
**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): June 21, 2017

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., 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.

On June 21, 2017, Ardelyx, Inc. (the “Company”) updated its corporate presentation (the “Corporate Presentation”) in connection with upcoming investor conferences. A copy of the Corporate Presentation is furnished as Exhibit 99.1 to this Current Report on Form 8-K, and incorporated by reference herein.

The information furnished under this Item 7.01 (including Exhibit 99.1) 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 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: June 21, 2017

ARDELYX, INC.

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

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Corporate presentation of Ardelyx, Inc.



**BREAKTHROUGH
SCIENCE FOR
BETTER HEALTH**

ARDELYX

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 Ardelyx's product candidates in treating the diseases and conditions for which they are being developed; Ardelyx's future development plans for its product candidates and the expected timing thereof; Ardelyx's expected timing for the receipt of results from its clinical trials evaluating its product candidates; the commercial potential for Ardelyx's product candidates; and the potential of Ardelyx's drug discovery and design platform. 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 in the manufacture of clinical trial material, including process development, and scale up of manufacturing processes; 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 May 5, 2017, and its subsequent current and periodic reports filed and to be filed with the Securities and Exchange Commission.



CREATING FIRST-IN-CLASS MEDICINES

OUR GOAL IS TO DRAMATICALLY ENHANCE THE TREATMENT OF
PATIENTS WITH GASTROINTESTINAL AND CARDIORENAL
DISEASES.

ARDELYX[®]



TENAPANOR: DRIVING TOWARDS COMMERCIALIZATION

A \$1B+ OPPORTUNITY

PRIMARY ENDPOINT ACHIEVED IN 1ST PHASE 3 FOR IBS-C

2ND Phase 3 fully enrolled & data early Q4;
Preparing for 2018 NDA submission

PRIMARY ENDPOINT ACHIEVED IN 1ST PHASE 3 FOR HYPERPHOSPHATEMIA

2ND Phase 3 to begin mid-2017

APPROVABILITY

supported by 1st Phase 3
readouts in IBS-C and
hyperphosphatemia

COMMERCIALY DISTINCT

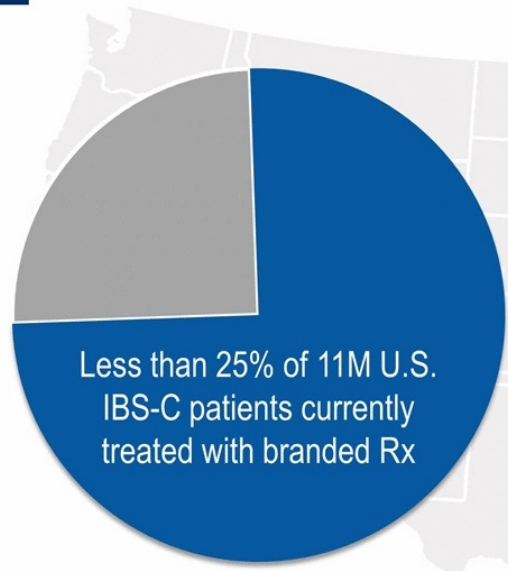
and competitive products to
address significant markets

FIRST-IN-CLASS

with new mechanism of
action approaches



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
- Reduced abdominal pain
- Return of health-related quality of life and work productivity

THE ROLE FOR TENAPANOR

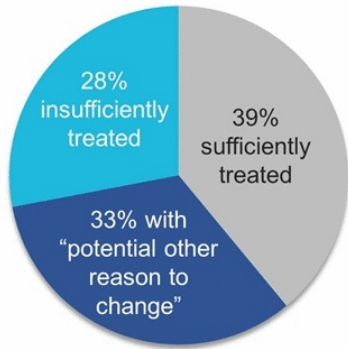
- Distinct mechanism of action
- Expanding market footprint; similar overall response rates among treatments
- Potential in CIC (15% of adults in U.S. and EU have CIC)
- Potential in opioid-induced constipation (common side effect of opioids)



