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 11, 2023

PROKIDNEY CORP.

(Exact name of Registrant as Specified in Its Charter)

Cayman Islands	**001-40560**	**98-1586514**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

2000 Frontis Plaza Blvd.
Suite 250
Winston-Salem, North Carolina **27103**
(Address of Principal Executive Offices) **(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.

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.

Exhibit No.	Description of Exhibit
99.1	Investor Presentation
104	Cover Page Interactive Data File (embedded within Inline XBRL document)

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 hereunto duly authorized.

PROKIDNEY CORP.

Date: September 11, 2023

By: /s/ Todd Girolamo

Name: Todd Girolamo
Title: Chief Legal Officer

Exhibit 99.1

PROKIDNEY

Corporate Presentation

September 2023

A Step Closer to Potential Dialysis Prevention

REACT® [**RE**nal **A**utologous **C**ell **T**herapy]

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 REACT®?

REACT is a cell therapy solution for patients with Chronic Kidney Disease (CKD), worldwide

Unmet Needs

- More than **37 million U.S. adults** have CKD[1]. Greater than 120,000 progress to need dialysis every year.[2]
- Total annual costs to Medicare for patients with CKD / ESRD exceed $130B[1]
- Average per person per year cost for ESRD **for commercially insured members $180K**[3]

Our Goals

- **Preserve kidney function**
- **Reduce or eliminate time spent on dialysis**
- **Return autonomy to patients and their families**

Our Product

- REACT® is a **proprietary** cell therapy using the patient's own kidney cells
- **Preclinical activity** and mechanism of action **translated to clinical activity**
- REACT® includes three cell subtypes with the potential to help **preserve kidney function**

Our Plan

- Phase 3 clinical program received FDA and EMA guidance and RMAT designation; **proact 1** underway
- Potential label expansion to re-dose REACT for long-term dialysis prevention
- **Target commercial launch YE 2026**

1. *CDC Fact Sheet. https://www.cdc.gov/kidneydisease/publications-resources/ckd-national-facts.html*
2. *USRDS 2020 Annual Report*
3. *JAMA Int Medicine 2019*

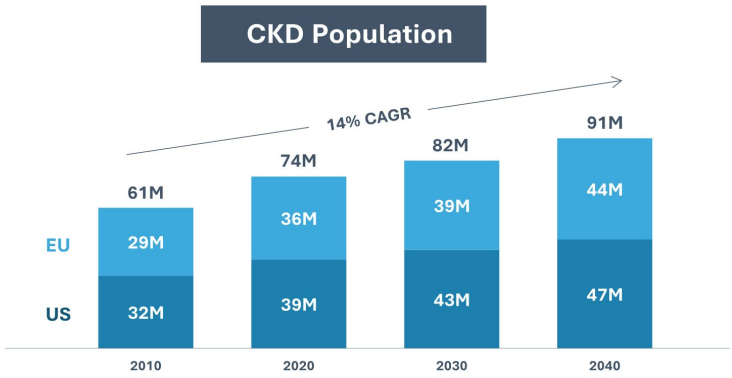
CKD is Serious Public Health Problem Today

One of the largest healthcare expenditure categories in the U.S.

Medicare spend on Chronic Kidney Disease	Medicare spend on End Stage Renal Disease	Medicare annual cost per patient on dialysis[1]
$80B+	**$50B+**	**$93K+**

Private insurance may pay up to 4x Medicare costs[2]

Highly prevalent in the U.S. and EU



Kidney failure costs represent one of the largest line items of Medicare Budget

1. Medicare spend and per patient dialysis cost as of 2018. United States Renal Data System - USRDS 2020 Annual Report
2. JAMA Int Medicine 2019

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

Standard of Care has Limitations

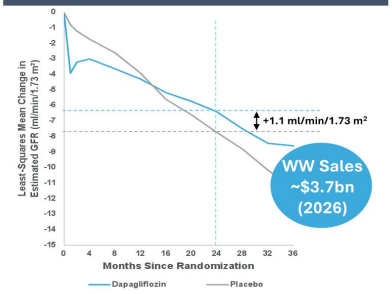
Current standard of care for DKD Stage 2/3a (eGFR above 40) merely slows the eventual loss of kidney function

Current Therapies are Blockbusters

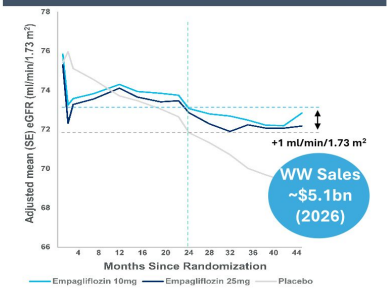
While patients continue to lose kidney function on existing therapies, those therapies still generate nearly $10 billion WW sales annually

Canagliflozin: +2.2 ml/min/1.73 m² Improvement
Baseline mean eGFR of ***56*** ml/min/1.73 m²

Dapagliflozin: +1.1 ml/min/1.73 m² Improvement
Baseline mean eGFR of ***43*** ml/min/1.73 m²



Empagliflozin: +1 ml/min/1.73 m² Improvement
Baseline adjusted mean eGFR of ***76*** ml/min/1.73 m²



