



ProKidney confirms Phase 3 program for autologous kidney cell therapy REACT®

April 12, 2022 12:00 PM EDT

Two Phase 3 controlled trials with substantially similar design to enroll 1,200 subjects with diabetic CKD

Winston-Salem, NC, April 12, 2022 — ProKidney LP (“ProKidney”), a leading clinical-stage cellular therapeutics company focused on therapies for chronic kidney disease (“CKD”), today announced the updated design for its REACT® Phase 3 program.

REGEN-006 and REGEN-016 are expected together to enroll up to 1,200 subjects with CKD on optimized standard of care in two Phase 3 trials. Each trial is expected to enroll approximately 600 subjects with CKD due to type 2 diabetes in multiple centers in the United States, Europe, Latin America, and Asia Pacific. The FDA has indicated that these trials may be sufficient to support regulatory filing of a Biologic License Application (BLA) for our transformational cell therapy for CKD if they meet the primary and key secondary endpoints.

Subjects will be randomized 1:1 into either a REACT® treatment arm and undergo a kidney biopsy or a sham control arm. The primary objective of each study is to assess the efficacy of up to two REACT® injections given three months apart and delivered into biopsied and non-biopsied contralateral kidneys using a minimally invasive percutaneous approach. The primary composite endpoint is the time from first injection to the earliest of:

- at least 40% reduction in eGFR, using the 2009 CKD-EPI serum creatinine equation, sustained for 30 days; or
- eGFR <15 mL/min/1.73m² using the 2009 CKD-EPI serum creatinine equation, sustained for 30 days and/or chronic dialysis, and/or renal transplant; or
- renal or cardiovascular death

A new Phase 2 trial will be opened to eligible subjects from the sham arms of the Phase 3 trials to allow them access to REACT® treatment after completing the trial or experiencing a qualifying event that would require the subject to discontinue participation in the trial.

“At ProKidney we are forging a potential new path for patients with chronic kidney disease. After consultation with FDA, we believe we are in a position to work toward registrational trials for REACT®. We opened the first clinical trial centers earlier this year, and the first subjects already have been enrolled,” said Tim Bertram, ProKidney’s CEO. “We expect our Phase 3 program to deliver a robust dataset with the possibility to announce interim data and file for approval with the FDA in 2025.”

About REACT®

REACT® has the potential not only to slow the progression of CKD, but in some cases drive meaningful improvement in kidney function – a groundbreaking first in CKD therapies.

A cell therapy product produced from a patient’s own kidney cells, REACT® comprises a proprietary mixture of progenitor cells that have been taken from a patient, selected and grown and then returned to the patient’s kidney. This minimally invasive procedure, starting with a standard biopsy, provides the cells that harness the body’s intrinsic ability to repair and restore damaged kidney tissue. The outpatient reinjection procedure has been shown to be better tolerated than contemporary biopsy and renal failure treatment options, such as dialysis and organ transplant.

About ProKidney

ProKidney, a pioneer in the treatment of chronic kidney disease (CKD) through innovations in cellular therapy, was founded in 2015 after a decade of research. ProKidney’s lead product candidate, REACT® (Renal Autologous Cell Therapy), is a first-of-its-kind, patented disease-modifying autologous cellular therapy with the potential not only to slow and stabilize the progression of CKD, but in some cases drive meaningful improvement in kidney function. REACT® has received Regenerative Medicine Advanced Therapy (RMAT) designation, as well as FDA and EMA guidance, supporting a global registrational program, which launched in the United States on schedule in January 2022. On January 18, 2022, ProKidney announced that it would become a publicly traded company via a business combination with Social Capital Suvretta Holdings Corp. III (Nasdaq: DNAC). For more information, visit www.prokidney.com.

Additional Information and Where to Find It

In connection with the proposed transaction between Social Capital Suvretta Holdings Corp. III ("SCS") and ProKidney, SCS filed a preliminary proxy statement with the U.S. Securities and Exchange Commission (the "SEC") on February 14, 2022 and intends to file a definitive proxy statement with the SEC. SHAREHOLDERS OF SCS ARE ADVISED TO READ THE PRELIMINARY PROXY STATEMENT, AND WHEN AVAILABLE, ANY AMENDMENTS THERETO, THE DEFINITIVE PROXY STATEMENT AND ALL OTHER RELEVANT DOCUMENTS FILED OR THAT WILL BE FILED WITH THE SEC IN CONNECTION WITH THE PROPOSED TRANSACTION AS THEY BECOME AVAILABLE BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION. HOWEVER, THESE DOCUMENTS WILL NOT CONTAIN ALL THE INFORMATION THAT SHOULD BE CONSIDERED CONCERNING THE PROPOSED TRANSACTION. THEY ARE ALSO NOT INTENDED TO FORM THE BASIS OF ANY INVESTMENT DECISION OR ANY OTHER DECISION IN RESPECT OF THE PROPOSED TRANSACTION. When available, the definitive proxy statement will be mailed to the shareholders of SCS as of a record date to be established for voting on the proposed transaction. Shareholders will also be able to obtain copies of the preliminary proxy statement, the definitive proxy statement and other documents filed with the SEC that will be incorporated by reference therein, without charge, once available, at the SEC's website at <http://www.sec.gov>.

