
**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): August 6, 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))
-
-

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 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 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: August 6, 2014

ARDELYX, INC.

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

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
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ARDELYX[®]

Investor Presentation

Mike Raab
CEO



AUGUST 2014

Forward Looking Statements and Further Information



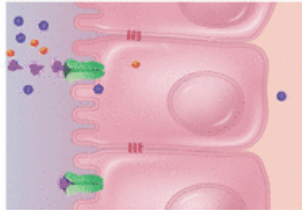
Special Note Regarding Forward-Looking Statements

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 availability and timing of data from ongoing tenapanor clinical trials, potential milestone payments from our collaboration partners, and the potential sufficiency of capital resources available to further develop our pipeline and our drug discovery and design platform. Such forward-looking statements involve substantial risks and uncertainties that could cause the development of tenapanor, 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 the clinical development process, Ardelyx's reliance upon AstraZeneca for the development of tenapanor, Ardelyx's reliance upon Sanofi for the discovery and development under the licensed NaP2b inhibitor program, and the uncertainties inherent in the research and discovery 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 prospectus filed with the Securities and Exchange Commission on June 19, 2014, and its future periodic reports to be filed with the Securities and Exchange Commission.



Clinical-Stage Biopharmaceutical Company

Oral, Small Molecule,
Non-Systemic, First-in-Class Drugs



Rapid, Efficient Drug Discovery
and Design Platform

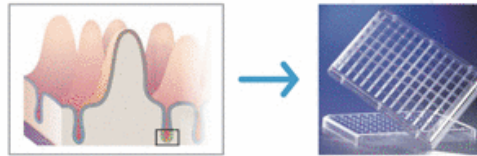


Fig 1



Large, Global Patient
Populations and Markets

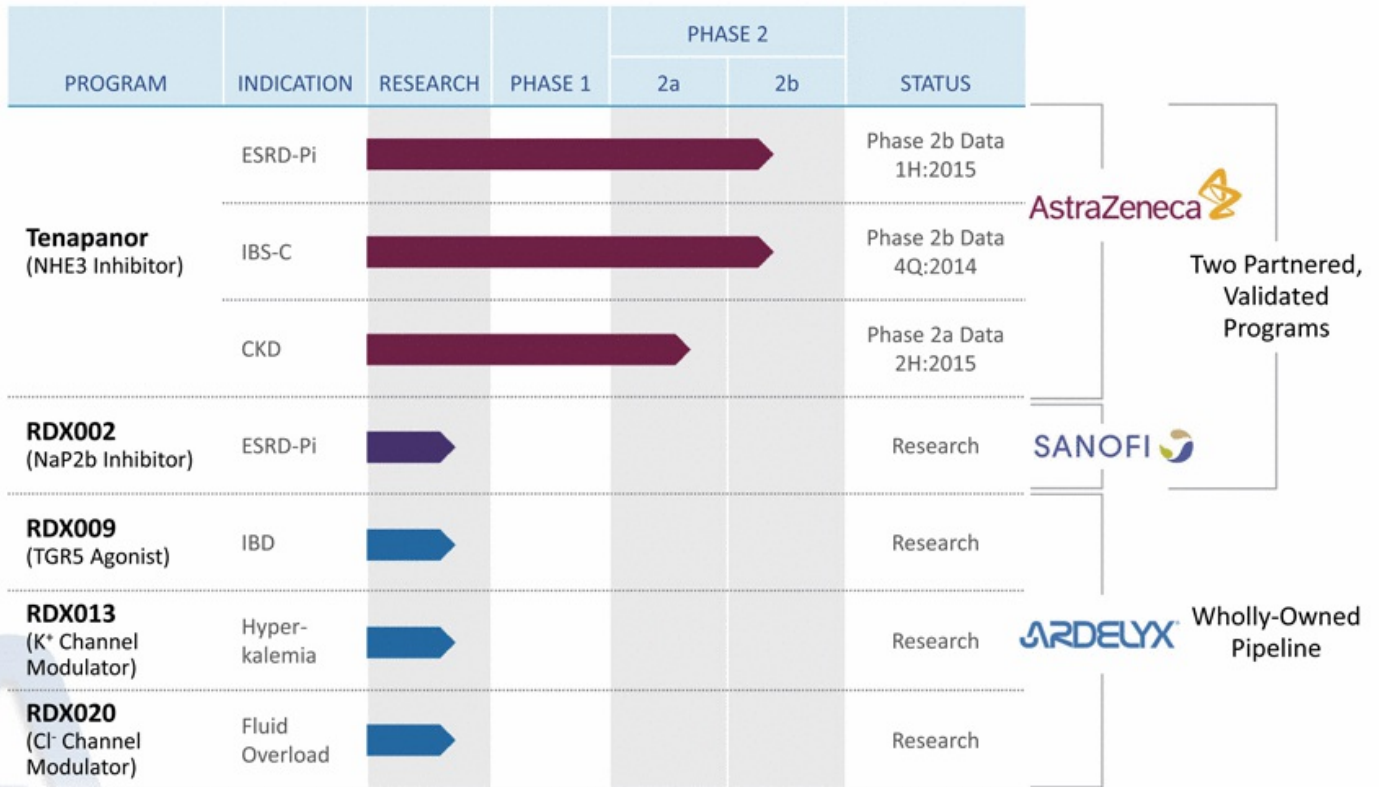


Multiple
Phase 2 Programs for Tenapanor



Figure 1 from Sato T and Clevers H., "Growing self-organizing mini-guts from a single intestinal stem cell: mechanism and applications." Science. 2013 Jun 7;340(6137):1190-4

The Result: Robust Product Pipeline



A History of Rapid, Capital Efficient Development



DEVELOPMENT

TENAPANOR

Idea to P2a Data in 3 Years

Company Formed
 NHE3 Sodium Transport Inhibitor Proposed
 Lead Candidate Identified
 IND Filed 1st Subject Dosed
 P1 Completed P2a Top Line Data in IBS-C



FINANCINGS

\$26M Series A
 NEA & CMEA

\$30M Series B
 NEA & CMEA
 Amgen Ventures

\$69M IPO
 \$60.2M net

LICENSES



\$35M
 Upfront

\$15M
 Development
 Milestone

\$25M
 Development
 Milestone

Up to \$870M for Tenapanor



Up to \$198M for
 NaP2b



Proven Management Team



MIKE RAAB	Chief Executive Officer	NEA	genzyme	Bristol-Myers Squibb
DOMINIQUE CHARMOT, PhD	Chief Scientific Officer	ILYPSA	Symyx	Rhodia
MARK KAUFMANN	Chief Financial Officer	MedImmune	CELMED	nexia
DAVID ROSENBAUM, PhD	VP Drug Development	GeTtex	Trine	Arthur D Little
ELIZABETH GRAMMER	VP and General Counsel	genzyme	GeTtex	EDWARDS ANGELL PALMERS DODGE
JEFF JACOBS, PhD	VP Chemistry	sunesis	gsk	AFFYMAX
GEORGE JUE	VP Finance and Operations	HYPERION	PDL BioPharma	Genentech
ROB BLANKS	Sr. Dir. Regulatory Affairs and QA	Idenix	GeTtex	Repligen Corporation
ANDY SPENCER, PhD	Sr. Dir. R&D Alliance Management	ALVINE	PDL BioPharma	Mirus



