UNITED STATES SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): January 10, 2023

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

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:

Trading
Symbol(s)

Class A ordinary shares, \$0.0001 par value per share

PROK

Name of each exchange on which registered

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. \Box

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 <u>Investor Presentation</u>

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 thereunto duly authorized.

PROKIDNEY CORP.

Date: January 10, 2023 By: /s/ Todd Girolamo

Name: Todd Girolamo Title: Chief Legal Officer



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 world leader in treating Chronic Kidney Disease (CKD)

 \$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 Currently, no treatment options (other than transplant) exist to stop decline of kidney function \$130 billion Medicare cost to care for CKD patients and EU Reduce the lifetime cost of care for CKD patients and payers REACT® is a proprietary cell therapy using the patient's own kidney cells Mechanism of action has been observed to result in clinical activity REACT® is a proprietary cell therapy using the patient's own kidney cells Mechanism of action has been observed to result in clinical activity REACT® is a proprietary cell therapy using the patient's own kidney cells Mechanism of action has been observed to result in clinical activity REACT® includes therapy using the patient's own kidney cells Ongoing Phase 2 trials to expand clinical program received Hond EMA guidance and RMAT designation; proact 1 underway Potential tabel expansion could expand TAM to nearly all chronic kidney diseases Reduce overall cost to the healthcare system 	The Problem	The Goal	The Product	The Plan	Contribution to Society
	Medicare cost to care for the 40 million CKD/ESKD patients in U.S. 75 million CKD patients in the U.S. and EU Currently, no treatment options (other than transplant) exist to stop decline of kidney	Reduce the lifetime cost of care for CKD	proprietary cell therapy using the patient's own kidney cells Mechanism of action has been observed to result in clinical activity REACT® includes three specific cell types with the potential to help restore kidney	program received FDA and EMA guidance and RMAT designation; proact 1 underway Ongoing Phase 2 trials to expand clinical insights Target commercial	includes millions of moderate-severe diabetic CKD patients Potential label expansion could expand TAM to nearly all chronic kidney diseases Reduce overall cost to the healthcare





REACT®: REnal Autologous Cell Therapy for CKD

Advancing a comprehensive clinical plan to demonstrate commercial potential

1H 2023

REGEN-003 Phase 2 Trial fully enrolled Interim results anticipated 2Q23

- 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-007 Phase 2 Enrollment ongoing Interim results anticipated 2H23

- Safety & efficacy
- Open-label trial DKD Stage 3 / 4 (eGFR≤50 – 20)
- Bi-lateral kidney and dose triggers
- Cryopreserved commercial formulation
- · Ph3 "preview"

REGEN-015 Multi-dose trial

- Safety & efficacy of repeat dosing
- Previously treated DKD
- Dosing triggers, redosing, and durability

2024 and beyond

REACT® Phase 3 DKD Trials

proact 1: Ongoing enrollment in U.S., Canada, and EU; Interim anticipated YE24 proact 2: 1H23 ROW enrollment; Interim anticipated by YE25

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

Cash Position (as of 9/30/22)

\$506M 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

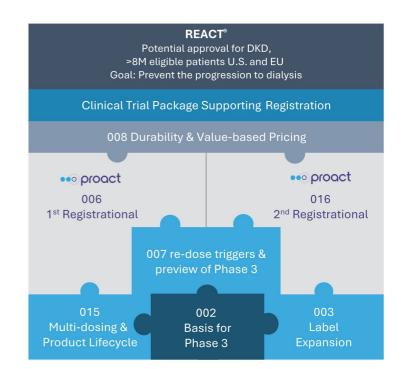




Building a Comprehensive Data Package

Clinical designed to expand potential patient population and support premium pricing

- Assess potential benefit of multiple REACT® doses (REGEN-015)
- Determine durability of REACT® injection (REGEN-008 and RMCL-002)
- 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 valuebased pricing (REGEN-008)







Why ProKidney?

