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): January 7, 2019

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.

On January 7, 2019, 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.

The information furnished under this Item 7.01 shall not be considered "filed" under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), nor shall it be incorporated by reference into any future filing under the Securities Act of 1933, as amended, or under the Exchange Act 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.

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: January 7, 2019

ARDELYX, INC.

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

Exhibit 99.1

ARDELYX®

BREAKTHROUGH SCIENCE FOR **BETTER HEALTH**

J.P. Morgan Healthcare Conference 2019

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 statements regarding 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; the commercial potential for Ardelyx's product candidates; Ardelyx's ability to establish collaborations in the future; the potential for Ardelyx to receive milestone and royalty payments from its collaborators; and Ardelyx's expectations regarding the exhaustion of its current capital resources. 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 November 7, 2018, and its future current and periodic reports to be filed with the Securities and Exchange Commission.

- Developing first-in-class, disruptive medicines
- Lead product candidate, tenapanor, with >$1B market potential
- Opportunity for U.S.-focused renal commercial organization
- Expanding treatment access world-wide via strategic collaborations
- Seasoned management team with proven track record
- Operating runway extended through 2020

A Cardiorenal Biotech Company

FOCUSED ON ADVANCING TENAPANOR TO REACH PATIENTS

BREAKTHROUGH TREATMENT FOR HYPERPHOSPHATEMIA

- Successful first Phase 3 study
- Second Phase 3 study underway
- $500-700M commercial opportunity
- Preclinical data demonstrate synergy of tenapanor and sevelamer combination

NOVEL APPROACH TO TREATING IBS-C

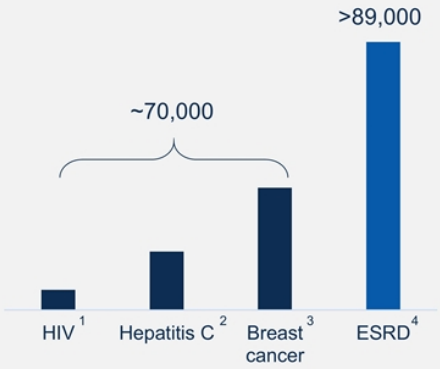
- Phase 3 program completed
- NDA accepted for review with PDUFA date September 12, 2019
- 11M people with IBS-C estimated in the U.S. alone

COLLABORATIONS TO ACCESS MARKETS

- Kyowa Hakko Kirin for cardiorenal diseases in Japan: $30M upfront, up to $55M in total development milestones and 8.5B yen in commercialization milestones, high-teen royalties
- Fosun Pharma for HP and IBS-C in China: $12M upfront, $113M in milestones, mid-teen to 20% royalties
- Knight for HP and IBS-C in Canada: CAD 25M including upfront payment and milestones, double-digit royalties

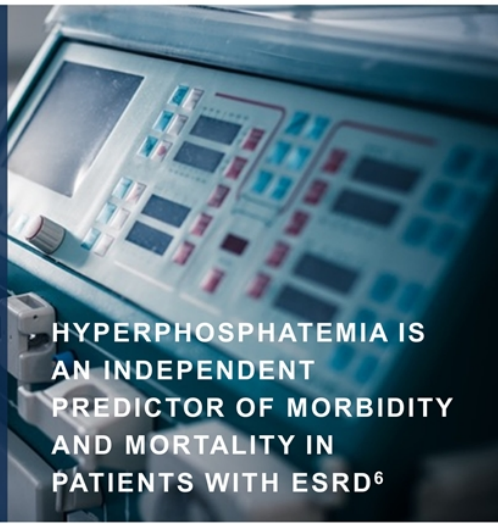
End-Stage Renal Disease (ESRD) Patients on Dialysis
REQUIRE OUR ATTENTION

More ESRD patient deaths in the U.S. each year than breast cancer, HCV and HIV combined



95%

of ESRD patients need phosphate control[5]



HYPERPHOSPHATEMIA IS AN INDEPENDENT PREDICTOR OF MORBIDITY AND MORTALITY IN PATIENTS WITH ESRD[6]

