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): September 25, 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
(650) 284-4433
(Address and telephone number, including area code, of registrant's principal executive offices)

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:

☐ 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	**RNXT**	**The 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 8.01 Other Events.

On September 25, 2024, RenovoRx, Inc., a Delaware corporation, issued a press release announcing increased production of its FDA-Cleared RenovoCath® Delivery System and expanded relationship with its manufacturing partner Medical Murray, Inc. (the "Press Release"). The Press Release is attached hereto as Exhibit 99.1 and incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1	Press Release regarding Medical Murray, Inc., dated September 25, 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: September 25, 2024 By: */s/ Shaun R. Bagai*

Name: Shaun R. Bagai
Title: Chief Executive Officer

Exhibit 99.1

RenovoRx Increases Production of FDA-Cleared RenovoCath® Delivery System in Response to Strong Demand from Oncology and Interventional Radiology Physicians

Company expands relationship with manufacturing partner Medical Murray, and continues active exploration of standalone opportunities for RenovoCath

LOS ALTOS, CA – September 25, 2024 – RenovoRx, Inc. ("RenovoRx" or the "Company") (Nasdaq: RNXT), a life sciences company developing novel targeted oncology therapies based on a local drug-delivery platform, today announced that it is increasing the production of its FDA-cleared **RenovoCath** catheter-based delivery system due to increased demand for targeted delivery of diagnostic and/or therapeutic agents from oncologists and interventional radiologists.

RenovoRx has signed a new project work order with its principal manufacturing partner, Medical Murray of North Barrington, IL, providing for an expanded relationship and as RenovoRx continues its exploration of commercial opportunities for RenovoCath beyond RenovoRx's currently ongoing clinical programs. To create performance incentives for Medical Murray, RenovoRx will issue Medical Murray a warrant to purchase up to 709,500 shares of RenovoRx common stock. This warrant vests over time and only if Medical Murray achieves certain manufacturing milestones.

In parallel, RenovoRx remains fully engaged and committed to its ongoing pivotal Phase III TIGeR-PaC clinical trial in locally advanced pancreatic cancer (LAPC). As recently announced, additional well known clinical sites are now participating in the study with the goal of accelerating patient enrollment. TIGeR-PaC is using the TAMP™ (Trans-Arterial Micro-Perfusion) therapy platform to evaluate RenovoRx's first drug-device combination product candidate (intra-arterial infusion of chemotherapy, gemcitabine HCl) to target the tumor in LAPC. The study is comparing treatments with TAMP to the current standard of care (systemic intravenous chemotherapy).

Leesa Gentry, Chief Clinical Officer of RenovoRx, commented, "As we continue to make steady progress with our pivotal Phase III trial in LAPC, we have received feedback from oncology and interventional radiology physicians and key opinion leaders expressing the desire to purchase RenovoCath as a standalone device to be used in clinical practice. RenovoCath has been used in over 500 procedures by interventionalists over the past several years. We have published data from completed early-stage clinical trials that highlight the potential benefits to patients receiving targeted therapy with RenovoCath, including less toxicity and better outcomes, over the current standard of care."

Shaun Bagai, Chief Executive Officer of RenovoRx, commented, "We announced in our most recent SEC quarterly report that we are actively exploring commercial opportunities to meet what we see as growing demand for our proprietary RenovoCath technology. Beyond LAPC, we believe there are many clinical applications for RenovoCath to improve targeted delivery of diagnostic and therapeutic agents. Securing the manufacturing capacity for this strategy with our partner Medical Murray is a great first step. We are also in active discussions with many interested customers to purchase supplies of RenovoCath as well as potential distribution partners. When launched, we expect our commercial strategy to accelerate our path to revenue generation, which we hope will occur during 2025. At the same time, even without incremental revenues from this commercial strategy, we maintain sufficient cash on hand from our successful fundraisings earlier this year to achieve both our next interim read-out on TIGeR-PaC, which will be triggered by the 52nd event (i.e., patient death), estimated to occur in late 2024 or early 2025, and fund our current efforts for our RenovoCath go to market activities."

Mr. Bagai continued, "In preparation for commercialization of RenovoCath as a stand-alone device, and in addition to accelerating our manufacturing capacity with Medical Murray, we are pleased to have promoted Robert Strasser to Vice President of R&D and Operations. Bob has been an important part of our interface with Medical Murray and with our commercial strategy plans, and we look forward to his continued contributions in this new role."

Robert 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. Mr. Strasser has served as RenovoRx's Senior Director of R&D and Operations since October 2022, the same year he started managing the Company's relationship with Medical Murray.

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. RenovoCath is intended for general intravascular and peripheral vascular in arteries for vessel entry and occlusion ranging between 3mm and 11mm in diameter. The diagnostic and/or therapeutic agents are to be used in accordance with specifications outlined by the respective agent manufacturer.

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 the 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 HCl.

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 a 6-month 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, which is estimated to occur in late 2024 or early 2025.

About RenovoRx, Inc.

RenovoRx is a life sciences company developing novel targeted oncology therapies based on a local drug delivery platform for high unmet medical need with a goal to improve therapeutic outcomes for cancer patients undergoing treatment. 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. Our 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®,** 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 gemcitabine HCl by 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 HCl by the RenovoCath catheter is currently under investigation and has not been approved for commercial sale.

RenovoRx is committed to transforming the lives of patients by providing innovative solutions to enable targeted delivery of diagnostic and therapeutic agents.

For more information, visit www.renovorx.com. Follow RenovoRx on Facebook, LinkedIn, and Twitter.

Cautionary Note Regarding Forward-Looking Statements

This press release and statements of the Company's management made in connection therewith and at the investor conference 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 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 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.

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