Investment Highlights



PROPRIETARY PLATFORM

Discovery and Design of Non-Systemic, Small Molecule Therapeutics

2 VALIDATED PROGRAMS

Tenapanor: AstraZeneca Collaboration; Phase 2 in Three Indications

NaP2b Inhibition: Sanofi Collaboration

Multiple Near-Term Catalysts

WHOLLY-OWNED PIPELINE

Pipeline Provides Additional Opportunity

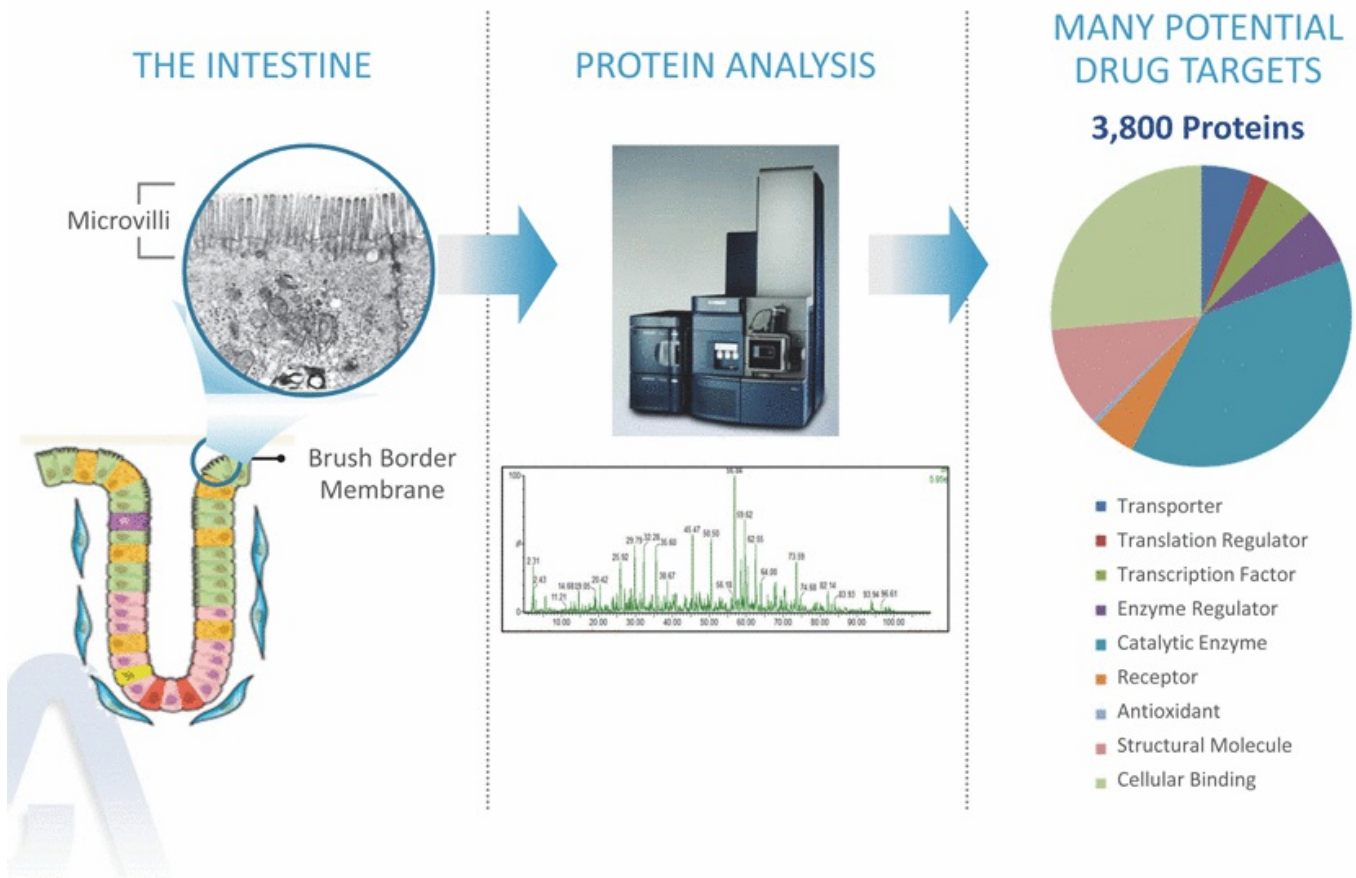
CAPITAL EFFICIENCY

Strong History

PROVEN MANAGEMENT TEAM

Deep Domain Expertise

Intestinal Epithelium Is Rich with Potential Targets



Ardelyx Primary Enterocyte and Colonocyte Culture System

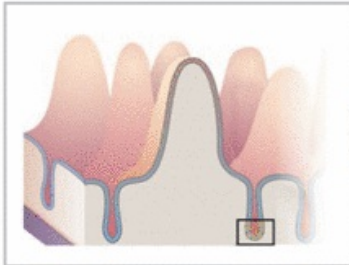
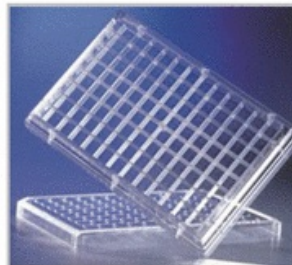
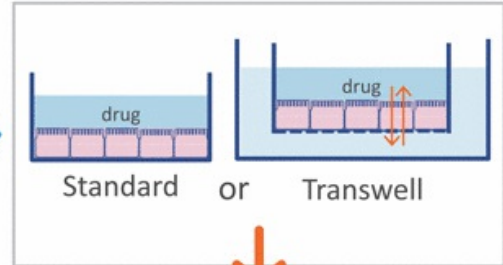


Fig 1
Harvest Stem Cells
from Gut



Grow in Monolayer
Format



Standard or Transwell
Measure Drug Response

THE BENEFITS

- **Discovery:** Rapid Screening of Drugs
- **Translation to Humans:** Simulate Relevant Gut Cell Physiology
- **Powerful Tool:** Mechanisms, Targets, Phenotypic Screening

Tenapanor and Our Collaboration with AstraZeneca



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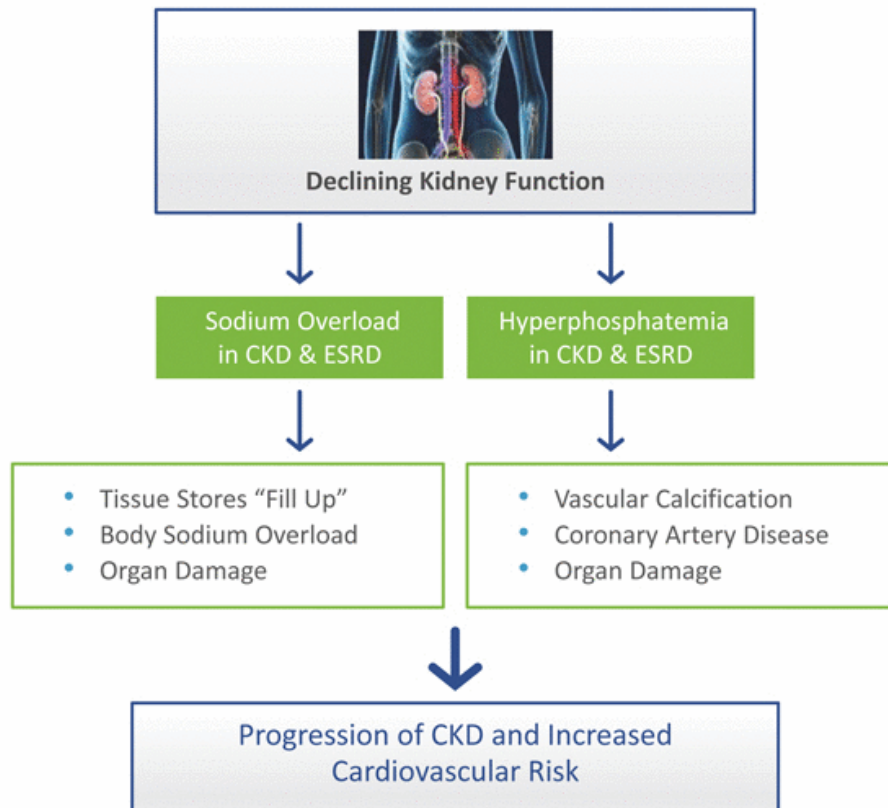
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The Impact of Sodium and Phosphorus Overload