ARDELYX

1. CDC HIV in the United States 2014 (~6,700)
2. CDC Hepatitis C 2016 (~18,000)
3. ACS Breast Cancer Facts & Figures 2017-2018 (~41,000)
4. National Kidney Foundation, ESRD in the U.S. 2016
5. Savica, V Nephrol Dial Transplant 2006 21: 2065-2068
6. Emmett M Dialysis & Transplantation. 2006

~1 OUT OF 2 PATIENTS IS NOT COMPLIANT
with their hyperphosphatemia treatments[1]

2 OUT OF 3 PATIENTS NOT AT TARGET
based on serum phosphorus levels tested at any point in time[2]

NO CHANGES TO TREATMENT APPROACH SINCE INTRODUCTION OF PHOSPHATE BINDERS IN 1970s

Control of serum phosphorus limited by poor compliance and adherence to phosphate binder treatment

1. Fissel 2016
2. DOPPS Practice Monitor, December 2015. www.dopps.org/DPM

PILL BURDEN AND DOSE:

The #1 Challenge for Patients with Hyperphosphatemia

POTENTIAL TO IMPROVE COMPLIANCE THROUGH CONVENIENT DOSING

One week dose of today's SOC[1]

One week dose of tenapanor[2]

1. 800mg of Renvela (sevelamer carbonate) up to three times per day with meals per package insert
2. Investigational small molecule currently in Phase 3 development. Target dose 10-30 mg BID. (10 mg shown here)

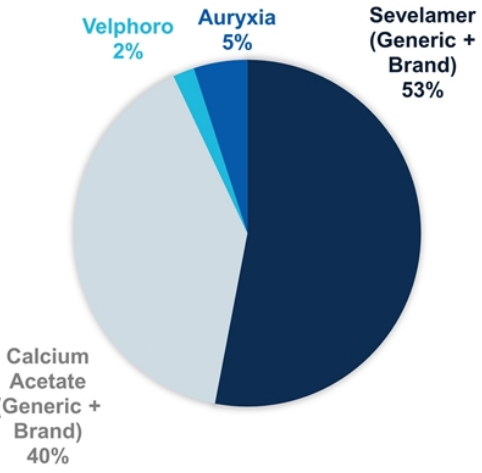
HP Patients and Physicians Ready for the

FIRST NON-BINDER TREATMENT OPTION

New evidence from three randomized controlled trials supports a more general recommendation to ***RESTRICT CALCIUM-BASED PHOSPHATE BINDERS*** *in hyperphosphatemic patients across all severities of CKD.*[1]

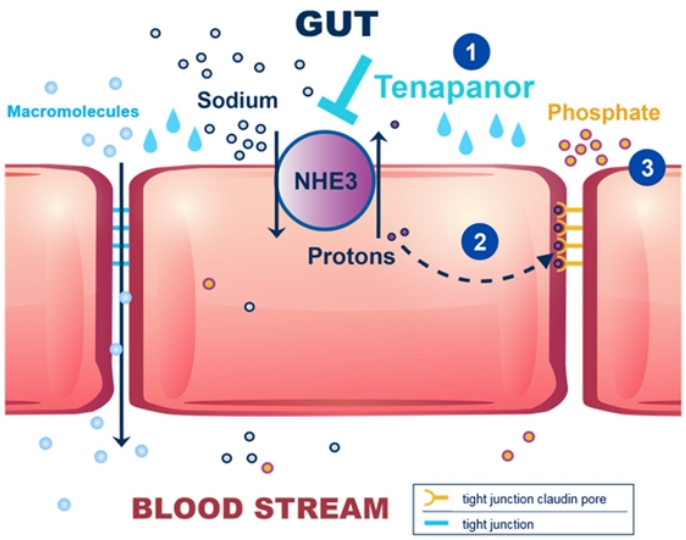
BINDERS REMAIN THE ONLY TREATMENT OPTION TODAY[2]

TRx Unit Market Share



1. 2017 KDIGO CKD-MBD Guideline Update; Kidney International (2017) 92, 26–36
2. IQVIA binder TRx Market Share 12 months through November 2018

