1) 92 (31.4)	 192 (64.0) 92 (30.7)	 377 (63.6) 184 (31.0)
Baseline BMI (m^2/kg)	30.50	30.88	30.69
Baseline Mean Weekly CSBM	0.13	0.10	0.11
Baseline Mean Weekly Abdominal Pain	6.26	6.27	6.26

T3MPO-2: 6 OF 12-WEEK RESPONDER RESULTS

	Tenapanor 50 mg BID (n=293)	Placebo (n=300)	p-value
Combined responder (abdominal pain and CSBM responder)	36.5%	23.7% (12.9 Δ)	p <0.001
CSBM responder (increase ≥ 1 CSBM from baseline)	47.4%	33.3% (14.1 Δ)	p <0.001
Ab pain responder (≥ 30% pain reduction from baseline)	49.8%	38.3% (11.5 Δ)	p =0.004

PHASE 3 COMPARISON: 6 of 12-WEEK COMBINED RESPONDER RATES

Non Head-to-Head Phase 3 Trials



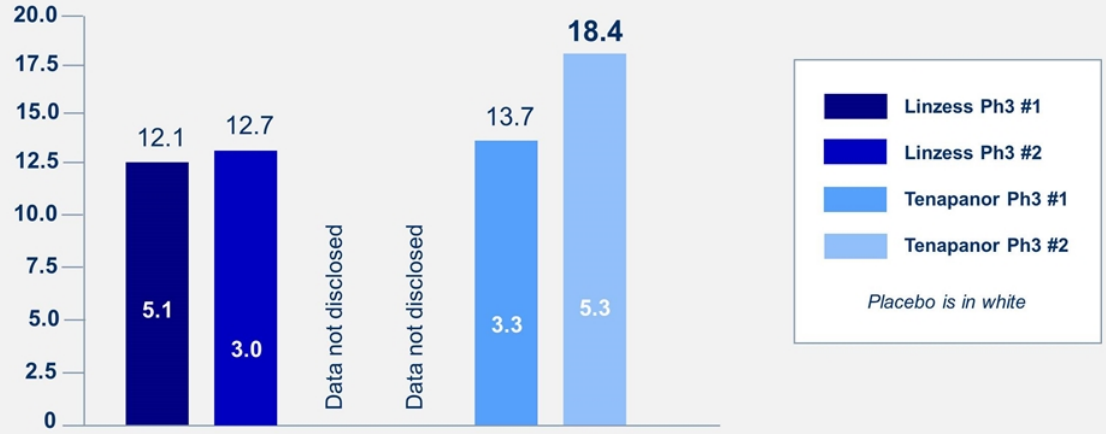
Linzess results are from Chey et al. Am J Gastro 2012 and Rao et al Am J Gastro 2012
Trulance results are from data presented at DDW 2017 for 3mg dose

T3MPO-2: 9 OF 12-WEEK RESPONDER RESULTS

	Tenapanor 50 mg BID (n=293)	Placebo (n=300)	p-value
Combined responder (abdominal pain and CSBM responder)	18.4%	5.3%	p <0.001
	13.1 Δ		
CSBM responder (≥ 1 CSBM increase from baseline and ≥ 3 CSBM)	22.2%	6.0%	p <0.001
	16.2 Δ		
Ab pain responder (≥ 30% pain reduction from baseline)	35.8%	26.7%	p=0.015
	9.2 Δ		

