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RenovoRx Advances Commercialization of RenovoCath® with Several New Purchase Orders, Including Customer Reorders

Initial Revenues Expected this Quarter, and Customer Pipeline for RenovoCath Standalone Device Continues to Expand, Including High Volume National Cancer Institute-Designated Centers

RenovoCath Gaining Validation in an Initial U.S. Market Estimated at \$400 Million Annually

MOUNTAIN VIEW, Calif.--(BUSINESS WIRE)-- [RenovoRx, Inc.](#) ("**RenovoRx**" or the "**Company**") (**Nasdaq: RNXT**), a life sciences company developing novel targeted oncology therapies and commercializing **RenovoCath**, a novel, FDA-cleared drug-delivery device, today announced continuing momentum with the Company's RenovoCath commercial strategy, with new purchase orders received from several esteemed, high volume National Cancer Institute-designated centers.

Additionally, RenovoRx reported that utilization of RenovoCath devices by its initial customers announced this past December has led to repeat purchase orders. Together, these announcements demonstrate that RenovoRx is continuing on the path to initial revenue generation from RenovoCath sales this quarter and that revenues could begin to ramp during the course of 2025.

RenovoRx continues to expand the pipeline of medical institutions that have expressed interest in RenovoCath as a standalone device that addresses high unmet medical needs. RenovoRx expects an average of 5 to 8 annual procedures per patient and pricing similar to other specialty catheters on the market today, ranging from \$7,000 to \$9,000 per unit. Based on these assumptions and the number of initial target customers being focused on by RenovoRx, the Company believes that the initial total addressable market for RenovoCath has the potential for up to \$400 million in peak annual U.S. sales as a standalone device.

"The commercialization momentum with both new and now repeat customers for our proprietary RenovoCath device has accelerated through expanded relationships with high-volume oncology centers across the country. This not only puts us in a position to potentially generate and grow our initial revenues on our own but also puts us in a strengthened negotiation position with potential commercial sales collaborators," said Shaun Bagai, CEO of RenovoRx. "We are encouraged by the reception for RenovoCath for targeted therapeutic delivery and potential benefits for improved patient outcomes. We believe targeted therapeutic delivery with RenovoCath via our TAMP technology has the potential to transform oncology treatment by enabling precise delivery of agents. We look forward to riding this momentum forward and providing updates as the year progresses."

About RenovoCath

Based on its FDA clearance, **RenovoCath®** is intended for the isolation of blood flow and delivery of fluids, including diagnostic and/or therapeutic agents, to selected sites in the peripheral vascular system. RenovoCath is also indicated for temporary vessel occlusion in applications including arteriography, preoperative occlusion, and chemotherapeutic drug infusion. For further information regarding our RenovoCath Instructions for Use (“IFU”), please see: [IFU-10004-Rev.-F-Universal-IFU.pdf](#).

About RenovoRx, Inc.

RenovoRx is a life sciences company developing innovative targeted oncology therapies and commercializing **RenovoCath®**, a novel, U.S. Food and Drug Administration (FDA)-cleared local drug delivery device, targeting high unmet medical needs. RenovoRx’s patented **Trans-Arterial Micro-Perfusion (TAMP™)** therapy platform is designed to ensure precise therapeutic delivery across the arterial wall near the tumor site to bathe the target tumor, while potentially minimizing a therapy’s toxicities versus systemic intravenous therapy. RenovoRx’s novel approach to targeted treatment offers the potential for increased safety, tolerance, and improved efficacy, and its mission is to transform the lives of cancer patients by providing innovative solutions to enable targeted delivery of diagnostic and therapeutic agents.

In addition to the RenovoCath device, RenovoRx is also evaluating our novel Phase III drug-device oncology product candidate. It is being investigated under a U.S. investigational new drug application that is regulated by the FDA’s 21 CFR 312 pathway. The investigational drug-device combination candidate utilizes RenovoCath, the Company’s FDA-cleared drug-delivery device, indicated for temporary vessel occlusion in applications including arteriography, preoperative occlusion, and chemotherapeutic drug infusion. The intra-arterial infusion of chemotherapy, gemcitabine, utilizing the RenovoCath device is currently being evaluated for the treatment of locally advanced pancreatic cancer (LAPC) by the Center for Drug Evaluation and Research (the drug division of FDA).

