

February 6, 2024



# RenovoRx CEO Issues Letter to Shareholders

*Recent financing will drive Company towards second interim analysis on pivotal Phase III TIGeR-PaC clinical trial by end of 2024*

LOS ALTOS, Calif.--(BUSINESS WIRE)-- [RenovoRx, Inc.](#) ("**RenovoRx**" or the "**Company**") (**Nasdaq: RNXT**), a clinical-stage biopharmaceutical company developing novel precision oncology therapies based on a local drug-delivery platform, today provided a letter to shareholders from Chief Executive Officer, Shaun Bagai.

Dear Fellow RenovoRx Shareholders,

2023 was a pivotal year for RenovoRx, and we believe our accomplishments bode well for the achievement of our anticipated 2024 milestones.

Our team worked diligently on advancing the development of our proprietary targeted combination therapy platform, **Trans-Arterial Micro-Perfusion (TAMP™)**, involving our novel and proprietary delivery system, designed to improve the standard of care for patients diagnosed with difficult-to-treat cancers. We are proud to have achieved several key milestones described below, including, importantly, an initial positive interim analysis on our pivotal Phase III TIGeR-PaC clinical trial in locally advanced pancreatic cancer (LAPC).

Among our significant milestones achieved, our recent completion of a \$6.1 million private placement has extended our cash runway, allowing us to drive towards our key goal of a second interim analysis for our TIGeR-PaC study, which is expected by late 2024.

TIGeR-PaC is an ongoing Phase III randomized multi-center study evaluating our lead product candidate, **RenovoGem™** for the treatment of LAPC. RenovoGem is a novel oncology drug-device combination product utilizing our TAMP administration technology combined with the FDA-approved cancer drug, gemcitabine. The study is comparing treatment with RenovoGem to the current standard of care of systemic intravenous chemotherapy.

The first interim analysis in the TIGeR-PaC study at the 26<sup>th</sup> event of the specified events (deaths), was completed in March 2023, with the Data Monitoring Committee recommending a continuation of the study. The TIGeR-PaC study's primary endpoint is a 6-month Overall Survival benefit with secondary endpoints including reduced side effects versus standard of care. The data was first presented at the 2023 American Association for Cancer Research Annual Meeting in April 2023 and then as a Late Breaker Oral Presentation with additional secondary endpoint data at the 2023 European Society of Medical Oncology World Congress on Gastrointestinal Cancer in June 2023. The second interim analysis for this study is expected to occur at the 52<sup>nd</sup> event which is estimated to occur in late 2024.

In a further validation of our TAMP platform, in July 2023, we announced a collaboration with Imugene (ASX: IMU) to explore expansion of our TAMP product pipeline with Imugene's CF33 oncolytic virus therapy for the treatment of difficult-to-access tumors. We are constantly in discussions regarding similar collaborations and potentially out-licenses of RenovoGem as we gear up for the New Drug Application filing (assuming we meet our study endpoints) and commercialization of RenovoGem (if approved by FDA).

As a result of the positive progress that we have made in advancing TAMP with our TIGeR-PaC study, we made important additions to our management team, Board of Directors, and Scientific Advisory Board, bolstering our strong leadership. These additions enhance our already deep expertise resident at RenovoRx.

As we make strong progress on our clinical pathway, it is critically important that we continue to invest in our intellectual property. In December 2023, we filed an additional international patent application under the Patent Cooperation Treaty for our novel TAMP therapy platform. RenovoRx already holds a strong intellectual property portfolio with nine patents issued and nine pending patents for our proprietary TAMP platform and delivery system in the US, EU, and Asia.

This patent application further bolsters the value of TAMP as a novel platform in oncology, beyond our current Phase III clinical asset, and may expand its use into the delivery of larger therapeutic assets across DNA/RNA Altering Modalities, Cell Therapy, and Antibody-Based Therapies. If issued, this new patent will broaden our intellectual property coverage, creating new market potential, while increasing TAMP's commercial value.

While many companies are tackling cancer treatment in a variety of ways, we believe we are building a better way, with benefits not only for oncology patients, and their clinicians and loved ones, but for our shareholders. There is no question that cancer treatment needs a better, more effective method for drug delivery. Our data thus far suggests that we may be on the forefront of innovating the standard of care for treatment of difficult-to-access tumors. Your support enables our steadfast commitment to improve patients' lives and lifespans by delivering therapies that have the potential to revolutionize the current paradigm of cancer care.

We encourage anyone interested to visit our website, [renovorx.com](https://renovorx.com), to learn more, and email us at [renovorx@kcsa.com](mailto:renovorx@kcsa.com) to get in touch with us.

Sincerely,

Shaun R. Bagai  
CEO  
RenovoRx

#### **About RenovoRx, Inc.**

RenovoRx is a clinical-stage biopharmaceutical company developing proprietary targeted combination therapies for high unmet medical need with a goal to improve therapeutic outcomes for cancer patients undergoing treatment. The Company's proprietary Trans-Arterial Micro-Perfusion (TAMP™) therapy platform is designed to ensure precise therapeutic delivery to directly target the tumor while potentially minimizing a therapy's

toxicities versus systemic (intravenous (IV) therapy). RenovoRx's unique approach to targeted treatment offers the potential for increased safety, tolerance, and improved efficacy. Our Phase III lead product candidate, RenovoGem™, a novel oncology drug-device combination product, is being investigated under a US IND that is regulated by FDA 21 CFR 312 pathway. RenovoGem 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.)

RenovoRx is committed to transforming the lives of patients by delivering innovative solutions to change the current paradigm of cancer care. RenovoGem is currently under investigation for TAMP therapeutic delivery of gemcitabine and has not been approved for commercial sale.

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

### **Cautionary Note Regarding 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 (i) the use of proceeds from the Company's January 2024 private placement described herein and (ii) our clinical trials and studies, including anticipated timing, statements regarding the potential of RenovoCath®, RenovoGem™ or TAMP™ or regarding our ongoing TIGeR-PaC Phase III clinical trial study in LAPC, (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 expand our intellectual property. 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, 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 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) circumstances which would adversely impact our ability to efficiently utilize our cash resources on hand or raise additional funding, (ii) the timing of the initiation, progress and potential results (including the results of interim analyses) of our preclinical studies, clinical trials and our research programs; (iii) 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, (iv) 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; (v) future potential regulatory milestones for our product candidates, including those related to current and planned clinical studies; (vi) our ability to use and expand our therapy platform to build a pipeline of product candidates; (vii) our ability to advance product candidates into, and successfully complete, clinical trials; (viii) the timing or likelihood of regulatory filings and approvals; (ix) 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; (x) the commercialization potential of our product candidates, if approved; (xi) our ability and the potential to successfully manufacture and supply our product candidates for clinical trials and for commercial use, if approved; (xii) future strategic arrangements and/or collaborations and the potential benefits of such arrangements; (xiii) our estimates regarding expenses, future revenue, capital requirements and needs for additional financing and our ability to obtain additional capital; (xiv) the sufficiency of our existing cash and cash equivalents to fund our future operating expenses and capital expenditure requirements; (xv) our ability to retain the continued service of our key personnel and to identify, and hire and retain additional qualified personnel; (xvi) the implementation of our strategic plans for our business and product candidates; (xvii) the scope of protection we are able to establish and maintain for intellectual property rights, including our therapy platform, product candidates and research programs; (xviii) our ability to contract with third-party suppliers and manufacturers and their ability to perform adequately; (xix) the pricing, coverage and reimbursement of our product candidates, if approved; and (xx) 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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