PHASE 3 COMPARISON: 9 of 12-WEEK COMBINED RESPONDER RATES

Non Head-to-Head Phase 3 Trials



Linzess results from Chey et al. Am J Gastro 2012 and Rao et al Am J Gastro 2012

T3MPO-2: DURABLE RESPONDER RESULTS

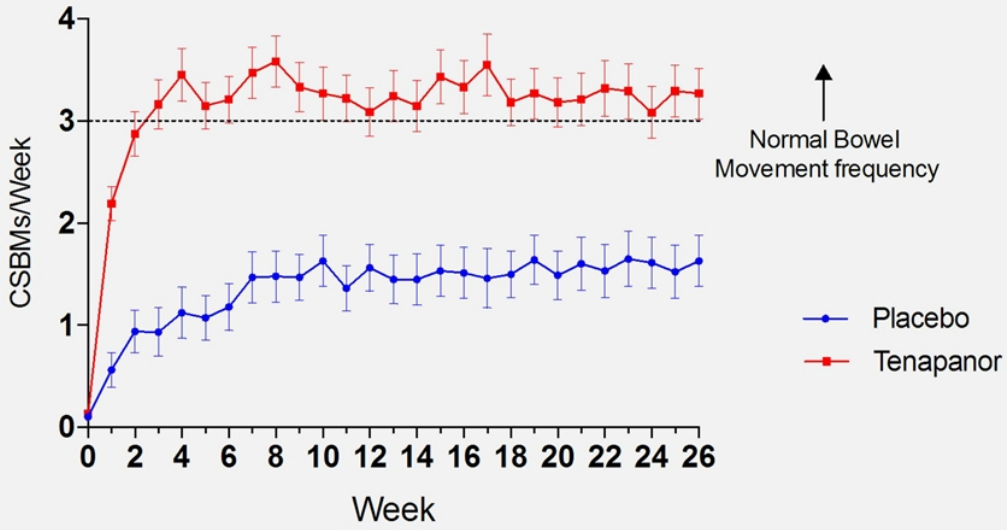
9 of 12-Weeks and 3 of the Last 4 Weeks

	Tenapanor 50 mg BID (n=293)	Placebo (n=300)	p-value
Combined responder (abdominal pain and CSBM responder)	18.1%	5.0% (13.1 Δ)	p <0.001
CSBM responder (≥ 1 CSBM increase from baseline and ≥ 3 CSBM)	21.2%	5.7% (15.5 Δ)	p <0.001
Ab pain responder (≥ 30% pain reduction from baseline)	34.8%	26.7% (8.2 Δ)	p=0.028

T3MPO-2: 13 of 26-WEEK RESPONDER RESULTS

	Tenapanor 50 mg BID (n=293)	Placebo (n=300)	p-value
Combined responder (abdominal pain and CSBM responder)	35.5%	24.3% (11.2 Δ)	p =0.003
CSBM responder (≥ 1 CSBM increase from baseline)	41.3%	31.0% (10.3 Δ)	p =0.010
Ab pain responder (≥ 30% pain reduction from baseline)	50.2%	40.0% (10.2 Δ)	p=0.013

T3MPO-2: MEAN WEEKLY CSBMS
(COMPLETE SPONTANEOUS BOWEL MOVEMENTS)



T3MPO-2: TREATMENT EMERGENT ADVERSE EVENTS

TEAEs in ≥ 2% of patients treated and higher than placebo

Adverse Reactions	TEN 50mg n = 293	Placebo n = 300
Diarrhea	47 (16.0)	11 (3.7)
Abdominal Distension	10 (3.4)	1 (0.3)
Flatulence	9 (3.1)	3 (1.0)
Nasopharyngitis	13 (4.4)	11 (3.7)

T3MPO-1 and T3MPO-2 Blended AE rates (≥2%)

Linzess Package Insert vs Potential Tenapanor Package Insert

Adverse Reactions	Linzess 290 mcg n = 807[b] %	Placebo n = 798[b] %	Tenapanor 50 mg bid n = 602[b] %	Placebo n = 601[b] %
Gastrointestinal				
Diarrhea	20	3	15	3
Abdominal pain	7	5	-[a]	-
Flatulence	4	2	3	2
Abdominal distension	2	1	3	0
Infections and Infestations				
Viral gastroenteritis	3	1	-	-
Nervous System Disorders				
Headache	4	3	-	-

ARDELYX

a. Adverse event rate below reporting requirement
b. Combined n for both phase 3 clinical trials