The intra-arterial infusion of gemcitabine by the RenovoCath catheter is currently under investigation and has not been approved for commercial sale. RenovoCath with gemcitabine received Orphan Drug Designation for pancreatic cancer and bile duct cancer, which provides 7 years of market exclusivity upon NDA approval by the FDA.

RenovoRx is also engaged in implementing commercialization strategies utilizing its TAMP technology and FDA-cleared RenovoCath device as stand-alone device. In December 2024, RenovoRx announced the receipt of its first commercial purchase orders for RenovoCath devices. Additionally, certain of these customers have already initiated repeat orders as RenovoRx works to expand the number medical institutions that have initiated the process for RenovoCath purchase orders, including several esteemed, high volume National Cancer Institute-designated centers. To meet and satisfy the anticipated demand, RenovoRx will continue to actively explore further revenue-generating activity either on its own or in tandem with a medical device commercial partner.

For more information, visit www.renovorx.com. Follow RenovoRx on [Facebook](#), [LinkedIn](#), and [X](#).

Cautionary Note Regarding Forward-Looking Statements

This press release and statements of the Company's management made in connection described herein contain 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 (i) our pre-clinical and clinical trials and studies, including the overall timing and timing for additional interim data readouts for our ongoing TIGeR-PaC Phase III clinical trial study in LAPC, (ii) the potential of RenovoCath[®] or TAMP[™] as standalone commercial products, our anticipated timing for revenue generation from RenovoCath sales, and our commercialization plans in general, including our estimates of total addressable market (iii) the potential for our product candidates to treat or provide clinically meaningful outcomes for certain medical conditions or diseases and (iv) our efforts to explore commercialization strategies utilizing our TAMP technology. 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, commercial plans, intellectual property development, clinical trials, our therapy platform, business plans, financing plans, objectives and expected operating results, which are based on current expectations and assumptions that are subject to significant known and unknown risks and uncertainties that may cause actual results to differ materially and adversely 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: (i) the risk that our exploration of commercial opportunities for our TAMP technology may not lead to viable or repeating revenue generating operations; (ii) circumstances which would adversely impact our ability to efficiently utilize our cash resources on hand or raise additional funding, (iii) the timing of the initiation, progress and potential results (including the results of interim analyses) of TIGeR-PaC and any other preclinical studies, clinical trials and our research programs; (iv) the possibility that interim results may not be predictive of the outcome of our clinical trials, which may not demonstrate sufficient safety and efficacy to support regulatory approval of our product candidate, (v) that the applicable regulatory authorities may disagree with our interpretation of the data; research and clinical development plans and timelines, and the regulatory process for our product candidates; (vi) future potential regulatory milestones for our product candidates, including those related to current and planned clinical studies; (vii) our ability to use and expand our therapy platform to build a pipeline of product candidates; (viii) our ability to advance product candidates into, and successfully complete, clinical trials; (ix) the timing or likelihood of regulatory filings and approvals; (x) 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; (xi) the commercialization potential of our product candidates, if approved; (xii) our ability and the potential to successfully manufacture and supply our product candidates for clinical trials and for commercial use, if approved; (xiii) future strategic arrangements and/or collaborations and the potential benefits of such arrangements; (xiv) our estimates regarding expenses, future revenue, capital requirements and needs for additional financing and our ability to obtain additional capital; (xv) the

sufficiency of our existing cash and cash equivalents to fund our future operating expenses and capital expenditure requirements; (xvi) our ability to retain the continued service of our key personnel and to identify, and hire and retain additional qualified personnel; (xvii) the implementation of our strategic plans for our business and product candidates; (xviii) the scope of protection we are able to establish and maintain for intellectual property rights, including our therapy platform, product candidates and research programs; (xix) our ability to contract with third-party suppliers and manufacturers and their ability to perform adequately; (xx) the pricing, coverage and reimbursement of our product candidates, if approved; and (xxi) developments relating to our competitors and our industry, including competing product candidates and therapies. 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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