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, 2022**

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, 2022, RenovoRx, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended September 30, 2022. 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, 2022
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, 2022

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

Exhibit 99.1

RenovoRx Reports Third Quarter 2022 Financial Results

Los Altos, CA, November 14, 2022 - RenovoRx, Inc. (Nasdaq: RNXT), a biopharmaceutical company focused on the localized treatment of difficult-to-treat solid tumors through its proprietary RenovoRx Trans-Arterial Micro-Perfusion (RenovoTAMP®) therapy platform, today reported its financial results for the quarter ended September 30, 2022.

"Since our Inception, RenovoRx's mission has been to develop and refine our innovative therapy platform, RenovoTAMP ®, for targeted intra-arterial (IA) delivery of chemotherapy directly to difficult-to-treat solid tumors with the vision of disrupting the current standard of care," said Shaun Bagai, CEO of RenovoRx. "In Q4 of this year, we are anticipating our most significant milestone to date; the first prospective interim analysis of our Phase III TIGeR-PaC clinical trial. The results of this trial have the potential to revolutionize pancreatic cancer treatment, shifting patient focus from coping with their chemotherapy treatment and its typical harsh side effects, to spending more quality time with their family and loved ones. Additionally, the interim analysis will provide us with an important insight into RenovoTAMP and its possibilities as a therapeutic platform. We also anticipate the launch of our second clinical trial in extrahepatic cholangiocarcinoma (eCCA) in Q4 2022/Q1 2023. This will be an integral step in RenovoRx's growth trajectory, demonstrating the ability of our therapy platform on another difficult-to-treat and aggressive form of cancer."

Mr. Bagai continued, "I am confident in the team we have in place, especially with the recent addition of Angela Gill Nelms as our COO. Angela's experience and expertise in clinical trial management, driving innovation, and building high-functioning teams has already proven to be invaluable. This is an exciting time to be a part of the RenovoRx team as we continue to be laser-focused on advancing our Phase III TIGeR-PaC clinical trial, launching our Phase II/III clinical trial in eCCA, and expanding our clinical pipeline to fight difficult-to-treat cancers."

Financial Highlights for the Quarter Ended September 30, 2022

- As of September 30, 2022, the Company had cash and cash equivalents and short-term marketable securities of $8.1 million.
- Research and development expenses were $0.8 million for the quarters ended September 30, 2022, and September 30, 2021, respectively. Clinical consulting expenses increased $0.2 million including preclinical research and development and regulatory expenses of $0.2 million which was offset by a decrease in the Phase III TIGeR-PaC clinical trial costs of $0.4 million compared to the quarter ended September 30, 2021.
- General and administrative expenses were $1.3 million for the quarter ended on September 30, 2022, compared to $0.6 million for the quarter ended on September 30, 2021. This $0.7 million increase was primarily due to a $0.3 million increase in professional and consulting services, including legal fees, related to post-IPO support, $0.2 million increase for higher personnel related costs and $0.2 million for directors' and officers' liability premiums.
- Net loss was $2.1 million for the quarter ended on September 30, 2022, compared to a net loss of $1.5 million for Q3 ended September 30, 2021.
- As of September 30, 2022, the Company had 9,072,263 common shares outstanding.

About the Phase III TIGeR-PaC Clinical Trial

TIGeR-PaC is a randomized multi-center Phase III study using RenovoRx's innovative therapy platform, RenovoTAMP ™ (RenovoRx Trans-Arterial Micro-Perfusion). The study is evaluating the Company's first product candidate, RenovoGem™, to treat locally advanced pancreatic cancer (LAPC) through the intra-arterial delivery of gemcitabine (FDA-approved chemotherapy). The study has a primary endpoint of overall survival and several secondary endpoints, including quality of life.

TIGeR-PaC is currently enrolling unresectable LAPC patients at several sites across the US. To learn more about the study and the participating clinical trial sites, visit **https://renovorx.com/clinical-trial/**.

About RenovoRx, Inc.

RenovoRx is a clinical-stage biopharmaceutical company with a vision to disrupt the current paradigm of cancer treatment. The company's mission is to lead a revolution in oncology therapy by delivering its innovative and targeted intra-arterial (IA) delivery of chemotherapy directly to solid tumors. The proprietary RenovoRx Trans-Arterial Micro-Perfusion (RenovoTAMP®) therapy platform aims to avoid the harsh side effects typical of the current standard of care, thus improving patient well-being and extension of life so more time may be enjoyed with loved ones. RenovoTAMP utilizes approved chemotherapeutics with validated mechanisms of action and well-established safety and side effect profiles, with the goal of increasing their efficacy, improving their safety, and widening their therapeutic window. RenovoRx's lead product candidate, RenovoGem™, is a combination of gemcitabine and its patented delivery system, RenovoCath®, and is regulated by the FDA as a novel oncology drug product to treat unresectable locally advanced pancreatic cancer (LAPC). RenovoGem is currently being studied in the Phase III TIGeR-PaC trial for the treatment of LAPC.

RenovoRx's patent portfolio for its therapy platform and product candidates includes seven issued U.S. patents, one issued European patent, and several additional patents pending in the US, EU and Asia. RenovoRx has been granted Orphan Drug Designation for intra-arterial delivery of gemcitabine for the treatment of both pancreatic cancer and bile duct cancer (cholangiocarcinoma).

Learn more by visiting the RenovoRx website or following RenovoRx on Facebook, LinkedIn and Twitter.

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 our clinical trials and studies, including anticipated timing, statements regarding the

potential of RenovoTAMP™, RenovoCath® or RenovoGem™ or regarding our ongoing TIGeR-PaC Phase III clinical trial in LAPC, and statements regarding the potential for our product candidates to treat or provide clinically meaningful outcomes for certain medical conditions or diseases. 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, clinical trials, therapy platform, business 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 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: the timing of the initiation, progress and potential results of our preclinical studies, clinical trials and our research programs; our ability to use and expand our therapy platform to build a pipeline of product candidates; our ability to advance product candidates into, and successfully complete, clinical trials; the timing or likelihood of regulatory filings and approvals; 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; the commercialization potential of our product candidates, if approved; our ability and the potential to successfully manufacture and supply our product candidates for clinical trials and for commercial use, if approved; future strategic arrangements and/or collaborations and the potential benefits of such arrangements; our estimates regarding expenses, future revenue, capital requirements and needs for additional financing and our ability to obtain additional capital; the sufficiency of our existing cash and cash equivalents to fund our future operating expenses and capital expenditure requirements; our ability to retain the continued service of our key personnel and to identify, hire and retain additional qualified personnel; the implementation of our strategic plans for our business and product candidates; the scope of protection we are able to establish and maintain for intellectual property rights, including our therapy platform, product candidates and research programs; our ability to contract with third-party suppliers and manufacturers and their ability to perform adequately; the pricing, coverage and reimbursement of our product candidates, if approved; developments relating to our competitors and our industry, including competing product candidates and therapies; negative impacts of the ongoing COVID-19 pandemic on our operations; and other risks. 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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