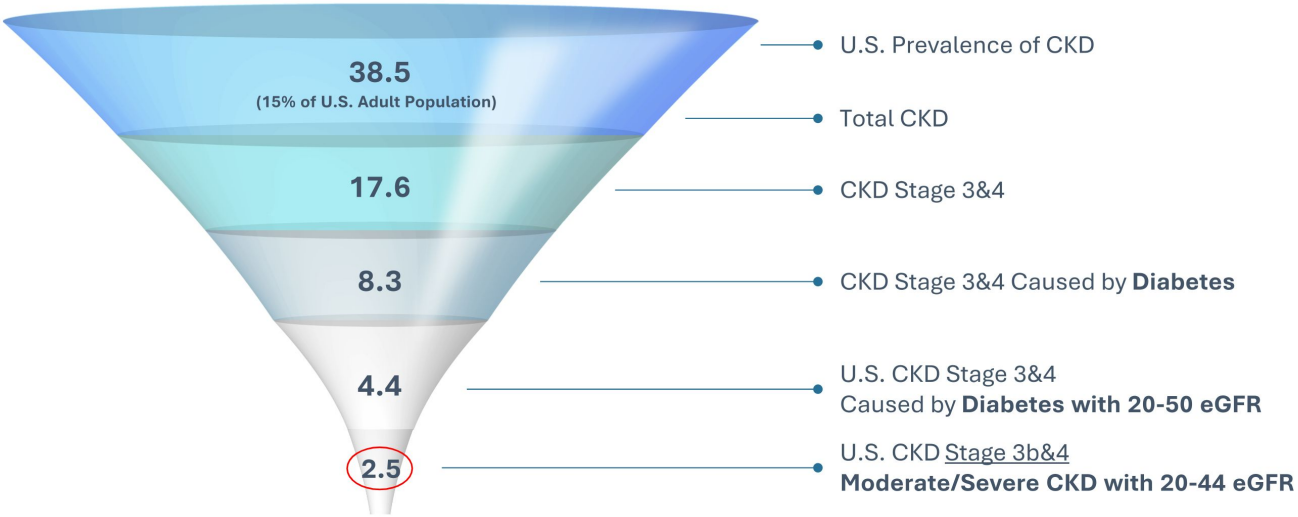
Estimated global market sales of Canagliflozin, Dapagliflozin and Empagliflozin are **~$10B** in 2026

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

REACT initially targets a defined subset of advanced T2D CKD

Potential for multiple label expansions

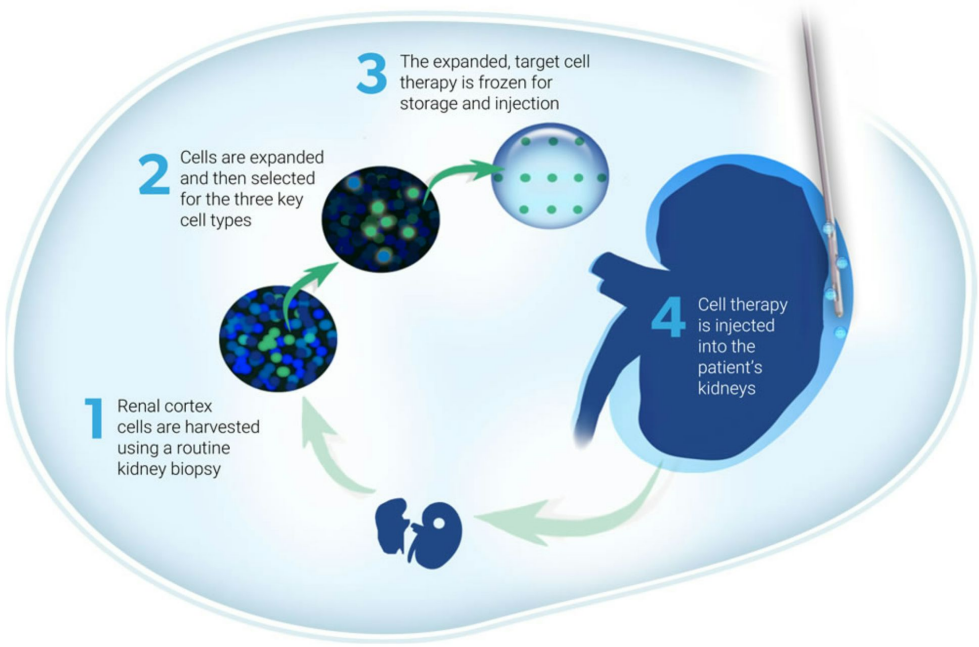
2020 U.S. CKD Prevalence (mm)[1]



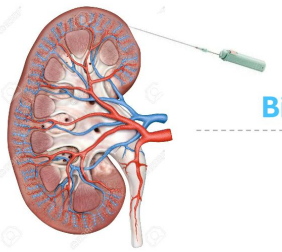
Total market data for the year ended 2020 is based on certain estimates of management. This information may prove to be inaccurate because of the method by which the underlying data for the estimates was obtained or because this information cannot always be verified with complete certainty due to the limits on the availability and reliability of raw data, the voluntary nature of the data gathering process and other limitations and uncertainties

REACT® Goal: Preservation of Kidney Function

ProKidney's REACT® Autologous Cell Therapy



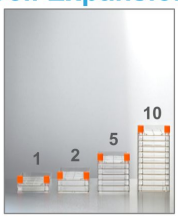
REACT® Goal: Preservation of Kidney Function



