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): **August 14, 2025**

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.)
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**

N/A
(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 August 14, 2025, RenovoRx, Inc. (the "Company") issued a press release announcing its financial results as of and for the quarter ended June 30, 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 and commercialization strategy 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 August 14, 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.

RENOVORX, INC.

Date: August 14, 2025

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

Exhibit 99.1

RenovoRx Reports Commercial Revenue Growth in the Second Quarter 2025 and Announces Positive Independent Data Monitoring Committee Recommendation to Continue Pivotal Phase III TIGeR-PaC Trial Based on Interim Data Review

Revenue from RenovoCath® device totaled over $400,000 for the Second Quarter 2025

As of June 30, 2025, the Company had $12.3 million in cash and cash equivalents

Management to host conference call today at 4:30p.m. ET

MOUNTAIN VIEW, Calif. – August 14, 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 update to shareholders for the second quarter ended June 30, 2025.

"We are pleased to report second quarter 2025 revenue of over $400,000. This growth highlights the strong clinical need and market demand for our patented RenovoCath device as a standalone targeted drug-delivery product among both new and existing customers. We are proud of the initial organic revenue growth over the first two full quarters since launching RenovoCath commercial sales, especially since this was achieved without a dedicated sales and marketing team. With the recent hiring of Phil Stocton as our Senior Director of Sales and Market Development, our goal is to stay lean, while also continuing to build commercialization momentum. We will continue to gather important data about our market (such as such as sales cycles, activation times, individual customer preferences and other commercial matters), as we seek to grow our customer base, fulfill repeat RenovoCath orders, and position ourselves for commercial growth over the long term," said Shaun Bagai, CEO of RenovoRx.

"At the same time, we are very excited to report that the independent Data Monitoring Committee (DMC) for our ongoing Phase III TIGeR-PaC trial recently completed their review of our second pre-planned interim analysis and has recommended that we continue the study. This is great news, as we believe the DMC's recommendation is an expression of confidence in the potential for a positive outcome in the trial overall," continued Mr. Bagai.

"With a view towards preserving the integrity of the TIGeR-PaC trial for FDA purposes, and following our review of general FDA guidance, discussions with the DMC, and consultation with regulatory advisors, we are deferring publishing our second interim data. Outside of our Chief Medical Officer, Dr. Ramtin Agah, who has been speaking directly with the DMC, our entire team will remain blinded to the interim data. We will revisit publishing the actual second interim data, most likely upon completion of the study as is common for pivotal Phase III trials. As of August 12, 2025, 95 patients have been randomized and 61 events have occurred, putting us on target to complete enrollment this year or early next year," concluded Mr. Bagai.

RenovoCath Commercialization Update

RenovoRx continued its RenovoCath commercialization progress, with thirteen cancer center customers approved to purchase the device, including several high-volume, National Cancer Institute (NCI)-designated academic and community centers, an increase from five centers in the first quarter of 2025. Four of these thirteen cancer centers have used the device in patients, and all have made repeat purchase orders subsequently. RenovoRx believes that many of the 18 cancer centers that have used RenovoCath as part of its ongoing, pivotal Phase III TIGeR-PaC trial could also be potential customers for RenovoCath after the completion of TIGeR-PaC enrollment, which is expected later this year or early next year. All of this is being accomplished in-house by RenovoRx without a dedicated sales and marketing team. RenovoRx plans to strategically add a small number of sales personnel in the second half of 2025 as it looks to widen market penetration in 2026.

RenovoRx believes that the initial total addressable market (TAM) for RenovoCath as a stand-alone device represents an estimated initial $400 million peak annual U.S. sales opportunity. Beyond historical RenovoCath usage, RenovoRx commercial efforts are already indicating the adoption of RenovoCath technology for the treatment of other solid tumors. This serves as the basis for our belief in the potential for a several-billion-dollar TAM as we expand into additional applications.