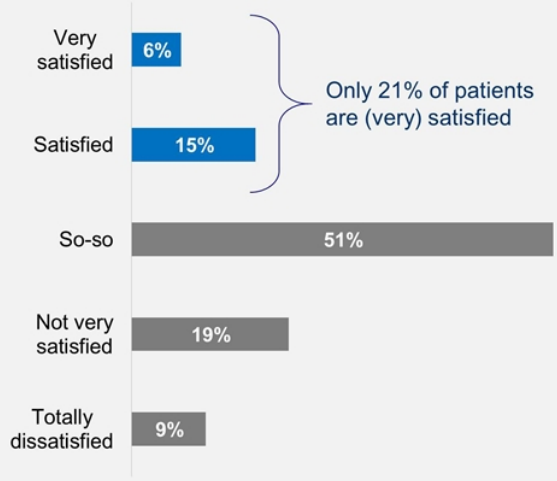
MARKET RESEARCH: IBS-C PATIENTS

ARDELYX

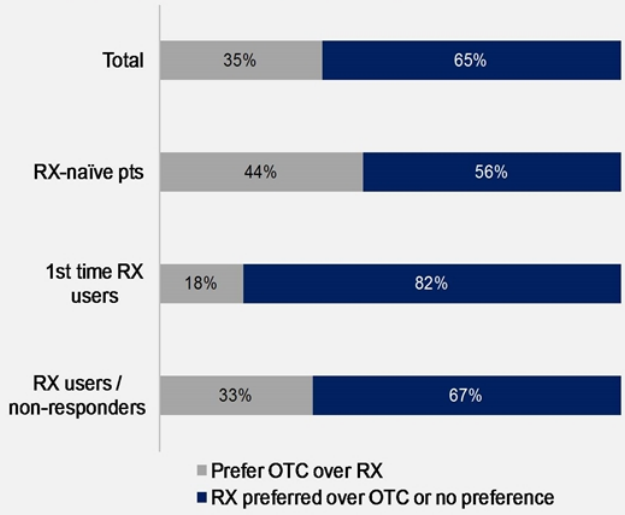
NASDAQ: ARDX

SIGNIFICANT OPPORTUNITY TO ADDRESS UNDERSERVED PATIENTS

>3/4 of Rx-treated patients are not currently satisfied

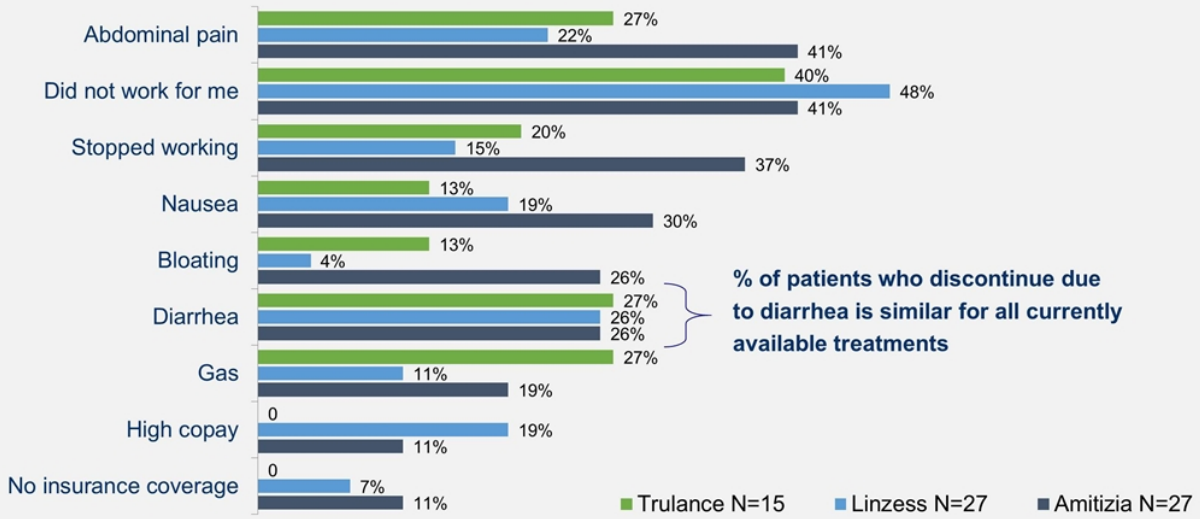


2/3 of IBS-C Patients Willing to Try Another Rx



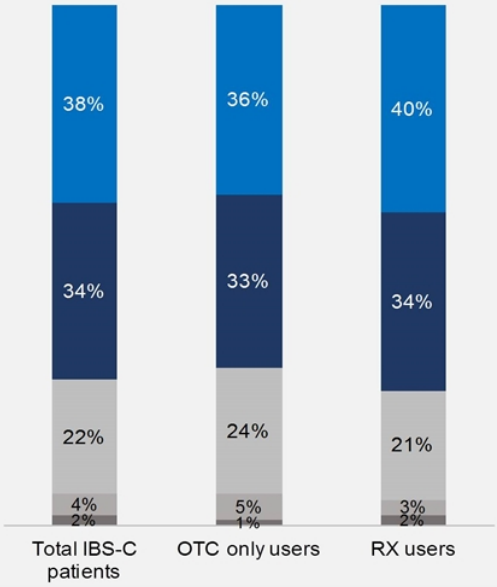
ARDELYX Market research projects conducted in 252 IBS-C patients by Perleberg Pharma Partner Health Research International GmbH, 2017