Biopsy

Biopsy Processing

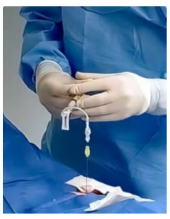
Cell Expansion



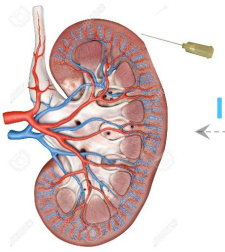
Cell Selection

Dose Preparation

Cell Delivery



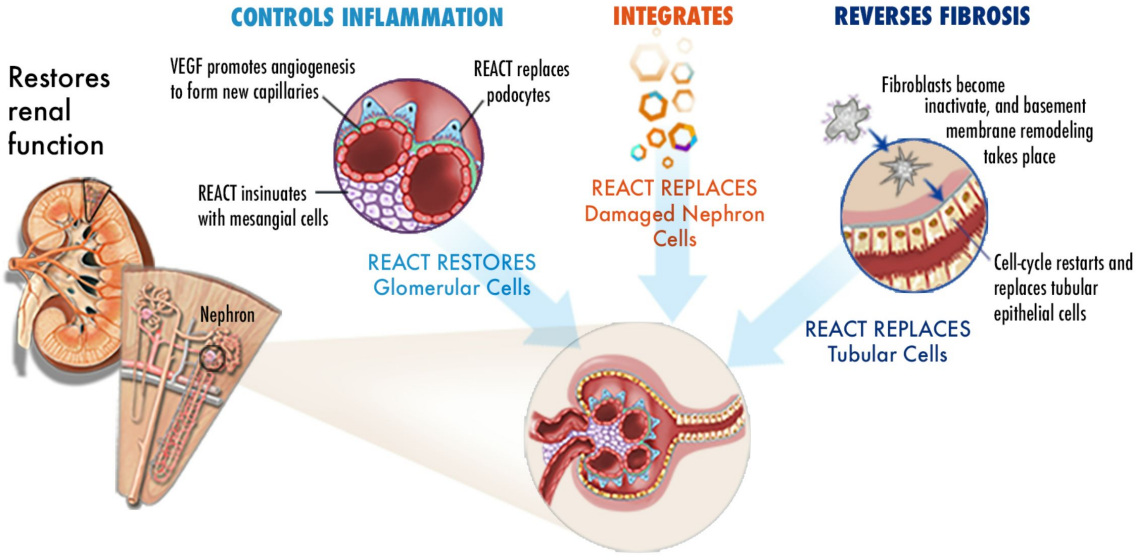
Implantation



12 weeks from biopsy to cell delivery

REACT® Impact on Kidney Function

Preclinical data suggests 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.

Remodeling of Nephrons

REACT® targets preservation of kidney function for dialysis-free living

REACT®: Autologous Homologous Triple Cell admixture

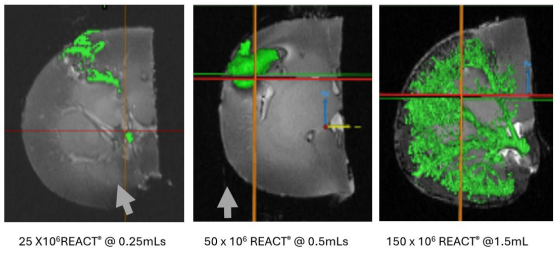
>50 Types of Cells in Adult Kidney → **3** Lineages in REACT®

Renal cells

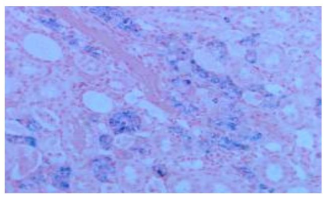
Cap Mesenchyme, Podocytes, and Ureteric Bud:

- Six-2/OSR1/PAX-2 (Cap Mesenchyme)
- RET (Ureteric Bud)
- Podocin / Nephrin

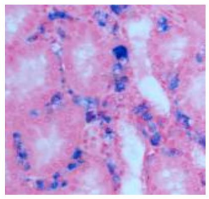
Cells shown to distribute throughout kidney and integrate into nephrons and interstitium



25 X10⁶REACT® @ 0.25mLs | 50 x 10⁶ REACT® @ 0.5mLs | 150 x 10⁶ REACT® @1.5mL



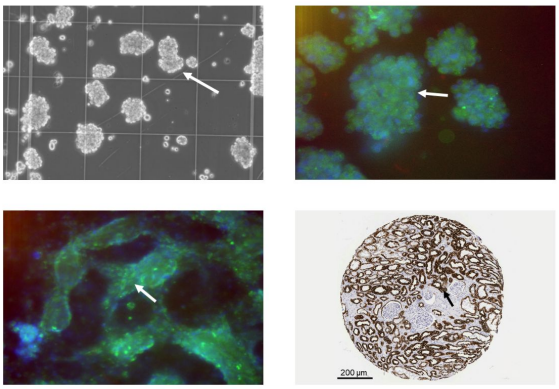
Intra-tubular and Glomerular (REACT® – Blue)



Interstitial (REACT® – Blue)

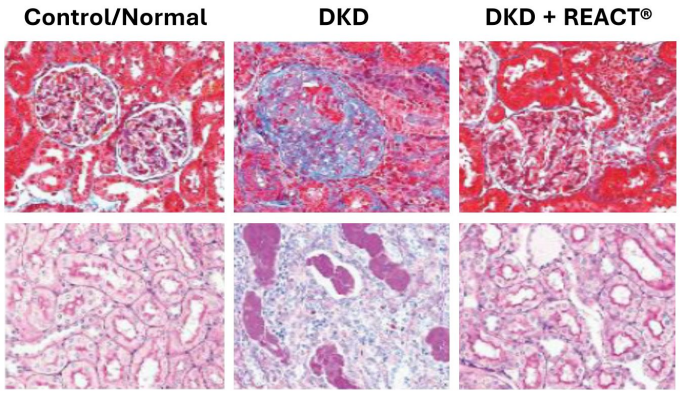
Kelly et al, Am J Physiol Renal Physiol 299: F1026-F1039, 2010. Bruce et al, Regenerative Medicine 10(7), 2015
Preclinical studies in rodents and canines, data on file.

REACT® MoA in CKD – ASN November 2022



SRC/REACT® in human cell culture

- Nephrogenic potential of SRCs may underlie renal restorative and reparative activity observed to-date
- SRCs participate in processes associated with kidney development
- SRCs forms organoids, which self-assemble into tubules *in vitro*



SRC/REACT® preserves kidney microarchitecture

REACT® treated kidney shows reduced glomerular and interstitial fibrosis and inflammation, protein leakage and tubular ectasia

Sources: Gene ontology reveals potentially unique mechanism of action underlying selected renal cells bioactivity. Narayan, et al. Poster at ASN 2022 Annual Meeting: November 4, 2022. Selected renal cells self-organize to form neo-nephrons and attenuate kidney disease. Narayan, et al. Poster at ASN 2022 Annual Meeting: November 4, 2022