Ongoing Pivotal Phase III TIGeR-PaC Trial Update

In the TIGeR-PaC trial, RenovoRx is evaluating its first investigational drug-device combination oncology product candidate which uses the proprietary Trans-Arterial Micro-Perfusion (TAMP™) therapy platform enabled by RenovoCath for the treatment of locally advanced pancreatic cancer (LAPC). RenovoRx's combination product candidate utilizes RenovoCath for the intra-arterial administration of the chemotherapy gemcitabine (or IAG).

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.

In the second quarter of 2025, the 52nd death triggered the second pre-planned interim analysis to be reviewed by the independent Data Monitoring Committee. The DMC has concluded its review and has recommended that the Company continue with the trial. To avoid compromising the integrity of the trial with the FDA, and after discussions with the DMC and consultation with its regulatory advisors, RenovoRx elected to defer publishing the interim data. RenovoRx will revisit publishing the actual second interim data, most likely upon completion of the study as is common for pivotal Phase III trials.

Second Quarter 2025 and Subsequent Key Highlights

During the second quarter of 2025, RenovoRx increased production of the RenovoCath device to meet increased demand for the targeted delivery of diagnostic and/or therapeutic agents from oncologists and interventional radiologists. The principal manufacturer of RenovoCath devices is Medical Murray Inc., based in the U.S. in North Barrington, IL.

RenovoRx highlighted strong progress in its commercialization efforts. Since launching its commercial efforts in December 2024, RenovoRx has established commercial momentum for RenovoCath, with thirteen cancer center customers approved to purchase the device, including several high-volume, National Cancer Institute (NCI)-designated academic and community centers, an increase from five centers in the first quarter of 2025. Four of these thirteen cancer centers have used the device in patients, and all have made repeat purchase orders subsequently.

This momentum highlights the growing clinical demand across the United States for novel, localized solid tumor drug-delivery options beyond methods like systemic intravenous delivery of chemotherapy. RenovoRx believes that many of the 18 cancer centers that have used RenovoCath as part of its ongoing, pivotal Phase III TIGeR-PaC trial could also be potential customers for RenovoCath after the completion of TIGeR-PaC enrollment, which is expected later this year or early next year.

To coordinate, execute, and expand its commercial efforts for RenovoCath, subsequent to the quarter, RenovoRx hired Philip Stocton as Senior Director of Sales and Market Development. Mr. Stocton brings over 25 years of experience in MedTech sales, marketing, and leadership from various commercial positions at Terumo, Johnson & Johnson, Varian (acquired by Siemens), and, most recently, Sirtex Medical. Over the past 10 years, he has specialized in interventional oncology in both domestic and international roles. Prior to his hiring, Mr. Stocton had been consulting for RenovoRx in connection with its RenovoCath commercial launch planning efforts.

During the quarter, RenovoRx initiated patient enrollment with Johns Hopkins Medicine for the Phase III TIGeR-PaC clinical trial, becoming the newest addition to a distinguished network of clinical cancer sites across the United States participating in the trial.

RenovoRx also received an Issue Notification from the U.S. Patent and Trademark Office (USPTO) indicating that U.S. patent No. 12,290,564 became effective on May 6. This patent, titled “Methods for Treating Tumors,” expands protection of methods for drug delivery with RenovoRx’s TAMP therapy platform, enabled by RenovoCath. The patent covers new methods for treating a tumor by delivering drugs locally to a region of an artery or blood vessel that is near the tumor after treating this region to reduce the microvasculature. The new patent provides protection through November of 2037.

Subsequent to the quarter, RenovoRx launched a multi-center post-marketing registry study to follow patients undergoing cancer treatment delivered by its RenovoCath device to solid tumors. The PanTheR study is an important initiative aimed at evaluating the safety and effectiveness of RenovoCath in real-world clinical settings. This multi-center, post-marketing observational registry study is designed to assess long-term safety and survival outcomes in patients with solid tumors who receive targeted drug delivery via RenovoCath. By collecting real-world data on the use of RenovoCath across a broader range of tumor types, PanTheR aims to provide valuable insights into patient outcomes and support the generation of additional safety data.

