

PROKIDNEY

Developing Solutions for Dialysis Prevention



**Corporate
Presentation**

November 2024



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 beliefs that the FDA agrees that the Company’s Phase 3 REGEN-006 (PROACT 1) trial could be sufficient to support a potential BLA submission and full regulatory approval and that the Company could consider using eGFR slope as a surrogate endpoint on an accelerated approval pathway for rilparencel, expectations with respect to financial results and expected cash runway, including the Company’s expectation that current cash will support operating plans into 2027, future performance, development and commercialization of products, if approved, the potential benefits and impact of the Company’s products, if approved, potential regulatory approvals, the size and potential growth of current or future markets for the Company’s products, if approved, the advancement of the Company’s development programs into and through the clinic and the expected timing for reporting data, the making of regulatory filings or achieving other milestones related to the Company’s product candidates, and the advancement and funding of the Company’s developmental programs, generally. 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 risk that results of the Company’s clinical trials may not support approval; the risk that the FDA could require additional studies before approving the Company’s drug candidates; 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 fact that interim results from our clinical programs may not be indicative of future results; the impact of geo-political conflict on the Company’s business; and other risks and uncertainties included under the heading “Risk Factors” in the Company’s most recent Annual Report on Form 10-K, subsequent Quarterly Reports on Form 10-Q and other 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. This presentation shall not constitute an offer to sell or the solicitation of an offer to buy these securities, nor shall there be any sale of these securities in any state or jurisdiction in which such offer, solicitation, or sale would be unlawful prior to registration or qualification under the securities laws of any such state or jurisdiction.



Disrupting the CKD Treatment Landscape

Renal Autologous Cell Therapy:

Rilparencel (REACT[®]) proprietary autologous cellular therapy being evaluated to **preserve kidney function** in patients with diabetes and advanced chronic kidney disease



An Introduction to ProKidney

Goal

Preserve kidney function in advanced CKD patients

Preserve kidney function in patients with type 2 diabetes and advanced chronic kidney disease who are faced with limited options for care beyond transplantation or dialysis

Rilparencel

A proprietary autologous cellular therapy with RMAT designation

Currently in pivotal Phase 3 clinical development with REGEN-006 (PROACT 1)
Supported by three Phase 2 clinical trials in advanced CKD patient populations

Leadership

Leadership Team with Clinical Development & Regulatory Experience

Together the team brings over 150 years cumulative experience in the discovery, development, manufacturing and commercialization of biotechnology, pharmaceutical, and device products

