

**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): September 08, 2022**

**PROKIDNEY CORP.**

(Exact name of Registrant as Specified in Its Charter)

**Cayman Islands**  
(State or Other Jurisdiction  
of Incorporation)

**001-40560**  
(Commission File Number)

**98-1586514**  
(IRS Employer  
Identification No.)

**2000 Frontis Plaza Blvd.  
Suite 250  
Winston-Salem, North Carolina**  
(Address of Principal Executive Offices)

**27103**  
(Zip Code)

**Registrant's Telephone Number, Including Area Code: 336 999-7029**

(Former Name or Former Address, if Changed Since Last Report)

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))

**Securities registered pursuant to Section 12(b) of the Act:**

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Class A ordinary shares, \$0.0001 par value per share	PROK	The Nasdaq Stock Market

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.**

ProKidney Corp. (the "Company") has updated its investor presentation (the "Presentation"), which its senior management intends to use from time to time when interacting with investors and analysts, among others. The Presentation is available on the Company's website at <https://investors.prokidney.com/news-events/events-and-presentations>. The Presentation is also attached hereto as Exhibit 99.1.

The information in this report is being furnished, not filed, pursuant to Regulation FD. Accordingly, the information in Items 7.01 and 9.01 of this report will not be incorporated by reference into any registration statement filed by the Company under the Securities Act of 1933, as amended, unless specifically identified therein as being incorporated therein by reference. The furnishing of the information in this report is not intended to, and does not, constitute a determination or admission by the Company that the information in this report is material or complete, or that investors should consider this information before making an investment decision with respect to any security of the Company or any of its affiliates.

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**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits.

The exhibits filed as part of this Current Report on Form 8-K are listed in the index to exhibits immediately preceding the signature page to this Current Report on Form 8-K, which index to exhibits is incorporated herein by reference.

<b>Exhibit No.</b>	<b>Description of Exhibit</b>
99.1	<a href="#">Investor Presentation</a>
104	Cover Page Interactive Data File (embedded within Inline XBRL document)

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**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

**PROKIDNEY CORP.**

Date: September 8, 2022

By: /s/ James Coulston

Name: James Coulston

Title: Chief Financial Officer

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# Renal Autologous Cell Therapy

*A Step Closer to Potential Dialysis Prevention*

ProKidney Corp.  
Nasdaq: PROK

September 2022



## Forward-looking Statements

This presentation includes “forward-looking statements” within the meaning of the “safe harbor” provisions of the Private Securities Litigation Reform Act of 1995. ProKidney’s actual results may differ from its expectations, estimates and projections and consequently, you should not rely on these forward-looking statements as predictions of future events. Words such as “expect,” “estimate,” “project,” “budget,” “forecast,” “anticipate,” “intend,” “plan,” “may,” “will,” “could,” “should,” “believes,” “predicts,” “potential,” “continue,” and similar expressions (or the negative versions of such words or expressions) are intended to identify such forward-looking statements. These forward-looking statements include, without limitation, the Company’s expectations with respect to financial results, future performance, development and commercialization of products, if approved, the potential benefits and impact of the Company’s products, if approved, potential regulatory approvals, and the size and potential growth of current or future markets for the Company’s products, if approved. Most of these factors are outside of the Company’s control and are difficult to predict. Factors that may cause such differences include, but are not limited to: the inability to maintain the listing of the Company’s Class A ordinary shares on the Nasdaq; the inability to implement business plans, forecasts, and other expectations or identify and realize additional opportunities, which may be affected by, among other things, competition and the ability of the Company to grow and manage growth profitably and retain its key employees; the risk of downturns and a changing regulatory landscape in the highly competitive biotechnology industry; the inability of the Company to raise financing in the future; the inability of the Company to obtain and maintain regulatory clearance or approval for its products, and any related restrictions and limitations of any cleared or approved product; the inability of the Company to identify, in-license or acquire additional technology; the inability of Company to compete with other companies currently marketing or engaged in the biologics market and in the area of treatment of kidney diseases; the size and growth potential of the markets for the Company’s products, if approved, and its ability to serve those markets, either alone or in partnership with others; the Company’s estimates regarding expenses, future revenue, capital requirements and needs for additional financing; the Company’s financial performance; the Company’s intellectual property rights; uncertainties inherent in cell therapy research and development, including the actual time it takes to initiate and complete clinical studies and the timing and content of decisions made by regulatory authorities; the impact of COVID-19 or geo-political conflict such as the war in Ukraine on the Company’s business; and other risks and uncertainties indicated from time to time in the Company’s filings with the Securities and Exchange Commission. The Company cautions readers that the foregoing list of factors is not exclusive and cautions readers not to place undue reliance upon any forward-looking statements, which speak only as of the date made. The Company does not undertake or accept any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements to reflect any change in its expectations or any change in events, conditions or circumstances on which any such statement is based.

# What is ProKidney?

REACT™ Aims to be the Disruptive World Leader in Treating Chronic Kidney Disease (CKD)

## The Problem

- \$130 billion Medicare cost to care for the 40 million CKD/ESKD patients in U.S.
- 75 million CKD patients in the U.S. and EU

## The Goal

- Stabilize, or reverse the decline of kidney function to delay or prevent dialysis / renal transplantation
- Reduce the lifetime cost of care for CKD afflicted patients

## The Product

- REACT™ utilizes proprietary autologous cell therapy harvested from the patient's own kidney
- REACT™ includes three specific cell types with the potential to help restore kidney function

## The Plan

- Phase 3 clinical program received FDA and EMA guidance; trial underway
- Target commercial launch in 2026

## The Mission

- Meaningfully reduce the number of people on dialysis or requiring transplantation each year
- Target population includes millions of diabetic CKD patients
- Potential indications expand up to 33 million patients in the U.S. and EU alone

# We are ProKidney

## Novel Investigational Cell Therapy Platform in Late-stage Clinical Trials Aimed at Transforming CKD Treatment

- REACT™ autologous cell therapy currently conducting Phase 3 trials for diabetic CKD
- Pre-clinical through Phase 2 programs in additional indication
- 2019: Acquired technology in development since 2004
- 80+ employees
- \$597M received from July 2022 business combination with Social Capital Suvretta Holdings III and concurrent PIPE
- Nasdaq-listed: PROK
- Top shareholder: Pablo Legorreta (~40% of shares outstanding); 4-year lockup on 50% of shares

Summary of Active Clinical Studies

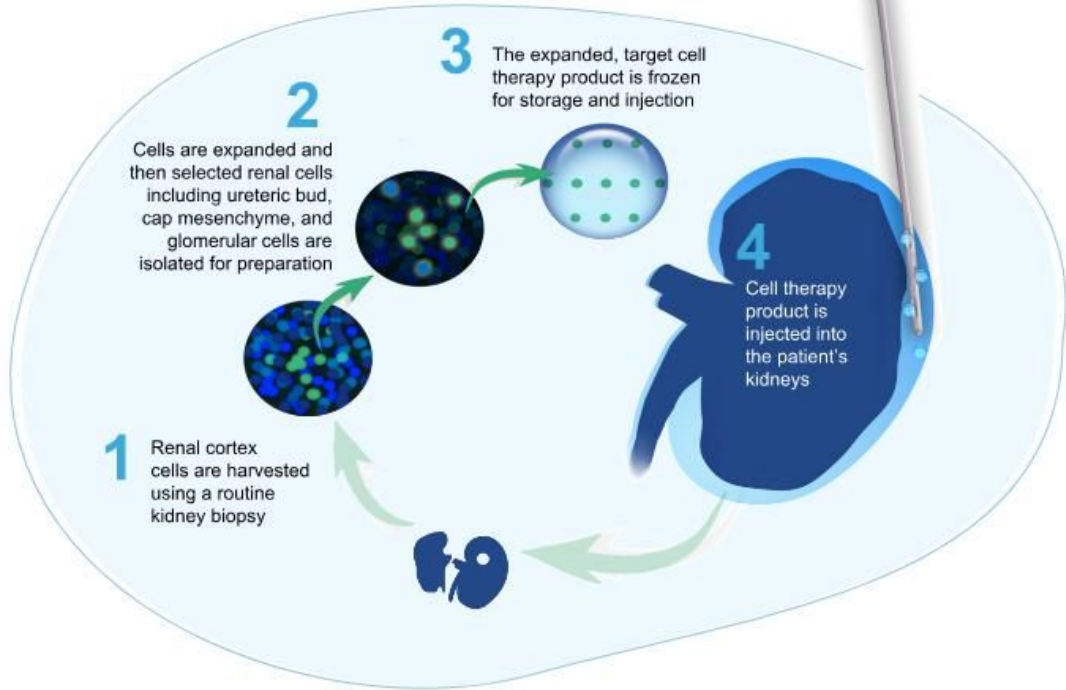
Study	Objective	Status	Projected Data Readout
RMCL-002 (Ph2)	Safety & efficacy in Stage 3b/4 CKD	Fully enrolled	4Q 2023
REGEN-003 (Ph2)	Safety & efficacy in Stage 4/5 CKD	Fully enrolled	1H 2023
REGEN-007 (Ph2)	Bilateral injections Frozen product	Enrolling	2Q/3Q 2023
REGEN-006 / 016 (Ph3)	US Registration (006) OUS Registration (016)	Enrolling in U.S.	4Q 2024 (006)

