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RENOVO | RX
INVESTOR RELATIONS

RenovoRx Reports Initial Revenues from RenovoCath® Commercialization, and Provides Update on Ongoing Pivotal Phase III TIGeR-PaC Clinical Trial

Revenues from RenovoCath Expected to Grow Sequentially During 2025 with Expansion of New Customer Purchase Orders and Customer Reorders

Completion of TIGeR-PaC Clinical Trial Enrollment and Review of Second Interim Analysis by Data Monitoring Committee on Target for 2025

Reports 2024 Financial Results Including $7.2 Million Cash Position as of December 31, 2024, with Additional $12.1 Million in Gross Proceeds Raised in February 2025

Company to Host Fireside Chat on Thursday, April 3rd at 12 p.m. ET

MOUNTAIN VIEW, Calif.--(BUSINESS WIRE)-- **RenovoRx, Inc. ("RenovoRx"** or the **"Company") (Nasdaq: RNXT)**, a life sciences company developing innovative targeted oncology therapies and commercializing **RenovoCath®**, a novel, FDA-cleared drug-delivery device, today announced its financial results and business updates for the fourth quarter and full year ended December 31, 2024.

"The fourth quarter of 2024 marks a significant milestone in our company history as we have generated our first revenue from sales of our proprietary RenovoCath device on a standalone basis, with expectations for meaningful revenue growth going forward. Importantly, we believe our current commercial strategy can be accomplished without a material increase in our capital expenditures, regardless of whether we self-commercialize or choose to partner with a larger organization and use their existing sales force and channels. Further, we believe that the gross proceeds from our February 2025 public offering of $12.1 million together with our cash on hand of $7.2 million at year end fully funds our current operational plan as we look to scale RenovoCath revenues and progress our Phase III TIGeR-PaC clinical trial towards key milestones. Moreover, we expect that growing RenovoCath revenues will reduce our burn rate as we prudently deploy our cash on hand to drive shareholder value," said Shaun Bagai, CEO of RenovoRx.

"Based on our internal analysis with current clinical applications, we believe that our initial total addressable market (TAM) for RenovoCath represents an estimated $400 million peak annual U.S. sales opportunity. Beyond this, there are expansion opportunities across other indications that could create the potential for a several billion-dollar U.S. TAM for RenovoCath over time," continued Mr. Bagai. "We expect revenue to increase to the low six figure range for the first quarter of 2025 followed by sequential quarter-over-quarter increases for the remainder of the year."

RenovoCath Commercialization Update

In December 2024, RenovoRx received first commercial purchase orders for its RenovoCath device, which resulted in revenue generation of approximately $43,000 for the fourth quarter of 2024.

RenovoRx is seeing strong organic demand for RenovoCath. More than ten medical institutions have initiated the process for RenovoCath purchase orders, and purchase orders have already been received from several esteemed, high volume National Cancer Institute-designated centers. Additionally, utilization of RenovoCath devices by initial customers has led to repeat purchase orders. Moreover, RenovoRx believes the twenty cancer centers that have used RenovoCath as part of its TIGeR-PaC trial could also be potential customers for RenovoCath after completion of TIGeR-PaC enrollment later this year.

RenovoRx has identified its initial target market for RenovoCath to be approximately $400 million in peak annual U.S. sales, based on the Company's internal assumptions[1]. Moreover, expansion opportunities across other clinical indications could create a several billion-dollar total addressable market potential for RenovoCath over time. It's management's belief that the Company can achieve meaningful market penetration with a small commercial team targeting the top 200 high-volume treatment centers.

Importantly, there is a current reimbursement code with the Centers for Medicare and Medicaid Services covering procedures utilizing specialty pressure-mediated delivery catheters, which creates incentives for hospitals to adopt more advanced technology, like RenovoCath.