FIRST-IN-CLASS TREATMENT FOR ESRD PATIENTS WITH HYPERPHOSPHATEMIA



1. Tenapanor inhibits NHE3 which transports luminal sodium in exchange for cellular protons
2. Cellular proton retention reduces tight junction permeability to phosphate
3. Reduced tight junction phosphate permeability results in reduced paracellular absorption of luminal phosphate

Paracellular transport is quantitatively the most important mechanism of phosphate absorption in the GI tract

Selective NHE3 Inhibition in the GI tract blocks paracellular transport of phosphate via tight junctions

Clinical and preclinical data suggest GI NHE3 inhibition has no overall effect on absorption of nutrients or other ions

TENAPANOR EFFICACY

Demonstrated in First Phase 3 HP Study[1]

ROBUST TREATMENT EFFECT IN RESPONDERS[2]

- 2.56 mg/dL mean change in serum phosphorus levels in responder population (baseline to end of 8-week treatment period)

STATISTICALLY SIGNIFICANT RESULTS*

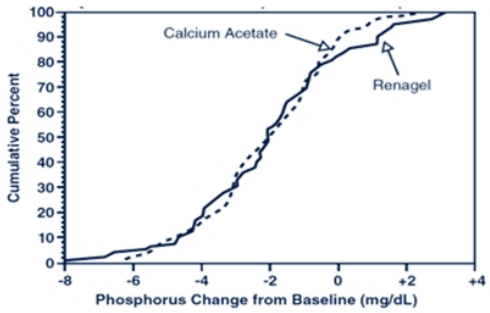
- 1.01 mg/dL mean delta between placebo and tenapanor (95% CI -1.44, -0.21)
- Primary endpoint: -0.82 mg/dL LS mean; p=0.01

FAVORABLE TOLERABILITY

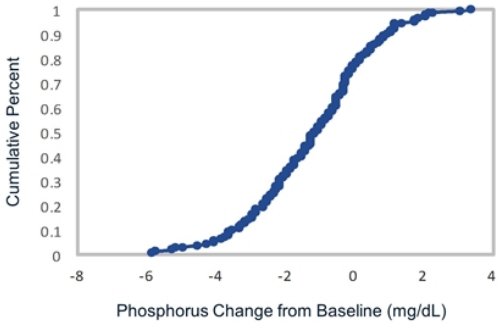
- No discontinuations due to diarrhea in placebo-controlled randomized withdrawal period

*Serum phosphorus level from end of 8-week treatment period to end of 4-week randomized withdrawal period for tenapanor vs placebo in responders

Renagel Package Insert Data[3]
(sevelamer n=81; Calcium Acetate n=83)