Existing therapies slow the progression of CKD;  
**REACT's objective is to reverse it**

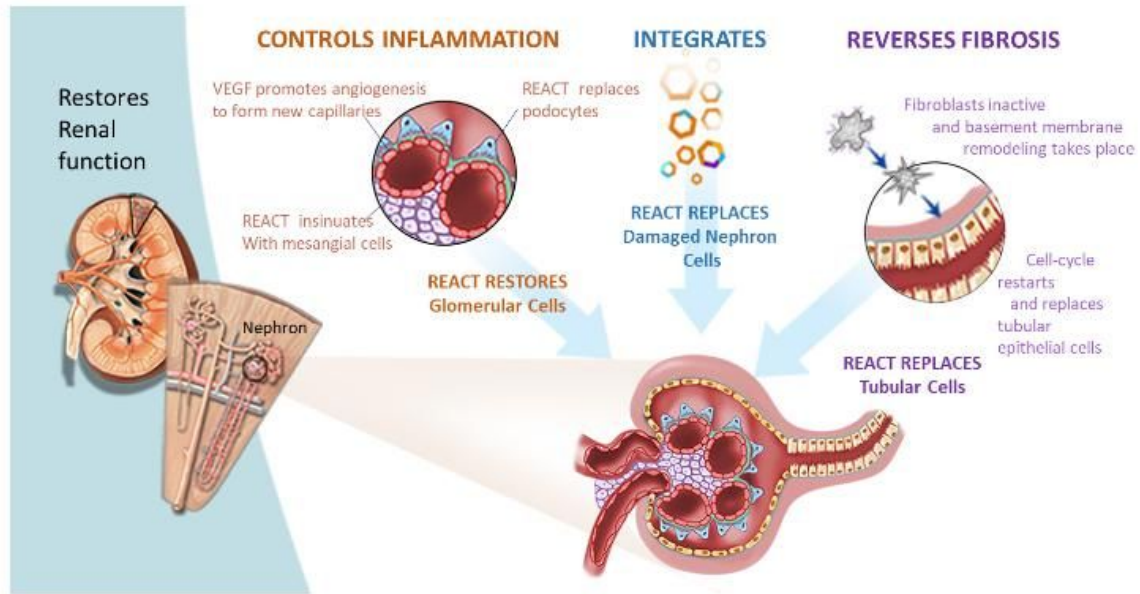


# REACT™ Goal: Restoration of Kidney Function

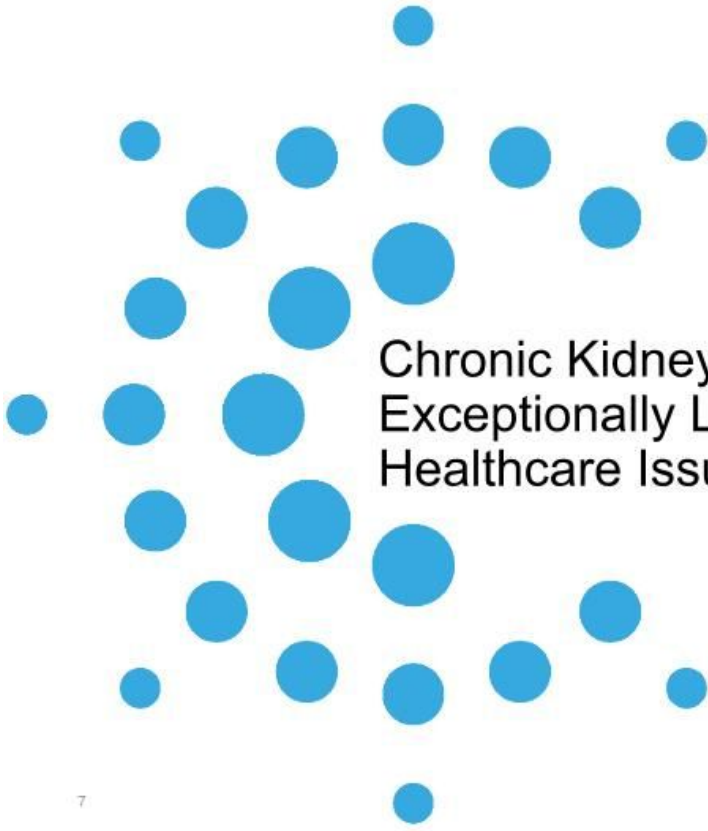
ProKidney's REACT™ Autologous Cell Therapy



## Preclinical Data Suggest REACT™ Treatment May Improve Kidney Function Via Multiple Mechanisms



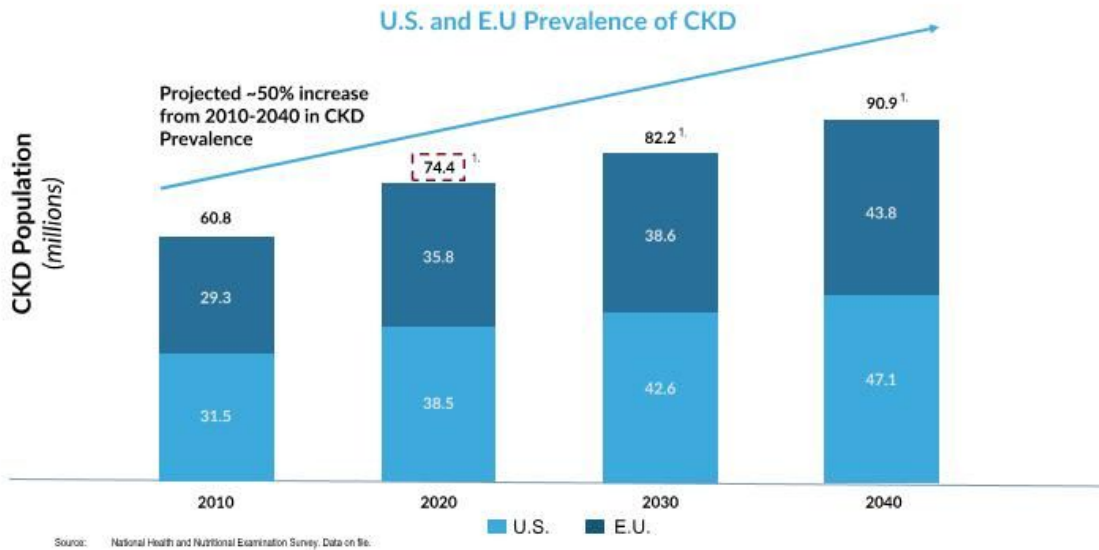
Kelly et al, Am J Physiol Renal Physiol 299: F1026-F1039, 2010. Bruce et al, Regenerative Medicine 10(7), 2015. Preclinical studies in rodents and canines, data on file.