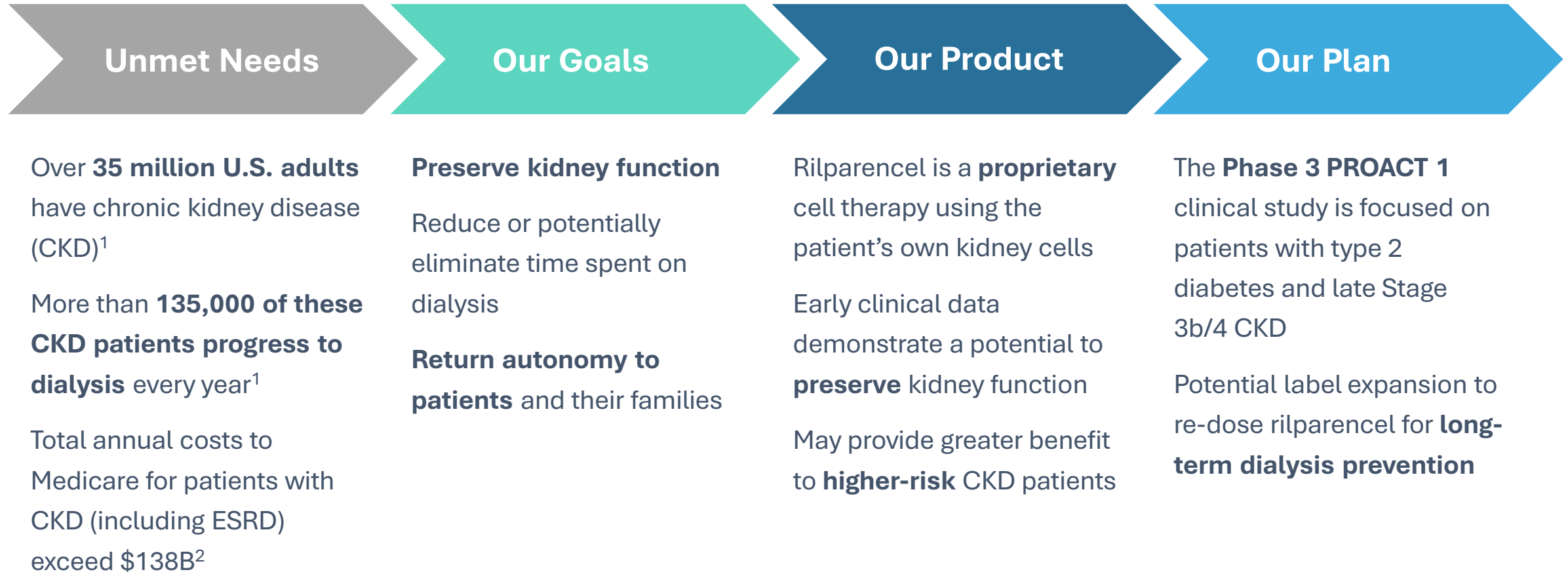
Recent Developments

Meaningful Recent Developments

FDA confirmed in a Type B meeting that PROACT 1 could be sufficient to support a full U.S. approval of rilparencel
Additionally, the FDA confirmed that the accelerated approval pathway is available if an acceptable surrogate endpoint, which may include eGFR slope, is used

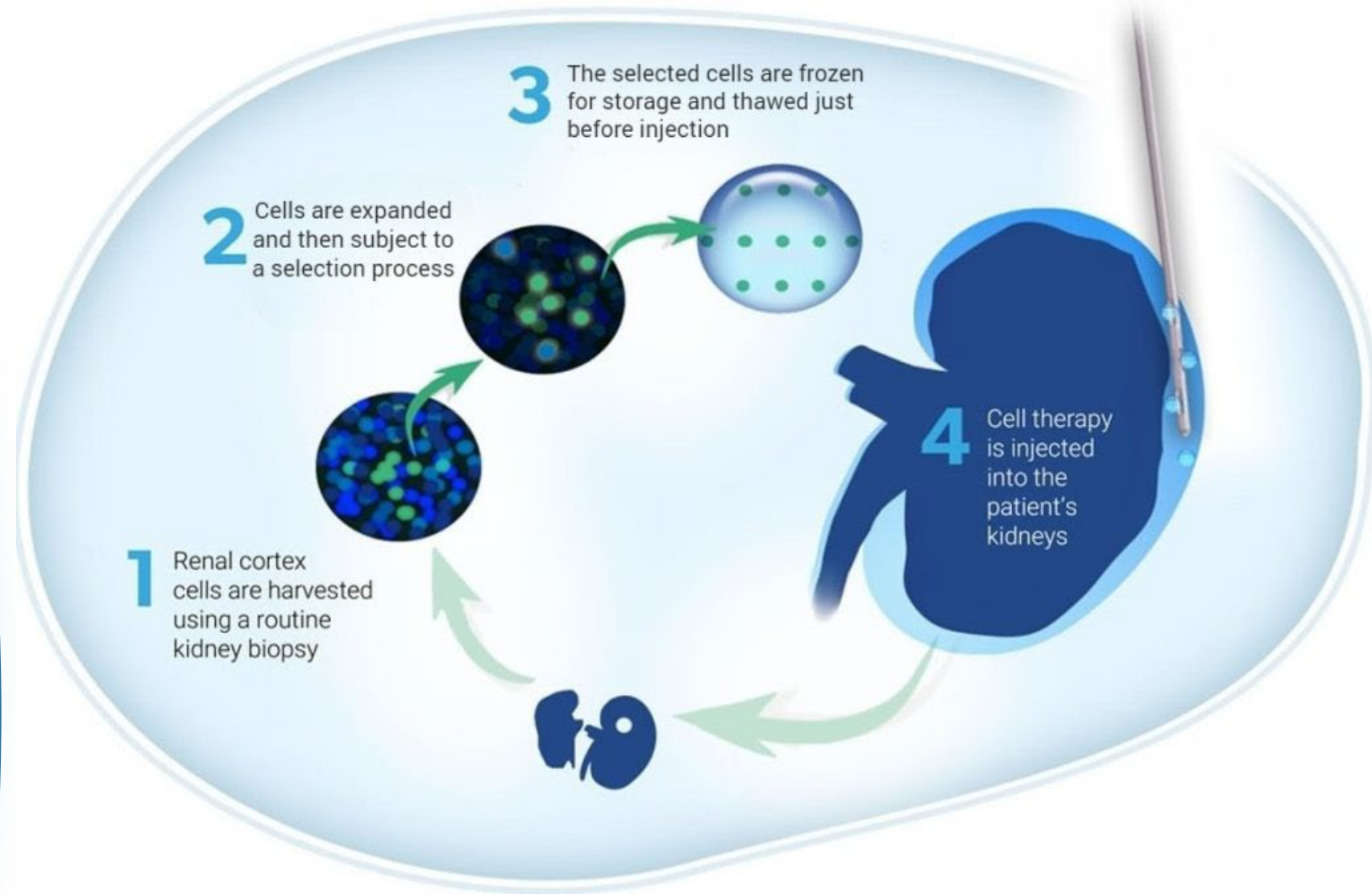
Completed an upsized common stock offering of \$140 million in June 2024 extending cash runway into 2027

What is Rilparencel and Why is it Relevant?







