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): March 06, 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

(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)

Dere-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	
Title of each class	Symbol(s)	Name of each exchange on which registered
Class A ordinary shares, \$0.0001 par value per share	PROK	The Nasdag 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 \boxtimes

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 8.01 Other Events.

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.

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: March 6, 2023

By: /s/ Todd Girolamo

Todd Girolamo Chief Legal Officer PROKIDNEY

Corporate Overview

March 2023

A Step Closer to Potential Dialysis Prevention REACT® [**RE**nal **A**utologous **C**ell **T**herapy] Exhibit 99.1

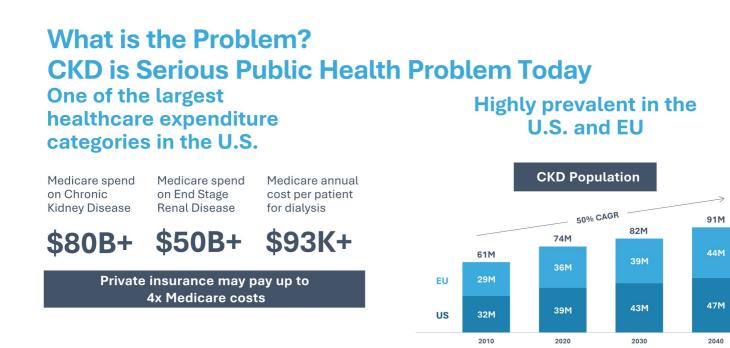
Forward-looking Statements

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," "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 Stop kidney failure • Reduce the lifetime cost of care for CKD patients and payers • 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 specific cell types with the potential to help restore kidney function • Phase 3 clinical program received FDA and EMA guidance and RMAT designation; proact 1 underway • Potential label 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 Preclinical activity and mechanism of action translated to 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



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 for DKD Stage 2/3a (eGFR <u>above</u> 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



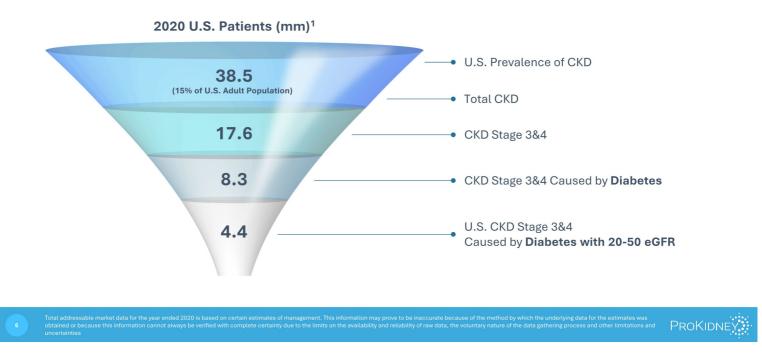
Estimated global market sales of Canagliflozin, Dapagliflozin and Empagliflozin are ~\$10B in 2026

REACT[®] evaluating more severe CKD (20-50 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

	The New England Journal of Medicine. EvaluatePharma

REACT's Addressable U.S. Patient Population

Initially targeting advanced type 2 diabetic CKD with potential for multiple label expansion indications



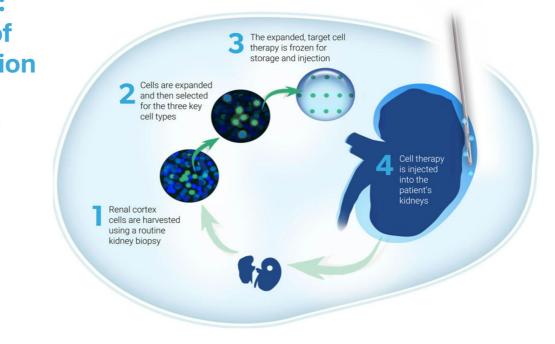
REACT®: <u>REnal Autologous Cell Therapy for CKD</u>