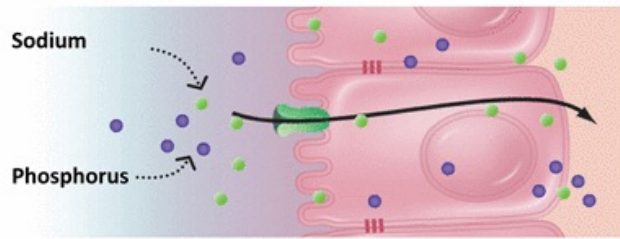


Tenapanor Reduces Sodium and Phosphorus Absorption



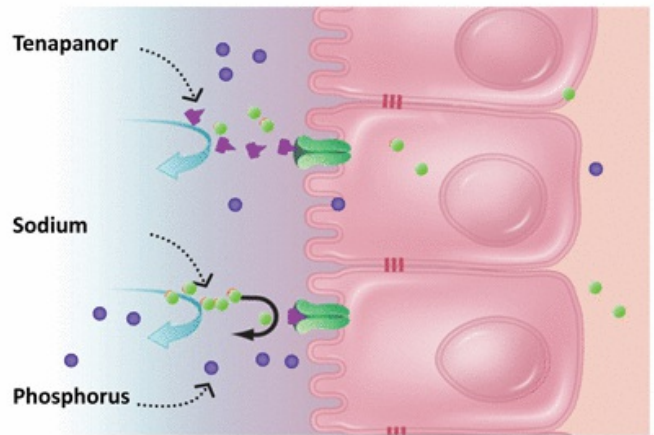
WITHOUT TENAPANOR

Dietary Sodium/Phosphorus Passes Into Circulation



WITH TENAPANOR

Diverts Sodium/Phosphorus from Circulation



Local Activity in the Gut

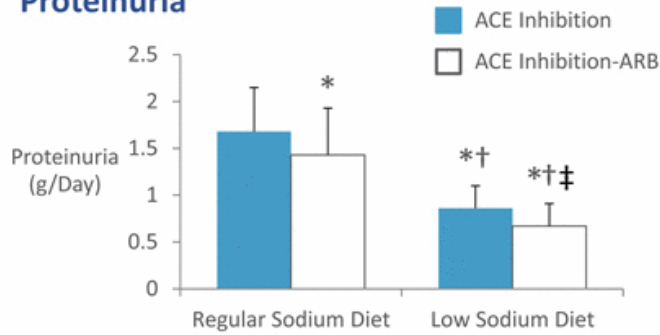


Studies Support Impact of Treating Elevated Sodium and Phosphorus

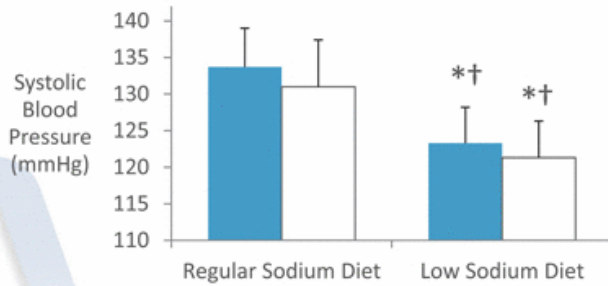


SODIUM¹

Proteinuria

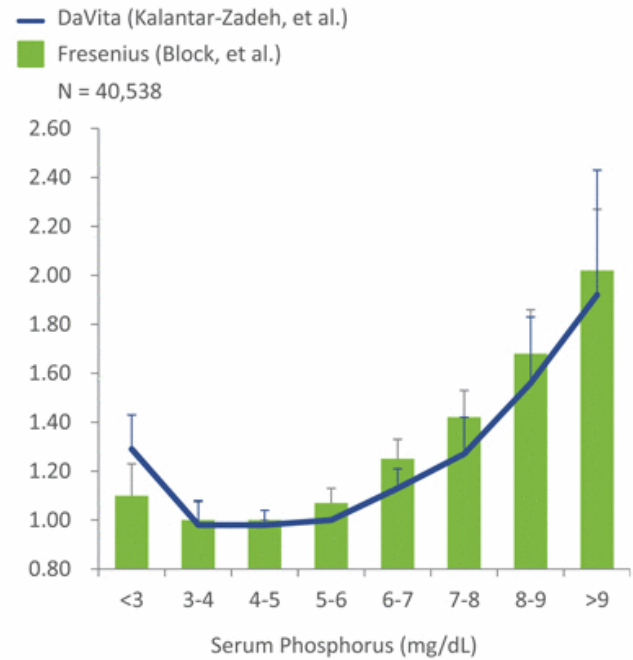


Systolic Blood Pressure



PHOSPHORUS²

Relative Risk of Death*



*Not adjusted for active vitamin D intake; serum phosphorus 4-5 mg/dL was normalized to 1.0

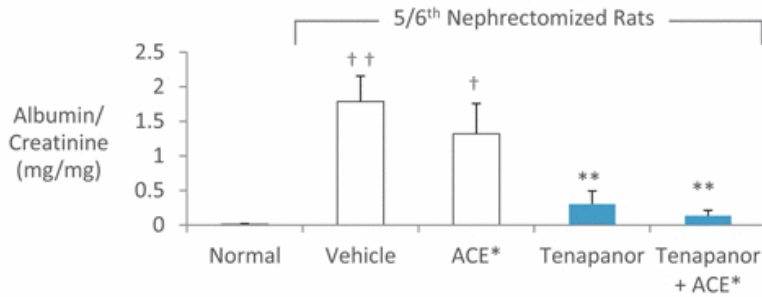
1. Slagman, et al., *BMJ* (2011) 343:d4366; 2. Block, et al. *JASN* (2004) 15:2208-2218; 3. Kalantar-Zadeh, et al. *KI* (2006) 70:771-780
*P<0.05 v ACE inhibition on regular sodium diet. †P<0.05 v ACE inhibition plus ARB on regular sodium diet. ‡P<0.05 v ACE inhibition on low sodium diet