Chronic Kidney Disease Represents an  
Exceptionally Large, Worldwide  
Healthcare Issue

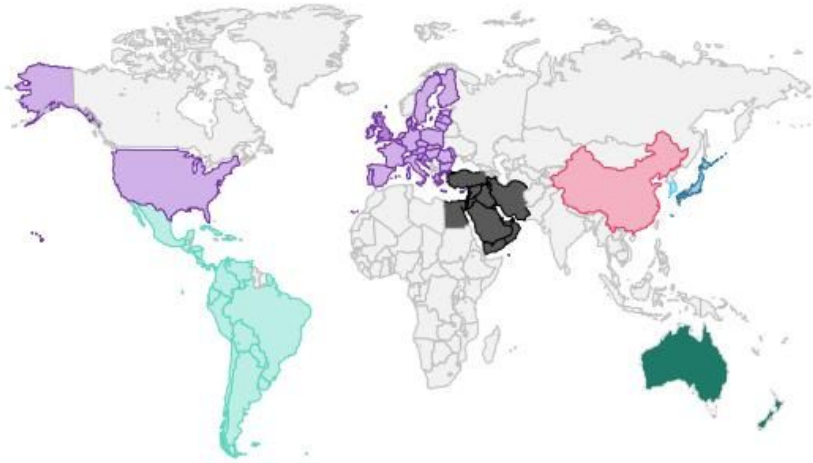
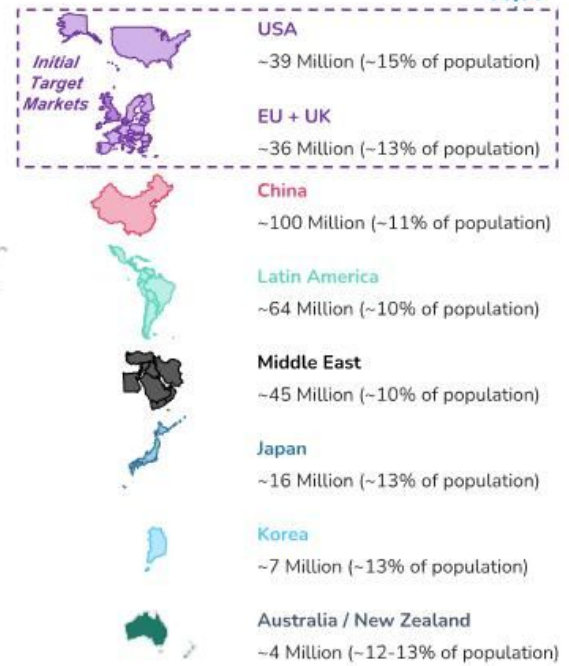
# CHRONIC KIDNEY DISEASE MARKET IS BIG

CKD is Highly Prevalent in the U.S. & E.U.



# CKD Global Market Opportunity

CKD Presents Attractive Core US And EU Market Opportunity of **~75 Million** Individuals with an Additional **230+ Million** Individuals in ROW



Source: International Society of Nephrology Global Kidney Health Atlas; Saudi Center for Organ Transplantation; Imai et al, Prevalence of chronic kidney disease in the Japanese general population. Clin Exp Nephrol. 2009; Oh, KH., Park, S.K., Park, H.C. et al. KNOW-CKD (KoreaN cohort study for Outcome in patients With Chronic Kidney Disease): design and methods. BMC Nephrol 15, 80 (2014); White et al, Comparison of the prevalence and mortality risk of CKD in Australia using the CKD Epidemiology Collaboration (CKD-EPI) and Modification of Diet in Renal Disease (MDRD) Study GFR estimating equations: the AusDiab (Australian Diabetes, Obesity and Lifestyle) Study. Am J Kidney Dis. 2010 Apr; USRDS 2020 Annual Data Report; National Health and Nutrition Examination Survey (NHANES)



# Treating CKD is Very Costly

## CKD/Dialysis is One of the Largest Healthcare Expenditure Categories in the U.S. and ROW

**~\$80 Billion**

Annual Medicare spend on Chronic Kidney Disease

**~\$50 Billion**

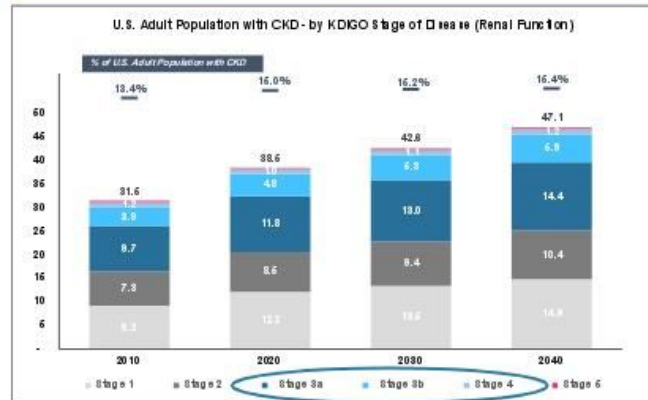
Annual Medicare spend on End Stage Renal Disease

**~\$93 Thousand**

Medicare annual cost per patient for dialysis

Private insurance may pay up to **4x** Medicare costs

The Rates of CKD & ESKD and Associated Expenditures are Expected to Continue to Rise



Source: Medicare spend and per patient dialysis cost as of 2018. United States Renal Data System - USRDS 2020 Annual Report (<https://adr.usrds.org/2020/about-the-new-adr/>). KDIGO refers to Kidney Disease Improving Global Outcomes Data for the year ended 2020 and any subsequent years are based on certain estimates of management. This information may prove to be inaccurate because of the method by which the underlying data for the estimates was obtained or because this information cannot always be verified with complete certainty due to the limits on the availability and reliability of raw data, the voluntary nature of the data gathering process and other limitations and uncertainties.

## Standard of Care has Limitations

- Current Standard of Care merely slows the expected eventual loss of kidney function
- Preliminary Phase 2 data suggest REACT™ has the potential to stabilize or even improve kidney function

## Current Therapies are Blockbusters

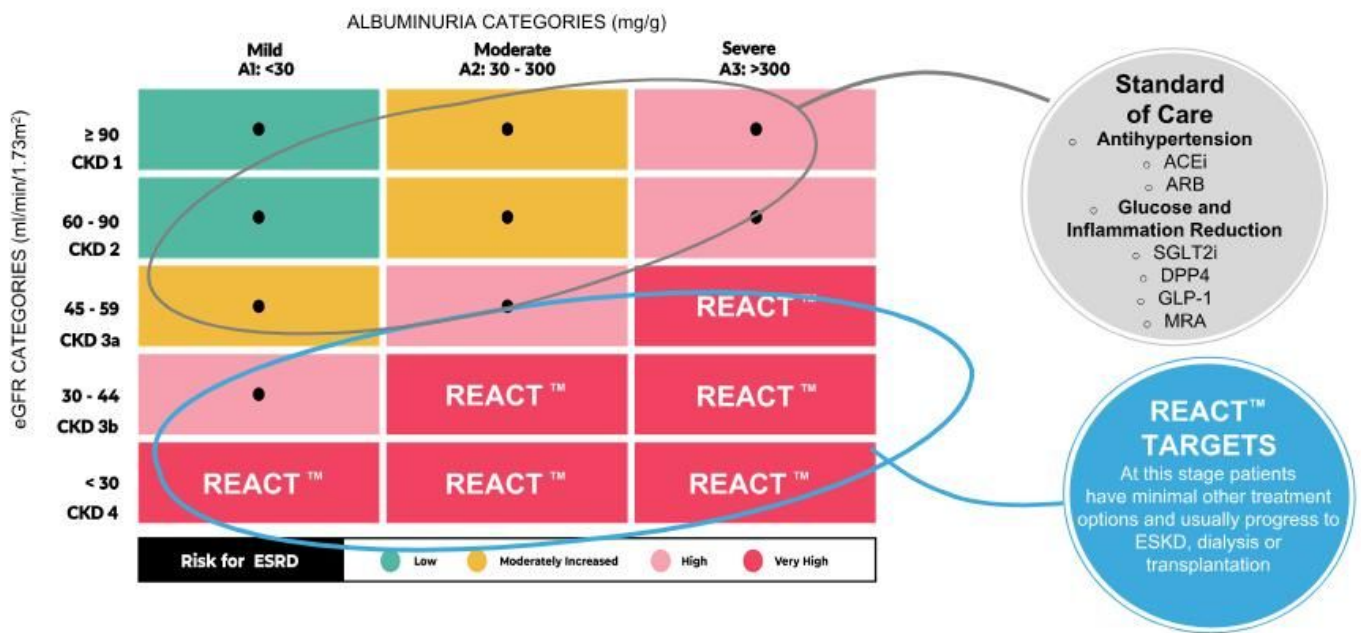
- While patients continue to lose kidney function despite use of existing therapies, these therapies generate multi-billion dollars in sales
- SGLT2 WW revenue (FY 2021, \$USD)

- Dapagliflozin	\$3,000M
- Empagliflozin	\$4,300M
- Canagliflozin	\$ 563M
<i>Total</i>	<i>&gt;\$ 7,800M</i>