REACT® Trials Designed to Address Multiple Types of CKD

Lead Platform Programs (Clinical Development)		PRECLINICAL	IND	PHASE 1	PHASE 2	PHASE 3	STATUS
	Pivotal Trial Progam						
REACT® Diabetic Kidney Disease (DKD)	**Diabetes Type II – Prevent/Delay CKD 3/4** (20-50 ml/min/1.73m², N = 600)	006/proact 1					Enrolling
	Diabetes Type II – Prevent/Delay CKD ¾ stratified for SGLT2i use (20-44 ml/min/1.73m², N = 600)	016/proact 2					US/OUS 2H2023
	Long term follow-up study for patients previously treated with REACT	008					Enrollment 3Q2023
	Supportive Trials						
	Diabetes Type II – Delay CKD 4/5 (14-20 ml/min/1.73m², N = 10)	003					Trial Completed
	Diabetes Type II – Prevent/Delay CKD 3/4 (20-50 ml/min/1.73m², N = 81)	002					Fully Enrolled
	Diabetes Repeat Dose Prevent/Delay CKD 3/4 (20-50 ml/min/1.73m², N= 50*)	007					Fully Enrolled
	Multi / extended-dosing for previously REACT-treated patients	015					Enrolling
REACT® (CAKUT)	**Congenital Anomalies – Prevent/Delay** (14-50 ml/min/1.73m², N= 5)	004					Trial Completed

Frozen product

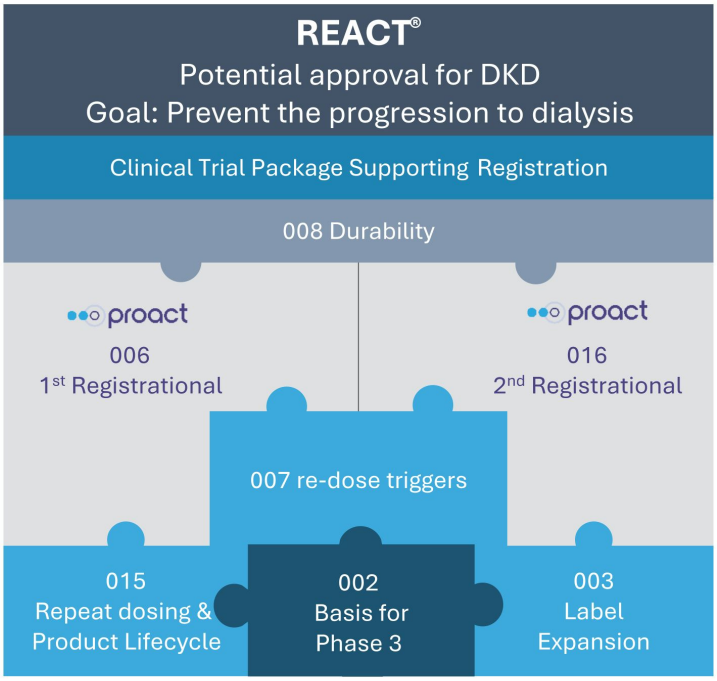
Unilateral injections

bilateral injections

Building a Comprehensive Data Package

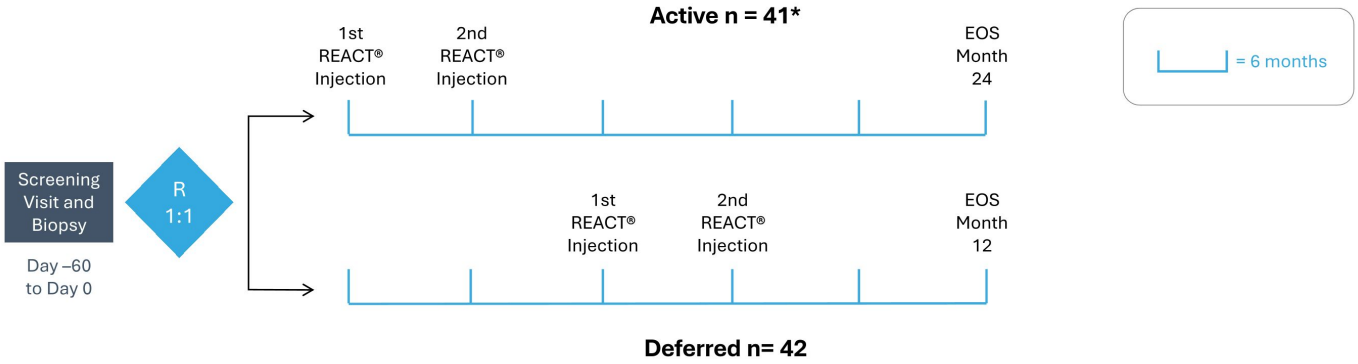
Clinical program designed to expand potential patient population and support premium pricing

- Assess potential benefit of repeat REACT® doses (REGEN-015)
- Determine durability of REACT® injection (REGEN-008)
- Identify re-dosing triggers (REGEN-007)
- Assess potential benefit of bilateral REACT® injections (REGEN-007)
- Support potential label expansion (REGEN-003)
- Support durability, reimbursement and value-based pricing (REGEN-016 & REGEN-008)



RMCL-002: Study in Diabetics with CKD Stages 3A, 3B & 4

Clinical trial design



Key Entry Criteria

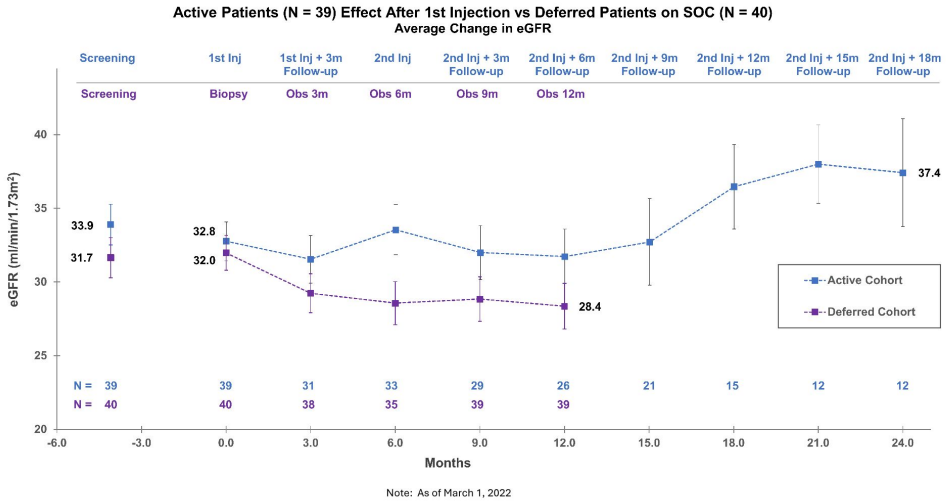
- Type 2 Diabetic Mellitus (DKD)
- Male or female 30-80 years of age
- eGFR ≥20 and ≤50 mL/min/1.73m2
- Not on renal dialysis, HbA1c <10%

