March 30, 2022

RenovoRx Reports Full Year 2021 Financial Results

LOS ALTOS, Calif.--(BUSINESS WIRE)-- RenovoRx, Inc. (“RenovoRx” or the “Company”) (Nasdaq: RNXT), a biopharmaceutical company and innovator in targeted cancer therapy, today is reporting its financial results for the year ended December 31, 2021.

“2021 was a transformative year for RenovoRx. We successfully closed on our initial public offering and listed on the NASDAQ under ‘RNXT,’” said Shaun Bagai, CEO of RenovoRx. “Importantly, despite challenges created by the COVID-19 pandemic, we maintained steady enrollment in our Phase 3 clinical trial in locally advanced pancreatic cancer. We recently achieved approximately 50% of the target enrollment under the current statistical analysis plan. One of the issues with systemic chemotherapy is the significant side effects to the entire body. RenovoRx is addressing this problem by localizing therapy to treat tumors via our proprietary RenovoTAMP™ (RenovoRx Trans-Arterial Micro-Perfusion) therapeutic platform. Today, we have the strategy and team to build on our progress in treating pancreatic cancer with the opportunity to extend the RenovoTAMP platform to other cancers. We are challenging the bounds typically associated with treating solid tumors to improve survival and quality of life for patients undergoing chemotherapy.”

2021 Operational Highlights:

- Issuance of seventh U.S. patent extending the intellectual property coverage of the RenovoTAMP therapy platform.
- Closed on IPO and listed on the Nasdaq Capital Market under the ticker symbol, “RNXT.”
- Received new 510(k) clearance for the RenovoCath® delivery system (the device component of the Company’s initial product, RenovoGem™). RenovoRx received its initial 510(k) for the RenovoCath delivery system in 2014.
- Announced final data from RR2 observational registry study. Phase 1/2 trials demonstrated that prior radiation treatment, together with targeted chemotherapy delivered via RenovoTAMP, reduced the tolerability issues typically associated with systemic chemotherapy and improved survival.

2022 Operational Highlights and Upcoming Targeted Milestones:

- Began enrolling patients at Columbia University’s New York-Presbyterian Hospital Irving Medical Center in ongoing TIGeR-PaC Phase 3 Clinical Trial.
- TIGeR-PaC achieved approximately 50 percent of the target enrollment under the current statistical analysis plan.
- Plans to meet with the FDA to discuss trial design for a second indication, extrahepatic (or outside the liver) cholangiocarcinoma (bile duct cancer), or eCCA. Pending the outcome of that meeting and protocol submission, Phase 2 trial in eCCA may be launched in 2H 2022.
- Expects to conduct TIGeR-PaC interim analysis.

Financial Highlights for the Fiscal Year Ended December 31, 2021

- Cash and cash equivalents as of December 31, 2021, were $15.2 million.
- Research and development expenses were $3.0 million for the year ended December 31, 2021, compared to $2.4 million for the year ended December 31, 2020. The increase was primarily due to higher clinical development employee-related costs.
- General and administrative expenses were $2.6 million for the year ended December 31, 2021, compared to $0.8 million for the year ended December 31, 2020. The increase was primarily due to higher professional and consulting expenses related to preparing for our IPO in August 2021, including employee-related costs and insurance costs for Directors and Officers Liability Insurance.
- Net loss was $6.3 million for the ended December 31, 2021, compared to net loss of $3.8 million for year ended December 31, 2020.
- As of March 25, 2022 the Company had 9,029,305 common shares outstanding.

About the Phase 3 TIGeR-PaC Clinical Trial

TIGeR-PaC is a randomized multi-center Phase 3 study using RenovoRx's innovative therapy platform, RenovoTAMP (RenovoRx Trans-arterial Micro-perfusion). The study is evaluating the Company's first product candidate, RenovoGem, to treat locally advanced pancreatic cancer (LAPC) through the intra-arterial delivery of gemcitabine (an FDA-approved chemotherapy). The study has a primary endpoint of overall survival and several secondary endpoints, including quality of life.

TIGeR-PaC is currently enrolling unresectable LAPC patients at several sites across the U.S. To learn more about the study and the participating clinical trial sites, visit **https://renovorx.com/clinical-trial/**.

About RenovoRx, Inc.