Advancing a comprehensive clinical plan to demonstrate commercial potential

1H 2023	2H 2023		2024 and beyond
 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 patient with imminent risk of renal failure/dialysis 	dooo triggoro	 REGEN-015 Multi-dose trial Launch projected Mid-2023 Safety & efficacy of repeat dosing Previously treated DKD Repeat dosing and durability 	 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 REACT[®] Stage 3b / 4 DKD (eGFR≤50-20) FDA-defined time-to-event endpoints
(as of 9/30/22) thes	06M cash sufficient to fund se key milestones, and to rrim Phase 3 data	• RMAT de	MA agreement on pivotal study design esignation in U.S. r Assay Matrix alignment
			ProKidne

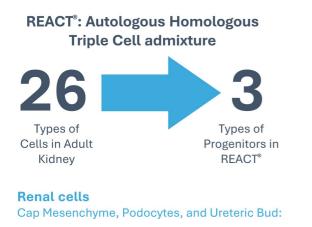
REACT[®] Goal: Restoration of Kidney Function

ProKidney's REACT® Autologous Cell Therapy



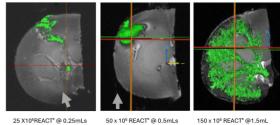
Remodeling and Renovation of Nephrons

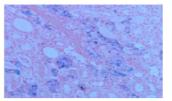
REACT® aims to preserve kidney function for dialysis-free living



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

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

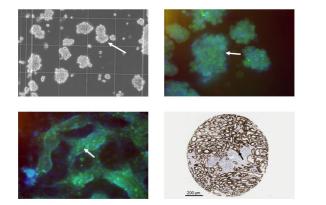




Intra-tubular and Glomerular (REACT[®] – Blue)

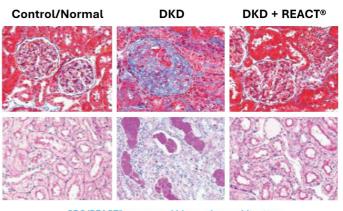
Interstitial (REACT[®] - Blue)

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

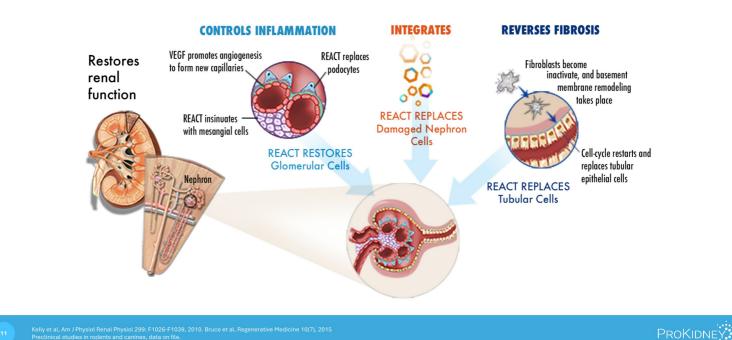


SRC/REACT® preserves kidney microarchitecture

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



REACT® Trials Designed to Address Multiple Areas of CKD

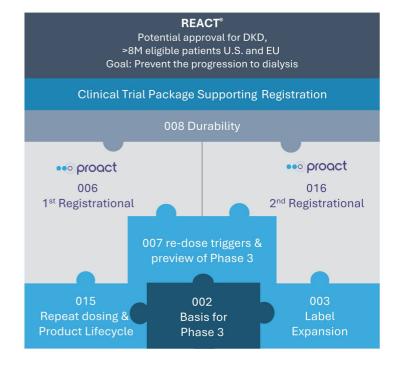
Potential therapeutic indications

Lead Platform Pro	grams (Clinical Development)	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)	Phase 2	D 🖥		002		Fully Enrolled
	Diabetes Type II - Prevent/Delay CKD 3/4 (20-50 ml/min/1.73m ² , N = 1,200)	Phase 3 G) 🚦 🗱		• ⊚proact • ⊚proact (0	06/016)	Ongoing US/ OUS 1H2023
REACT® Diabetic Kidney	Diabetes Type II – Delay CKD 4/5 (14-20 ml/min/1.73m ² , N = 10)	Phase 2 🖧	Ð		003		Trial Completed
Disease (DKD)	Diabetes Repeat Dose Prevent/Delay CKD 3/4 (20-50 ml/min/1.73m², N= 50*)	Phase 2	ið 🚦 🗱 Þþ		007		Enrolling
	Multi / extended-dosing for previously REACT-treated patients	Phase 1/2	nd 🗱 🕅		015		Enrollment 2Q2023
	Long term follow-up study for patients previously treated with REACT	Phase 3			008		Enrollment 3Q2023
REACT® Congenital Anomalies of the Kidney and Urinary Tract (CAKUT)	Congenital Anomalies – Prevent/Delay (14-50 ml/min/1.73m², N= 5)	Phase 1		004			Trial Completed
		eGFR 50-20	2010		Frozen product Re-dosing		ProKidn