Rilparencel Goal: Preservation of Kidney Function

ProKidney's Autologous Cell Therapy



Overview of the Rilparencel Clinical Program

		PRECLINICAL	IND	PHASE 1	PHASE 2	PHASE 3	STATUS
Pivotal Trial Program							
Diabetes Type II – Prevent/Delay ESRD in Stage 3b/4 CKD (20-35 mL/min/1.73m ² , n=685)		006/PROACT 1					Ongoing
Long term follow-up study for patients previously treated with rilparencel		008					Ongoing
Supportive Trials							
Diabetes Type II – Prevent/Delay ESRD in Stage 3/4 CKD (20-50 mL/min/1.73m ² , n=83)		002					Final Data Presented
Diabetes Type I & II – Prevent/Delay ESRD in Stage 3/4 CKD (20-50 mL/min/1.73m ² , n=53)		007					Fully Enrolled
Completed Trials							
Diabetes Type II – Delay ESRD in Stage 4/5 CKD (14-20 mL/min/1.73m ² , n=10)		003					Trial Completed
Congenital Anomalies – Prevent/Delay ESRD (14-50 mL/min/1.73m ² , n=5)		004					Trial Completed



Frozen product



Unilateral injections



Bilateral injections

ESRD = End-Stage Renal Disease

Advancing a Comprehensive Clinical Plan

2024

RMCL-002 Phase 2 Trial; Results published Q2 2024

- Open-label safety & efficacy of rilparencel in patients with type 2 diabetes and Stage 3/4 CKD (eGFR 20-50)
- Potential to preserve kidney function for up to 30 months in several patient groups

REGEN-007 Phase 2 Trial; Enrollment complete; Interim results published Q2 2024

- Open-label safety & efficacy of rilparencel in patients with diabetes and Stage 3/4 CKD (eGFR 20-50)
- Bilateral kidney injections & cryopreserved commercial formulation

PROACT 1 Phase 3 Randomized Controlled Trial – type 2 diabetes and Stage 3b/4 CKD

- **PROACT 1** is enrolling patients

2025 and beyond

REGEN-007 Phase 2 Trial; Full 12 month data from Group 1 expected in 1H 2025

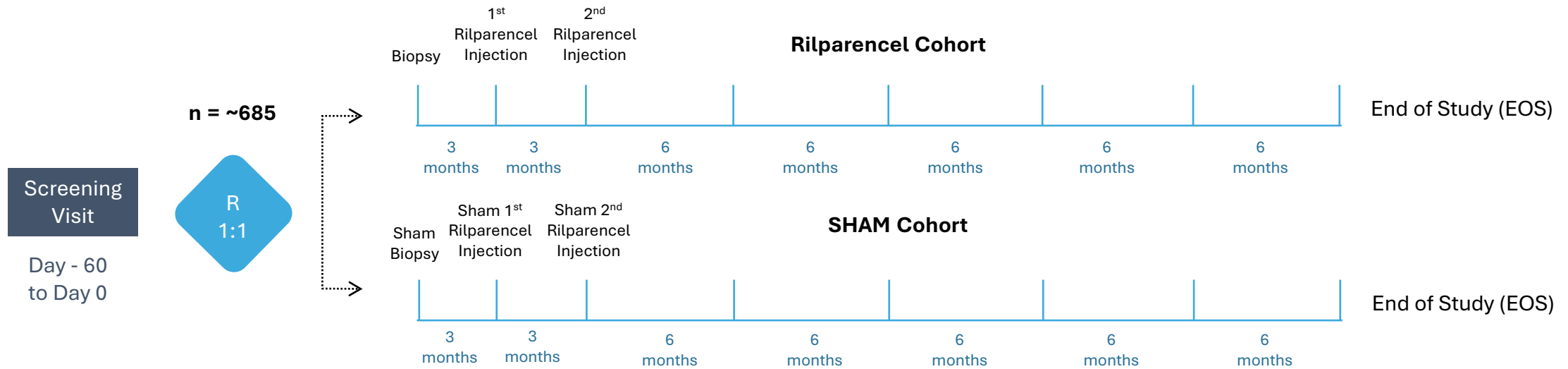
Update on rilparencel mechanism of action in 2H 2025

PROACT 1 Phase 3 Randomized Controlled Trial – type 2 diabetes and Stage 3b/4 CKD

- Full topline results for **PROACT 1** anticipated in Q3 2027
- FDA confirmed in a recent Type B meeting that the **accelerated approval** pathway is available for rilparencel if an acceptable surrogate endpoint, which may include eGFR slope, is used; additional details will be provided in 2025

Rilparencel Registrational Program: proact1 (REGEN-006)

PROACT 1 eGFR enrollment criteria range of ≥ 20 to ≤ 35 mL/min/1.73m² aligns with Phase 2 study results and payer / clinical feedback



Key Entry Criteria

- Type 2 diabetes and CKD
- Male or Female 30-80 years of age
- eGFR ≥ 20 and ≤ 35 mL/min/1.73m²
- UACR 300-5,000 mg/g for eGFR 30-35
- Not on renal dialysis, HbA1c <10%

