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 15, 2021**

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

Delaware	**001-40708**	**27-1448452**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

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

On November 15, 2021, RenovoRx, Inc. (the "Company") issued a press release announcing its unaudited financial results for the third quarter ended September 30, 2021. 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) 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 15, 2021

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: November 15, 2021

RENOVORX, INC.

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

FOR IMMEDIATE RELEASE

RenovoRx Announces Third Quarter 2021 Financial Results

Los Altos, CA, November 15, 2021 – **RenovoRx**, Inc. (Nasdaq: RNXT), a biopharmaceutical company and innovator in targeted cancer therapy, today reported its unaudited financial results for the third quarter ended September 30, 2021.

"The third quarter of 2021 marked an important juncture in the growth of our company as we completed our IPO in late August and our seventh U.S. patent was issued for our RenovoTAMP™ (RenovoRx Trans-Arterial Micro-Perfusion) therapy platform. Our team remains patient-focused, supporting the clinical sites, their patients and families enrolled in our Phase 3 TIGeR-PaC clinical trial for the treatment of locally advanced pancreatic cancer (LAPC)," said Shaun Bagai, Chief Executive Officer of RenovoRx.

Mr. Bagai added, "At two recent pancreatic cancer-focused meetings, we presented incremental positive study data from our foundational clinical trials that support the potential for more tolerable and targeted treatment of LAPC through intra-arterial delivery of chemotherapy. Through preliminary pharmacokinetic data (data describing the absorption, distribution, metabolism, and excretion of chemotherapy) from five patients in the TIGeR-PaC study, we found an approximate two-thirds reduction in systemic gemcitabine, when compared to systemic levels in historical control patients receiving traditional IV infusion of gemcitabine. This finding reinforces the potential for intra-arterial delivery to improve tolerability, reduce typical, and often debilitating, side-effects associated with systemic chemotherapy and ultimately improve quality of life. In addition, the final data we presented from our RR2 Observational Registry Study suggests that when RenovoTAMP is used in combination with radiation therapy, it may reduce arterial microvasculature, which minimizes leakage during chemotherapy delivery, and thereby increases the chemotherapy directly reaching the tumor."

GAAP Financial Results

For the Third Quarter Ended September 30, 2021 (Unaudited)

- Net loss for the third quarter of 2021 was $1.5 million, compared to $1.1 million for the third quarter of 2020.
- Research and development expenses for the third quarter of 2021 were $0.8 million, compared to $0.7 million for the same period in 2020. The increase was primarily due to higher clinical development personnel costs.
- General and administrative expenses for the third quarter of 2021 were $0.6 million, compared to $0.2 million for the same period of 2020. The increase was primarily due to higher professional and consulting expenses related to preparing for our IPO in August 2021, including personnel costs and insurance costs for directors and officers liability insurance.

For the Nine Months Ended September 30, 2021 (Unaudited)

- Net loss for the nine months ended September 30, 2021 was $4.0 million, compared to $2.9 million for the same period in 2020.
- Research and development expenses for the nine months ended September 30, 2021 and 2020 were each $1.9 million. Research and development expenses during the 2021 period were higher overall, primarily due to higher clinical development personnel costs, but were offset by lower leased software expenses and payments received from clinical sites for the use of our RenovoCath® delivery system in our Phase 3 clinical trial.
- General and administrative expenses for the nine months ended September 30, 2021 were $1.4 million, compared to $0.6 million for the same period of 2020. The increase was primarily due to higher professional and consulting expenses related to preparing for our IPO in August 2021, including personnel costs and insurance costs for directors and officers liability insurance.

As of September 30, 2021, the Company had cash and cash equivalents of $17.7 million and no outstanding debt obligations.

About the Phase 3 TIGeR-PaC Clinical Trial

The TIGeR-PaC clinical trial is a randomized multi-center study using the RenovoTAMP™ platform to evaluate RenovoRx's first product candidate, RenovoGem™ to treat unresectable LAPC through the intra-arterial delivery of gemcitabine, an approved chemotherapeutic agent. TIGeR-PaC is currently enrolling locally advanced, unresectable pancreatic cancer patients. 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 focused on fighting cancer through the localized treatment of difficult to treat tumors via its proprietary RenovoRx Trans-Arterial Micro-Perfusion (RenovoTAMP™) therapy platform. RenovoTAMP delivers approved small molecule chemotherapeutic agents locally to the solid tumors. RenovoRx's lead product candidate, RenovoGem™, uses intra-arterial delivery of gemcitabine, an approved chemotherapeutic agent, to treat unresectable locally advanced pancreatic cancer (LAPC) and is currently being studied in the Phase 3 TIGeR-PaC trial for the treatment of LAPC.

RenovoRx's patent portfolio includes seven U.S. patents for its technology. RenovoRx has been granted Orphan Drug Designation for intra-arterial delivery of gemcitabine for the treatment of both pancreatic cancer and bile duct cancer.

RenovoRx won the Drug Delivery Technology category of the Fierce Innovation Awards – Life Sciences Edition 2020 for its RenovoTAMP technology.

Learn more by visiting the RenovoRx **website** or following us 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 Phase 1 (RR1) and Observational Registry (RR2) studies, statements regarding the potential of RenovoTAMP™, RenovoCath® or RenovoGem™ or regarding our ongoing TIGeR-PaC Phase 3 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 COVID-19 pandemic on our operations; general economic and market conditions 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.

Contact:
Chris Lehman, (650) 284-4433

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