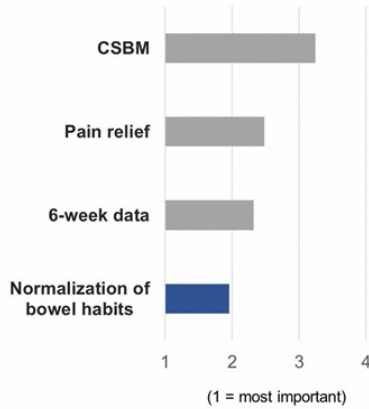
A CLEAR NEED FOR NEW IBS-C TREATMENTS WITH NOVEL MOA

Recently conducted internal market research (post T3MPO-1) among 50 healthcare providers (GIs and PCPs)

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



Legend:
■ An Rx-Product with a novel MOA
■ A new generation of an existing Rx product



TENAPANOR: ROLE IN IBS-C BASED ON T3MPO-1 DATA

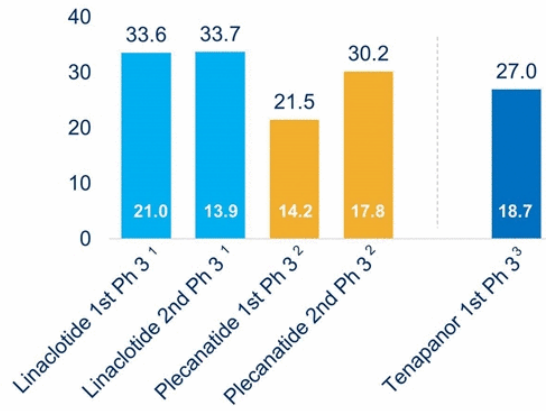
✓ ACHIEVED STATISTICALLY SIGNIFICANT PRIMARY ENDPOINT

✓ ABILITY TO NORMALIZE BOWEL HABITS

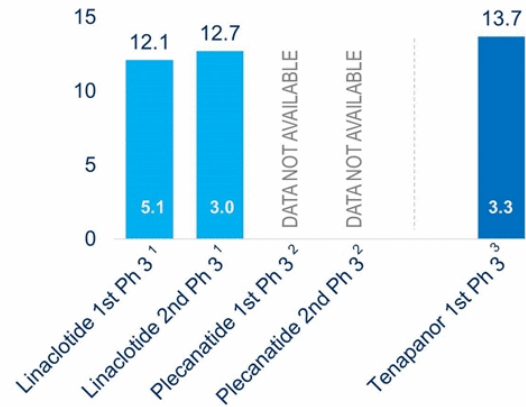
✓ WELL-TOLERATED

✓ FIRST-IN-CLASS MECHANISM OF ACTION

6 of 12 Weeks Combined Responder Rates
(non head-to-head trials)



9 of 12 Weeks Combined Responder Rates
(non head-to-head trials)



ARDELYX

1. Chey et al. Am J Gastro 2012 and Rao et al Am J Gastro 2012
2. Data Presented at DDW 2017
3. Tenapanor T3MPO-1 Trial Results; May 12, 2017



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

Recently conducted internal market research (post T3MPO-1) among 50 healthcare providers (GIs and PCPs)

58% of HCPs think tenapanor is “different/very different” from currently available IBS-C treatments