PATIENTS CITE MULTIPLE REASONS FOR DISCONTINUING TREATMENT



ARDELYX Market research projects conducted in 252 IBS-C patients by Perleberg Pharma Partner Health Research International GmbH, 2017

SIGNIFICANT OPPORTUNITY TO ADDRESS UNDERSERVED PATIENTS



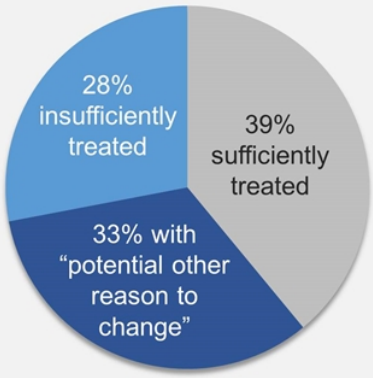
- Patients with IBS-C are seeking effective treatments that relieve their symptoms
- In 170 patients surveyed:
  - 72% of patients currently treated with a prescription would be interested in using tenapanor
  - 69% of IBS-C patients treated with OTC therapies only would be interested in using tenapanor
- Feedback reaffirmed by an additional 180 patients surveyed

Market research projects conducted in 252 IBS-C patients by Perleberg Pharma Partner Health Research International GmbH, 2017

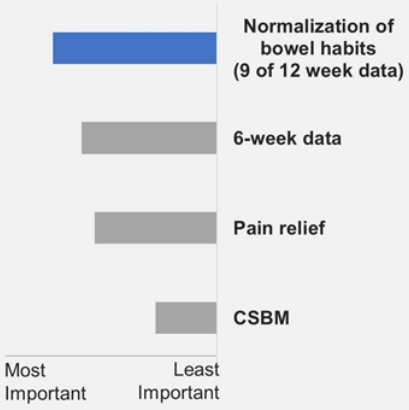
A CLEAR NEED FOR NEW IBS-C TREATMENTS WITH NOVEL MOA

Feedback from 50 healthcare providers (GIs and PCPs) post-T3MPO-1 reaffirmed by an additional 250 providers in a second market research study

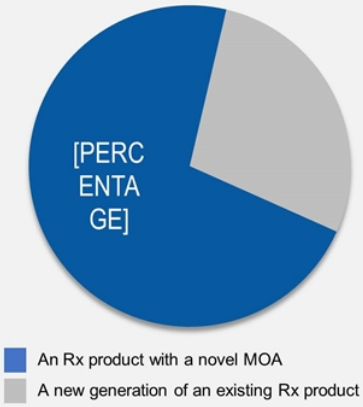
Only 2 of 5 patients are sufficiently treated today



Normalization of bowel movements (3/week – 3/day) seen as most important attribute



72% of HCPs prefer a new treatment with a novel MOA to manage IBS-C

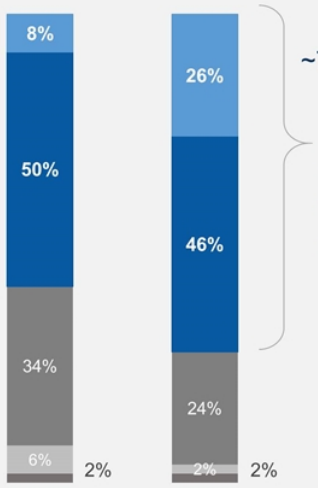


ARDELYX Market research projects conducted in ~300 HCPs managing IBS-C by Perleberg Pharma Partner Health Research International GmbH, 2017

T3MPO-1 PROFILE: THE VIEW FROM IBS-C TREATING PHYSICIANS

Majority of HCPs are interested in using tenapanor due to novel MOA and sustained relief for patients

~60% of HCPs think tenapanor is "different/ very different" from currently available IBS-C treatments

