**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): May 29, 2024**

# 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: 336 999-7019**

**(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") provided investors with a presentation setting forth final data from the Company's Phase 2 RMCL-002 clinical trial (the "Presentation"). 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 |
|---|---|
| 99.1 | Investor Presentation |
| 104 | Cover Page Interactive Data File (embedded within Inline XBRL document) |

**SIGNATURES**

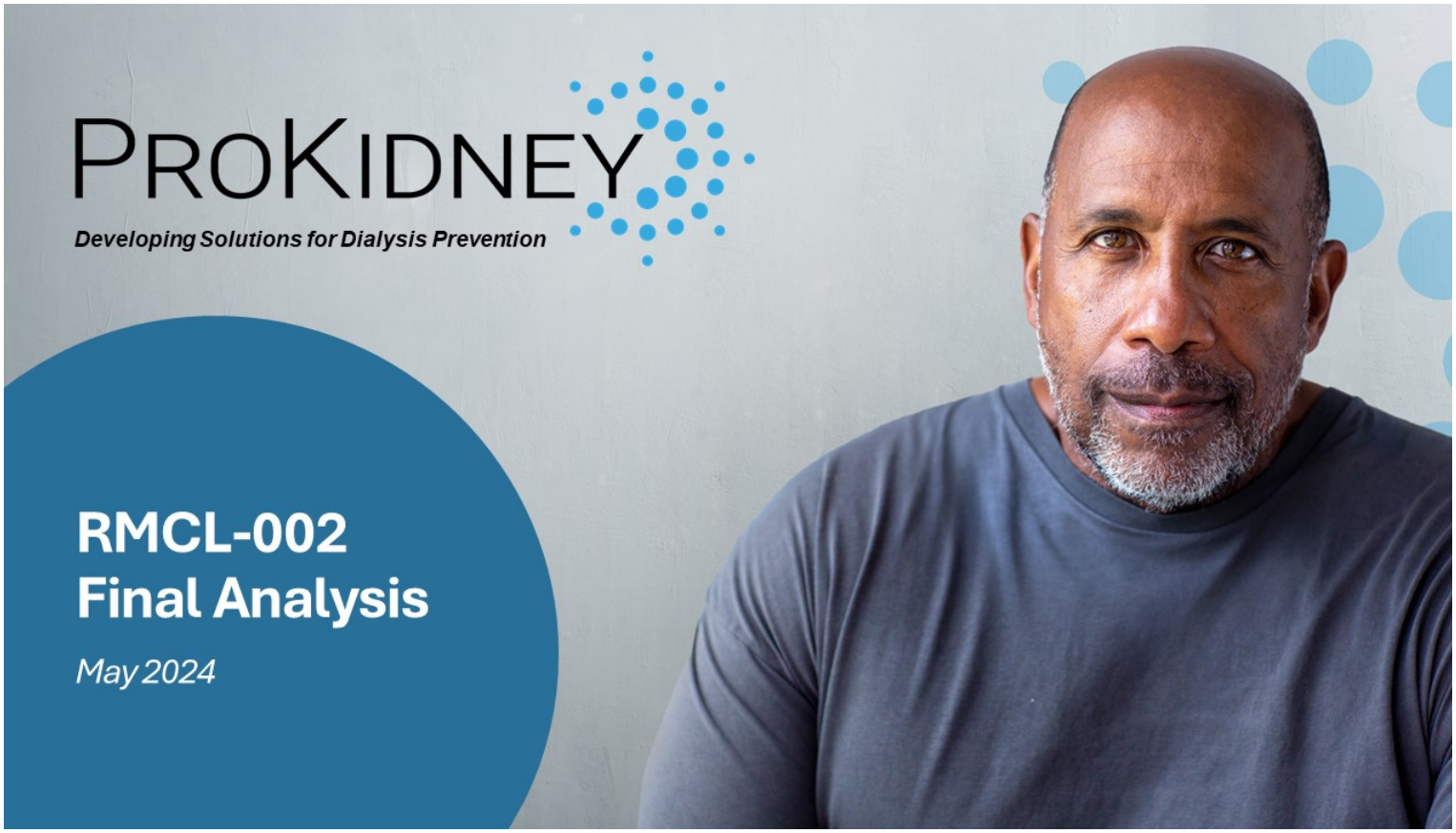
Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

PROKIDNEY CORP.