# REACT™ May Rescue Highest-Risk Progressors before ESKD

## Unrelenting Progression of CKD with No Available Cures



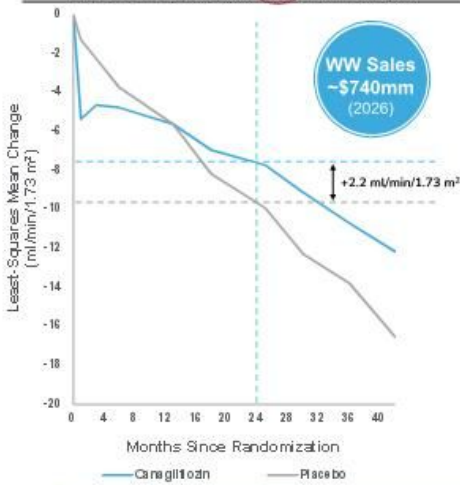
# While New Therapies are a Step Forward, Patients Still Lose Kidney Function



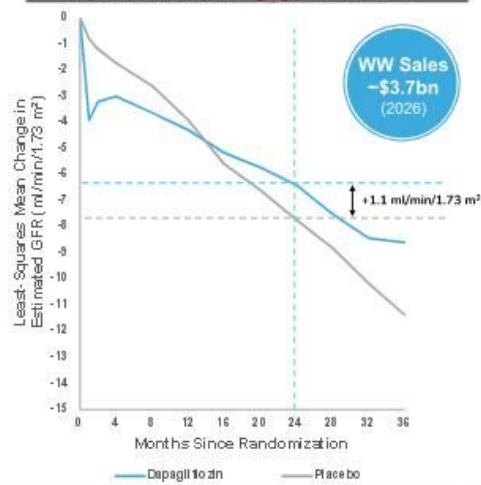
Recently Approved CKD Drugs Incrementally Slow eGFR Loss, but CKD has No Known Cure

## Treatment Effect at 24 Months

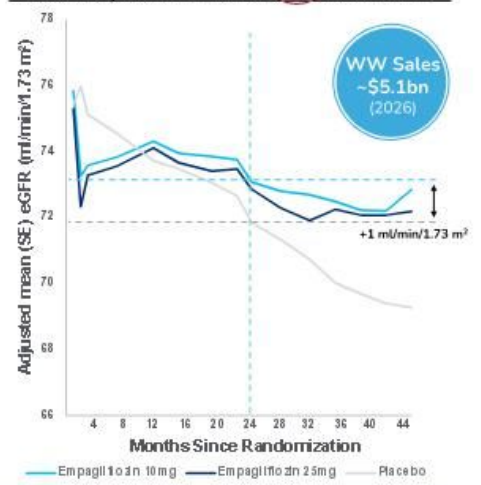
**Canagliflozin:** +2.2 ml/min/1.73 m<sup>2</sup> Improvement  
Baseline mean eGFR of **56.2** ml/min/1.73 m<sup>2</sup>



**Dapagliflozin:** +1.1 ml/min/1.73 m<sup>2</sup> Improvement  
Baseline mean eGFR of **43.1** ml/min/1.73 m<sup>2</sup>



**Empagliflozin:** +1 ml/min/1.73 m<sup>2</sup> Improvement  
Baseline adjusted mean eGFR of **76** ml/min/1.73 m<sup>2</sup>



Estimated Global Market Sales of Canagliflozin, Dapagliflozin and Empagliflozin are ~\$10bn in 2026

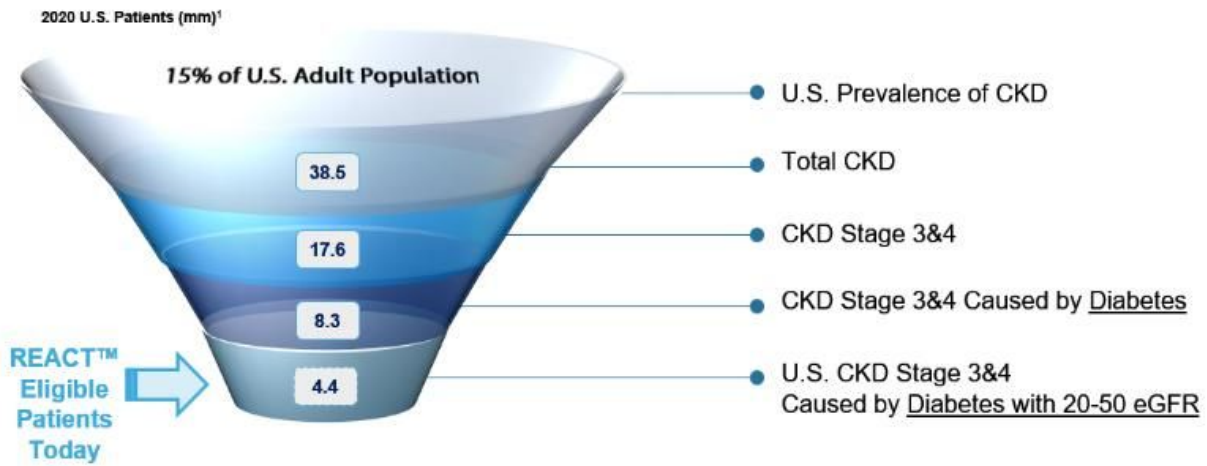
**REACT™** evaluating more severe CKD (30-50 eGFR; mean 32.5 in Ph 2) and data suggests potential to stabilize or even improve kidney function relative to SGLT2s

Source: The New England Journal of Medicine, EvaluatePharma  
Note: 2026 sales estimates for therapies reflect all indications and are not limited to CKD

# The Potential To be Disease Modifying Could Result In Significant Patient Benefits and Reduced Costs to the Healthcare System

# REACT's Addressable U.S. Patient Population

Initially Targeting a 4-5 Million Patient Segment with Multiple Potential Label Expansion Indications