RenovoRx is a clinical-stage biopharmaceutical company focused on fighting cancer through the localized treatment of difficult to treat tumors via its proprietary RenovoRx Trans-Arterial Micro-Perfusion (RenovoTAMP™) therapy platform. RenovoTAMP utilizes approved chemotherapeutics with validated mechanisms of action and well-established safety and side effect profiles, with the goal of increasing their efficacy, improving their safety, and widening their therapeutic window. RenovoRx's lead product candidate, RenovoGem™, is a combination of gemcitabine and our patented delivery system, RenovoCath®, and is regulated by the FDA as a novel oncology drug product to treat unresectable locally advanced pancreatic cancer (LAPC). RenovoGem is currently being studied in the Phase 3 TIGeR-PaC trial for the treatment of LAPC.

RenovoRx's patent portfolio for its therapy platform and product candidates includes seven U.S. patents, one European patent and several additional patents pending in the US, EU and Asia. RenovoRx has been granted Orphan Drug Designation for intra-arterial delivery of gemcitabine for the treatment of both pancreatic cancer and bile duct cancer.

RenovoRx won the Drug Delivery Technology category of the Fierce Innovation Awards – Life Sciences Edition 2020 for its RenovoTAMP technology.

Learn more by visiting the RenovoRx website or following us on Facebook, LinkedIn and Twitter.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, and Section 21E of the Securities Exchange Act of 1934, including but not limited to statements regarding our Phase 1 (RR1) and Observational Registry (RR2) studies, statements regarding the potential of RenovoTAMP™, RenovoCath® or RenovoGem™ or regarding our ongoing TIGeR-PaC Phase 3 clinical trial in LAPC, and statements regarding the potential for our product candidates to treat or provide clinically meaningful outcomes for certain medical conditions or diseases. Statements that are not purely historical are forward-looking statements. The forward-looking statements contained herein are based upon our current expectations and beliefs regarding future events, many of which, by their nature, are inherently uncertain, outside of our control and involve assumptions that may never materialize or may prove to be incorrect. These may include estimates, projections and statements relating to our research and development plans, clinical trials, therapy platform, business plans, objectives and expected operating results, which are based on current expectations and assumptions that are subject to known and unknown risks and uncertainties that may cause actual results to differ materially from those expressed or implied by these forward-looking statements. These statements may be identified using words such as “may,” “expects,” “plans,” “aims,” “anticipates,” “believes,” “forecasts,” “estimates,” “intends,” and “potential,” or the negative of these terms or other comparable terminology regarding RenovoRx’s expectations strategy, plans or intentions, although not all forward-looking statements contain these words. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, that could cause actual events to differ materially from those projected or indicated by such statements, including, among other things: the timing of the initiation, progress and potential results of our preclinical studies, clinical trials and our research programs; our ability to use and expand our therapy platform to build a pipeline of product candidates; our ability to advance product candidates into, and successfully complete, clinical trials; the timing or likelihood of regulatory filings and approvals; our estimates of the number of patients who suffer from the diseases we are targeting and the number of patients that may enroll in our clinical trials; the commercialization potential of our product candidates, if approved; our ability and the potential to successfully manufacture and supply our product candidates for clinical trials and for commercial use, if approved; future strategic arrangements and/or collaborations and the potential benefits of such arrangements; our estimates regarding expenses, future revenue, capital requirements and needs for additional financing and our ability to obtain additional capital; the sufficiency of our existing cash and cash equivalents to fund our future operating expenses and capital expenditure requirements; our ability to retain the continued service of our key personnel and to identify, hire and retain additional qualified personnel; the implementation of our strategic plans for our business and product candidates; the scope of protection we are able to establish and maintain for intellectual property rights, including our therapy platform, product candidates and research programs; our ability to contract with third-party suppliers and manufacturers and their ability to perform adequately; the pricing, coverage and reimbursement of our product candidates, if approved; developments relating to our competitors and our industry, including competing product candidates and therapies; negative impacts of the COVID-19 pandemic on our operations; and other risks.

Information regarding the foregoing and additional risks may be found in the section entitled “Risk Factors” in documents that we file from time to time with the Securities and Exchange Commission. Forward-looking statements included herein are made as of the date hereof, and RenovoRx does not undertake any obligation to update publicly such forward-looking statements to reflect subsequent events or circumstances, except as required by law.

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