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

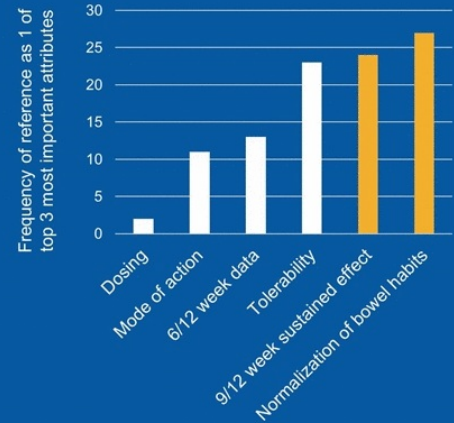


72% of HCPs are “very interested/interested” in using tenapanor

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



HCPs view T3MPO-1 efficacy (normalization) and 9-week data as most important



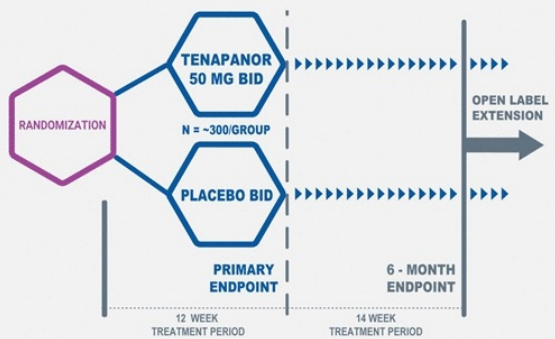


T3MPO PROGRAM: FULLY ENROLLED & ON WAY TO COMPLETION

T3MPO-1: 3-MONTH TENAPANOR IBS-C PHASE 3 TRIAL COMPLETED & PRIMARY ENPOINT ACHIEVED

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

- Same design and patient population as T3MPO-1 and Phase 2b
- Same 12-week treatment period primary endpoint
- Data readout in early Q4 2017
- Preparing for 2018 NDA submission



T3MPO-3 OPEN-LABEL SAFETY STUDY; RESULTS EXPECTED IN LATE 2017



IBS-C MARKET DRIVERS FOR TENAPANOR'S COMMERCIAL POTENTIAL

IMPORTANT OPPORTUNITY TO EXPAND INTO CIC AND OIC

~\$1 BILLION
IN ANNUAL REVENUES BY
BRANDED RX'S TODAY¹

Limited IBS-C Rx treatment options available

Two-thirds of patients do not respond to currently available branded Rx treatments²

MODEST PENETRATION WITH
TENAPANOR REPRESENTS
\$400M - \$500M
COMMERCIAL OPPORTUNITY

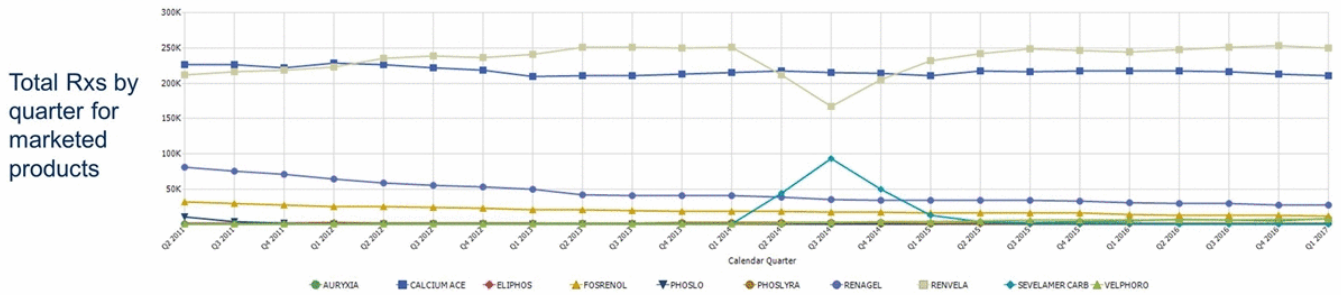
Market research supports meaningful role for tenapanor for the treatment of patients with IBS-C

Expand footprint and optimize access to tenapanor through potential strategic partnerships



TENAPANOR: GAME CHANGING FOR HYPERPHOSPHATEMIA

Phosphate Binders are ONLY HP treatment today¹



GROWTH DRIVERS FOR HYPERPHOSPHATEMIA²

- Aging baby boomers
- Increase in ESRD prevalence in U.S. by 5% per year
- ESRD patients make up 1% of U.S. Medicare population, but account for 7% of Medicare budget
- >100,000 U.S. patients on kidney transplant list; <20,000 available donor kidneys each year