Building a Comprehensive Data Package

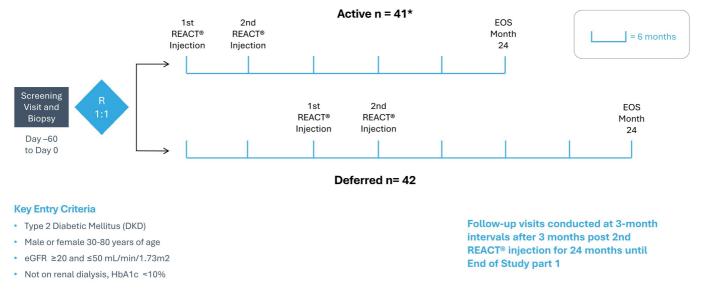
Clinical program designed to expand potential patient population and support premium pricing

- 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)



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

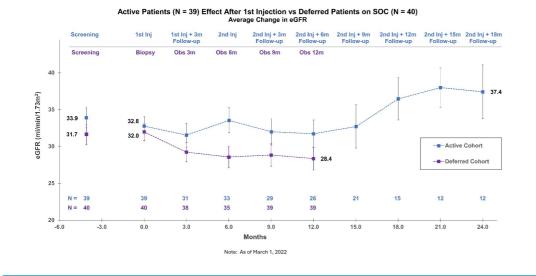
Clinical trial design



ProKidney

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



REACT®

Renal function *improved* 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

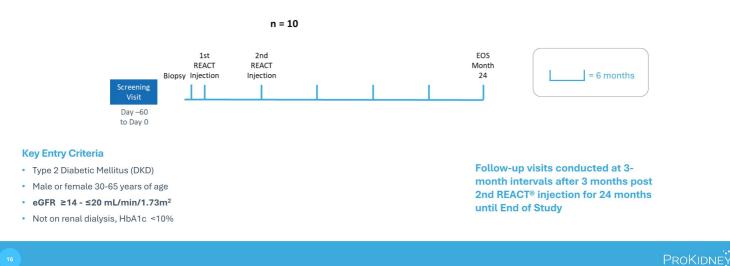
ProKidney

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

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

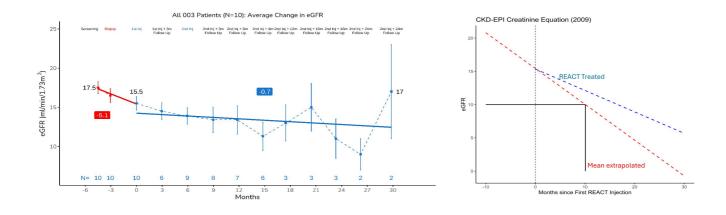
UACR mean 3190 mg/gr; mean eGFR 15.5 mL/min/1.73m²; >90% probability of dialysis initiation

No other marketed drug is indicated for these patients



REGEN-003: Pre-Dialysis Patients Benefit from REACT

- 7/10 patients had 30% increase in dialysis free living (median of ~16 mo.)
- 6/10 patients observed to have improved eGFR or stabilization
- 2/10 patients have preservation of renal function >2+ years post injection



17 Sta

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

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

Construction of the second sec	- /
Serious Adverse Event	
Hematoma*	1
Transfusion*	1
Acute Kidney Injury*	1
Macroscopic Hematuria	0
Angiographic Intervention	0

Surgery Death

CKD progression

Cortical Scar

Renal vascular event

Renal arteriovenous fistula

Events observed in 4/83 participants.