Ongoing Pivotal Phase III TIGeR-PaC Clinical Trial Update

During the fourth quarter 2024, RenovoRx added several additional renowned clinical oncology sites to participate in the TIGeR-PaC study. The initiation of these sites allows for new patient enrollment at the Sarah Cannon Research Institute Oncology Partners in Nashville, TN and at the Northwell Health Cancer Institute Clinical Site in New Hyde Park, NY which are key additions to the number of clinical sites to support RenovoRx's path to completing patient enrollment for the trial. RenovoRx is continuing to target additional clinical oncology sites, with the expectation that the study will achieve full enrollment during 2025.

The current protocol and statistical analysis plan for the TIGeR-PaC trial requires 114 randomized patients, with 86 events (deaths) necessary to complete the final analysis. As of March 28, 2025, 90 patients have been randomized with 50 events having occurred. A second interim analysis will be triggered by the 52nd event.

The timing required to analyze the data after the 52nd event is expected to take several months and includes a full review with recommendations by the TIGeR-PaC Data Monitoring Committee. RenovoRx currently anticipates the 52nd event to occur during the second quarter of 2025. The key recommendation from the Data Monitoring Committee on whether or not to continue the study based on the data reviewed is expected to be announced in the second half of 2025.

Fireside Chat Strategic Update

RenovoRx will host a fireside chat with Shaun Bagai, Chief Executive Officer, on **Thursday, April 3, 2025, at 12:00 p.m. ET**. During the event, Mr. Bagai will discuss the momentum of RenovoRx's commercialization efforts for its RenovoCath device, including an update on initial revenues generated, and continued progress on the ongoing Phase III TIGeR-PaC clinical trial. Additionally, one of RenovoCath's initial customers, Gregory Tiesi, MD, FACS, FSSO, Medical Director of Hepatobiliary Surgery, Division of Surgical Oncology, Hackensack Meridian Jersey Shore University Medical Center, will join Mr. Bagai. He will share his insights on the Trans-Arterial Micro-Perfusion (TAMP™) therapy platform and its impact on patient care. Hackensack Meridian Jersey Shore University Medical Center began using the RenovoCath device with oncology patients in December 2024.

Fireside Chat Details:
Date: Thursday, April 3, 2025
Time: 12:00 p.m. ET
Webcast: https://ir.renovorx.com/news-events/ir-calendar-events

A question and answer session will occur at the end of the call, and a link to the recording of this presentation will be available on RenovoRx's Investor Relations website after the event.

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[1] Assumptions: (i) pressure-mediated delivery catheters on market today, which are analogous to RenovoCath, have an average selling price of $6,500-$8,500 per unit; (ii) approximately 7,000 initial target patients at peak market penetration; and (iii) an average of approximately 8 annual procedures per patient.

Additional Key Fourth Quarter 2024 and Subsequent Highlights

During the fourth quarter, RenovoRx expanded its Intellectual property Portfolio to include 18 issued patents and 13 pending patents for the novel TAMP therapy platform. In addition, during and subsequent to the fourth quarter, RenovoRx presented abstracts at the ASCO Gastrointestinal Cancers Symposium 2025, the Society of Interventional Oncology 2025, and the Society of Surgical Oncology 2025 supporting the TAMP therapy platform via additional human pharmacokinetic (PK) data and pre-clinical data. Additionally, a publication supporting TAMP for targeted locoregional drug delivery will be recognized in the Journal of Vascular and Interventional Radiology Award-Winning Paper Scientific Session during the upcoming the Society of Interventional Radiology 2025.

Financial Highlights for the Year Ended December 31, 2024

- **Revenue:** Beginning December 2024, RenovoRx reported initial revenues of approximately $43,000 through sales of RenovoCath devices on a standalone basis directly to end users.

- **Cash Position:** Cash and cash equivalents as of December 31, 2024, were $7.2 million, with an additional $12.1 million in gross ($10.9 million in net) proceeds raised in a common stock only public offering in February 2025.