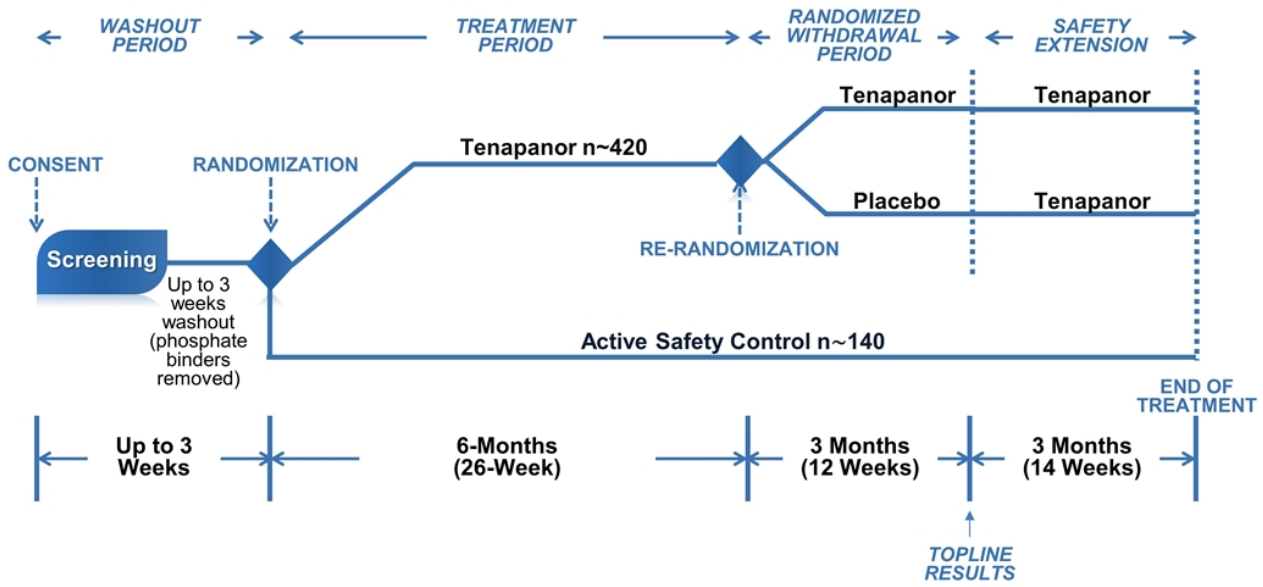


Tenapanor 1st Phase 3 Trial (n=164)[1,3]



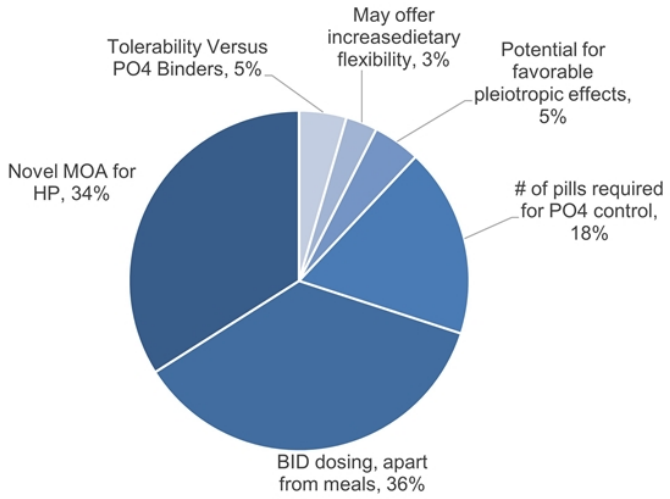
1. Tenapanor is an investigational medicine; Phase 3 data reported February 2017
2. 49% (80 of 164) responders (serum phosphorus decrease of ≥ 1.2 mg/dL) in first Phase 3 trial
3. Renagel and tenapanor have not been evaluated in head-to-head studies

Tenapanor Second Phase 3 Registration Study Enrolled Topline Results in 4Q 2019



APPEAL AND USE OF TENAPANOR

Single Most Appealing Aspect of Tenapanor



How Would You Use Tenapanor?

34% Would use tenapanor first line *before* phosphate binders

47% Would add tenapanor to the binder regiment to boost efficacy

19% Would use second line as a monotherapy if first line binder failed

The US Dialysis Market: Implications for tenapanor; provided for Ardelyx's Renal Day September 2018; Slide 42

- What would you say is the single most appealing aspect of tenapanor? Please select one. (n=103)
- How would you be most likely to use this product in your HD patients assuming it had cost parity with non-calcium phosphate binders? Forced choice (n=103)

COMBINATION USE WITH BINDERS

Tenapanor potential differentiation

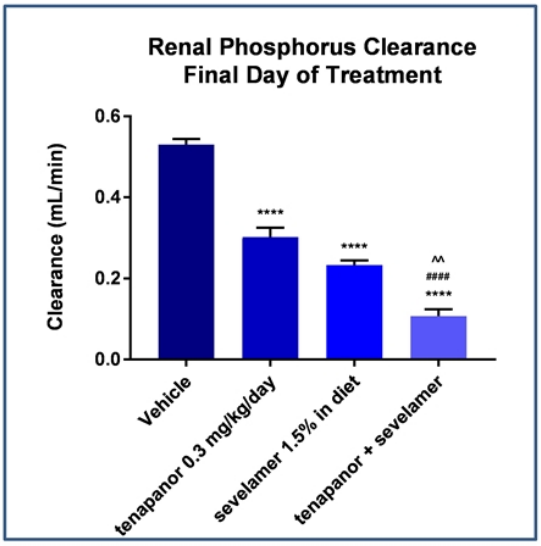
- Efficacy / adherence & compliance a large issue
  - 65% of patients >4.5mg/dL[1]
- Only 11% of HD patients being treated with binders currently take more than one brand[2] (no efficacy benefit)
  - Manage side effects
  - Manage costs
- Tenapanor's effect is synergistic in rats when added to sevelamer
- Ardelyx to begin Phase 3 combination study in early 2019
- With successful results, tenapanor would be the first and only phosphate lowering therapy to be indicated for use in combination with binders

