
**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): **May 15, 2025**

RENOVORX, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-40738
(Commission
File Number)

27-1448452
(IRS Employer
Identification No.)

2570 W El Camino Real, Suite 320
Mountain View, CA
(Address of principal executive offices)

94040
(Zip Code)

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

4546 El Camino Real, Suite B1, Los Altos, CA 94022
(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 May 15, 2025, RenovoRx, Inc. (the “Company”) issued a press release announcing its financial results for the quarter ended March 31, 2025. The full text of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 8.01 Other Events.

In addition to announcing certain financial results, the Company’s press release provides certain updates of the Company’s clinical trial described in such press release. The full text of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	Description
99.1	Press Release of RenovoRx, Inc., dated May 15, 2025
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.

Date: May 15, 2025

RENOVORX, INC.

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



RenovoRx Reports First Quarter 2025 Financial Results and Business Highlights

Q1 2025 RenovoCath[®] Revenues of ~\$200,000, Exceeding Expectations and Anticipated to Continue Growing Sequentially with New Customer Purchase Orders and Reorders

Cash on Hand of \$14.6 Million Anticipated to Fully Fund both RenovoCath Commercialization Scale-up and Continued Progress Towards the Completion of the Ongoing Phase III TIGeR-PaC Clinical Trial

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

Company to Host Conference Call at 4:30 p.m. ET

MOUNTAIN VIEW, Calif. – May 15, 2025 – 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 first quarter ended March 31, 2025. RenovoCath powers RenovoRx’s patented **Trans-Arterial Micro-Perfusion (TAMP[™])** therapy platform.

“I am pleased to report a milestone event for RenovoRx: Q1 was our first full quarter of RenovoCath commercial sales, generating approximately \$200,000 in revenue. Moreover, this revenue exceeded our internal expectations, and we anticipate this positive trend to continue as we expect sequential quarterly growth for the foreseeable future,” said Shaun Bagai, CEO of RenovoRx. “Additionally, we believe that the approximately twenty cancer centers that have used RenovoCath as part of our ongoing Phase III TIGeR-PaC trial could also become potential customers after the planned completion of trial enrollment later this year. Our enthusiasm about the value proposition of our company has never been higher as we dual track the growth of our commercial efforts and progress our clinical trial towards important milestones later this year.”

RenovoCath Commercialization Update

The first quarter of 2025 represented RenovoRx’s first full quarter of generating revenue from commercial sales. This is the result of the important strategic decision in 2024 to focus on implementing a commercial strategy for RenovoCath in tandem with the ongoing Phase III TIGeR-PaC trial.

RenovoRx planned to launch its commercial efforts for RenovoCath during the first quarter of this year in response to anticipated strong demand for the patented RenovoCath device. However, the Company received purchase orders ahead of schedule, generating \$43,000 in revenue in December alone. RenovoCath is gaining strong traction, with over ten non-TIGeR-PaC medical institutions including several esteemed, high-volume, academic and community, and National Cancer Institute-designated centers who have initiated purchase orders. RenovoRx believes that many of the twenty cancer centers that have used RenovoCath as part of the TIGeR-PaC trial could also be potential customers for RenovoCath after completion of TIGeR-PaC enrollment, anticipated for later this year. Additionally, early utilization of RenovoCath devices by initial customers has led to repeat purchase orders.

RenovoRx believes that the initial total addressable market for RenovoCath (TAM) represents an estimated \$400 million peak annual U.S. sales opportunity. In calculating this sales opportunity, the Company is assuming an average of 8 procedures per patient and 7,000 initial target patients at peak market penetration in patient populations where RenovoRx already has clinical usage, with catheter pricing between \$6,500-\$8,500 per device.

Looking ahead, RenovoRx sees expansion opportunities across other cancer indications that could create the potential for a several-billion-dollar U.S. TAM for RenovoCath over time. The prospect of penetrating even a small portion of this market combined with the potential to help patients is driving the Company's excitement about this opportunity.

Ongoing Pivotal Phase III TIGeR-PaC Trial Update

During the first quarter of 2025, RenovoRx announced that Johns Hopkins Medicine has now initiated enrollment in the ongoing Phase III TIGeR-PaC trial. This is a valuable addition to the distinguished network of clinical cancer sites across the U.S. participating in this important trial as RenovoRx works towards full enrollment. RenovoRx is continuing to evaluate additional sites and expects that Phase III TIGeR-PaC trial will achieve full enrollment during 2025.

The current protocol and statistical analysis plan for the Phase III TIGeR-PaC trial requires 114 randomized patients, with 86 events, or deaths, necessary to complete the final analysis. As of May 2, 2025, 91 patients have been randomized and 56 events have occurred, triggering the second interim analysis. RenovoRx anticipates the Phase III TIGeR-PaC Data Monitoring Committee will review trial data in the third quarter of 2025 and looks forward to receiving their recommendations and feedback.