Beneficial Effects of Tenapanor on Sodium and Phosphorus in CKD Models

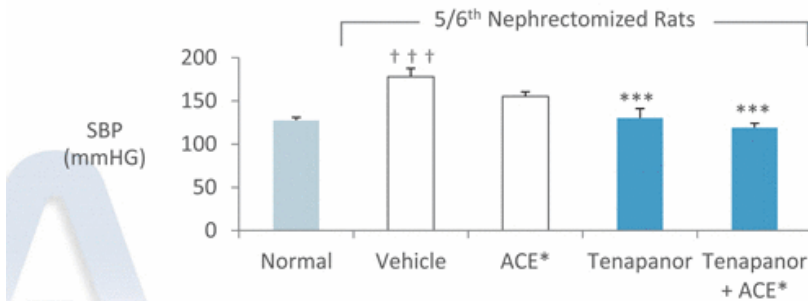


SODIUM

Urinary Albumin/Creatinine



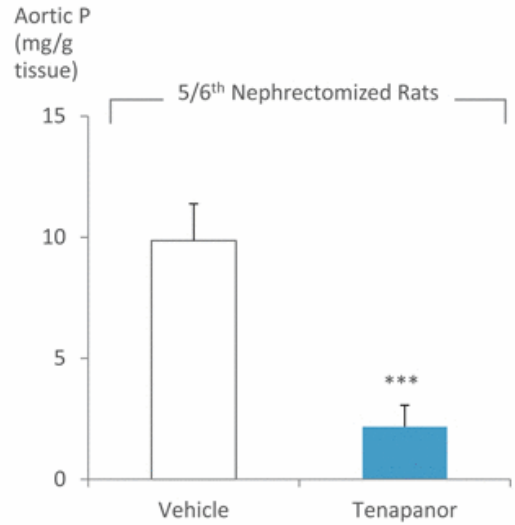
Systolic Blood Pressure



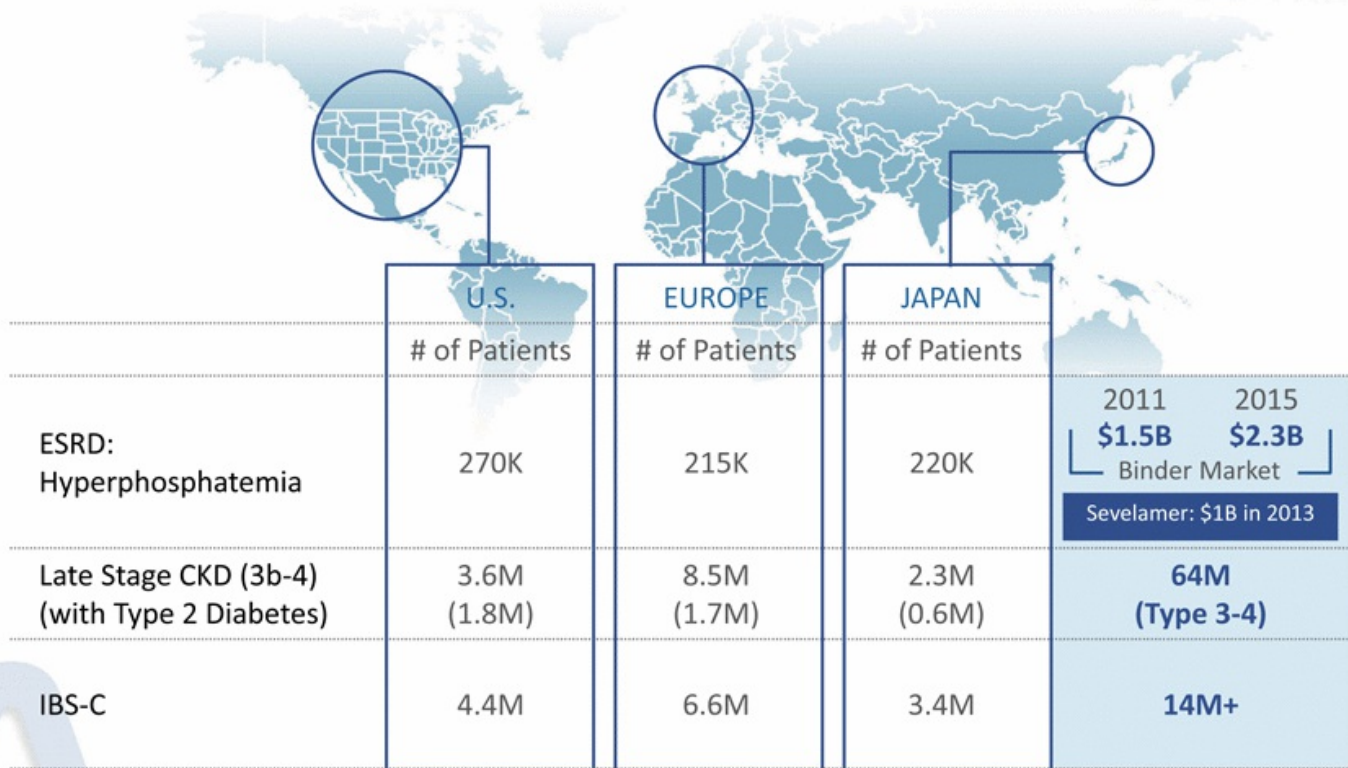
*ACE = Enalapril ; One way Anova, followed by Dunnett's test;
 ** p<0.01; *** p<0.001 vs. vehicle; † p<0.05; † †; p<0.01; † † † p<0.001 vs. sham; N=12/group

PHOSPHORUS

Aortic Mineral Content



Significant Market Opportunity for Tenapanor

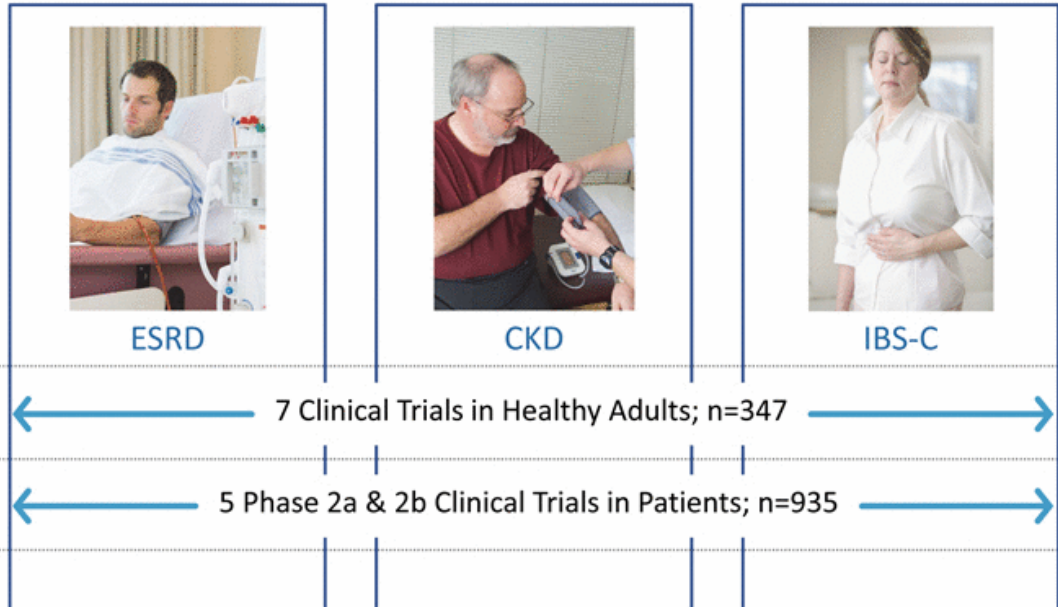


Sources: Technavio Insights: Global Hyperphosphatemia Drugs Market 2011-2015, USRDS 2013 Atlas of CKD & ESRD, Dialysis Outcomes and Practice Patterns Study (DOPPS), Am J Kidney Dis. 2012 Jul, European ERA-EDTA Registry Annual report 2011, Ther Apher Dial. 2010 Dec, JAMA. 2007 Nov, J Chin Med Assoc. 2010 Oct, BioTrends TreatmentTrends 2013, Patient Prefer Adherence 2008, Clin Gastroenterol Hepatol. 2012, Aliment Pharmacol Ther. 2005, Aliment Pharmacol Ther. 2003.