Date: May 29, 2024

By: /s/ Todd Girolamo
Todd Girolamo
Chief Legal Officer

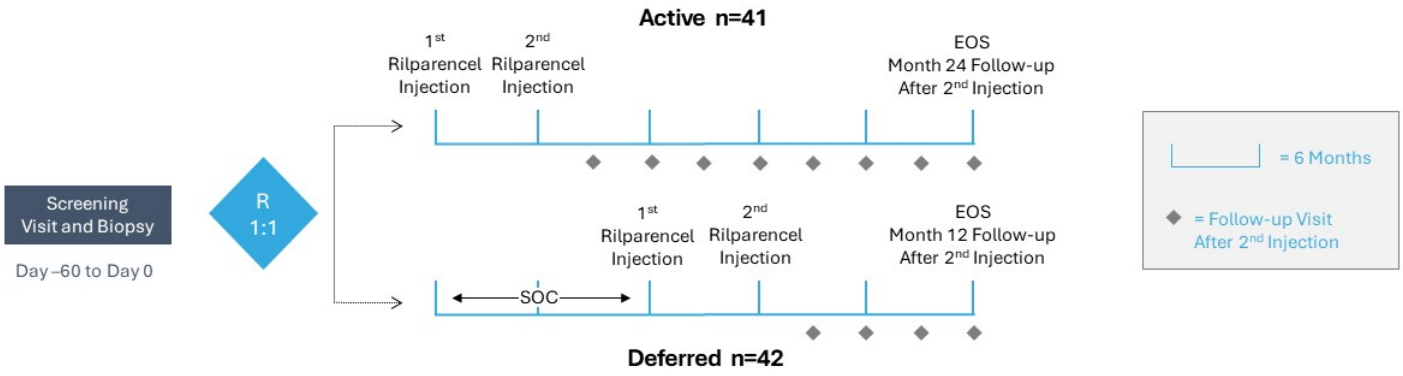
Exhibit 99.1


PROKIDNEY
Developing Solutions for Dialysis Prevention
RMCL-002
Final Analysis
May 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 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.

# RMCL-002: Trial Design




| Key Entry Criteria | Study Endpoints | Study Timeframe |
|---|---|---|
| Type 2 Diabetes Mellitus (DKD) | **Rilparencel and procedure related adverse events** | First patient injected in 2017 |
| Male or female 30-80 years of age | **Change in kidney function (assessed by eGFR)** | RMAT granted for Phase 3 program in January 2022 |
| eGFR ≥20 and ≤50 mL/min/1.73m$^2$ | | |
| Not on kidney dialysis, HbA1c <10% | | |



RMAT = Regenerative Therapy Advanced Medicine; SOC = Standard of Care

# RMCL-002: Study Objectives and Endpoints

**Study Objectives**

- To assess the safety and efficacy of up to two rilparencel injections given 6 months apart and delivered into the biopsied kidney using a percutaneous approach

**Study Endpoints**

- Procedural and investigational product-related adverse events
- Change in kidney function as measured by serial measurements of estimated glomerular filtration rate (eGFR)

# RMCL-002 Baseline Subject Characteristics are Balanced and Represent a High-Risk CKD Population

| | ACTIVE ARM (n=41) | DEFERRED ARM (n=42) |
|---|---|---|
| **Age, years *(mean +/- SD)*** | 66.1 +/- 9.9 | 64.6 +/- 8.9 |
| **Female : Male, %** | 29% : 71% | 36% : 64% |
| **Hispanic or Latino, %** | 17% | 10% |
| **Race, %** | | |
| Black or African American | 2.5% | 14% |
| White | 95% | 74% |
| Other | 2.5% | 12% |
| **Blood pressure, mm HG** | 133 / 72 | 135 / 73 |
| **eGFR, ml/min/1.73m$^2$ *(mean +/- SD)*** | 33.9 +/- 8.6 | 31.7 +/- 7.4 |
| **Stage 3A CKD, n (%)** | 5 (12%) | 3 (7%) |
| **Stage 3B CKD, n (%)** | 21 (51%) | 18 (43%) |
| **Stage 4 CKD, n (%)** | 15 (37%) | 21 (50%) |
| **UACR mg/g *(median +/- interquartile range)*** | 740 (68, 1597) | 598 (58, 1985) |
| **Geometric Mean of UACR mg/g** | 389 | 330 |
| **HbA1c, % *(mean +/- SD)*** | 7.2 +/- 1.0 | 7.1 +/- 1.0 |