The documents filed by SCS with the SEC also may be obtained free of charge at SCS's website at <https://socialcapitalsuvrettaholdings.com/dnac> or upon written request to 2850 W. Horizon Ridge Parkway, Suite 200, Henderson, NV 89052.

Participants in the Solicitation

SCS and ProKidney and their respective directors and executive officers may be deemed to be participants in the solicitation of proxies from SCS's shareholders in connection with the proposed transaction. A list of the names of such directors and executive officers and information regarding their interests in the proposed transaction between ProKidney and SCS will be contained in the definitive proxy statement when available. You may obtain free copies of these documents as described in the preceding paragraph.

No Offer or Solicitation

This communication shall not constitute a solicitation of a proxy, consent or authorization with respect to any securities or in respect of the proposed transaction. This communication shall not constitute an offer to sell or the solicitation of an offer to buy any securities, nor shall there be any sale of securities in any states or jurisdictions in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of such state or jurisdiction. No offering of securities shall be made except by means of a prospectus meeting the requirements of Section 10 of the Securities Act of 1933, as amended or an exemption therefrom.

Forward-Looking Statements

This communication may contain certain forward-looking statements within the meaning of the federal securities laws, including with respect to the proposed transaction between ProKidney and SCS and the timing of enrollment of ProKidney's clinical trials, availability of clinical data and obtainment of regulatory approvals. These forward-looking statements generally are identified by the words "believe," "project," "expect," "anticipate," "estimate," "intend," "strategy," "future," "opportunity," "plan," "may," "should," "will," "would," "will be," "will continue," "will likely result," and similar expressions. Forward-looking statements are predictions, projections and other statements about future events that are based on current expectations and assumptions and, as a result, are subject to risks and uncertainties. Many factors could cause actual future events to differ materially from the forward-looking statements in this communication, including but not limited to: (i) the risk that the proposed transaction may not be completed in a timely manner or at all, which may adversely affect the price of SCS's securities, (ii) the risk that the proposed transaction may not be completed by SCS's business combination deadline and the potential failure to obtain an extension of the business combination deadline if sought by SCS, (iii) the failure to satisfy the conditions to the consummation of the proposed transaction, including the adoption of the definitive agreement related to the business combination between SCS and ProKidney (the "Business Combination Agreement") by the shareholders of SCS and the satisfaction of the minimum cash condition, (iv) the lack of a third-party valuation in determining whether or not to pursue the proposed transaction, (v) the inability to complete the private placement entered into in connection with the transaction, (vi) the occurrence of any event, change or other circumstance that could give rise to the termination of the Business Combination Agreement, (vii) the effect of the announcement or pendency of the transaction on ProKidney's business relationships, operating results, and business generally, (viii) risks that the proposed transaction disrupts current plans and operations of ProKidney and potential difficulties in ProKidney employee retention as a result of the transaction, (ix) the outcome of any legal proceedings that may be instituted against ProKidney or against SCS related to the Business Combination Agreement or the proposed transaction, (x) the ability to maintain the listing of SCS's securities on a national securities exchange, (xi) the price of SCS's securities may be volatile due to a variety of factors, including changes in the competitive and highly regulated industries in which SCS plans to operate or ProKidney operates, variations in operating performance across competitors, changes in laws and regulations affecting SCS's or ProKidney's business, and changes in the combined capital structure, (xii) the ability to implement business plans, forecasts, and other expectations after the completion of the proposed transaction, and identify and realize additional opportunities, (xiii) the risk of downturns and a changing regulatory landscape in the highly competitive biotechnology industry, and (xiv) 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 foregoing list of factors is not exhaustive. You should carefully consider the foregoing factors and the other risks and uncertainties described in the "Risk Factors" section of SCS's preliminary proxy statement on Schedule 14A (File No. 001-40560) filed with the SEC on February 14, 2022, SCS's annual report on Form 10-K for the year ended December 31, 2021 filed with the SEC on March 28, 2022, the definitive proxy statement of SCS, when available, including those under "Risk Factors" therein and other documents filed by SCS from time to time with the SEC. These filings identify and address other important risks and uncertainties that could cause actual events and results to differ materially from those contained in the forward-looking statements. Forward-looking statements speak only as of the date they are made. Readers are cautioned not to put undue reliance on forward-looking statements, and ProKidney and SCS assume no obligation and do not intend to update or revise these forward-looking statements, whether as a result of new information, future events, or otherwise. Neither ProKidney nor SCS gives any assurance that either ProKidney or SCS, or the combined company, will achieve its expectations.

Contact:

Investors:

Lee Roth

Burns McClellan

lroth@burnsmc.com

+1 (212) 300-8331