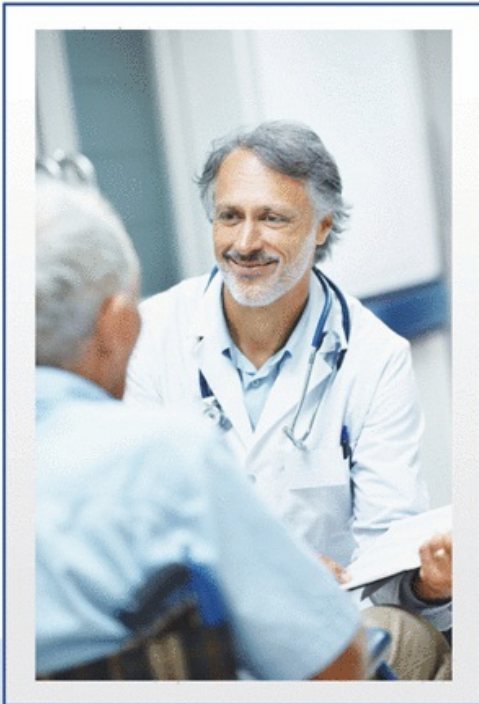
Extensive Clinical Experience with Tenapanor in Multiple Indications



12 Clinical Trials in 1,200+ Subjects



Tenapanor Generally Well-Tolerated



- 830+ Subjects Exposed to Drug
 - 291 Healthy Volunteers
 - ~415 IBS-C Subjects
 - ~125 CKD and ESRD-HD Subjects
- Single Dose Up to 900 mg
- 3 Months Up to 100 mg/Day
- Non-Systemic: >99.3% of All Tested Serum Samples Had No Detectable Levels of Tenapanor
- Most AEs Due to Exaggerated Pharmacology of Drug (e.g. Loose Stools/Diarrhea)
- **No Drug-Related Serious Adverse Events (SAEs)**

Tenapanor for Hyperphosphatemia in ESRD



LIMITATIONS OF PHOSPHATE BINDERS:

Pill Burden

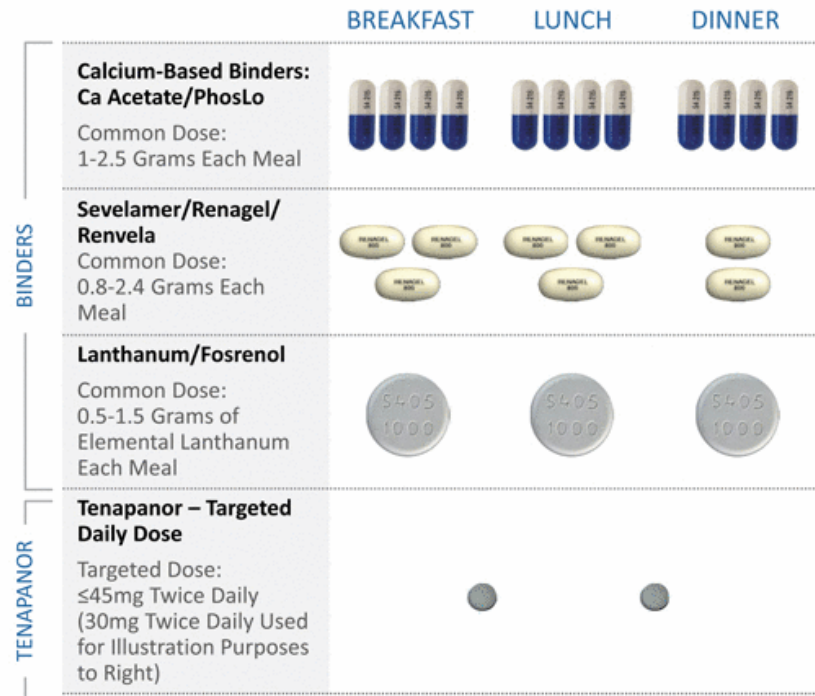
- ESRD Patients Take 10-14 Oral Medications Daily
- Prescribed Binder Doses Intolerable for Many Patients; Water Intake Limited
- Non-Compliance Often Results in Reduced Efficacy

Safety and Tolerability

- Long-Term Vascular Calcification with Calcium-Based Binders
- Gastrointestinal Side Effects



PILL BURDEN: TENAPANOR VS. BINDERS

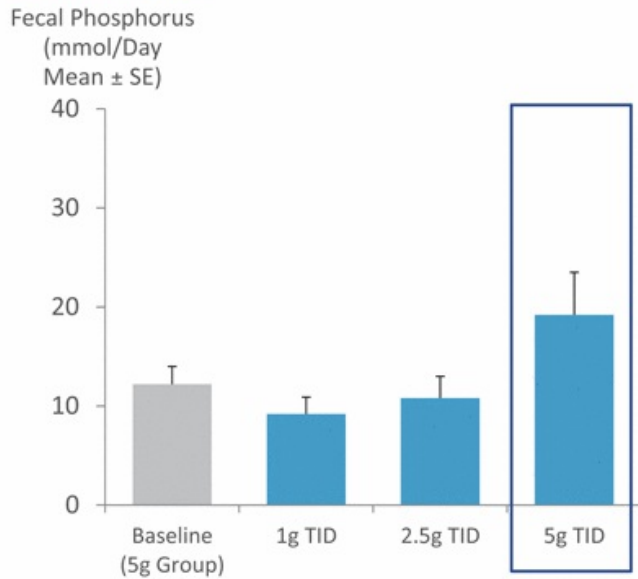


Not Actual Size; However, Relative Sizes Are to Scale

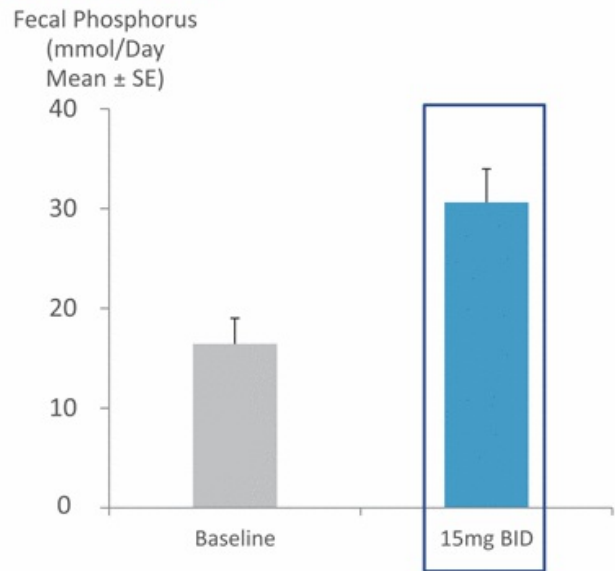
Comparative Human Response: Sevelamer vs. Tenapanor