Maximize dialysisfree living

Too many CKD patients end up requiring dialysis

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

Of ~75 million total CKD patients in U.S. & EU, we estimate ~8.5 million are REACT® eligible

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

••• proact 1 Phase 3 trial underway. interim 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 throughout 2023 +

Contribution to Society: Stop Kidney Failure

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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 for dialysis

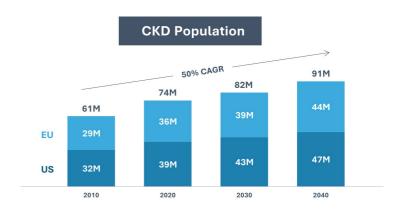
\$80B+

\$50B+

\$93K+

Private insurance may pay up to 4x Medicare costs

Highly prevalent in the U.S. and EU



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





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

Standard of Care has Limitations

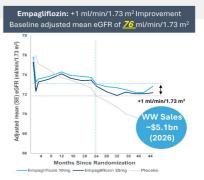
Current standard of care merely slows the eventual loss of kidney function

Current Therapies are Blockbusters

While patients continue to lose kidney function on existing therapies, those therapies still generate multi-billion \$ sales







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

REACT® evaluating more severe CKD (15-50 eGFR; mean <30 ml/min/1.73m² in Ph 2) and data suggests potential to preserve kidney function in patients with very high risk of kidney failure



iource: The New England Journal of Medicine. EvaluatePharma

Note: 2026 sales estimates for therapies reflect all indications and are not limited to C



REACT's Addressable U.S. Patient Population

Initially targeting a 4-5 million patient segment with multiple potential label expansion indications







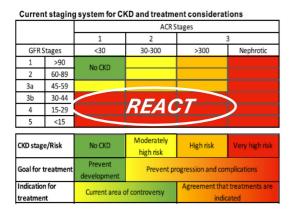
Total addressable market data for the year ended 2020 is based on certain estimates of management. This information may prove to be inaccurate because of the method by which the underlying data for the estimates was obtained or because this information cannot always be verified with complete certainty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

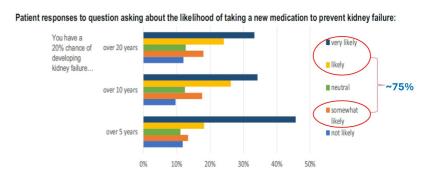
Increatinities



High Patient Acceptance for New Medications

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





- 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."

10 Inker et al Am J Kidney Dis. 8



Drug Pricing for Disease Modification

Recently Launched Novel Targeted Therapies Command High Prices



Targeted therapies that share four characteristics:

- These are "game changing"
 (disease modifying medicines) for
 the afflicted patients
- These targeted therapies treat only between 5k to 70k patients (potentially 290k with Vutrisiran)
- 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

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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



Potential REACT® Market Opportunity in US and EU

Anticipate significant penetration in sicker CKD patients

Stage 4 CKD eGFR 15-29

Diabetes primary cause of CKD

(Estimates after 5-year ramp)

950,000 to 1 million CKD 4 patients

(includes estimated 300-350k eGFR 15-19)

Penetration ~20% prevalent patients (mean of recently launched disease modifying therapies)

~200,000 potential patients

Estimated incidence 150,000

Stage 3b CKD eGFR 30-44

Diabetes primary cause of CKD

(Estimates after 5-year ramp)

4.8 to 5.0 million CKD 3b patients

Penetration ~5% prevalent patients

~250,000 potential patients

Estimated incidence 750,000

~450,000
Potential
patients
per year

Repeat-dosing (REGEN-015) will provide terminal growth for REACT

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otal addressable 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 inbained 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 a incertainties.

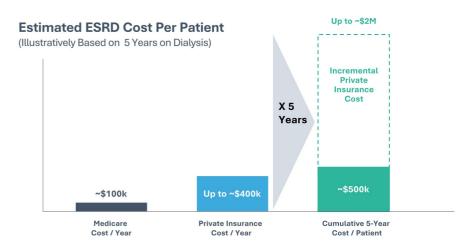


Significant Cost Savings Potential

A disease-modifying drug in CKD could reduce cost of kidney failure

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



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

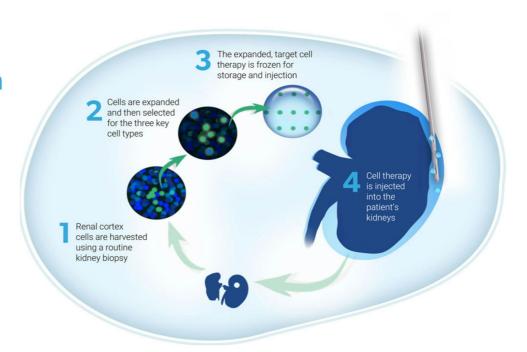


United States Renal Data System - USRDS 2020 Annual Report (https://adr.usrds.org/2020/about-the-new-adr), National Kidney Foundation