Financial Highlights for the Second Quarter Ended June 30, 2025

Revenue: RenovoRx reported second quarter revenues of approximately **$422,000** from commercial sales of the RenovoCath device, driven by new customer purchase orders and early repeat orders from our initial sites. June 30, 2025 marked our second full quarter of revenue generation from RenovoCath sales.

Cash Position: As of June 30, 2025, the Company had **$12.3 million** in cash and cash equivalents. The Company's plan is for revenues from RenovoCath sales to reduce its burn rate over time. The Company believes that cash as of June 30, 2025 will fully fund both ongoing RenovoCath scale-up efforts and additional progress towards the completion in the Phase III TIGeR-PaC trial.

R&D Expenses: Research and development expenses were **$1.4 million**, for the quarter ended June 30, 2025, compared to $1.5 million for the quarter ended June 30, 2024. The $0.1 million decrease was primarily driven by a decrease in other clinical and regulatory expenses including an allocation of selling, general and administrative expenses to research and development of $0.2 million. This decrease was offset by an increase in non-recurring engineering costs to scale manufacturing and the development of our next generation RenovoCath delivery system by $0.1 million to support and expand our commercial program.

SG&A Expenses: Selling, general, and administrative expenses were approximately **$1.5 million**, for the quarter ended June 30, 2025, remaining relatively unchanged from the same period in the prior year.

Net Loss: Net loss was **$2.9 million** for the quarter ended June 30, 2025, compared to a net loss of $2.4 million for the quarter ended June 30, 2024. The $0.5 million increase was primarily due to the change in the fair value of the warrant liability of $0.9 million offset by a decrease in loss from operations of $0.4 million.

Shares Outstanding: As of August 11, 2025, shares of common stock outstanding totaled **36,645,884.**

Conference Call Details

Event:	RenovoRx Second Quarter 2025 Financial Results Conference Call
Date:	Thursday, August 14, 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 September 14, 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: 13754672.

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)

	June 30, 2025	December 31, 2024
Cash and cash equivalents	$ 12,314	$ 7,154
Total assets	**$ 13,643**	**$ 8,118**
Total liabilities	$ 3,002	$ 3,640
Total stockholders' equity	10,641	4,478
Total liabilities and stockholders' equity	**$ 13,643**	**$ 8,118**

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Revenues	$ 422	$ -	$ 619	$ -
Cost of revenues	152	-	246	-
Gross profit	$ 270	$ -	$ 373	$ -
Operating expenses:				
Research and development	1,426	1,542	3,068	2,799
Selling, general and administrative	1,522	1,492	3,093	2,711
Total Operating expenses	2,948	3,034	6,161	5,510
Loss from operations	(2,678)	(3,034)	(5,788)	(5,510)
Change in fair value of warrant liability	(350)	507	234	1,870
Interest and dividend income	133	138	239	175
Total other (expense) income, net	(217)	645	473	2,045
Net loss	**$ (2,895)**	**$ (2,389)**	**$ (5,315)**	**$ (3,465)**
Net loss per share, basic and diluted	$ (0.08)	$ (0.10)	$ (0.16)	$ (0.18)
Weighted-average shares of common stock outstanding, basic and diluted	36,576,567	24,049,113	34,000,539	19,498,306

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.-G-Universal-IFU.pdf.

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 for 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 its novel drug-device combination oncology product candidate (intra-arterial gemcitabine via RenovoCath, known as IAG) in the ongoing Phase III TIGeR-PaC trial. IAG is being evaluated by the Center for Drug Evaluation and Research (the drug division of the 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 patented, 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 by 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 seven years of market exclusivity upon new drug application approval by the FDA.

RenovoRx is also actively commercializing its TAMP technology and FDA-cleared RenovoCath as a stand-alone device. In December 2024, RenovoRx announced the receipt of its first commercial purchase orders for RenovoCath devices. Additionally, several of these customers have already initiated repeat orders in parallel to RenovoRx expanding the number of medical institutions initiating new RenovoCath 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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