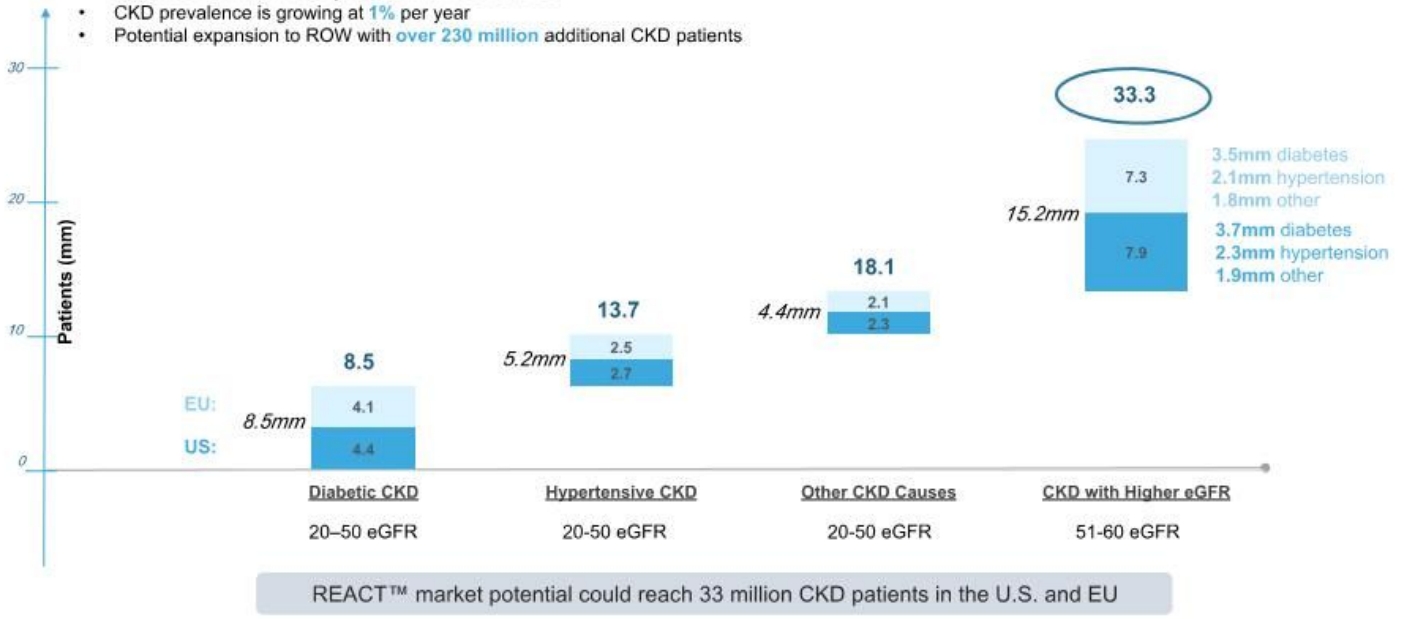


# REACT's Potential Market Expansion in Core US and EU Markets



REACT's target market can reach >30 million patients in the US and EU alone

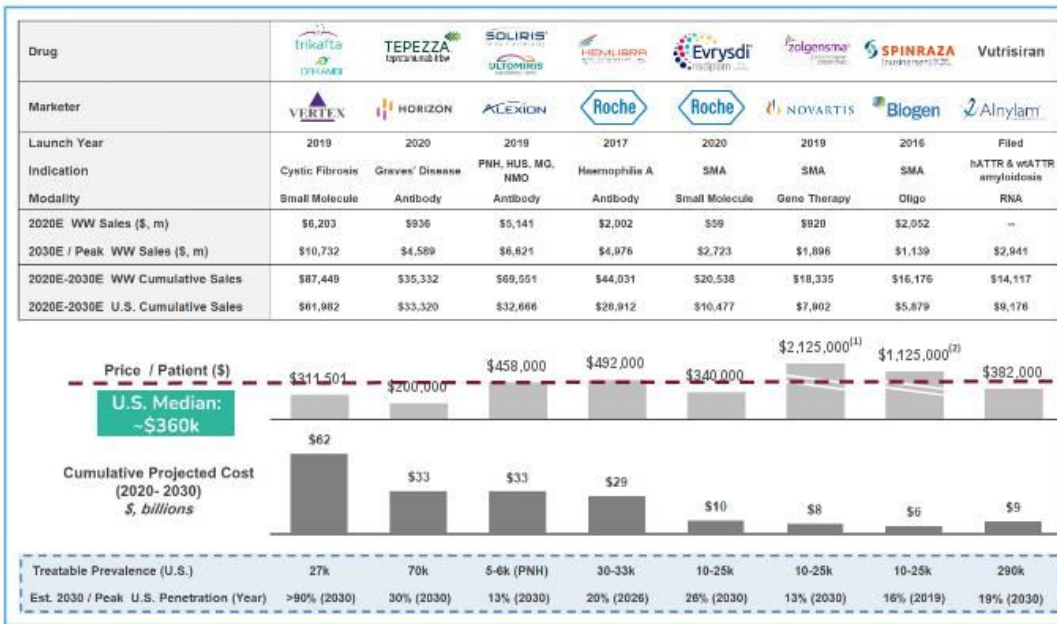
- Estimated 75 million CKD patients in the U.S. and EU
- CKD prevalence is growing at 1% per year
- Potential expansion to ROW with **over 230 million** additional CKD patients



17 Source: Company estimates based upon USRDS Annual Report, and NHANES source data. EU prevalence estimated to be 93% of US prevalence based upon ERA-EDTA registry 2018 Annual Report. Data on file.

# Drug Pricing for Disease Modification

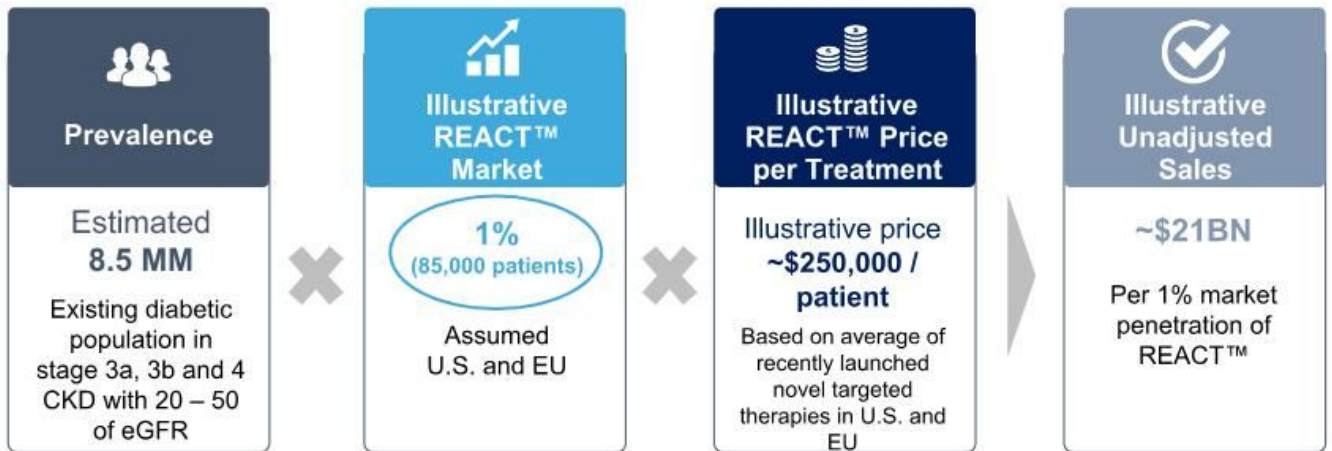
## Recently Launched Novel Targeted Therapies Command High Prices



- Targeted therapies that share 4 characteristics:
1. These are "game changing" (disease-modifying medicines) for the afflicted patients
  2. These targeted therapies treat only between 5k to 70k patients (potentially 290k with Vutrisiran)
  3. These medicines are extremely expensive – cost per patient of \$200k to up to \$2m (mean \$680k) and many billions to healthcare budgets
  4. While expensive and benefitting small numbers of patients, payors have agreed to reimburse them
- Clinical benefit ranges from strong to marginal, yet drugs expected to reach market penetration rates of between 13% to 30% (mean 20%; >90% for CF). These penetration rates are well over REACT's assumed rates

10 Source: Evaluate Pharma, company press release and Wall Street Research for U.S. and WW sales (2020 to 2030); Price per patient from company press releases, trade journals, online pharmacies, etc.; Estimated penetration in U.S. from Wall Street Research or calculated based on forecasted U.S. sales, U.S. price and prevalent population.

## Meaningful Potential Payoff For REACT™ For Every 1% (85,000 Patients) Market Penetration



Source: Data on file.

# Significant Cost Savings Potential

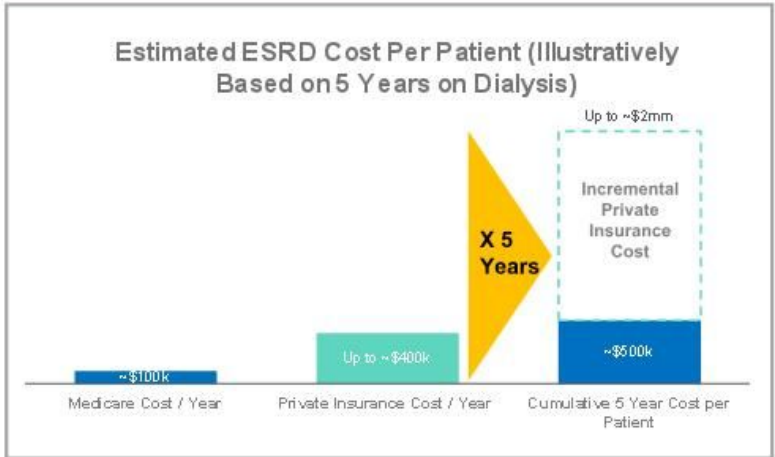
A Disease Modifying Drug in CKD Could Reduce Treatment Cost



ESKD Patients Remain on Dialysis for 5-10 Years on Average

## Potential Impact of a Disease Modifying Product

- Improve Patients' Quality of Life
- Enable Patients to be Productive
- Reduce Burden to Families
- Reduce Healthcare System Costs