SEVELAMER¹



TENAPANOR²



Dose

15,000 mg/Day

30 mg/Day

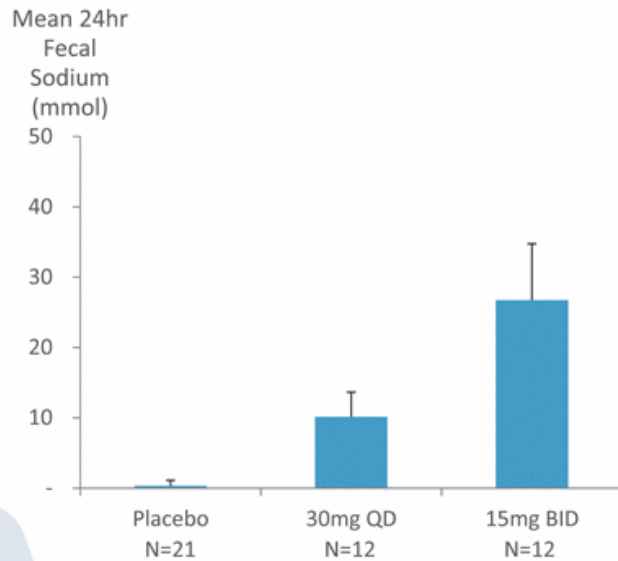
Similar Results,
But **1/500th** the Dose

¹ Burke et al. 1997; ² Study D5611C00002

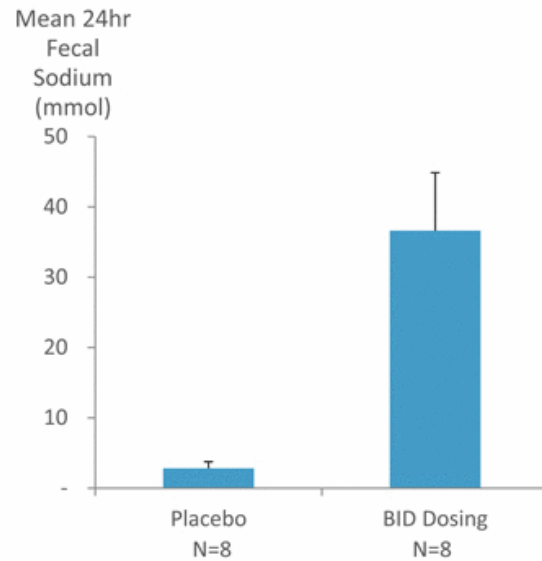
Tenapanor Diverts Dietary Sodium to the Feces in Healthy Adults and ESRD Patients



PHASE 1 IN HEALTHY ADULT VOLUNTEERS¹



PHASE 2a ESRD-FLUID IN SUBSET OF ESRD PATIENTS²



¹ RDX5791-102; ² Study D5611C00001

ESRD FLUID PHASE 2a

- **Design:** Double-Blind; 4 Weeks of Treatment, n=88 (45 Active/43 Placebo)
- **Objective:** Safety, Tolerability, and Pharmacodynamics of Tenapanor in ESRD-HD Patients with Fluid Overload
- **Status:** Completed

ESRD- HYPERPHOSPHATEMIA PHASE 2b

- **Design:** Double Blind; 4 Weeks Of Treatment, n=150 (125 Active/25 Placebo)
- **Objective:** Efficacy and Safety of Tenapanor for the Treatment of Hyperphosphatemia in ESRD-HD Patients; Determination of Phase 3 Dose(s)
- **Status:** Enrolling; Data Expected 1H 2015





Sodium and
Fluid Overload

LIMITATIONS OF CURRENT TREATMENTS TO DELAY CKD PROGRESSION

- Poor Compliance with Low Sodium Diets
- Diuretics Lose Efficacy and Cause Electrolyte Disorders
- ACE Inhibitors Reduce Blood Pressure but Hyperkalemia Limits Widespread Use in CKD Patients

CKD PHASE 2a

- **Design:** Double-Blind, 12 Weeks of Treatment, n=140 (70 Active/70 Placebo)
- **Objective:** Safety, Tolerability, and Pharmacodynamics of Tenapanor in CKD Patients with Type 2 Diabetes Mellitus and Albuminuria
- **Status:** Enrolling, Data Expected 2H 2015





GI Disorder:
Constipation and
Abdominal Pain

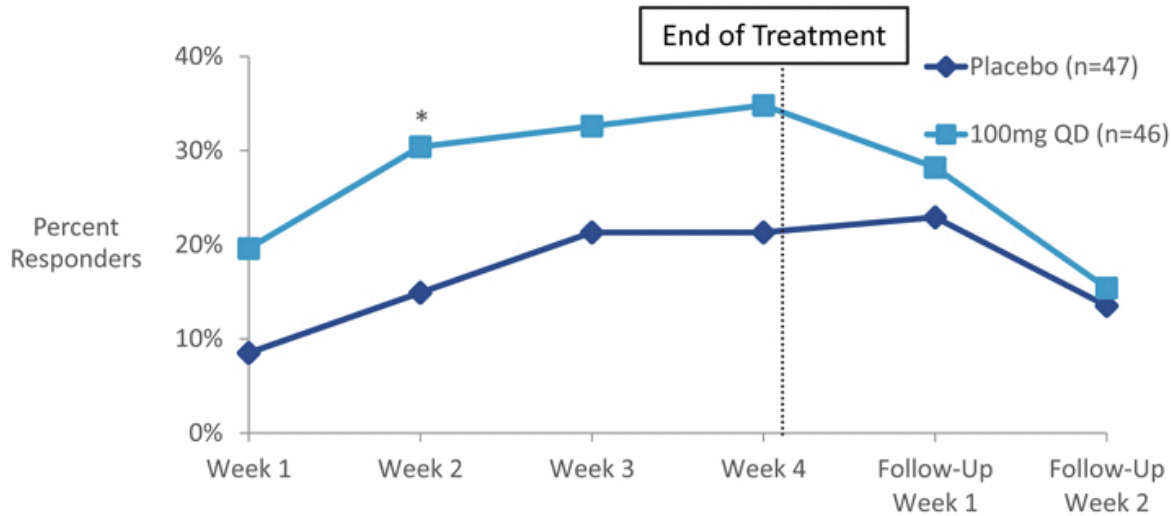
LIMITATIONS OF CURRENT TREATMENTS

- 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., Diarrhea)
- Medical Need for Improved Therapies with Better Efficacy, Excellent Safety and Tolerability

Phase 2a Demonstrates Consistent Effects of Tenapanor in Multiple Endpoints and Supports Ongoing Phase 2b Study



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



- Although the Primary Endpoint, Change in CSBM from Baseline to Week 4, Was Not Met, We Did Note Improvements in Degree of Bloating and Abdominal Pain, as Well as Relief of IBS Symptoms, Severity and QOL Measurements
- These Data Were the Basis for Our Decision to Take Tenapanor into a Phase 2b Clinical Study

* p<0.05 versus placebo

IBS-C PHASE 2a

- **Design:** Double-Blind, 4 Weeks of Treatment, n=186 (139 Active/47 Placebo)
- **Objective:** Safety, Tolerability, and Pharmacodynamics of Tenapanor for the Treatment of IBS-C
- **Status:** Completed

