UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **November 14, 2024**

RENOVORX, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-40738**	**27-1448452**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

4546 El Camino Real, Suite B1 Los Altos, CA	**94022**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: **(650) 284-4433**

Not Applicable
(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instructions A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.0001 par value per share	RNXT	Nasdaq Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition.

On November 14, 2024, RenovoRx, Inc. issued a press release announcing its financial results for the quarter ended September 30, 2024. The full text of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

All of the information furnished in this Item 2.02 and Item 9.01 (including Exhibit 99.1) of this Current Report on Form 8-K shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and shall not be incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release of RenovoRx, Inc., dated November 14, 2024
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

RENOVORX, INC.

Date: November 14, 2024

By: */s/ Shaun R. Bagai*
Name: Shaun R. Bagai
Title: Chief Executive Officer

Exhibit 99.1

RenovoRx Reports Third Quarter 2024 Financial Results and Operational Highlights

Near-Term Revenue Potential with Commercialization Plan for FDA-Cleared RenovoCath® Delivery System in Both Direct and Commercial Partner Channels

Renowned Clinical Oncology Sites Participating in Ongoing Pivotal Phase III TIGeR-PaC Clinical Trial; Trial Moving Towards Next Interim Analysis and Full Enrollment

As of September 30, 2024, the Company had $9.6 million in Cash, Sufficient to Fund Operations to Achieve Next Interim Read-Out and Fund Current RenovoCath Commercialization Efforts

Los Altos, CA, November 14, 2024 - RenovoRx, Inc. ("RenovoRx" or the "Company") (Nasdaq: RNXT), a life sciences company developing novel targeted oncology therapies and offering **RenovoCath**, a novel, FDA-cleared local drug-delivery platform, today announced its financial results and operational highlights for the third quarter ended September 30, 2024.

"We made significant progress in the third quarter of 2024 towards our goal of patient enrollment completion of our pivotal Phase III TIGeR-PaC clinical trial in locally advanced pancreatic cancer (LAPC), which is expected in the first half of 2025," said Shaun Bagai, CEO of RenovoRx. "In parallel, we have made important headway on commercialization plans for our FDA-cleared RenovoCath delivery system, creating the potential for near-term revenue generation."

Mr. Bagai added, "As part of our evolving commercialization strategy plans, we have increased production of RenovoCath supplies, and if we hit our targets (including developing or partnering for sales and marketing capabilities), we see the potential for near-term revenue in 2025. Importantly, with $9.6 million in cash as of September 30, we have sufficient cash on hand to achieve our next interim TIGeR-PaC analysis, which will be triggered by the 52nd event, estimated to occur in late 2024 or early 2025, and fund our current RenovoCath commercialization efforts."

Key Business Third Quarter and Recent Highlights:

- Commercialization efforts for the RenovoCath delivery system progressed in response to increasing demand from oncology and interventional radiology physicians indicating a need for improved, targeted delivery of diagnostic and/or therapeutic agents.
- Notably, RenovoRx signed a new work order with its manufacturing partner Medical Murray to increase production of RenovoCath devices. With manufacturing arrangements in place, RenovoRx is presently considering its best course for RenovoCath marketing and sales activities, which could be done directly or, more likely, via a commercial partner. RenovoCath is indicated for temporary vessel occlusion in applications including arteriography, preoperative occlusion, and chemotherapeutic drug infusion.

- RenovoRx expects its RenovoCath commercial strategy to potentially generate revenue in 2025.
- Promoted Robert Strasser to Vice President of R&D and Operations. Strasser is a highly experienced, results-oriented, strategic business leader with a proven track record in operations and product commercialization management with prior roles at Cordis (Johnson & Johnson) and Boston Scientific. Strasser has served as RenovoRx's Senior Director of R&D and Operations since October 2022, the same year he started managing RenovoRx's relationship with Medical Murray.
- Enrolled the first patient at the University of Nebraska Medical Center (UNMC) for the ongoing pivotal Phase III TIGeR-PaC clinical trial. UNMC is the most recent clinical site to join TIGeR-PaC clinical study. UNMC is expected to drive enrollment of the TIGeR-PaC trial to completion in 2025 due to the large number of pancreatic patients they treat.
- Announced the publication of positive early-stage clinical data in an international peer-reviewed journal, The Oncologist®. The article titled "Treatment of Locally Advanced Pancreatic Cancer (LAPC) Using Localized Trans-Arterial Micro Perfusion (TAMP) of Gemcitabine: Combined Analysis of RR1 and RR2," is a publication of early-stage clinical data, primarily procedure safety, overall survival (OS), and evaluation of factors associated with OS, in LAPC patients undergoing TAMP from the foundational studies conducted by RenovoRx.