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

Potential Accelerated Pathway

- FDA confirmed that the accelerated approval pathway is available for rilparencel if an acceptable surrogate endpoint, which may include eGFR slope, is used
- Additional details will be provided in 2025

Unmet Clinical and Payer Need in High-Risk CKD Patients

- CKD is defined as abnormalities of kidney structure or function, present for > 3 months
- CKD is classified based on Cause, GFR category (G1-G5), and Albuminuria (A1-A3), abbreviated as CGA

Risk for ESRD

- Low
- Moderately Increased
- High
- Very High

				Persistent albuminuria categories Description and range		
				A1	A2	A3
				Normal to mildly increased	Moderately increased	Severely increased
				<30 mg/g <3 mg/mmol	30-300 mg/g 3-30 mg/mmol	>300 mg/g >30 mg/mmol
GFR categories (mL/min/1.73 m ²) Description and range	G1	Normal or high	≥90			
	G2	Mildly decreased	60-89			
	G3a	Mildly to moderately decreased	45-59			
	G3b	Moderately to severely decreased	30-44			
	G4	Severely decreased	15-29			
	G5	Kidney failure	<15			

Standard of Care

Antihypertensives

- ACEi
- ARB

Glucose & Inflammation Reduction

- SGLT2i
- DPP-4
- GLP-1

Rilparencel's Target Population

Today, clinical priorities for patients with Stage 4 CKD (G4) are largely focused on treating co-morbidities and preparing patients for transplantation or dialysis

Therapeutic Options that Delay the Need for Dialysis in Patients with Stage 4 Chronic Kidney Disease are Limited

Study	Active Product	Subjects with Stage 4 CKD
Canagliflozin and Renal Outcomes in Type 2 Diabetes and Nephropathy ¹	Canagliflozin (SGLT2 inhibitor)	0%
Dapagliflozin in Patients with CKD ²	Dapagliflozin (SGLT2 inhibitor)	14%
Empagliflozin in Patients with CKD ³	Empagliflozin (SGLT2 inhibitor)	34%
Effect of Finerenone on Cardiovascular and Kidney Outcomes in Patients with Type 2 Diabetes and CKD ⁴	Finerenone (Selective MRA)	7%
Effects of Semaglutide on Chronic Kidney Disease in Patients with Type 2 Diabetes ⁵	Semaglutide (GLP-1RA)	11%

All recent landmark clinical trials in CKD primarily focus on Stage 2 and 3 CKD

1. Perkovic V et al. N Eng J Med 2019
 2. Heerspink H et al. N Engl J Med 2020

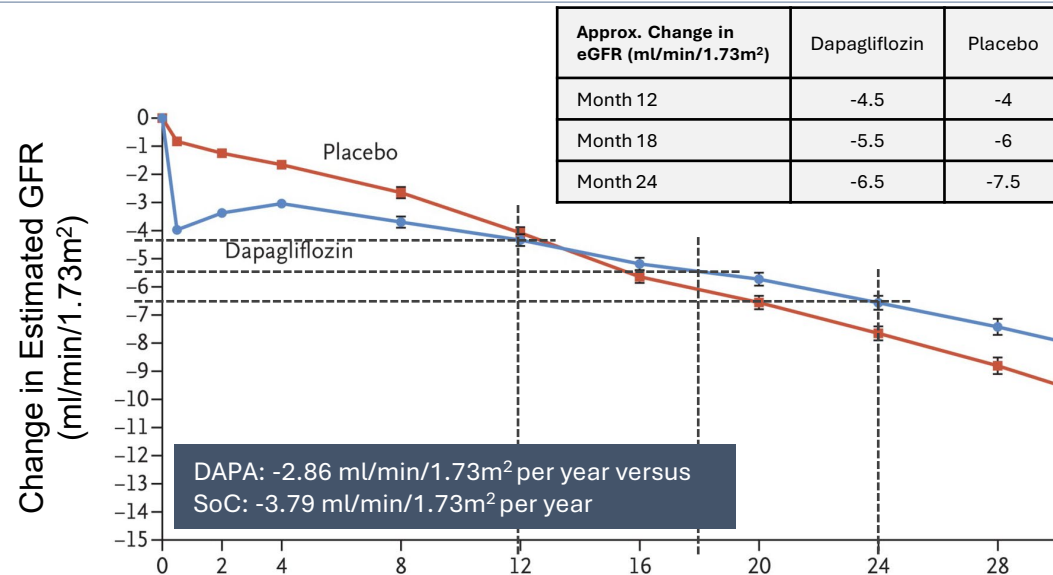
3. Herrington et al. N Engl J Med 2023
 4. Agarwal. R et al. Eur Heart J. 2022;
 Sarafidis. P et al. Clin J Am Soc Nephrol 2023