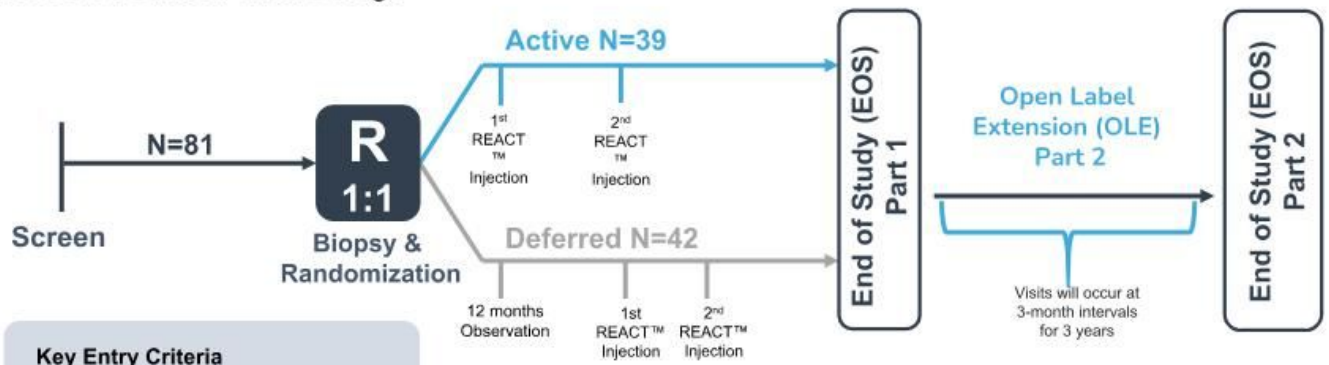
Source: United States Renal Data System - USRDS 2020 Annual Report (<https://adr.usrds.org/2020/about-the-new-adr/>), National Kidney Foundation (<https://www.kidney.org/atoz/content/dialysisinfohow-long-can-you-live-dialysis>), company estimates



## Initial Clinical Data Suggest REACT™

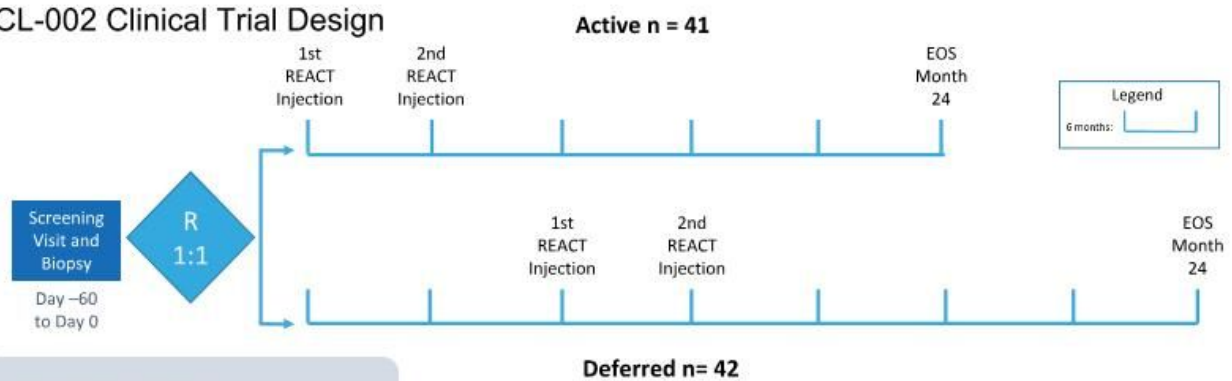
could potentially stop the progression of,  
or even improve, kidney function  
for Individuals with Class 3/4 Diabetic Chronic  
Kidney Disease (CKD)

RMCL-002 Clinical Trial Design



- Key Entry Criteria**
- Type 2 Diabetic Mellitus (DKD)
  - Male or Female 30-80 years of age
  - eGFR  $\geq 20$  and  $\leq 50$  mL/min/1.73m<sup>2</sup>
  - Not on renal dialysis, HbA1c <10%

RMCL-002 Clinical Trial Design



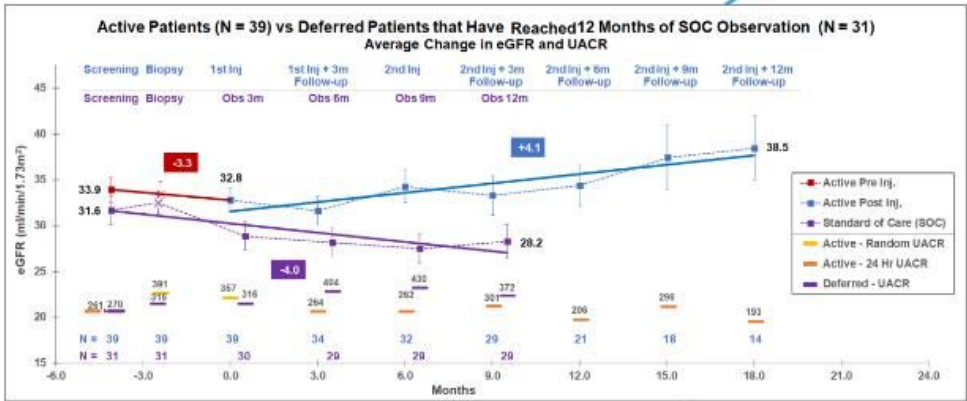
**Key Entry Criteria**

- Type 2 Diabetic Mellitus (DKD)
- Male or Female 30-80 years of age
- eGFR  $\geq 20$  and  $\leq 50$  mL/min/1.73m<sup>2</sup>
- Not on renal dialysis, HbA1c <10%

Follow-up visits conducted at 3-month intervals after 3 months post 2<sup>nd</sup> REACT injection for 24 months until End of Study part 1

# Preliminary Results From RMCL-002 Phase II Trial In Diabetics With CKD Stages 3A, 3B & 4

Comparing Effect of REACT™ vs Standard of Care in Phase 2 Study



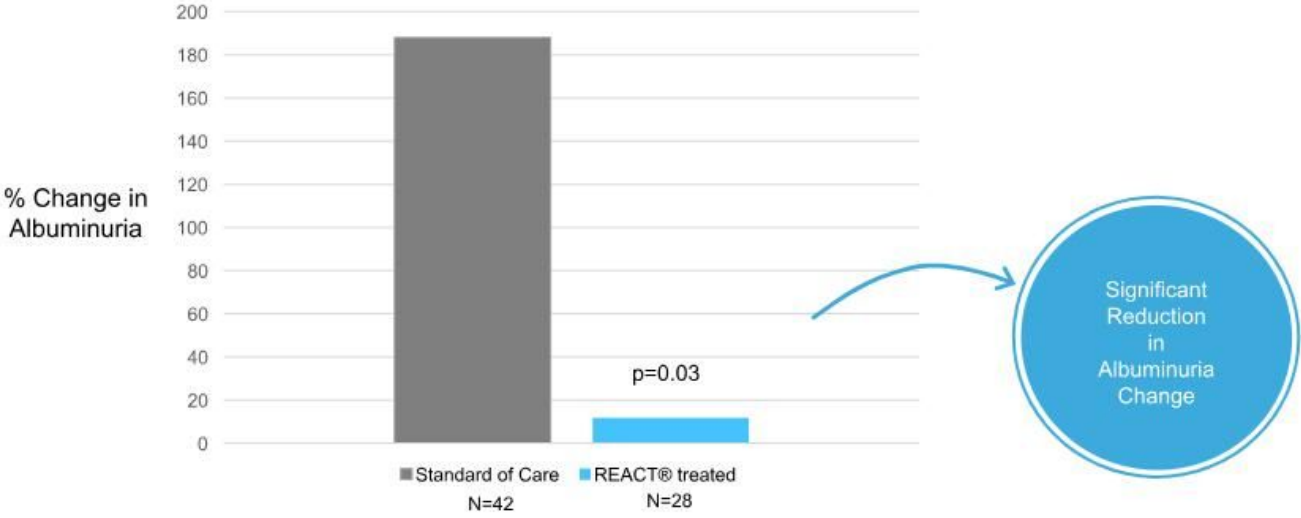
**REACT™**  
Renal function *improved* by  
**+ 4.1 ml/min/1.73m<sup>2</sup>/yr**  
An absolute improvement over 18 months of  
**+ 5.7 ml/min/1.73m<sup>2</sup>**

**Standard of Care**  
Progressive *decline* in renal function of  
**-4.0 ml/min/1.73m<sup>2</sup>/yr**  
A characteristic of SOC for CKD 3a, 3b, and 4

Note: As of August 3, 2021, 31 of 42 patients randomized to Deferred Cohort had reached 12 months of follow-up while maintained on best Standard of Care (SOC). The other 11 patients were enrolled in H220 and expected to reach 12 months of follow-up later in 2021