THE ROLE FOR TENAPANOR

- New treatment mechanism to replace phosphate binders
- Significant reduction in serum phosphorous and FGF-23
- Substantially reduced pill burden and pill sizes
- Easy formulation without tablet chewing or powders
- Convenient dosing; potentially with or without food
- Tolerable with limited GI side effects



1. IMS Health website 2. <https://pharm.ucsf.edu/kidney/need/statistics>



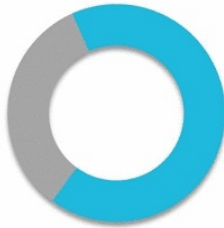
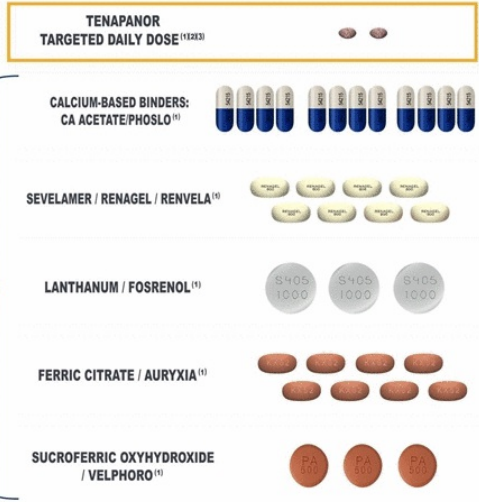
TENAPANOR: IMPACT ON TREATMENT OF HP

DAILY DOSE

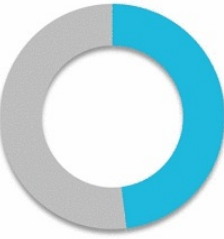
POOR COMPLIANCE AND ADHERENCE LIMITS CHRONIC USE RESULTING IN SUBOPTIMAL RESULTS

PILL BURDEN

(19+ pills/day; ½ are phosphate binders⁴) and side-effects associated with binders prohibit necessary adherence and compliance



2/3 OF PATIENTS ARE NOT AT TARGET SERUM PHOSPHORUS LEVELS AT ANY POINT IN TIME⁵



NEARLY HALF OF PATIENTS ARE NOT COMPLIANT WITH THEIR CURRENT TREATMENT⁶



1. Not actual size; however, relative sizes are to scale
 2. Tenapanor pill color may change
 3. Tenapanor (10 mg twice daily used for illustration purposes)

4. Chiu 2009
 5. DOPPS Practice Monitor, December 2015. www.dopps.org/DPM
 6. Lederer 2016



TENAPANOR: ON THE PATH FOR APPROVAL FOR HP TREATMENT

FIRST PHASE 3 SUCCESSFULLY COMPLETED

- ✓ Statistically significant primary endpoint
- ✓ Clinically meaningful change in serum phosphorus levels
- ✓ Reduced pill burden with just 2 tiny pills
- ✓ Convenient dosing; potentially with or without food
- ✓ Favorable tolerability
- ✓ No discontinuations due to diarrhea in placebo-controlled RW period
- ✓ Profile supports long-term Rx compliance and may result in better outcomes