5. Perkovic V et al. N Engl J Medicine 2024

While New Therapies Are a Step Forward, Patients Still Lose Kidney Function and Experience Clinically Significant Events

SGLT2 inhibitors Do Not Prevent Progression of Advanced CKD

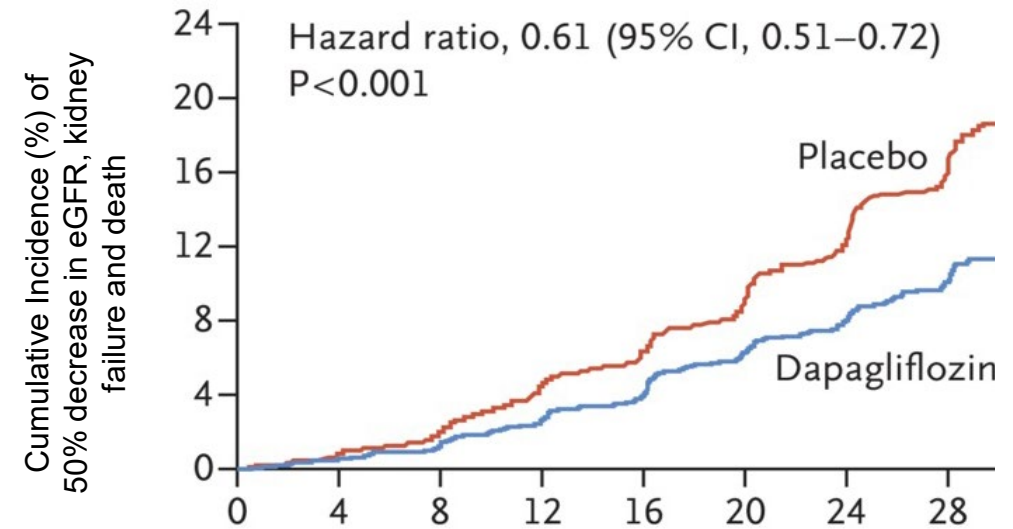
Patients continue to lose kidney function on SGLT2 inhibitors and progress to Stage 4/5 CKD



While dapagliflozin demonstrated <1.0 ml/min/yr difference in eGFR, it was able to achieve a reduction in clinically important events

Standard of Care has Limitations

Current standard of care¹ does not prevent events in ~50-75% of people with diabetic kidney disease²



Dapagliflozin: 19 patients required treatment to prevent one primary outcome event



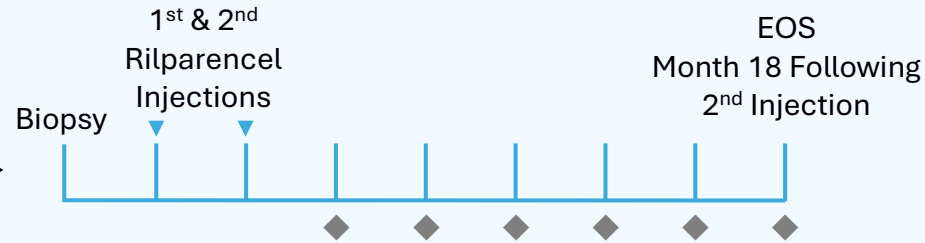
**REGEN-007 Interim
Analysis**
Data as of May 7, 2024



REGEN-007 Trial Design

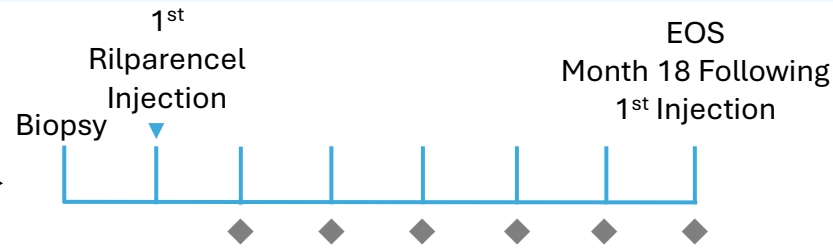
Group 1 Dosing Regimen and Use of Cryopreserved Product Mirrors Phase 3 Program

**Group 1
(Ph3 Dosing Regimen)
n = 27**

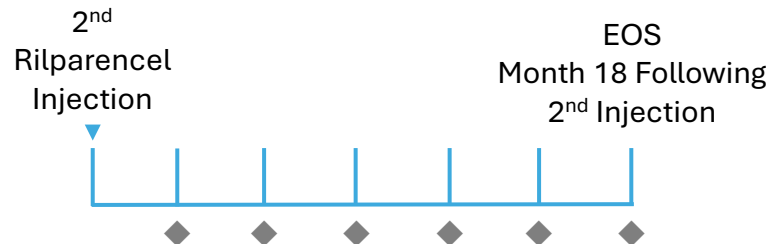


**R
1:1**

**Group 2
(Exploratory Dosing
Regimen)
n = 26**



Assess 2nd Injection Trigger (Months 3-15)