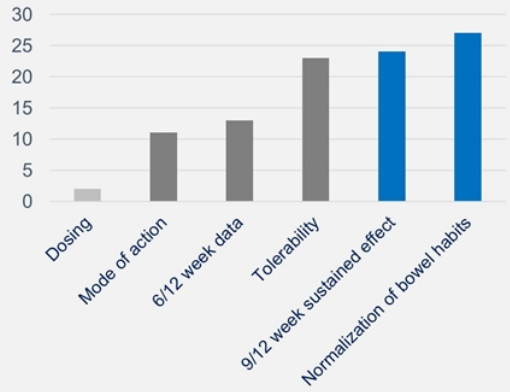


(5) Very Different
(4)
(3)
(2)
(1) Very Similar

~75% of HCPs are "very interested/ interested" in using tenapanor

(5) Very Interested
(4)
(3)
(2)
(1) Not At All Interested

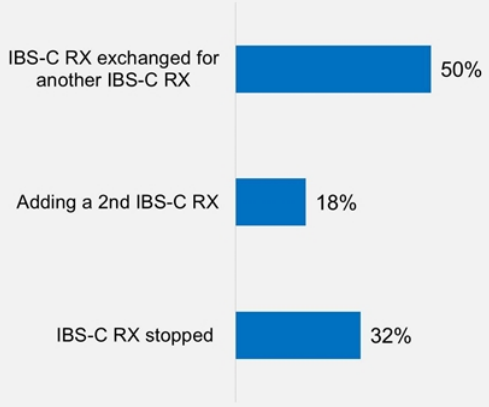
HCPs view normalization of bowel function and 9-week data as most important



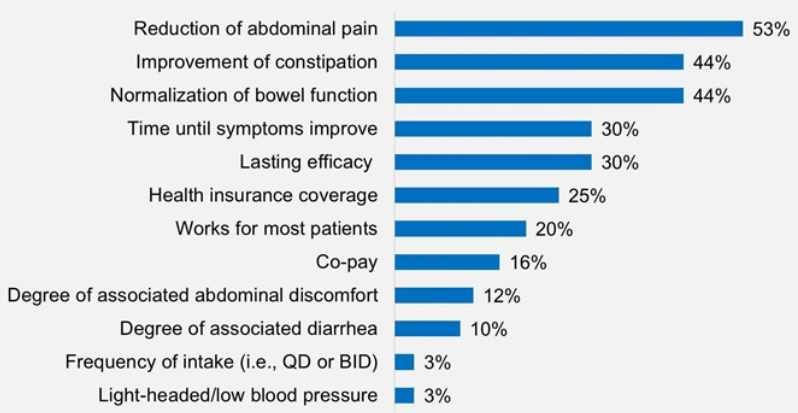
ARDELYX Market research projects conducted in ~300 HCPs managing IBS-C by Perleberg Pharma Partner Health Research International GmbH, 2017

PHYSICIANS SUPPORT THAT THE MAJORITY OF NON-RESPONDING PATIENTS WILL SWITCH TO ANOTHER RX

Majority of non-responding patients will switch to another prescription treatment



Most important features of an IBS-C RX medication underscore the potential role of tenapanor