CONFIRMATORY PHASE 3 TO BEGIN MID-2017

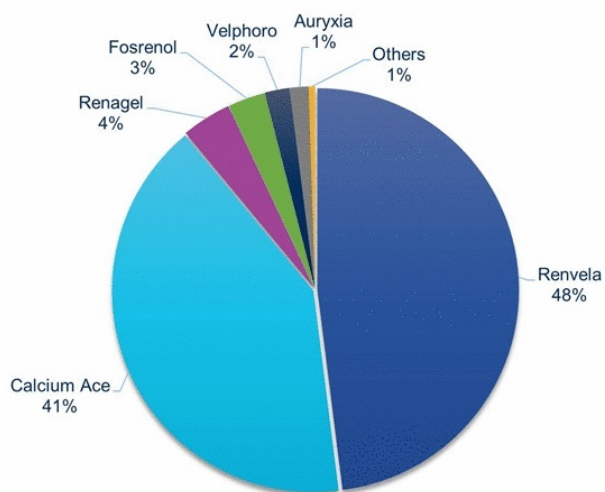
- Planned design: 26-week randomized treatment period followed by up to 12-week, double-blind, placebo-controlled, randomized withdrawal (RW) and open-label extension study
- Same primary endpoint as 1st Phase 3 study
- 320 ESRD patients
- Tenapanor 30 mg BID with the ability to titrate
- Study completion and data in 2019

FIRST SMALL MOLECULE, NON-PHOSPHATE BINDER TREATMENT FOR HP



TENAPANOR FOR HP: A CARDIORENAL FRANCHISE OPPORTUNITY

2016 MARKET SHARE BY TOTAL Rx¹



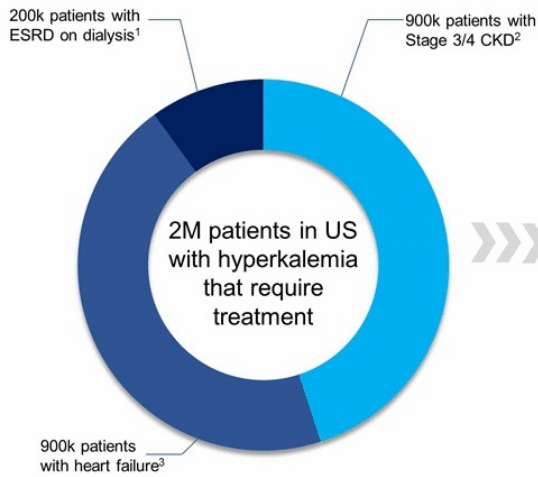
IMPROVING COMPLIANCE AND ADHERENCE HAS POTENTIAL TO CHANGE PATIENT OUTCOMES

- Cardioresnal presents an opportunity to build a specialized commercial infrastructure of ~75-100 people (alternative options available)
- Plan to focus efforts on U.S. commercialization; leverage strategic partnerships for ex-U.S.
- Efficient investment to build a profitable business
- Deep and successful internal cardioresnal drug development and commercial expertise

\$500M-\$700M MARKET OPPORTUNITY



MASSIVE HYPERKALEMIA MARKET WAITING TO BE TAPPED



DRIVERS TO CREATING A HYPERKALEMIA MARKET

- New treatments to shape a chronic market
- Expanding use of life-saving RAAS inhibitors cause hyperkalemia
- New anti-diabetics cause hyperkalemia
- Building of a chronic market

THE ROLE FOR RDX7675

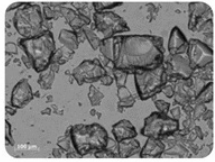
- Novel enhancements over long-standing generic treatment
- Effective reduction in potassium levels would limit RAASi and anti-diabetic drug dose reductions
- Increased patient compliance through better palatability
- Sodium and sorbitol free formulations
- Dosing convenience

1. Independent Market Research, Spherix Global Insights
2. Einhorn LM, et al. Arch Intern Med. 2009 Jun 22;169(12):1156-62
3. Mozaffarian D, et al. Circulation. 2015 Jan 27;131(4):e29-322