Data as 2/23. Source: Stavas et al. SIR March 202

0

0

1

1

1

0

-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

Leens ooserved in nor o participants. Hematoms, transfusion, & All events occurred in one patient pre-needle design-change in Sept. 2017, other SAE events occurred post-needle design change in Sept. 2017, other SAE events occurred post-needle design change in Sept. 2017, other SAE events occurred post-needle design change in Sept. 2017, other SAE events occurred post-needle design change in Sept. 2017, other SAE events occurred post-needle design change in Sept. 2017, other SAE events occurred post-needle design change in Sept. 2017, other SAE events occurred post-needle design change in Sept. 2017, other SAE events occurred post-needle design change in Sept. 2017, other SAE events occurred post-needle design change in Sept. 2017, other SAE events occurred post-needle design change in Sept. 2017, other SAE events occurred post-needle design change in Sept. 2017, other SAE events occurred post-needle design change in Sept. 2017, other SAE events occurred post-needle design change in Sept. 2017, other Sept. 2

-004 Procedure-related events: Renal Related (N=5 pt biopsies, 9 injection	
Serious Adverse Event	
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 report	od

No cell product related SAEs were reported Data on file and as of 1/23. -007 Interim procedurerelated events: Renal Related (N=39 pt biopsies, 42 injections)

Serious Adverse Event	
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 injecti	ion.

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 moderatesevere CKD at high risk for renal failure

Consistently aiming 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

CJASN

What are the complications associated with native kidney biopsy?

	Systematic review and meta-analysis of the literature		Complication rates of native kidney biopsies performed using automated		11% Hematoma	Bleeding requiring transfusions
	Published from Jan 1983 to Mar 2018		devices under kidney imaging		1.3%	6 0.3%
	1139 manuscripts in initial PubMed search	S é	Native kidney biopsies n = 118,064		Pain at biopsy site	Bleeding requiring intervention 0.06% or
Y	Pre-determined selection criteria		events 30 – 79 years Patient age range	Main biopsy complications	Macroscopic hematuria	1 in 1,667 Death in patients who undergo a native kidney biopsy
	87 manuscripts in final analysis	ŧ	45% Female	Complication rates Hospitaliz patients		Patients with acute kidney injury

Emilio D. Poggio, Robyn L. McClelland, Kristina Blank, Spencer Hansen, et al. Systematic Review and Meta-Analysis of Native Kidney Biopsy Complications. CJASN doi:10.2215/CJN4710420. Visual Abstract by Michelle Lim, MBChB, MRCP

REACT Phase 2 Safety Profile Summary

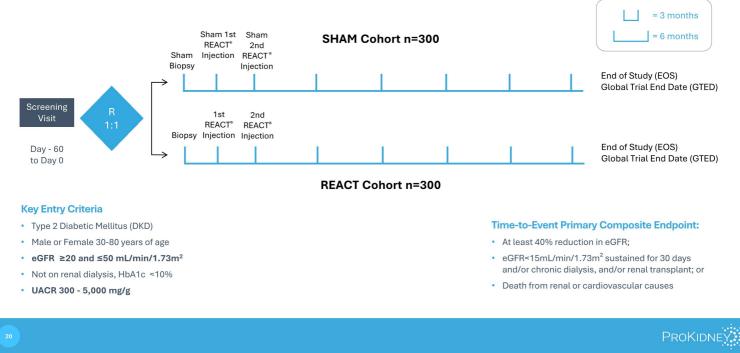
Category	Biopsy # of patients (%) (N=133)	REACT Injection # of patients (%) (N=202)
Hematoma	4 (3.0)	3 (1.5)
Pain	0	3 (1.5)
Hematuria	1 (0.7)	0
Transfusion	1 (0.7)	1 (0.5)
Bleed + intervention	0	0
Death	0	0

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

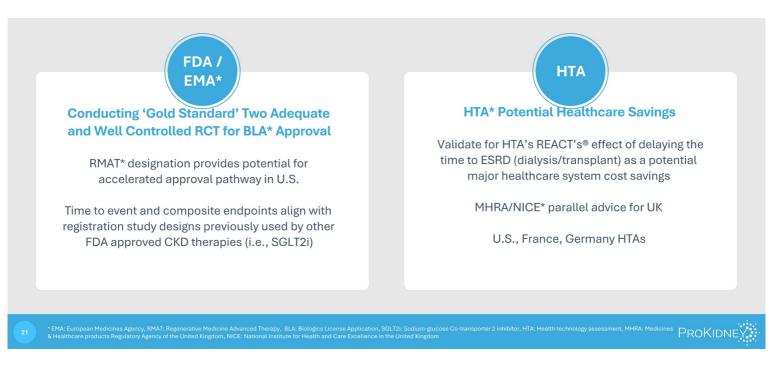
REACT® Registrational Program: •• proact 1 & •• proact 2 (REGEN-006 / 016)