First Quarter 2025 and Subsequent Key Highlights

During and subsequent to the first 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 was recognized in the Journal of Vascular and Interventional Radiology Award-Winning Paper Scientific Session during the Society of Interventional Radiology 2025 conference.

Subsequent to the first quarter of 2025, RenovoRx announced the issuance of a new U.S. patent for the Company's TAMP therapy platform, further enhancing the Company's intellectual property protection. RenovoRx now holds a robust portfolio of 19 patents in multiple countries across the globe, including 9 U.S. patents as well as 7 U.S. patents pending. RenovoRx's strong and growing intellectual property portfolio provides key support to the Company's continuing commercialization of RenovoCath. The issuance of this new patent highlights the innovation behind the TAMP therapy platform and strengthens the Company's competitive position.

Finally, during the first quarter 2025, RenovoRx announced that in the most recent open trading window, members of the management team and Board purchased an aggregate of approximately 143,000 shares of the Company's stock in multiple open market purchases.

Financial Highlights for the First Quarter Ended March 31, 2025:

- **Revenue:** RenovoRx reported revenues of approximately **\$200 thousand** from commercial sales of the RenovoCath device.
- **Cash Position:** As of March 31, 2025, the Company had **\$14.6 million** in cash and cash equivalents. The Company anticipates that the growing revenues from RenovoCath will reduce its burn rate, and that cash as of March 31, 2025, will fully fund both the RenovoCath scale-up and the continued progress towards completion in the Phase III TIGeR-PaC trial.
- **R&D Expenses:** Research and development expenses were **\$1.7 million**, compared to \$1.3 million in Q1 2024. The \$0.4 million increase was due to an increase in employee compensation due to cost-of-living adjustments, an increase in manufacturing and non-recurring engineering costs to support commercial scale-up, an increase in conference and trade show activity, and an increase in other R&D activity.
- **SG&A Expenses:** Selling, general, and administrative expenses were approximately **\$1.6 million**, up from \$1.2 million for Q1 2024. The \$0.4 million increase was due to an increase in personnel and benefits, an increase in professional and consulting fees to support commercialization, and an increase in other G&A activity.
- **Net Loss:** Net loss was **\$2.4 million**, compared to \$1.1 million in Q1 2024. The \$1.3 million increase was due to an increase in loss from operations of \$0.6 million and a \$0.8 million decrease in the fair value of the common warrant liability.
- **Shares Outstanding:** As of May 9, 2025, shares of common stock outstanding totaled **36,572,232**.

Conference Call Details

Event: RenovoRx First Quarter 2025 Financial Results Conference Call
Date: Thursday, May 15, 2025
Time: 4:30 p.m. ET
Live Call: 1-877-407-4018 (U.S. Toll Free) or 1-201-689-8471 (International)
Webcast: <https://ir.renovorx.com/news-events/ir-calendar-events>

For interested individuals unable to join the conference call, a dial-in replay of the call will be available until May 29, 2025, and can be accessed by dialing 1-844-512-2921 (U.S. Toll Free) or 1-412-317-6671 (International) and entering replay pin number: 13753595.

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.

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

	March 31, 2025	December 31, 2024
Cash and cash equivalents	\$ 14,582	\$ 7,154
Total assets	\$ 16,014	\$ 8,118
Total liabilities	\$ 2,857	\$ 3,640
Total stockholders' equity	13,157	4,478
Total liabilities and stockholders' equity	\$ 16,014	\$ 8,118

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

	Three Months Ended	
	December 31,	
	2024	2023
Revenues	\$ 197	\$ -
Cost of revenues	94	-
Gross profit	103	-
Operating expenses:		
Research and development	1,642	1,257
Selling, general and administrative	1,571	1,219
Total Operating expenses	3,213	2,476
Loss from operations	(3,110)	(2,476)
Change in fair value of warrant liability	584	1,363
Interest and dividend income	106	37
Total other income	690	1,400
Net loss	\$ (2,420)	\$ (1,076)
Net loss per share, basic and diluted	\$ (0.08)	\$ (0.07)
Weighted-average shares of common stock outstanding, basic and diluted	31,395,888	14,947,500

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 Phase III TIGeR-PaC Trial

TIGeR-PaC is an ongoing Phase III randomized multi-center trial 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 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 TIGeR-PaC trial drug-device combination oncology product candidate (intra-arterial gemcitabine, known as **IAG**). IAG is being evaluated by the Center for Drug Evaluation and Research (the drug division of FDA) under a U.S. investigational new drug application that is regulated by the FDA’s 21 CFR 312 pathway. 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 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 the Phase III TiGeR-PaC trial 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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