1 DOPPS Practice Monitor, United States, Serum Phosphorus, most recent, National Sample, Feb 2018 https://www.dopps.org/DPM/Files/phosphmgdl_c_overallTAB.htm
2 RealWorld Dynamix Dialysis 2017; Spherix; Slide 16

COMBINATION USE WITH BINDERS

Presented at ASN 2018

Tenapanor and sevelamer are synergistic in their reduction of Pi in rats



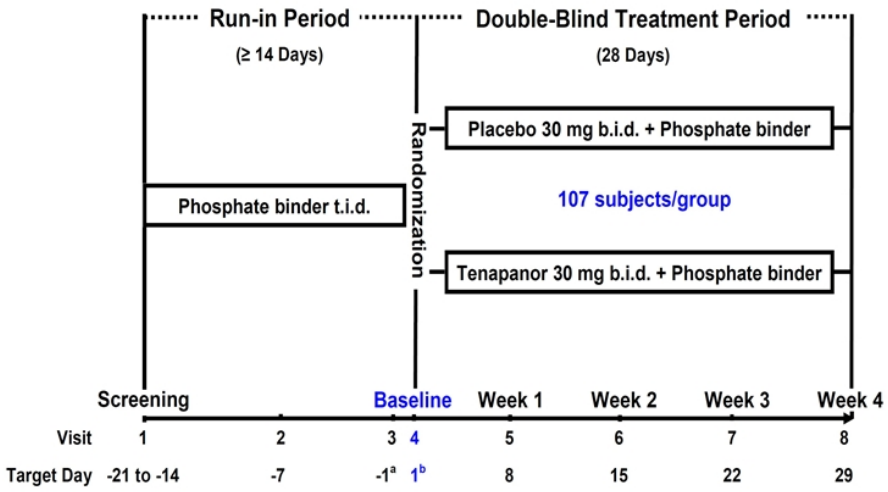
Percent Reduction of Phosphorus

	Tenapanor Alone	Tenapanor + Sevelamer	Tenapanor + Sevelamer		
	Actual	Predicted	Actual	Outcome	Interaction
Tenapanor	33.2	NA	NA	NA	NA
+ Sevelamer 0.75% w/w	21	47.2	64.8	Obs'd > predicted	Synergy
+ Sevelamer 1.5% w/w	57.9	71.2	80	Obs'd > predicted	Synergy
+ Sevelamer 3.0% w/w	76.5	84.3	90.2	Obs'd > predicted	Synergy

*Mean ± SEM data shown; One-way ANOVA; N=6/group; **** = $p < 0.0001$ compared to vehicle; #### = $p < 0.0001$ compared to tenapanor alone; ^^ = $p < 0.05$ compared to sevelamer alone*

TEN-02-202: *AMPLIFY*

Tenapanor as Adjuvant Therapy to Phosphate Binders



Study Design

Randomized, double-blind and placebo controlled

30 mg bid starting dose that can be titrated to 20 mg or 10 mg

Key Inclusion Criteria

- 3 doses of phosphate binders/day, serum phosphorus ≥ 5.5 mg/dL and ≤ 10 mg/dL at screening and Day -1

Primary Endpoint

- Difference in change between tenapanor and placebo of serum phosphate levels from randomization to end of 4-week treatment period

Sample size calculation

- 85% power to detect a treatment difference of 0.5 mg/dL with a common standard deviation of 1.0 mg/dL using a two-sample t-test with a two-sided significance level of α=0.01

BRINGING TENAPANOR TO HP PATIENTS

Clear Path to Commercialization

- Data-driven, KOL-led market
- Specialized U.S. commercial organization targeting nephrologists
- Access outside the U.S. via strategic collaborations