Follow-up visits conducted at 3-month intervals after 3 months post 2nd REACT® injection for 24 months for active arm and 12 months post 2nd REACT® injection for Deferred arm

** 2 'Active' patients dropped out of the study resulting in n=39 in subsequent slides.*

RMCL-002: Preliminary Results from Study in Diabetics with CKD Stages 3A, 3B & 4

Comparing effect of REACT® vs. standard of care (SoC) in Phase 2 study



Note: As of March 1, 2022

REACT®

Average eGFR was 4.6 ml/min/1.73m² higher at 24 months versus the average eGFR for all participants at baseline

Standard of Care

Progressive ***decline*** in kidney function over 12 months of

–3.6 ml/min/1.73m²

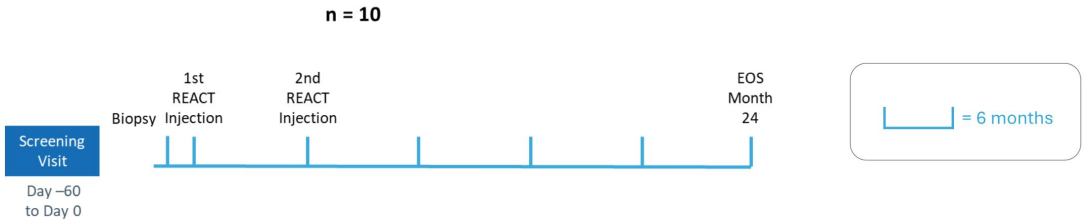
A characteristic of SOC for CKD 3a, 3b, and 4

REGEN-003: Phase 2 Study in Stage 4/5 Diabetic CKD Patients

Clinical trial design: Participants' baseline rate of eGFR decline served as comparator

UACR mean 3190 mg/gr; mean eGFR 15.5 mL/min/1.73m²;
>90% probability of dialysis initiation

No other marketed drug is indicated for these patients



Key Entry Criteria

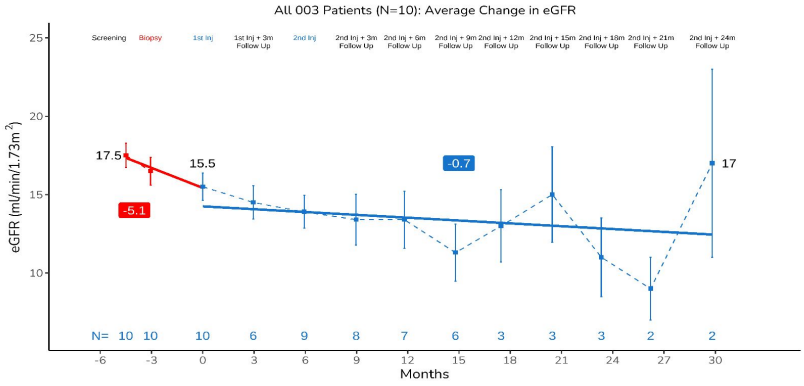
- Type 2 Diabetic Mellitus (DKD)
- Male or female 30-65 years of age
- **eGFR ≥14 - ≤20 mL/min/1.73m²**
- Not on renal dialysis, HbA1c <10%

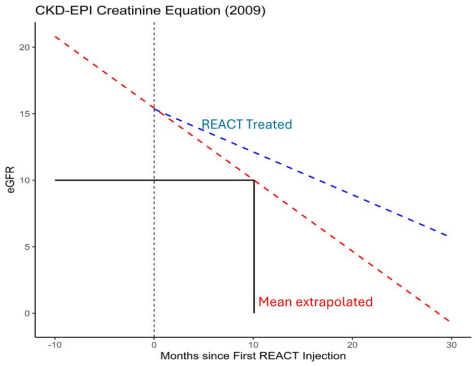
Follow-up visits conducted at 3-month intervals after 3 months post 2nd REACT® injection for 24 months until End of Study

ProKidney

REGEN-003: Pre-Dialysis Patients Benefit from REACT

- 7/10 patients had 30% increase in dialysis free living (median of ~16 mo.)
- 2/10 patients had preservation of renal function >2+ years post injection





Source: *Stavas, et al. Renal Autologous Cell Therapy in Type 2 Diabetes with Late Stage 4 Diabetes-Related Chronic Kidney Disease: Trial Design and Early Analysis. J Blood Purification. Published Online Jan 2023*

Interim Safety Profile: Safety of REACT in Phase 2 Diabetic CKD Stages 3A, 3B, 4, & 5 and CAKUT

-002 Interim procedure-related events: Renal Related
(N=83 pt biopsies, 132 injections)

Serious Adverse Event	n
Hematoma*	1
Transfusion*	1
Acute Kidney Injury*	1
Macroscopic Hematuria	0
Angiographic Intervention	0
Surgery	0
Death	0
CKD progression	1
Renal vascular event	1
Cortical Scar	1
Renal arteriovenous fistula	0

Events observed in 4/83 participants.
*Hematoma, transfusion, & AKI events occurred in one patient pre-needle design-change in Sept. 2017, other SAE events occurred post-needle design change.
Data as 2/23. Source: Stavas et al. SIR March 2023.

-003 Procedure-related events: Renal Related
(N=10 pt biopsies, 19 injections)

Serious Adverse Event	n
Hematoma	2
Transfusion	0
Acute Kidney Injury	2
Macroscopic Hematuria	0
Angiographic Intervention	0
Surgery	0
Death	0
CKD progression	1
Renal vascular event	0
Cortical Scar	0
Renal arteriovenous fistula	1

Events observed in 3/10 participants.
No cell product related SAEs were reported.
Source: Stavas et al. Blood Purif 2023;52:114–121
DOI: 10.1159/000527582

-004 Procedure-related events: Renal Related
(N=5 pt biopsies, 9 injections)

Serious Adverse Event	n
Hematoma	0
Transfusion	0
Acute Kidney Injury	0
Macroscopic Hematuria	0
Angiographic Intervention	0
Surgery	0
Death	0
CKD progression	0
Renal vascular event	0
Cortical Scar	0
Renal arteriovenous fistula	0

Events observed in 0/5 participants.
No cell product related SAEs were reported.
Data on file and as of 1/23.