- **R&D Expenses:** Research and development expenses were $6.0 million for the year ended December 31, 2024, compared to $5.7 million for the year ended December 31,

2023, an increase of $0.3 million. This increase in research and development expenses is due to an increase in manufacturing and non-recurring engineering costs to scale manufacturing to support the commercial effort on our RenovoCath delivery system of $0.3 million and other research development expenses including personnel expenses for employees and benefits of $0.3 million. This increase was offset by a decrease in clinical development and regulatory costs of $0.3 million.

- **SG&A Expenses:** Selling, general, and administrative expenses were $5.0 million for the year ended December 31, 2024, compared to $5.7 million for the year ended December 31, 2023, a decrease of $0.7 million. The decrease in selling, general, and administrative expenses was due to lower professional and consulting costs, including directors and officers' insurance and legal fees of $0.9 million. This decrease was offset by an increase in personnel expenses for employees and benefits of $0.2 million, which is primarily due to an increase in employee incentive compensation.

- **Net Loss:** Net loss was $8.8 million for the year ended December 31, 2024, compared to net loss of $10.2 million for the year ended December 31, 2023.

- **Shares Outstanding:** Shares of common stock outstanding as of March 25, 2025, were 36,546,752.

RenovoRx, Inc.
Selected Balance Sheet Data
(in thousands)

	December 31,	
	2024	**2023**
Cash and cash equivalents	$ 7,154	$ 1,173
Total assets	**$ 8,118**	**$ 1,466**
Total liabilities	$ 3,640	$ 4,466
Total stockholders' equity (deficit)	$ 4,478	$ (3,000)
Total liabilities and stockholders' equity (deficit)	**$ 8,118**	**$ 1,466**

RenovoRx, Inc.
Selected Statement of Operations Data
(in thousands, except for share and per share amount)

	Year Ended December 31,	
	2024	**2023**
Revenues	$ 43	$ -

Operating expenses:		
Research and development	6,025	5,667
Selling, general and administrative	4,988	5,729
Total Operating expenses	11,013	11,396
Loss from operations	(10,970)	(11,396)
Change in fair value of warrant liability	1,772	1,709
Interest income (expense), net	384	108
Financing costs allocated to warrant	-	(653)
Total other income (expense), net	2,156	1,164
Net loss	**$ (8,814)**	**$ (10,232)**
Net loss per share, basic and diluted	$ (0.40)	$ (0.99)
Weighted-average shares of common stock outstanding, basic and diluted	22,271,163	10,290,667

Additional information regarding RenovoRx's business and results of operations for 2024 can be found in its Annual Report on Form 10-K for the fiscal year ended December 31, 2024, which was filed with the SEC on March 31, 2025.

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 the TIGeR-PaC Clinical Trial

TIGeR-PaC is an ongoing Phase III randomized multi-center study evaluating the proprietary **TAMP™** (Trans-Arterial Micro-Perfusion) therapy platform for the treatment of LAPC. RenovoRx's first investigational drug-device combination product candidate using the TAMP therapy platform enabled with the Company's FDA-cleared **RenovoCath®** device for the intra-arterial administration of chemotherapy, gemcitabine (IAG).

About RenovoRx, Inc.

RenovoRx, Inc. (Nasdaq: RNXT) 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 targeted 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 combination oncology product candidate (intra-arterial gemcitabine, known as **IAG**). IAG is being evaluated under a U.S. investigational new drug application that is regulated by the FDA's 21 CFR 312 pathway. The investigational IAG 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 combination of intra-arterial infusion of chemotherapy, gemcitabine, and the RenovoCath device is currently being evaluated for the treatment of LAPC by the Center for Drug Evaluation and Research (the drug division of FDA).

The combination product candidate, which is enabled the RenovoCath device, 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 new drug application 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 therewith 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 and timing for full enrollment 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 and levels of for revenue generation from RenovoCath sales, and our commercialization plans in general, (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 execution of our commercial strategy for RenovoCath or 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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