IBS-C PHASE 2b

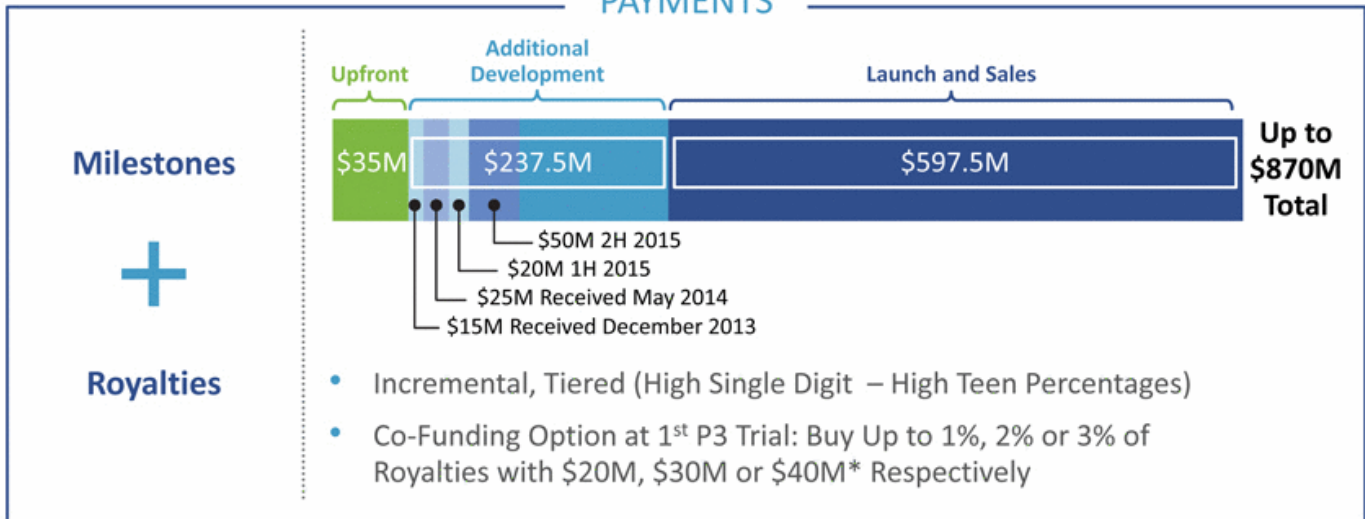
- **Design:** Double-Blind, 12 Weeks of Treatment, n=371 (3:1 Active: Placebo)
- **Objective:** Efficacy and Safety of Tenapanor for the Treatment of IBS-C; Determination of Phase 3 Dose(s)
- **Status:** Enrollment Completed, Data Expected 4Q 2014



The AstraZeneca/Tenapanor Collaboration



PAYMENTS



OTHER TERMS

AstraZeneca Responsibilities:	<ul style="list-style-type: none"> All R&D and Commercialization Expenses**
Ardelyx Rights:	<ul style="list-style-type: none"> Right to Co-Promote in the US

*Exercisable Within 60 Days After Decision to Proceed to P3 Clinical for the First Indication for Tenapanor
 **Subject to cap on obligation for IBS-C reimbursement

RDX002: NaP2b and Our Collaboration with Sanofi



PROPRIETARY PLATFORM

Discovery and Design of Non-Systemic, Small Molecule Therapeutics

2 VALIDATED PROGRAMS

Tenapanor: AstraZeneca Collaboration; Phase 2 in Three Indications

RDX002 NaP2b Inhibition: Sanofi Collaboration

Multiple Near-Term Catalysts

WHOLLY-OWNED PIPELINE

Pipeline Provides Additional Opportunity

CAPITAL EFFICIENCY

Strong History

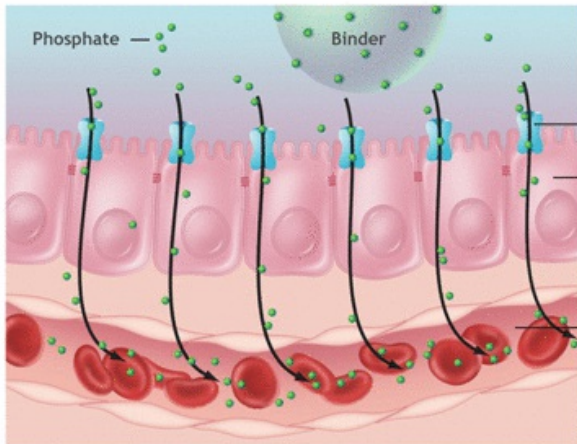
PROVEN MANAGEMENT TEAM

Deep Domain Expertise

Phosphate Binder vs. Phosphate Transport Inhibitor

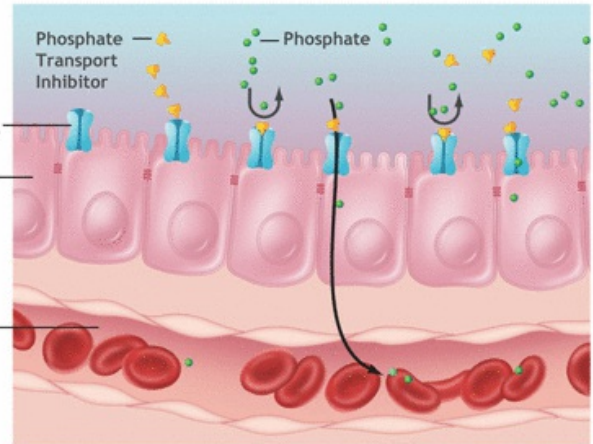


Binder



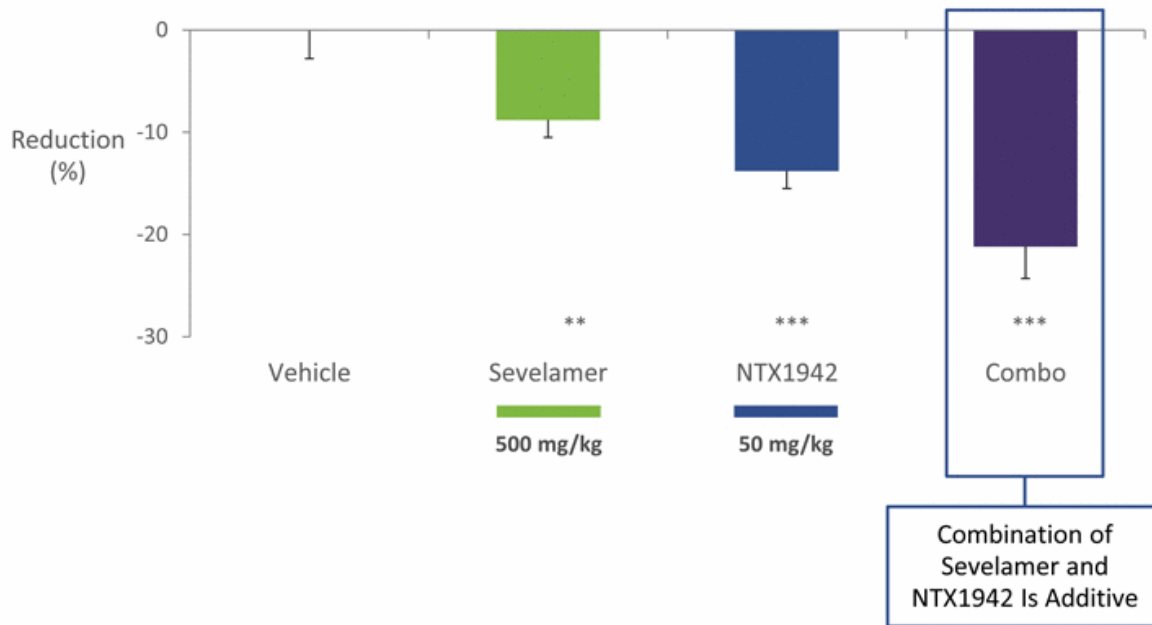
- GI-Upset/Pill-Burden
- Increased Calcium Load with Calcium Based Binders
- Concerns of Metal Accumulation with Metal Based Binders