= 3 Months
 = Follow-up Visit After Last Injection

Key Entry Criteria

- Type 1 or type 2 diabetes and CKD
- Subjects 30-80 years of age
- eGFR ≥ 20 and ≤ 50 mL/min/1.73m²
- UACR 30-5000 mg/g
- HbA1c <10%

Group 2 Re-Dosing Trigger

Sustained 30-Day:

- Decline in eGFR of $\geq 20\%$ from baseline, and/or
- Increase of $\geq 30\%$ and ≥ 30 mg/g in UACR from baseline

REGEN-007 Interim Analysis Objectives and Endpoints in Group 1

Objectives

- In subjects with at least 12 months follow-up after 2 injections, assess the safety and efficacy of cryopreserved rilparencel delivered into the biopsied and non-biopsied contralateral kidney using a percutaneous approach

Endpoints

- Procedural and investigational product-related adverse events
- Change in kidney function as measured by eGFR

Current Enrollment Status & Completion Expectations

53 Subjects were Randomized in REGEN-007 with 27 Subjects Randomized to Group 1
(1 Subject Withdrew Consent Pre-Biopsy)

26 Subjects in Group 1

Of the 26 Subjects who were Biopsied, 24 Subjects Received at-least 1 Injection (2 Subjects' Biopsies had Insufficient Cells for Injection)

24 Subjects

Of the 24 Subjects, 1 Subject had a Contra-indication (Bleeding Risk) for a 2nd Injection & 1 Subject Died before 12 Months Follow-up

22 Subjects Expected to Receive 2 Injections with 12 Months Follow-up

As of May 7, 2024: 13 Subjects Have Received 2 Injections with a Minimum of 12 Months Follow-up post 2nd Injection

Baseline Characteristics in Group 1 Subjects with a Minimum of 12 Months Follow-up after Two Rilparencel Injections

SUBJECTS WITH MINIMUM 12 MONTHS FOLLOW-UP AFTER 2ND INJECTION (n=13)

Age, years (mean +/- SD)	62.8 +/- 8.2
Female : Male, %	54% : 46%
Hispanic or Latino, %	0%
Race, %	
Black or African American	0%
White	100%
Other	0%
Blood pressure, mm HG	135 / 72
eGFR, ml/min/1.73m² (mean +/- SD)	29.7 +/- 9.5
UACR mg/g (median, min max)	239 (4, 2392)
HbA1c, % (mean +/- SD)	7.3 % +/- 1.6
ACE/ARB Use, %	69%
SGLT2 Use, %	31%
GLP-1 Use, %	46%

Externally Developed Control Arm to Contextualize REGEN-007 Interim Data

Objective

- Explore how 18 month change in kidney function in subjects enrolled in REGEN-007 might compare against matched contemporaneous controls

Methods

- In partnership with Dr. Navdeep Tangri (University of Manitoba), 13 subjects from REGEN-007 were matched 10:1 with diabetic subjects from recent CKD clinical trials
- Matching was independently performed based upon 2-year risk of kidney failure using [Klinrisk](https://www.klinrisk.com/)¹ software and comparable usage of SGLT2 inhibitors

Klinrisk Founding Team



Navdeep Tangri

- ◇ Co-Founder and CEO
- ◇ Founder and Scientific Director, Chronic Disease Innovation Centre
- ◇ Professor of Medicine, University of Manitoba



- Global leader in risk prediction who developed the most widely used algorithms in nephrology worldwide
- Published more than 380 manuscripts
- Risk equations have been integrated in electronic health records (Epic), laboratory information systems, and national & international clinical practice guidelines
- Strong track record of leading international clinical trials, developing trial endpoints with FDA and participating FDA discussions on drug approval and labeling
- Relationships with large pharmaceutical companies – considered a key opinion leader internationally in the CKD space