REACT® Goal: Restoration of Kidney Function

ProKidney's REACT® Autologous Cell Therapy







Remodeling and Renovation of Nephrons

REACT® aims to preserve kidney function for dialysis-free living

REACT[®]: Autologous Homologous Triple Cell admixture

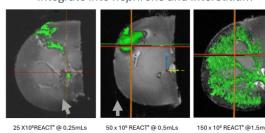
Types of Cells in Adult Kidney REACT*

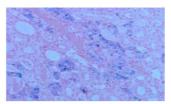
Renal cells

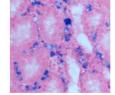
Cap Mesenchyme, Podocytes, and Ureteric Bud:

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

Cells rapidly distribute throughout kidney and integrate into nephrons and interstitium







Intra-tubular and Glomerular (REACT® – Blue)

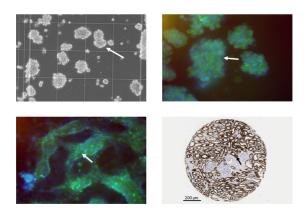
Interstitial (REACT® – Blue)



Relly et al, Am J Physiol Renal Physiol 299: F1026-F1039, 2010. Bruce et al, Regenerative Medicine 10(7), 201: Preclinical studies in rodents and canines, data on file.

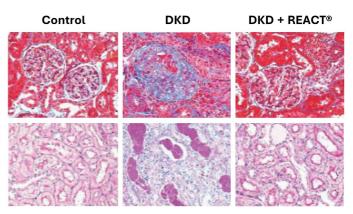


REACT® MoA in CKD – ASN November 2022



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

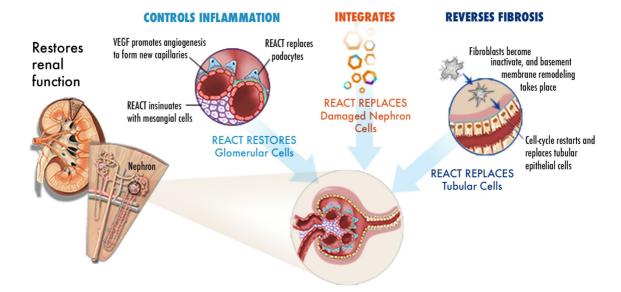
REACT® treated kidney shows reduced glomerular and interstitial fibrosis and inflammation, protein leakage and tubular ectasia





REACT® Impact on Kidney Function

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), 201



REACT® Designed to Address Multiple Areas of CKD

Potential therapeutic indications

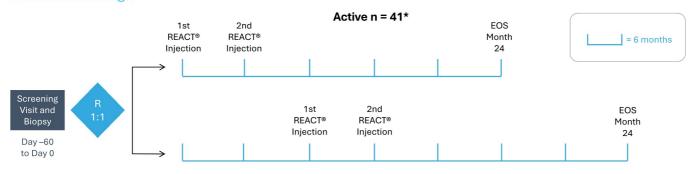
Lead Platform Prog	PRECLINICAL	IND	PHASE 1	PHASE 2	PHASE 3	STATUS	
	Diabetes Type II – Prevent/Delay CKD 3/4 (20-50 ml/min/1.73m ² , N = 81) Diabetes Type II – Prevent/Delay CKD 3/4 (20-50 ml/min/1.73m ² , N = 1,200)	Phase 2 (basis for Phase 3)		002 →002 OLE		> 008	Fully Enrolled Ongoing US/ exUS
REACT® Diabetic Kidney Disease (DKD)	Diabetes Type II – Delay CKD 4/5 (14-20 ml/min/1.73m², N = 10)	Phase 2 (late	Phase 2 (late-stage, high risk for kidney failure) 003				
	Diabetes Repeat Dose Prevent/Delay CKD 3/4 (20-50 ml/min/1.73m², N= 50*)	Phase 2 (injec	ting both kidneys ar	nd re-dose trigger)	007		Enrolling
	Multi / extended-dosing for previously REACT-treated patients	Phase 1/2 (add	ditional injections 3	mos apart) 01			Enrollment 2Q2023
REACT® Congenital Anomalies of the Kidney and Urinary Tract (CAKUT)	Congenital Anomalies – Prevent/Delay (14-50 ml/min/1.73m², N= 15)	Phase 2 (exp.	and application)	004			Trial Completed





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

Clinical trial design



Deferred n= 42

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 until End of Study part 1



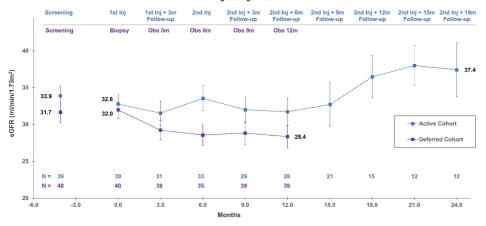
* 2 'Active' patients dropped out of the study resulting in n=39 in subsequent slide