Phosphate Transport Inhibitor



- Potential for Dramatically Reduced Pill-Burden
- Potential for Use in Combination with Phosphate Binders

RDX002: NTX1942 Reduces Urine Phosphorus Levels in Normal Rats and Is Additive to Sevelamer



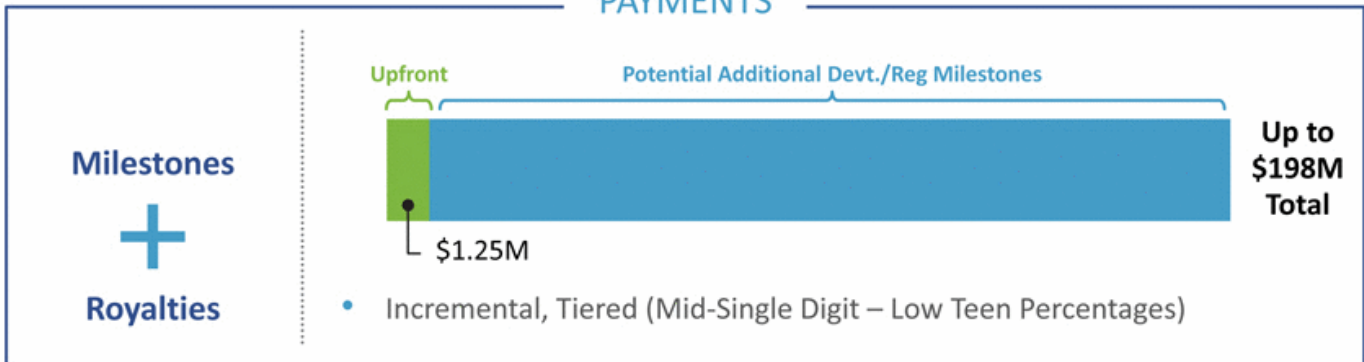
NTX1942 Response Is Superior to Sevelamer at $\approx 1/10$ of the Dose

Data Shown is the Mean \pm SEM; ** = p<0.01; *** =p<0.001, by one-way ANOVA, n= 12

The Sanofi/NaP2b Collaboration



PAYMENTS



- Licensed Technology**
- NaP2b Patent Portfolio and Related Know-how for Research to Complete Activities under Preclinical Development Plan
 - Option to Obtain Exclusive License to Develop, Manufacture and Commercialize NaP2b Inhibitors
- Other Terms**
- Sanofi Responsible for Completing Pre-Clinical Development Plan, and if It Exercises the Option, for All Development and Commercialization at Its Expense
 - Ardelyx Has the Right to Co-Promote in the US

Ardelyx-Owned Pipeline



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RDX009: TGR5 Agonists for Inflammatory Bowel Disease (IBD)



TGR5 STIMULATION

- Enhances GLP1 and GLP2 (Incretins) Secretion Directly to the GI Mucosa
- Anti-Inflammation and Mucosal Healing Effects
- Gattex® = GLP2 approved for Short Bowel Syndrome – Studied in Crohn’s
 - Daily Injections
- Intercept and Exelixis/BMS Both Have Systemic TGR5 Agonists
 - Gallbladder Emptying Issues
 - Short Lasting Incretin Secretion

ARDELYX TGR5 AGONISTS + DPP4 INHIBITOR

- No Gallbladder Issues
- Long Lasting Incretin Secretion
- Significantly Improves Mucosal Damage In Mouse Model of IBD

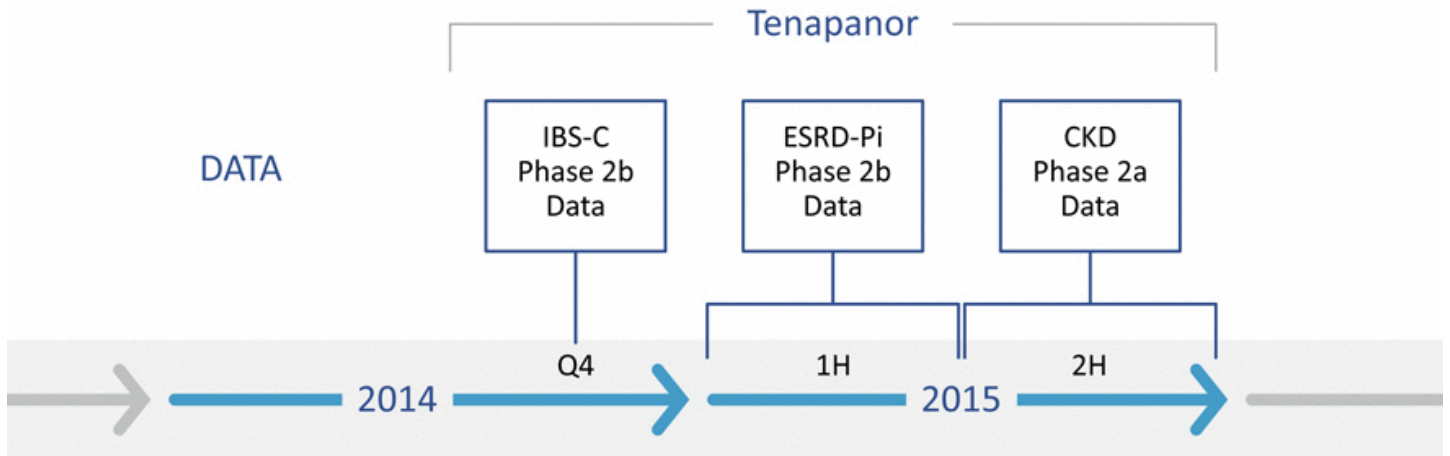
THE CHALLENGE

- All Potassium Binders (e.g. Patiromer) Have Limited Efficacy on per Gram Basis
- Therapeutic Dose for Kayexelate, Patiromer or ZS-9 Substantially the Same (15-30 g/day)
- The Limiting Factor in Efficacy is Not Binder Capacity but Availability of Potassium in the Colon

ARDELYX POTASSIUM “SECRETAGOGUE”

- To Move Potassium into Colon and Increase Fecal Excretion
- Used as a Stand Alone or in Combination with Potassium Binder
- Augment Patient Compliance
- Maintain Normal Serum Potassium with Optimal Dosing of Antihypertensives (RAAS Blockade Drugs)

Near-Term Catalysts to Drive Value



Financial Overview



\$ MILLIONS

Cash and Cash Equivalents	\$33.2M (as of 3/31/14) <ul style="list-style-type: none"> • \$25M Additional Received May 2014 • \$61M received from IPO in July 2014
Operating Expenses*	\$12.5M (12 Months Ended 3/31/14)
Debt	\$0

Capital Raised

<p>Series A \$26M</p> <div style="display: flex; justify-content: space-around;">   </div> <p>2008</p>	<p>Series B \$30M</p> <div style="display: flex; justify-content: space-around;">   </div> <p>AMGEN Ventures</p> <p>2011</p>	<p>IPO \$69M</p> <p>Nasdaq: ARDX</p> 
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*Excludes amounts reimbursed by AZN or associated with AZN agreement

Summary



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