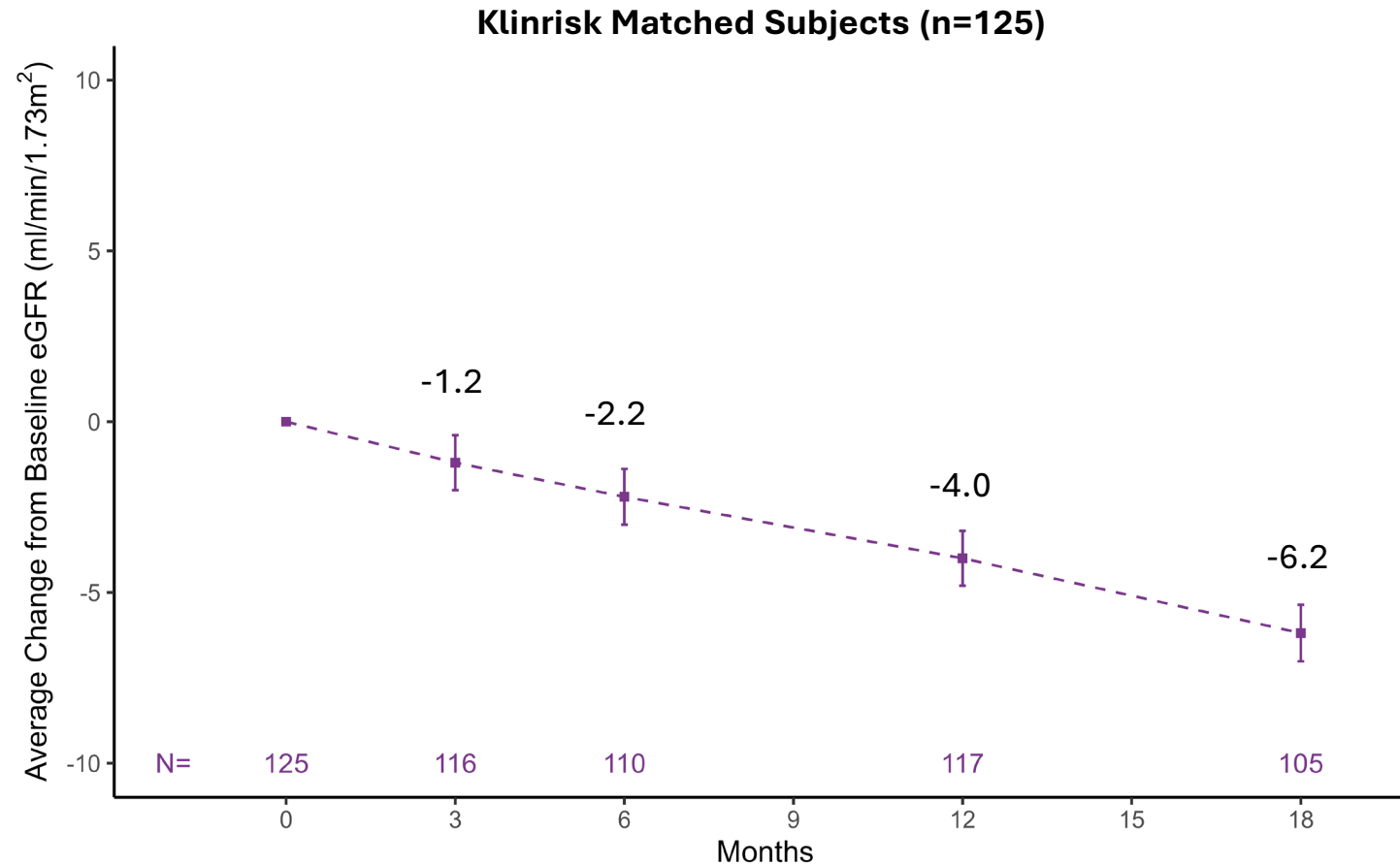
J.D. McCullough

- ◇ Chief Operating Officer
- ◇ Health tech executive specializing in regulated AI commercialization



- First autonomous AI FDA clearance and SaMD reimbursement including CMS coverage at Digital Diagnostics
- Closed seven figure deals with health systems, payors, labs, and biopharma companies
- Led FDA strategy and engagement for 10+ SaMD products, including Breakthrough, PMA, De Novo, and 510(k)
- Licensed over 50M patient records globally to drive AI & drug development
- Strategic advisor to Top 20 Biopharma, regulatory & reimbursement firms, and venture-backed startups
- Previous Commercial & Product Executive positions at Aegis Ventures, Arcturis Data, Digital Diagnostics

Matched Controls Showed a Continuous Decline in Kidney Function over 18 Months



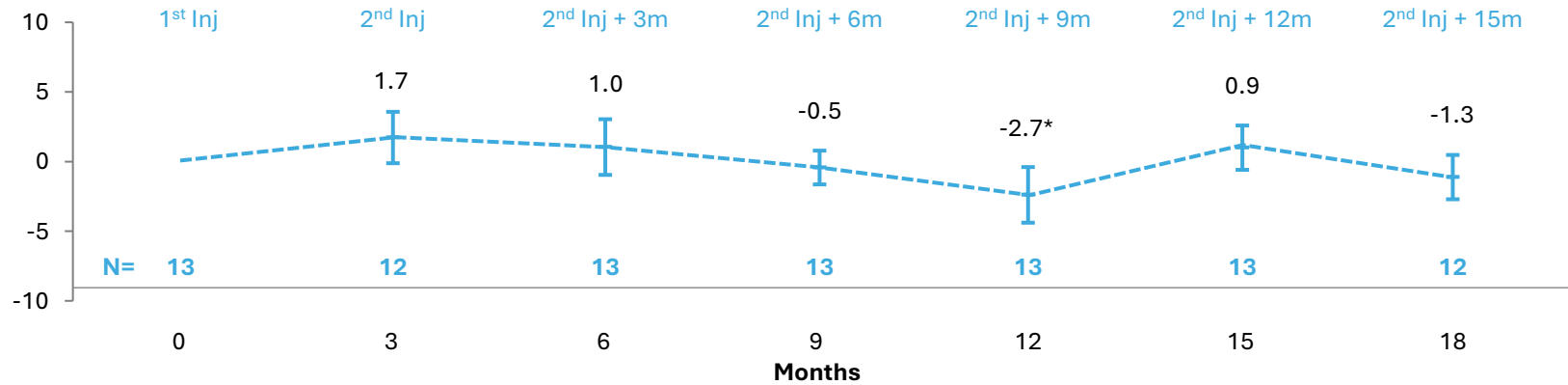
Average Change in eGFR from Baseline at 18 Months