-007 Interim procedure-related events: Renal Related
(N=39 pt biopsies, 42 injections)

Serious Adverse Event	n
Hematoma*	4
Transfusion	1
Acute Kidney Injury	2
Macroscopic Hematuria	1
Angiographic Intervention	0
Surgery	0
Death	0
CKD progression	0
Renal vascular event	0
Cortical Scar	0
Renal arteriovenous fistula	0

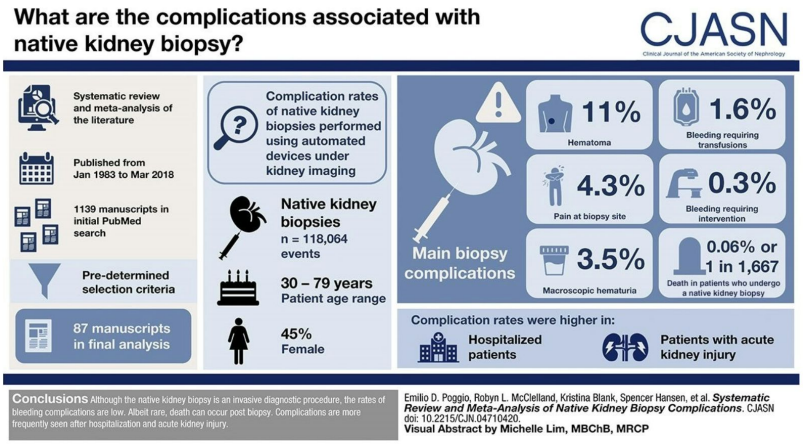
Events observed in 4/39 participants.
*One hematoma associated with an injection. Two hematomas, two AKI, and one hematuria occurred following biopsy.
Data on file and as of 1/23.

202 **REACT®** injections administered to date in Phase 1 and 2 clinical studies

REACT has been tolerated by patients with moderate-severe CKD at high risk for renal failure

Consistently striving to mitigate procedure-related risks while preserving kidney function for late-stage CKD patients

REACT Procedure Continued to Demonstrate a Complication Rate Below a Standard Kidney Biopsy



REACT Phase 2 Safety Profile Summary

Category	Biopsy # of patients (%) (N=133)	REACT Injection # of patients (%) (N=202)
Hematoma	4 (3.0)	3 (1.5)
Pain	0	3 (1.5)
Hematuria	1 (0.7)	0
Transfusion	1 (0.7)	1 (0.5)
Bleed + intervention	0	0
Death	0	0

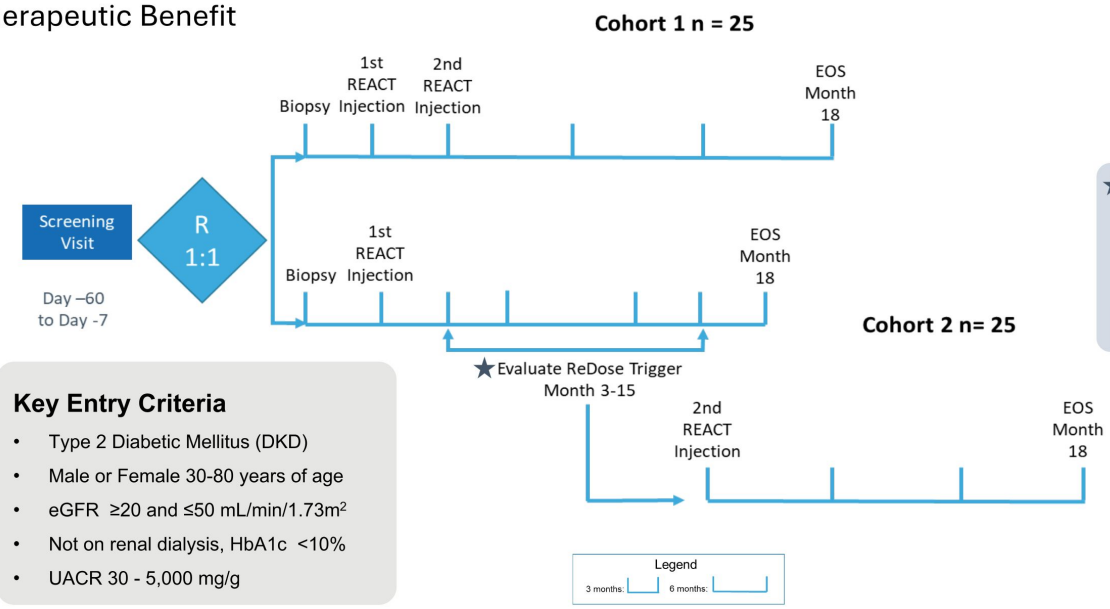
Includes data available from ongoing and completed phase 2 trials.
Data on file and as of 3/1/2023.

REACT procedure in Phase 2 clinical trials was tolerated with a safety profile similar to a standard biopsy

ProKidney

Phase 2 Study: REGEN-007

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



Key Entry Criteria

- Type 2 Diabetic Mellitus (DKD)
- Male or Female 30-80 years of age
- eGFR ≥20 and ≤50 mL/min/1.73m^2
- Not on renal dialysis, HbA1c <10%
- UACR 30 - 5,000 mg/g