# No Rilparencel-related SAEs Identified in RMCL-002

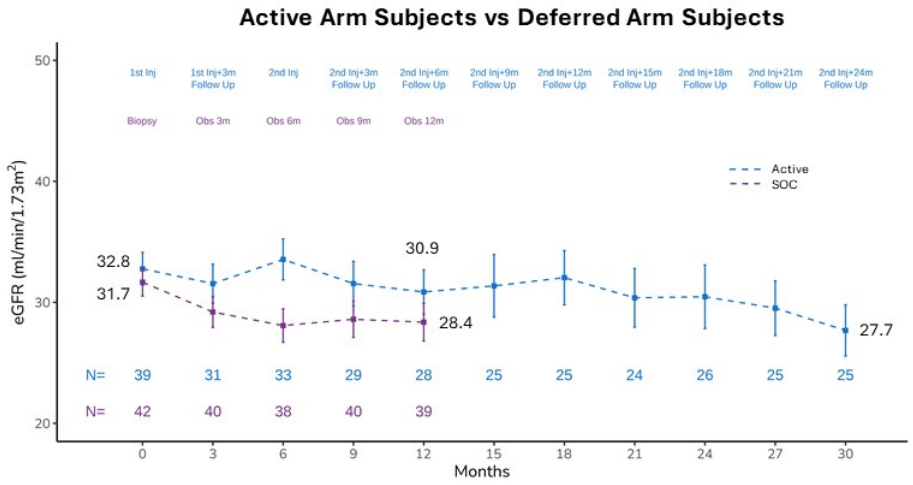
| ADVERSE EVENT | BIOPSY # of events (n=83)* | RILPARENCEL INJECTION # of events (n=132)* |
|---|---|---|
| **Hematoma (including Page Kidney during biopsy)** | 2 | 2 |
| **Pain** | 0 | 2 |
| **Acute Kidney Injury** | 1 | 1 |
| **CKD progression (eGFR progression)** | 0 | 1 |
| **Pyrexia** | 0 | 1 |
| **Anemia** | 0 | 1 |
| **Pneumonia** | 0 | 1 |
| **Creatinine increase** | 0 | 1 |

Other events with possible-relatedness include kidney fibrosis and indeterminate renal vessel occlusion or vasospasm



Data as of April 26, 2024; SAE = serious adverse events

# Active Cohort Subjects Showed No Clinically Meaningful eGFR Decline Over 30 Months



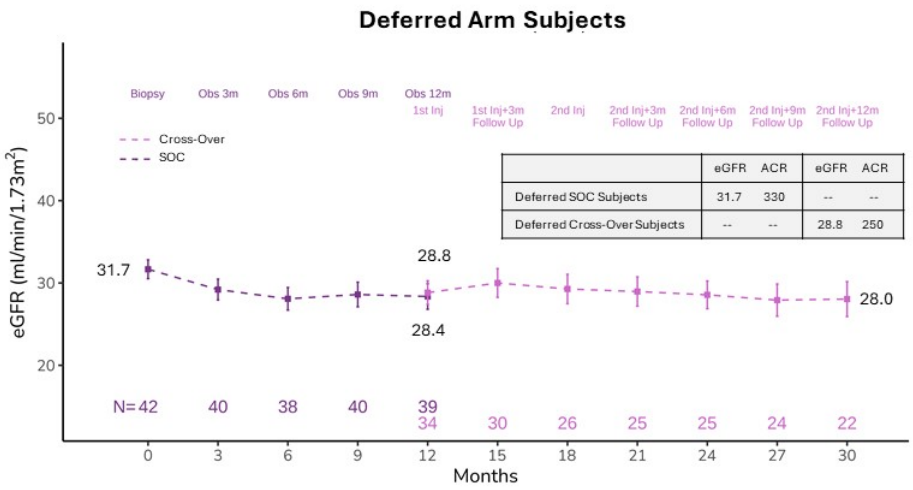

The Active Cohort showed a cumulative change in average eGFR of **-5.1 ml/min/1.73m² after 30 months**;