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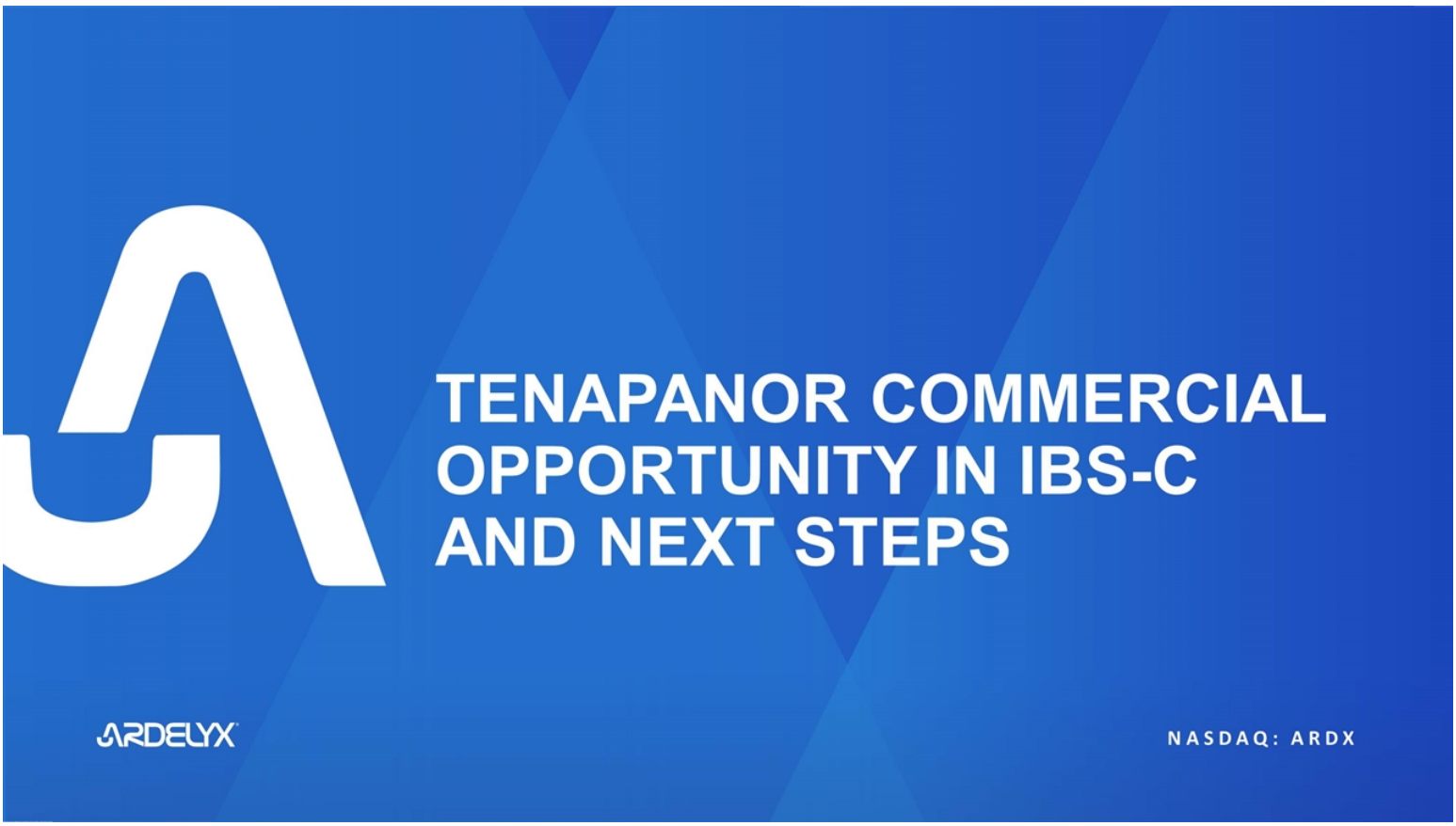
TENAPANOR COMMERCIAL OPPORTUNITY IN IBS-C AND NEXT STEPS
ARDELYX
NASDAQ: ARDX

TENAPANOR MARKET DRIVERS FOR IBS-C

IMPORTANT OPPORTUNITY TO EXPAND INTO CIC AND OIC

~$1 BILLION
IN ANNUAL REVENUES BY PRESCRIPTIONS TODAY[1]

- Very few IBS-C Rx treatment options available
- Unique MOA expands treatment options
- Two-thirds of patients do not respond to currently available Rx treatments[2]
- Only 1 in 4 patients are "very satisfied" with their treatment[3]

MODEST PENETRATION WITH TENAPANOR REPRESENTS
>$500M
COMMERCIAL OPPORTUNITY

- ✓ Market research supports meaningful role for tenapanor for the treatment of patients with IBS-C
- ✓ Expand footprint and optimize access to tenapanor through strategic partnerships

ARDELYX

1. 2016 product sales in SEC filings for branded Rxs
2. Based on Phase 3 data
3. 2015 AGA Report

POSITIVE T3MPO-2 STUDY SUPPORTS TENAPANOR REGISTRATION

T3MPO-2 RESULTS IN-LINE WITH PHASE 3 EXPECTATIONS

- Statistical significance achieved for primary endpoints, supporting approvability
- Statistical significance for all secondary endpoints evaluated in topline results
- Highest 6 of 12-week combined responder rate data across all Phase 3 clinical trials reported in the industry
- Best-in-class 9 of 12-week data demonstrate ability to normalize bowel function
- Quick onset-of-action (1 week) with consistent response across 26 weeks of the trial
- Well-tolerated profile with very low rate of discontinuations

ADVANCING TOWARD REGISTRATION

- First-in-class mechanism provides physicians a new approach to treating patients
- 9 of 12-week data support normalization of bowel function and lasting responses for patients
- Enrollment complete in T3MPO-3; study to conclude year-end 2017
- On-track for NDA submission in 2H 2018
- Durable responder data support tenapanor potential in CIC and other GI indications
- Pursuing ideal partner to maximize tenapanor market potential and expand into additional indications