Financial Highlights for Third Quarter ended September 30, 2024 (unaudited):

- **Cash Position:** Cash and cash equivalents as of September 30, 2024, were $9.6 million.
- **R&D Expenses:** Research and development expenses were approximately $1.7 million for the three months ended September 30, 2024, remaining flat compared to the same period last year. Employee and related benefit costs increased $0.1 million including additional increase in clinical conferences and trade shows of $0.1 million. These increases were partially offset by lower regulatory and clinical consulting costs and manufacturing for our proprietary catheter delivery device. We anticipate research and development expenses to increase as we increase manufacturing costs for our device and continue advancing our Phase III clinical trial study throughout the remainder of the year.
- **G&A Expenses:** General and administrative expenses were approximately $1.2 million for the three months ended September 30, 2024, a decrease of approximately $0.2 million compared to approximately $1.4 million for the same period last year. The decrease was primarily due to decreases of $0.2 million in professional and consulting fees, and legal fees, partially offset by an increase of $0.1 million in investor and public relations costs. We anticipate general and administrative expenses increasing moderately throughout the remaining year as we progress our commercialization activities for our RenovoCath device.
- **Net Loss:** Net loss was $2.5 million for the quarter ended September 30, 2024, compared to net loss of $1.4 million for the quarter ended September 30, 2023. The decrease is primarily due to a decrease of $1.3 million in the fair value of common warrants issued under our Registered Direct Offering in April 2023 and an increase in interest and dividend income of $0.1 million.
- **Shares Outstanding:** Shares of common stock outstanding, as of November 7, 2024, were 24,001,339.

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 Locally Advanced Pancreatic Cancer (LAPC.) RenovoRx's first product candidate using TAMP technology, is a novel investigational oncology drug-delivery combination utilizing the Company's FDA-cleared RenovoCath® device for the intra-arterial administration of chemotherapy, gemcitabine.

The first interim analysis in the Phase III clinical trial was completed in March 2023, with the Data Monitoring Committee recommending a continuation of the study. The TIGeR-PaC study is investigating TAMP in LAPC. The study's primary endpoint is an overall survival benefit with secondary endpoints including reduced side effects versus standard of care. The second interim analysis for this study will be triggered by the 52nd event (i.e., patient death), which is estimated to occur in late 2024 or early 2025. The second interim data readout would follow thereafter, with the timing for such readout depending on customary factors such as time needed for analysis. RenovoRx is also aiming to complete patient enrollment in the TIGeR-PaC study in the first half of 2025.

About RenovoRx, Inc.

RenovoRx is a life sciences company developing novel targeted oncology therapies and offering **RenovoCath®**, a novel, U.S. Food and Drug Administration (FDA)-cleared local drug-delivery platform, 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.

RenovoRx's Phase III lead product candidate is a novel oncology drug-device combination product. 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 **,** which is 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 catheter 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 also actively exploring other commercialization strategies utilizing its TAMP technology and FDA-cleared RenovoCath delivery system as a stand-alone device. 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.

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 clinical trials and studies, including the overall timing and timing for additional interim data readouts and completion of patient enrollment for our ongoing TIGeR-PaC Phase III clinical trial study in LAPC, (ii) the potential of RenovoCath® or TAMP™ as standalone commercial products 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 (iii) 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, 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) the risk that our exploration of commercial opportunities for our TAMP technology may not lead to viable, 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.

Contact:
KCSA Strategic Communications
Valter Pinto or Jack Perkins
T:212-896-1254
RenovoRX@KCSA.com