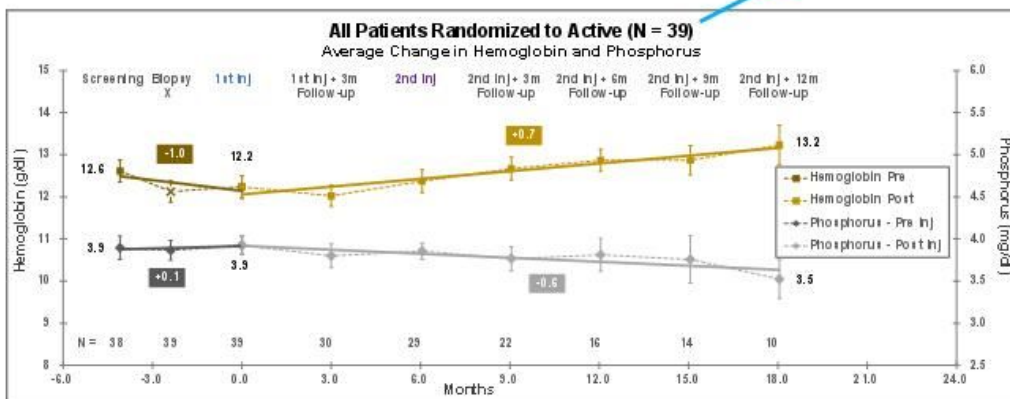
# Preliminary Results from RMCL-002 Trial In Diabetics With CKD Stages 3A, 3B & 4

## Impact on Albuminuria vs. Control in Phase 2 Study



# Preliminary Results From RMCL-002 Trial In Diabetics With CKD Stages 3A, 3B & 4

## Effect of REACT™ on Serum Hemoglobin and Phosphorus of Active Cohort in Phase 2 Study



**REACT™**  
Stabilization of CKD Comorbidities: Anemia and Phosphatemia

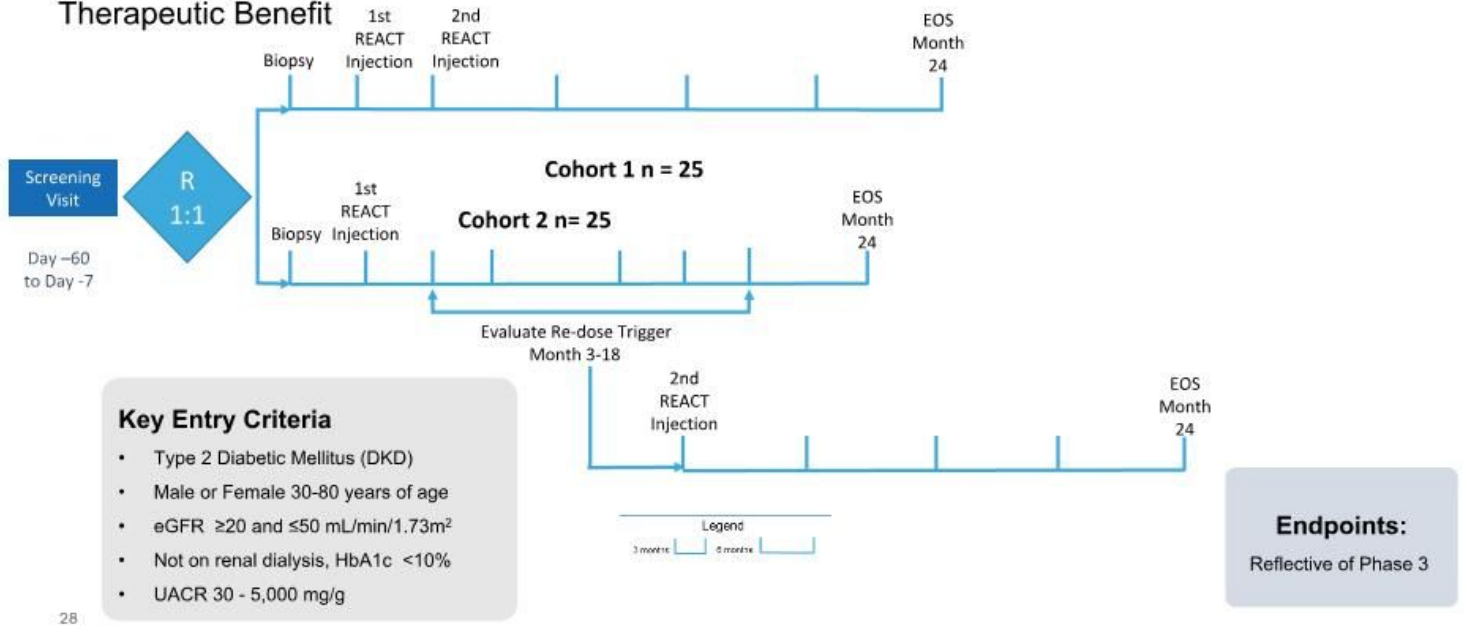


Potential Therapeutic Targets for Treatment of CKD

Lead Platform Programs (Clinical Development)		Preclinical	IND	Phase 1	Phase 2	Phase 3	Registration (BLA/MAA)
<b>REACT™</b> Diabetic Kidney Disease (DKD)	Diabetes Type II – Prevent/Delay CKD 3/4 (20-50 ml/min/1.73m <sup>2</sup> , N = 81)				Phase 2 002 →002 OLE	Fully Enrolled	
	Diabetes Type II – Prevent/Delay CKD 3/4 (20-50 ml/min/1.73m <sup>2</sup> , N = 1,200)				Phase 3 006/016 →008	Enrolling in U.S.	
	Diabetes Type II – Delay CKD 4/5 (14-20 ml/min/1.73m <sup>2</sup> , N = 10)				Phase 2 003	Trial Completed	
	Diabetes Repeat Dose Prevent/Delay CKD 3/4 (20-50 ml/min/1.73m <sup>2</sup> , N= 50*)				Phase 2 (injecting both kidneys w/ re-dose trigger) 007	Enrolling	
<b>REACT™</b> Congenital Anomalies of the Kidney and Urinary Tract (CAKUT)	Congenital Anomalies – Prevent/Delay (14-50 ml/min/1.73m <sup>2</sup> , N= 15)			Phase 1 004	Enrolling		

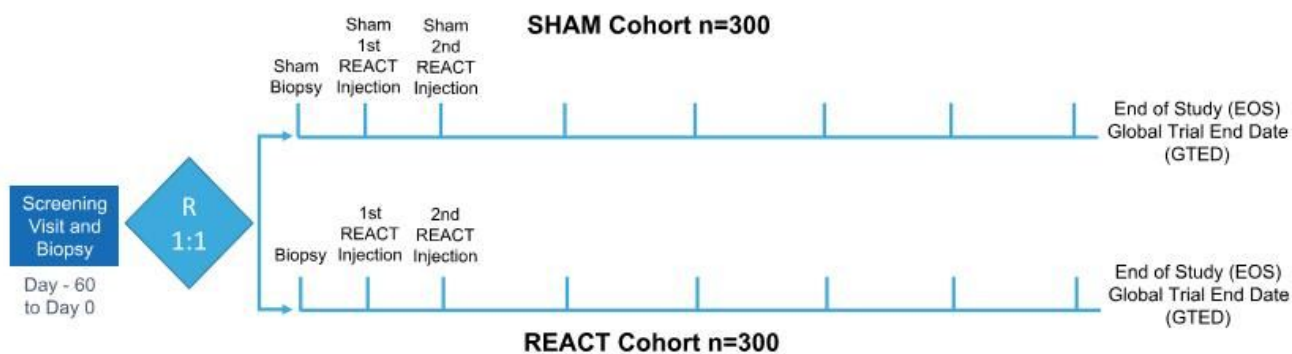
\* Increased from 30 as indicated in Proxy Amendment No. 1, page 289

## Safety Profile Supports Bilateral Dosing of REACT™ to Evaluate Potential for Increased Therapeutic Benefit





First Patients Enrolled Earlier This Year



Screening Visit and Biopsy  
Day - 60 to Day 0

R  
1:1

- Key Entry Criteria**
- Type 2 Diabetic Mellitus (DKD)
  - Male or Female 30-80 years of age
  - eGFR  $\geq 20$  and  $\leq 50$  mL/min/1.73m<sup>2</sup>
  - Not on renal dialysis, HbA1c <10%
  - UACR 300 - 5,000 mg/g



- Time-to-Event Primary Composite Endpoint:**
- At least 40% reduction in eGFR;
  - eGFR <15mL/min/1.73m<sup>2</sup> sustained for 30 days and/or chronic dialysis, and/or renal transplant; or
  - Death from renal or cardiovascular causes