-6.2 ml/min/1.73m²
(95% CI -7.8, -4.6)

Kidney Function Stabilizes for 18 Months After 1st Injection

Group 1 Subjects (n=13) with Minimum 12 Months Follow-up Data Post 2nd Injection

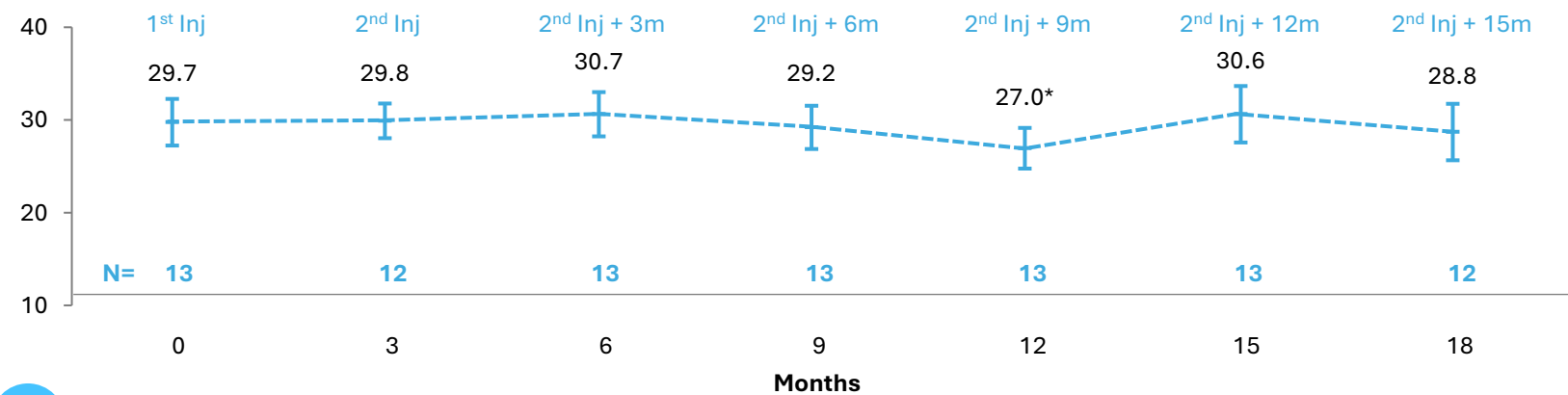
Average Change from Baseline eGFR (mL/min/1.73m²)



Average Change from Baseline with 18 Months Follow-up Post 1st Injection

-1.3 mL/min/1.73m²
(95% CI -5.1, 2.5)

Average eGFR (mL/min/1.73m²)



Average eGFR in Group 1 was 29.7 at Baseline vs 28.8 at 18 Months Post 1st Injection

[absolute difference -0.9 mL/min/1.73m² at 18-months]

No Rilparencel-related Serious Adverse Events have been Observed

ADVERSE EVENT	BIOPSY # of SAEs (n=51)	RILPARENCEL INJECTION # of SAEs (n=49)
Hematoma	2	1
Thrombosis	1	0
Hematuria	1	0
Hydronephrosis	1	0
Death	0	0
Acute Kidney Injury	2	0

REGEN-007 Interim Analysis Summary

Key Findings

- In Group 1 participants who had at least 12 months follow up after a second rilparencel injection, **kidney function was preserved for 18 months**
- Bilateral dosing of cryopreserved product showed safety profile consistent with prior studies and comparable to kidney biopsy

Next Steps

- We look forward to providing **full results for REGEN-007 in 1H 2025**
- We are focused on enrolling patients in our registrational **Phase 3 PROACT 1** study and anticipate full topline results in Q3 2027

Financial Highlights



NASDAQ: PROK

291,661,950 shares
outstanding*

\$407M Cash** on hand
expected to fund operations
into 2027



Headquarters:

Boston, MA
Winston-Salem, NC

Covering Research Analysts

Jason Gerberry	Bank of America
Yigal Nochomovitz	Citi
Jonathan Miller	Evercore
Vamil Divan	Guggenheim
Kelly Shi	Jefferies
Anupam Rama	JP Morgan
Judah Frommer	Morgan Stanley
Eliana Merle	UBS

*As of Nov 11, 2024

**Cash, cash equivalents and marketable securities as of September 30, 2024