First •• prooct 1 patients enrolled in 2022



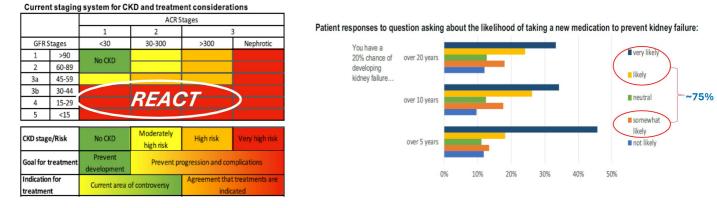
REACT® Registrational Program

Regulatory & reimbursement engagement plan: Diabetic Kidney Disease



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."

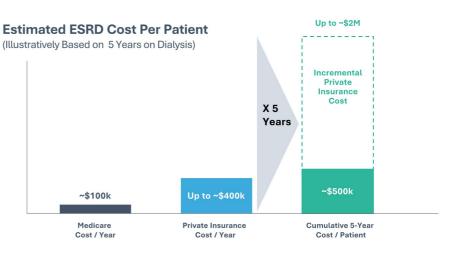
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Significant Cost Savings Potential

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

23 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/dialysisinfo#how-long-can-you-live-dialysis), company estimates	
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Manufacturing Strategies

Infrastructure strategy to reduce COGS and expand addressable market

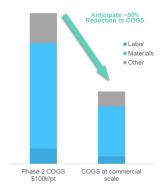
Manufacturing toward clinical and commercial opportunities

- Staged construction of commercial scale manufacturing facilities
- In-house manufacturing supports clinical program
- Scalable to meet initial commercial demand upon regulatory approval
- Future facilities will be built to meet market demand



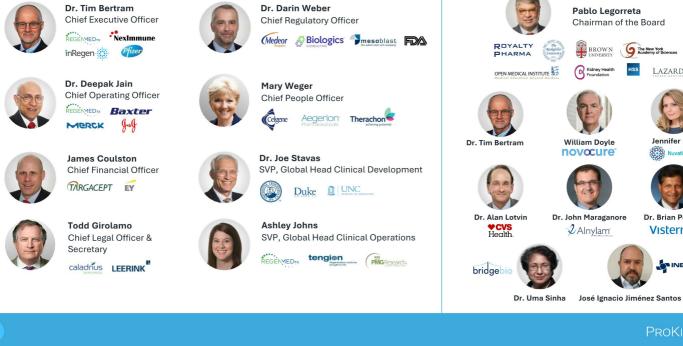
Cost of Goods Sold (COGS)

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



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World-class Leadership and Board of Directors



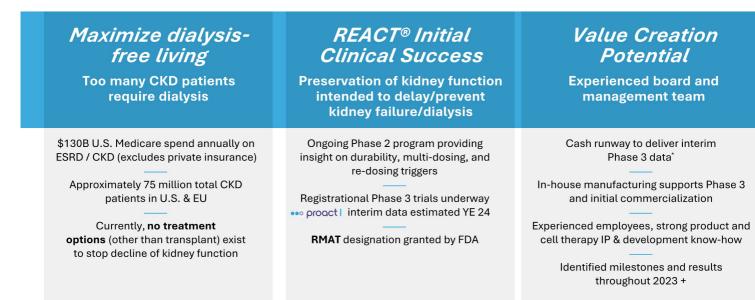
LAZARD

Jennifer Fox

Nuvation Bio

Dr. Brian Pereira

Why ProKidney?



Contribution to Society: Stop Kidney Failure



Corporate Overview

March 2023

A Step Closer to Potential Dialysis Prevention REACT® [**RE**nal **A**utologous **C**ell Therapy]