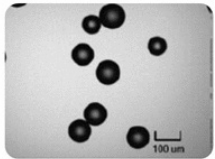


RDX7675: DISTINCT ADVANTAGES OVER TODAY'S STANDARD-OF-CARE

AVAILABLE TREATMENTS

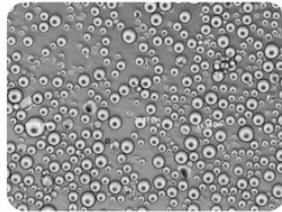


- Gritty texture
- Sodium counter-ion; leads to fluid overload and edema



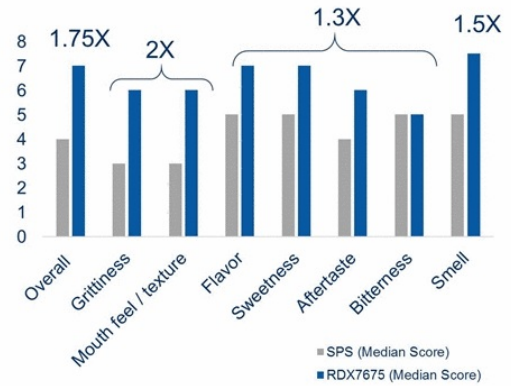
- Spherical beads
- Calcium-sorbitol counter-ion

RDX7675



- ✓ Bead design enhances mouth feel and palatability
- ✓ Lack of added sodium or sorbitol aligned with best clinical practice
- ✓ Issued composition of matter patent through 2034

RDX7675 SHOWS IMPROVED PALATABILITY IN HEALTHY VOLUNTEER TASTE TEST¹



Taste Test Scoring
 1 = Dislike Everything 2 = Dislike Very Much 3 = Dislike Moderately 4 = Dislike Slightly 5 = Neither like or Dislike
 6 = Like Slightly 7 = Like Moderately 8 = Like Very Much 9 = Like Extremely

RDX7675 ONSET OF ACTION DATA EXPECTED 3Q17



EXPANDING CARDIORENAL FRANCHISE WITH RDX7675

BRINGING RDX7675 TO MARKET FOR HK

\$3+ billion hyperkalemia market potential with new treatment¹

Chronic market not yet built

Synergistic opportunity within U.S. cardiorenal franchise

505(b)(2) pathway supports accelerated development and path to market

Simple distribution and storage with no need for refrigeration



\$300M+
MARKET
OPPORTUNITY





MANAGING BALANCE SHEET WHILE ADVANCING PIPELINE

FINANCIAL DISCIPLINE WITH PRUDENT PIPELINE INVESTMENTS

- ~\$173M in cash and securities at end of 1Q17
- No debt
- Current runway into 3Q18
- No plans to finance before T3MPO-2 data
- Multiple options to extend runway
- Significant partnering opportunities to efficiently bring tenapanor to market and strengthen balance sheet

EXPERT LEADERSHIP WITH TRACK RECORD OF SUCCESS

genzyme AstraZeneca  MedImmune


AFFYMAX[®]



Wyeth

FERRING
PHARMACEUTICALS

flexion

Organon


Allostera

CellTex
PHARMACEUTICALS, INC.


sunesis



EXECUTING TOWARD TENAPANOR COMMERCIALIZATION





INNOVATION THAT DRIVES VALUE

BUILDING A VALUABLE GI PORTFOLIO

- Completion of IBS-C T3MPO program by end of 2017
- Tenapanor on path for NDA submission for IBS-C in 2018
- Fast-follower programs with RDX8940, RDX011 and RDX023
- Significant opportunity to partner and access non-dilutive capital

BUILDING A VALUABLE CARDIORENAL PORTFOLIO

- Tenapanor NDA submission for hyperphosphatemia targeted for 2019
- Onset of action study and Phase 3 initiated for RDX7675 for hyperkalemia
- Fast-follower programs with RDX011 and RDX013
- Significant opportunities to partner or go-it-alone

CONDUCTING BREAKTHROUGH SCIENCE

- Unique R&D approach and platform to developing gut-restricted small molecules
- Rapid and efficient process to move from concept to compound to development

LEADING ARDELYX WITH A WORLD-CLASS TEAM

- Deep expertise in nephrology and GI drug discovery and development
- Extensive experience in successfully commercializing products
- Seasoned management across organization