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

Active Patients (N = 39) Effect After 1st Injection vs Deferred Patients on SOC (N = 40) Average Change in eGFR



REACT®

Renal function <u>improved</u> by an absolute improvement over 24 months of

+ 4.6 ml/min/1.73m²

Standard of Care

Progressive <u>decline</u> in kidney function over 12 months of —3.6 ml/min/1.73m²

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



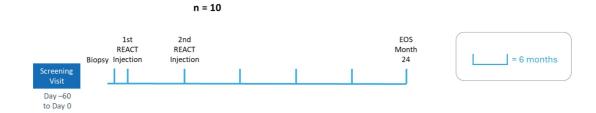


REGEN-003: Phase 2 Study in Stage 4/5 Diabetic CKD Patients

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%

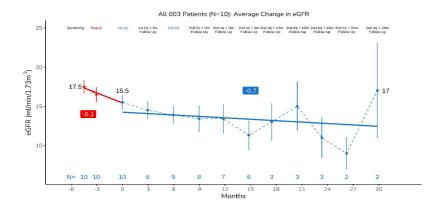
Follow-up visits conducted at 3month intervals after 3 months post 2nd REACT® injection for 24 months until End of Study part 1

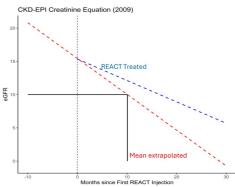




REGEN-003: Pre-Dialysis Patients Benefit from REACT

- 7/10 patients had 30% increase in dialysis free living (median of ~16 mo.)
- eGFR improvement of 38% (>2.5 ml/min/1.73 m²)
- 2/10 patients have preservation of renal function >2+ years post injection





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Staves at al. Ranal Autologous Call Therany in Tune 2 Dishates with Late Stare A Dishates Related Chronic Kidney Disease: Trial Design and Early Analysis | Blood Durify at 100 purity and 100 purity at 100 purity



REACT® Registrational Program: •• proact 1 & •• proact 2 (REGEN-006 / 016)

First •• proact 1 patients enrolled in 2022 = 3 months Sham 1st Sham = 6 months SHAM Cohort n=300 REACT® 2nd Sham Injection REACT® Biopsy Injection End of Study (EOS) Global Trial End Date (GTED) Screening 2nd Visit and REACT® REACT® Biopsy Biopsy Injection Injection End of Study (EOS) Day - 60 Global Trial End Date (GTED) to Day 0

REACT Cohort n=300

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- 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%
- UACR 300 5,000 mg/g

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

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REACT® Registrational Program

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

HTA* Potential Healthcare Savings

Validate REACT® delay in time to ESRD (dialysis/transplant) as major healthcare system cost savings with HTAs

MHRA/NICE* parallel advice for UK

U.S., France, Germany HTAs

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



Manufacturing Strategies

Infrastructure strategy to reduce COGS and expand addressable market

Manufacturing toward clinical and commercial opportunities

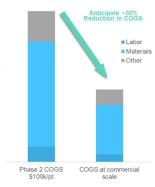
- Staged construction of commercial scale manufacturing facilities
- In-house manufacturing supports clinical trials and scalable and meet future commercial needs
- Future facilities will be built to meet market demand





Cost of Goods Sold (COGS)

- Phase 2 COGS ~\$100K / patient
- Anticipate COGS to potentially decrease by approximately 50% as scale-up for commercialization
 - Supply chain
 - Automation
 - Bioprocess developments
 - Formulation







World-class Leadership and Board of Directors



Dr. Tim Bertram Chief Executive Officer







Dr. Joe Stavas SVP, Global Head Clinical Development









Dr. Deepak Jain Chief Operating Officer REGENMEDTX Baxter



Dr. Darin Weber Chief Regulatory Officer











James Coulston Chief Financial Officer TARGACEPT EY



Ashley Johns SVP, Global Head Clinical Operations











Dr. Libbie McKenzie Chief Medical Officer





Todd Girolamo Chief Legal Officer & Secretary



caladrius LEERINK



Pablo Legorreta Chairman of the Board

















Jennifer Fox













Dr. Brian Pereira
VISterra







Dr. Uma Sinha

José Ignacio Jiménez Santos



Why ProKidney?

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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

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Identified milestones and results throughout 2023 +

Contribution to Society: Stop Kidney Failure

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