The Deferred Cohort, receiving standard of care, showed a cumulative change in average eGFR of **-3.3 ml/min/1.73m² after 12 months.**



Data points are mean +/- SEM ; Data as of April 26, 2024

# Deferred to Cross-Over Subjects Showed Preservation of eGFR after Rilparencel Injection




| | eGFR | ACR | eGFR | ACR |
|---|---|---|---|---|
| Deferred SOC Subjects | 31.7 | 330 | -- | -- |
| Deferred Cross-Over Subjects | -- | -- | 28.8 | 250 |

Average eGFR of the Deferred cohort was 31.7 at baseline vs 28.4 at 12 months

**[absolute difference of -3.3 ml/min/1.73m² over 12 months]**

Average eGFR at 1st injection after cross-over was 28.8 vs 28.0 at 18 months

**[absolute difference of -0.8 ml/min/1.73m² over 18 months]**

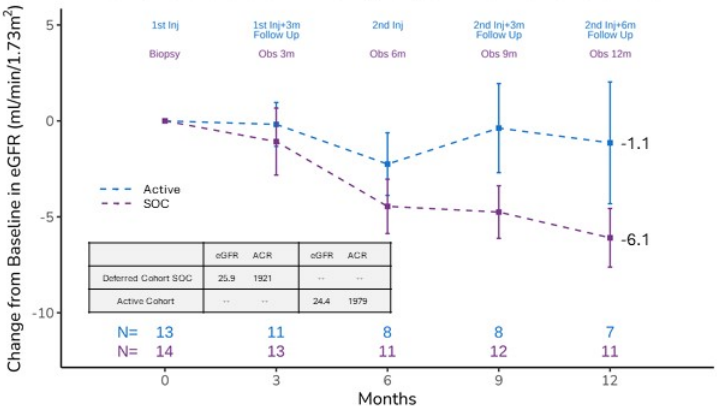


Data points are mean +/- SEM ; Data as of April 26, 2024

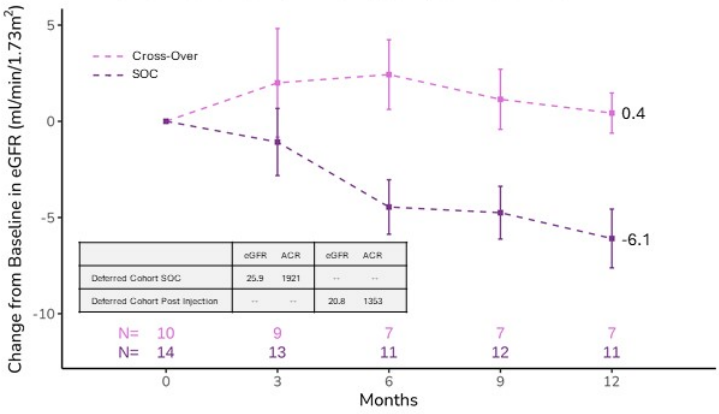
# Subgroup Analysis of Diabetic Subjects with CKD Stage 4 and Class A3 Albuminuria*

## Stabilization of Kidney Function in Active and Deferred Arm Subjects at 12 Months vs SOC

**UACR Severe & CKD4 Subgroups in Active vs Deferred Arm**




**UACR Severe & CKD4 Subgroups in Deferred Arm**




***Patients with Stage 4 CKD & Class A3 (Severe Albuminuria, >300 mg/g) are one of the fastest progressing CKD patient populations[1]**



Data points are mean +/- SEM ; Data as of April 26, 2024; 1. Oshima M, et al. Trajectories of kidney function in diabetes: a clinicopathological update. Nat Rev Nephrol. 2021;17(11):740-750. doi:10.1038/s41581-021-00462-y

# RMCL-002 Summary

## Key Findings

- Showed potential to **preserve kidney function** for up to 30 months in several patient groups
- Benefit to kidney function was most notable in subjects who had the **highest risk of kidney failure** (Stage 4 CKD with high UACR[1])
- Injections were **well tolerated** with a consistent safety profile comparable to kidney biopsy



1. UACR = urine albumin-to-creatinine ratio (a measure of albuminuria)