## Regulatory & Reimbursement Engagement Plan

### Diabetic Kidney Disease



#### Conducting 'Gold Standard' Two Adequate and Well Controlled RCT for BLA\* Approval

- RMAT\* Designation provides potential for accelerated approval pathway in U.S.
- Time to event and composite endpoints aligned with registration study designs followed by other CKD therapies (i.e., SGLT2i)



#### HTA\* Potential Healthcare Savings

- Validate REACT delay in time to ESKD (dialysis/transplant) as major healthcare system cost savings with HTAs
- MHRA/NICE\* parallel advice for UK
- U.S., France, Germany HTAs

## Strategy to Produce Commercial Quantities Efficiently

Reliable, established process in-place

Unique industrial process know-how

Step-by-step scale up & build out to peak market demand

Manufacturing efficiency and supply chain streamlining already underway expected to reduce COGS by up to 50% vs. Phase 2 manufacturing cost

## Infrastructure Development and Strategy to Reduce COGS to Serve Addressable Market

### Commercial Manufacturing

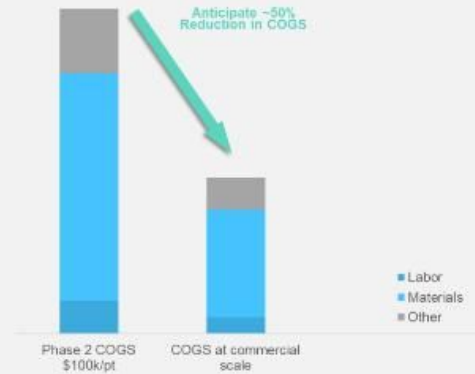
- Staged construction of commercial scale manufacturing facilities
- A facility with capacity of 40,000 patients p.a. is estimated to cost \$700M-\$750M
- Future facilities will be built to meet market demand



### Cost of Goods Sold (COGS)

- Phase 2 COGS for REACT is ~\$100K / patient
- Anticipate COGS to potentially decrease by approximately 50% as scale-up for commercialization

- Supply Chain
- Automation
- Bioprocess developments
- Formulation



# Why ProKidney?

Investment opportunity



## Sponsorship & Team

**Strong healthcare investors, funding runway to commercialization**

Social Capital, Suvretta Capital, existing PROK investors

Healthcare investor expertise already in PROK

\$597 million received through SCS business combination and concurrent PIPE

Experienced management team and Board



## Early Clinical Success

**Candidate kidney therapy seeking to delay/prevent dialysis in CKD**

Phase 2 data show potential to improving multiple kidney function

Open-label 007 Phase 2 will provide insight 2Q/3Q 2023

Phase 3 program underway

RMAT designation from FDA



## Financial Strength

**Strong balance sheet for transformative opportunity**

Capital raised supports Phase 3; Cash runway to interim Phase 3 data

Manufacturing in place for Phase 3, phased scale up planned contingent on approval

\$130 billion Medicare spend on ESKD/CKD

Strong IP & know-how

**Potential benefits to afflicted patients, society, and investors**

# World-class Leadership and Board of Directors



**Dr. Tim Bertram, CEO**

**Dr. Deepak Jain, COO**

**James Coulston, CFO**

**Dr. Libbie McKenzie, CMO**

**Dr. Joe Stavas, SVP Clinical Development**

**Dr. Darin Weber, SVP Regulatory Development**

**Ashley Johns, SVP Clinical Operations**

**Todd Girolamo, Chief Legal Officer & Secretary**

**Pablo Legorreta, Chairman of the Board**

**Dr. Tim Bertram**

**William Doyle**

**Jennifer Fox**

**Dr. Alan Lotvin**

**Dr. John Maraganore**

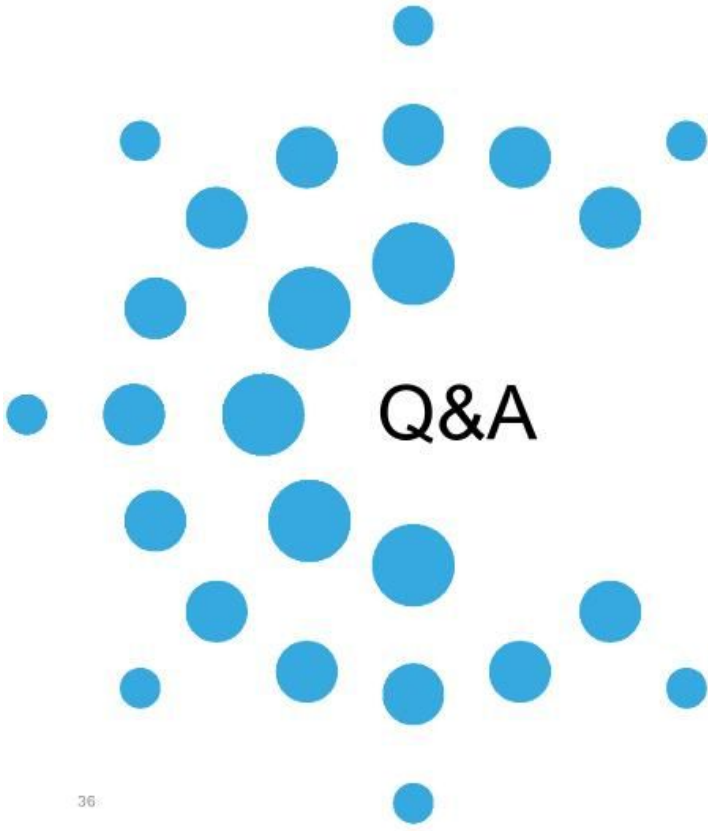
**Dr. Brian Pereira**

**Dr. Uma Sinha**

**José Ignacio Jiménez Santos**

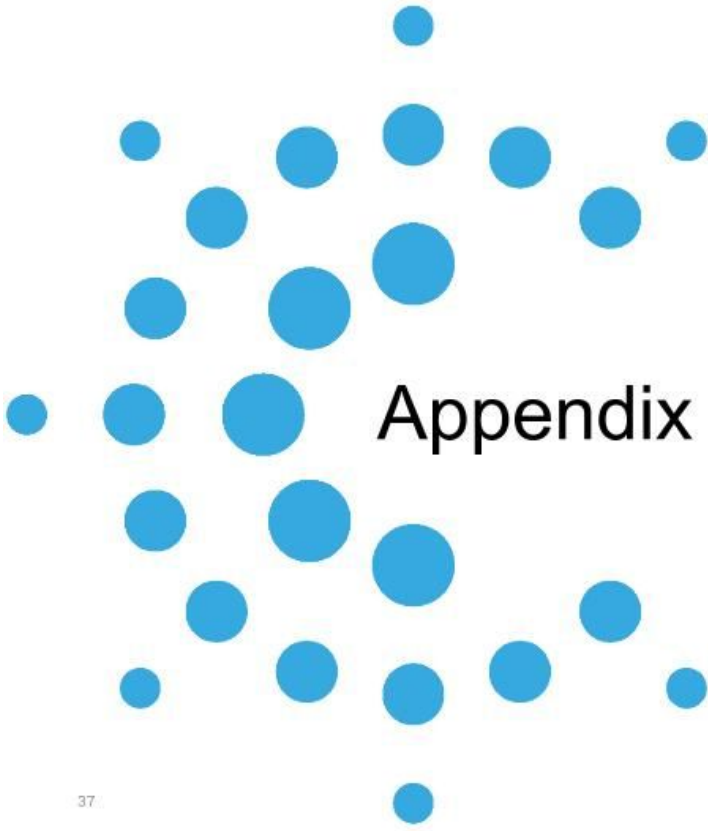
### Aim for Continual Updates on REACT™ Throughout 2022 and Beyond

Early / Mid-stage data updates – RMCL-002; REGEN-003	Throughout 2022, 2023 and 2024
015 Booster Protocol – FDA Feedback	4Q 2022
EMA Scientific Advice	3Q 2022
REGEN-007 – Early data	2Q/3Q 2023
Enrollment milestones – REGEN-006; REGEN-007; RMCL-002; REGEN-003	Throughout 2022, 2023 and 2024
Multiple peer-reviewed publications – Study designs; Clinical data; Mechanism of Action	Throughout 2022, 2023 and 2024



# Q&A





# Appendix