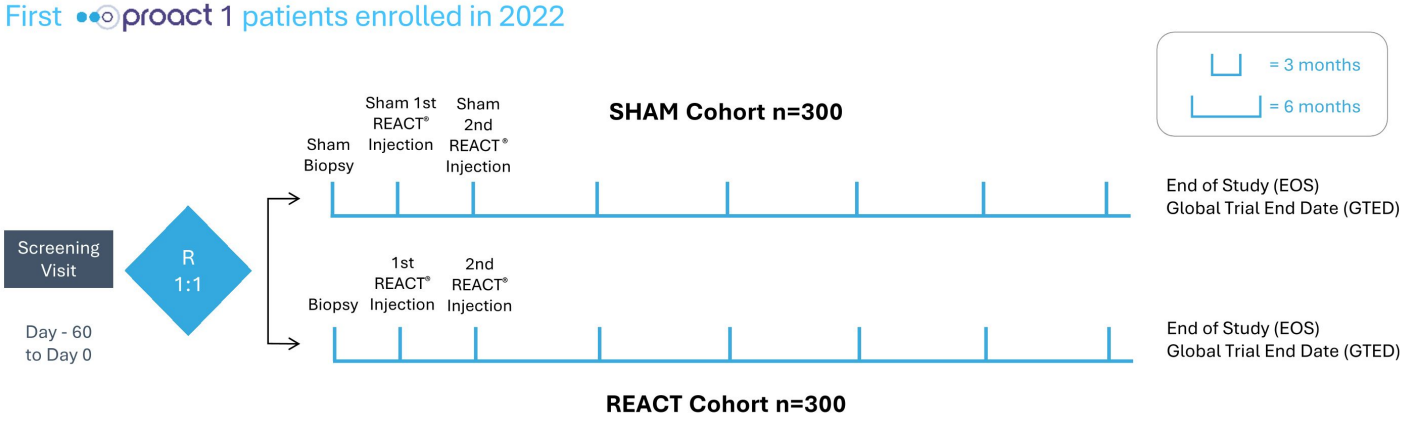
★ Re-Dosing Triggers

Sustained 30-day

- Decline in eGFR using CKD-EPI 2012 by at least 25% from baseline
- Increase of ≥30% and at least 30 mg/g in UACR from baseline

REACT® Registrational Program: proact 1 (REGEN-006)

First proact 1 patients enrolled in 2022



Key Entry Criteria

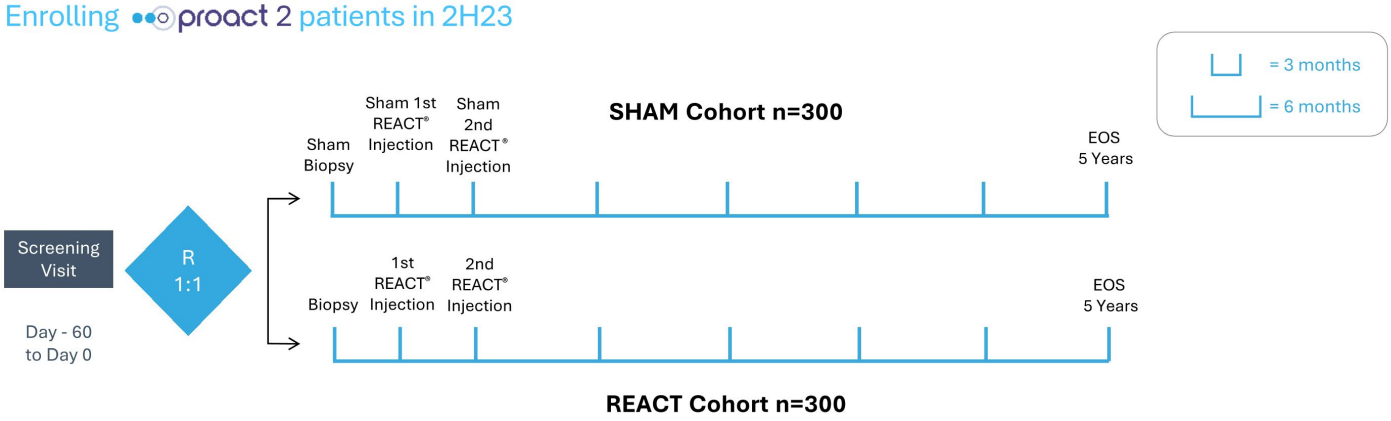
- Type 2 Diabetic Mellitus (DKD)
- Male or Female 30-80 years of age
- **eGFR ≥20 and ≤50 mL/min/1.73m^2**
- Not on renal dialysis, HbA1c <10%
- **UACR 300 - 5,000 mg/g**

Time-to-Event Primary Composite Endpoint:

- At least 40% reduction in eGFR;
- eGFR<15mL/min/1.73m^2 sustained for 30 days and/or chronic dialysis, and/or renal transplant; or
- Death from renal or cardiovascular causes

REACT® Registrational Program: proact 2 (REGEN-016)

Enrolling proact 2 patients in 2H23



Key Entry Criteria

- Type 2 Diabetic Mellitus (DKD)
- Male or Female 30-80 years of age
- **eGFR ≥ 20 and ≤ 44 mL/min/1.73m²**
- Not on renal dialysis, HbA1c <10%
- **UACR 300 - 5,000 mg/g**

Protocol modifications to support evolving standard of care, future regulatory, and commercial access

- Follow-up visits through 60 months (5 years)
- Stratification at randomization based on CKD stage and SGLT2 or sMRA use

Time-to-Event Primary Composite Endpoint:

- At least 40% reduction in eGFR;
- eGFR<15mL/min/1.73m² sustained for 30 days and/or chronic dialysis, and/or renal transplant; or
- Death from renal or cardiovascular causes

REACT® Registrational Program

Regulatory & reimbursement engagement plan: Diabetic Kidney Disease

FDA / EMA*

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 align with registration study designs previously used by other FDA approved CKD therapies (i.e., SGLT2i)

HTA

HTA* Potential Healthcare Savings

Validate REACT's® effect of delaying the time to ESRD (dialysis/transplant) as a potential major healthcare system cost savings

** EMA: European Medicines Agency, RMAT: Regenerative Medicine Advanced Therapy, BLA: Biologics License Application, SGLT2i: Sodium-glucose Co-transporter 2 inhibitor, HTA: Health technology assessment*