KYOWA KIRIN FOSUN PHARMA 复星医药 Knight

- Highly experienced renal team

$500 – $700M

COMMERCIAL OPPORTUNITY

PARTNERING to Bring Tenapanor to Patients with IBS-C Worldwide

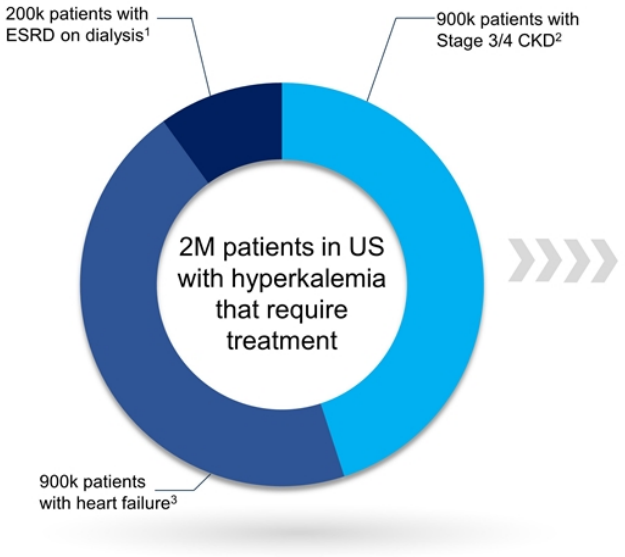
Strategic collaborations extend reach to patients worldwide

- Fosun Pharma and Knight granted development and commercialization rights in China and Canada
- Additional partnerships being pursued for U.S. commercialization
- Collaborations represent continued source of non-dilutive capital

NDA accepted for review
PDUFA date September 12, 2019

1. Lovell 2012

SIGNIFICANT HYPERKALEMIA MARKET WAITING TO BE TAPPED



THE POTENTIAL FOR RDX013

- Target Product Profile
  - Greatly improved pill burden
  - Improved efficacy in both acute and chronic settings
  - Exceptional safety
  - Administration alongside lifesaving drugs that can cause hyperkalemia (RAASi's, Entresto, Etc.)
- Build upon the market being created by Lokelma and Veltassa

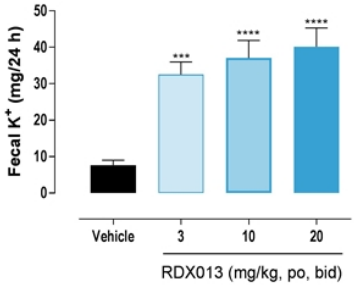
1. Independent Market Research, Spherix Global Insights
2. Einhorn LM, et al. Arch Intern Med. 2009 Jun 22;169(12):1156-62
3. Mozaffarian D, et al. Circulation. 2015 Jan 27;131(4):e29-322

RDX013 PROGRAM
Expanding Our Renal Footprint

RDX013 PROGRAM

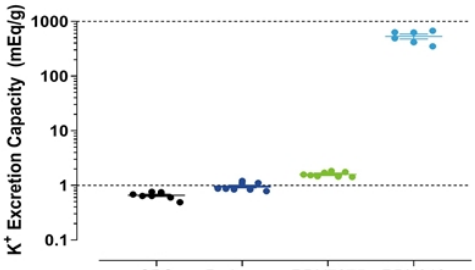
- Novel, oral potassium secretagogue program
- Convenient, small pill dosing
- Increases fecal potassium excretion; reduces serum potassium
- Allows optimal dosing of anti-hypertensives
- ~1000x improved *in vivo* efficiency vs binders

IN VIVO FECAL POTASSIUM EXCRETION



- RDX013 produces dose-dependent increases in fecal potassium excretion in rodents
- Preclinical studies indicate once-daily dosing is effective

~1000x improved *In Vivo* Efficiency vs Binders*



*K+ binding capacity determined in mouse

- First-in-class cardiorenal medicine with a unique and differentiated MOA
- Significant market opportunity in cardiorenal alone: hyperphosphatemia
- Go-to-market approach with specialized U.S.-focused cardiorenal commercial organization
- Optimizing global patient access through strategic collaborations
- Seasoned management with proven track record
- Multiple high value line extensions possible

Breakthrough Science for **BETTER HEALTH**

ARDELYX