High Patient Acceptance for New Medications

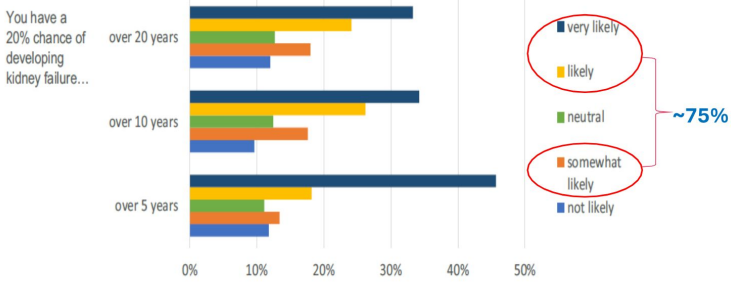
Survey participants were overwhelmingly willing to take a medication - even if side effects occurred (93.6%)

Current staging system for CKD and treatment considerations

		ACR Stages			
		1	2	3	
GFR Stages		<30	30-300	>300	Nephrotic
1	>90	No CKD			
2	60-89				
3a	45-59				
3b	30-44		REACT		
4	15-29				
5	<15				

CKD stage/Risk	No CKD	Moderately high risk	High risk	Very high risk
Goal for treatment	Prevent development	Prevent progression and complications		
Indication for treatment	Current area of controversy		Agreement that treatments are indicated	

Patient responses to question asking about the likelihood of taking a new medication to prevent kidney failure:



- **Panelist with the CKD stage 3a stated:** "....if I did see an appreciable decrease in my kidney health then I'm sure I would be much more open to trying some things."
- **Panelist with CKD stage 3b stated:** "Anything to help ... slow [the] progress of the kidney disease — I'm all for it."

Inker et al Am J Kidney Dis. 80(4):513-526

Preparing for Commercial Readiness

Infrastructure strategy to reduce COGS and address commercial demand

Manufacturing toward clinical and commercial opportunities

- Implementing staged construction to expand commercial-scale manufacturing capabilities
  - Addition of Greensboro facility provides scalability beyond Winston-Salem facility to address anticipated post-approval demand
- In-house manufacturing supports clinical programs and initial commercial launch
- Cryo-preserved REACT distribution enabled by Covid cold supply chain
- Potential to add and qualify additional CDMO sites for regional demand / surge capacity

Potential financial impact for ProKidney

- Approximately 2.5 million Stage 3b/4 diabetic CKD patients in U.S., >5 million OUS
- Estimated 128k U.S. patients enter dialysis each year and 2 million worldwide
- Potential to treat 50,000 patients per year WW
- Potential Value Proposition:
  - Dialysis cost avoidance for 2-5 years - $200-500k
  - Dialysis cost spend per year in U.S. = $50B by Medicare
- Maximum processing capacity of Winston-Salem and Greensboro facilities is over 20,000 patients/year

Phase 2 COGS for REACT® ~$100K / patient
Aim to decrease COGS by approximately 50% through scale-up for commercialization

World-class Leadership and Board of Directors

Dr. Tim Bertram
Chief Executive Officer

James Coulston
Chief Financial Officer

Mary Weger
Chief People Officer

Todd Girolamo
Chief Legal Officer & Secretary

Dr. Bruce Culleton
EVP, Clinical Development & Commercialization

Dr. Deepak Jain
Chief Operating Officer

Ashley Johns
SVP, Global Head Clinical Operations

Dr. Darin Weber
Chief Regulatory Officer

Dr. Joe Stavas
SVP, Global Head Clinical Development

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

REACT®: REnal Autologous Cell Therapy for CKD

Advancing a comprehensive clinical plan to demonstrate commercial potential

1H 2023

☑ **REGEN-003 Phase 2**
Trial completed
Results published 1Q23

- Safety & efficacy of REACT®
- DKD Stage 4 / 5 (eGFR < 20 – 14)
- Identify potential re-dosing triggers
- Assess impact on progression and time to dialysis in patients with imminent risk of renal failure/dialysis

2H 2023

REGEN-002 Phase 2
Enrollment complete
Interim Results 2H23

- Last patient last visit December 2023
- DKD Stage 3b / 4 (eGFR 50 – 20)
- 2 injections into biopsied kidney
- Open label safety & efficacy of REACT®

2024 and beyond

REGEN-007 Phase 2
Enrollment complete
Interim results anticipated first half of 2024

- Fully-enrolled
- Open-label trial DKD Stage 3 / 4 (eGFR ≤ 50 – 20)
- Bi-lateral kidney injections and dose triggers
- Cryopreserved commercial formulation

REACT® Phase 3 DKD Trials

proact 1: Ongoing enrollment in U.S., Canada, and EU; Interim anticipated YE24

proact 2: 2H23 ROW enrollment; Interim anticipated by YE25

- Global Phase 3 blinded, sham-controlled trials to establish safety & efficacy of REACT®
- Stage 3b / 4 DKD (eGFR ≤ 50 – 20)
- FDA-defined time-to-event endpoints

Cash Position
(as of 6/30/23)

$446M cash sufficient to fund these key milestones, and to interim Phase 3 data

Regulatory

- FDA / EMA agreement on pivotal study design
- RMAT designation in U.S.
- Potency Assay Matrix alignment

Why ProKidney?

Maximize dialysis-free living

Too many CKD patients require dialysis

$130B U.S. Medicare spend annually on ESRD / CKD (excludes private insurance)

Approximately 75 million total CKD patients in U.S. & EU

Currently, **no treatment options** (other than transplant) exist to stop decline of kidney function

REACT® Initial Clinical Success

Preservation of kidney function intended to delay/prevent kidney failure/dialysis

Ongoing Phase 2 program providing insight on durability, multi-dosing, and re-dosing triggers

Registrational Phase 3 trials underway

proact I interim data estimated YE 24

RMAT designation granted by FDA

Value Creation Potential

Experienced board and management team

Cash runway to deliver interim Phase 3 data*

In-house manufacturing supports Phase 3 and initial commercialization

Experienced employees, strong product and cell therapy IP & development know-how

Identified milestones and results anticipated throughout 2023 and 2024

Returning Autonomy to Patients and their Families

** Approximately $506M as of 9/30/22*

ProKidney

Corporate Presentation

September 2023

A Step Closer to Potential Dialysis Prevention

REACT® [**RE**nal **A**utologous **C**ell **T**herapy]