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): **June 29, 2023**

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 8.01 Other Events.

On June 29, 2023, RenovoRx, Inc., a Delaware corporation (the "Company"), issued a press release announcing new positive interim phase III data demonstrating RenovoGem™ delays cancer progression by eight months in locally advanced pancreatic cancer (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, dated June 29, 2023
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: June 29, 2023

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

June 29, 2023

RENOVO | RX
INVESTOR RELATIONS

RenovoRx Announces New Positive Interim Phase III Data Demonstrating RenovoGem™ Delays Cancer Progression by Eight Months in Locally Advanced Pancreatic Cancer

Six-Month Overall Survival Benefit with RenovoGem Versus Systemic Chemotherapy, and 65% reduction in adverse effects and clinically meaningful overall survival trend

Results highlight RenovoGem's potential to change treatment paradigm for Locally Advanced Pancreatic Cancer

LOS ALTOS, Calif.--(BUSINESS WIRE)-- RenovoRx, Inc. ("RenovoRx" or the "Company") (Nasdaq: RNXT), a clinical-stage biopharmaceutical company developing targeted combination therapies, today presented new positive data on progression-free survival (PFS) from the pivotal Phase III open label TIGeR-PaC study of RenovoGem (intra-arterial administration of gemcitabine) in locally advanced pancreatic cancer (LAPC). The interim data was featured as a late-breaking oral presentation at the 2023 ESMO World Congress on Gastrointestinal Cancer, and presented by Michael J. Pishvaian, M.D., Ph.D., Johns Hopkins Medicine and Principal Investigator (PI) of the TIGeR-PaC study.

The interim analysis demonstrated an eight-month median PFS benefit, 15 versus 7 months, in delaying the progression of cancer for patients receiving treatment with RenovoGem versus standard-of-care. PFS is the measure of the length of time from study randomization to either death or progression of disease.

"Clinical practice has been waiting decades for a meaningful advancement in the standard of care for pancreatic cancer treatment, with less toxicity and better outcomes. The new data from the TIGeR-PaC interim results support that RenovoGem has the potential to more than double progression-free survival compared to systemic chemotherapy alone in this difficult-to-treat cancer, which demonstrates support for a new treatment standard," said Michael J. Pishvaian, M.D., Ph.D., PI of the TIGeR-PaC study. "This data has the potential to be a paradigm-shifting treatment for patients at risk of cancer progression, including those who have limited well-tolerated options."

The study is designed to randomize 114 patients (57 in each arm) with all patients receiving upfront induction chemotherapy and stereotactic body radiation therapy (SBRT). The TIGeR-PaC Data Monitoring Committee met and determined the interim data is promising and warrants continuation of this pivotal trial. As of the date of the analysis, 45 patients from U.S. sites had been randomized in this trial and the survival status of all subjects was used for the analysis.

- 23 patients were randomized to intra-arterial (IA) gemcitabine (RenovoGem investigational treatment) arm and 22 patients to continuation of intravenous (IV) gemcitabine and nab-paclitaxel (standard-of-care) control arm.
- The median PFS data in the IV gemcitabine and nab-paclitaxel control arm was 7 versus 15 months in the IA RenovoGem arm.
- Patients had a greater than 65% reduction in adverse events compared to the control arm.
- The median overall survival in the IV gemcitabine and nab-paclitaxel control arm was 10 months, versus 16 months in the IA RenovoGem arm, from time of randomization. (NOTE: Both arms' median overall survival calculations do not include approximately 5.5 months of life from diagnosis to randomization during the induction chemotherapy and radiation phase of the trial.)

The TAMP™ (Trans-arterial Micro-perfusion) therapy platform delivers gemcitabine directly to the tumor site, potentially enhancing the therapeutic effectiveness while potentially minimizing the systemic side effects, commonly associated with traditional chemotherapy (IV) administration, and improving patient outcomes.

"The TIGeR-PaC study results reinforce the intended clinical advantage that TAMP brings to pancreatic cancer treatment, versus the non-targeted approach of the current standard of care (IV) therapy," said Ramtin Agah, M.D., Chief Medical Officer, RenovoRx. "The first look at interim analysis data of our pivotal trial supports this important advantage in overcoming the barrier of solid tumors in resisting drug uptake."

"Placing patients at the center of everything we do is a critical focus. We are thrilled to announce these pivotal TIGeR-PaC study results supporting RenovoGem's meaningful clinical benefit and impressive safety profile for patients with LAPC," said Shaun Bagai, CEO, RenovoRx. "We are committed to advancing this therapy as rapidly as possible, with the goal of delivering a treatment that is capable of improving survival outcomes while preserving patient quality of life in pancreatic cancer."

TIGeR-PaC is currently enrolling unresectable LAPC patients at several sites across the U.S. To learn more about the study and the participating clinical trial sites, visit https://renovorx.com/clinical-trial/. RenovoGem is currently under investigation for TAMP therapeutic delivery of gemcitabine and has not been approved for commercial sale.

About Locally Advanced Pancreatic Cancer (LAPC)

According to American Cancer Society's Cancer Facts & Figures 2023, pancreatic cancer has a 5-year combined overall survival rate of 12% (Stages I-IV) and is on track to be the second leading cause of cancer-related deaths before 2030. LAPC is diagnosed when the disease has not spread far beyond the pancreas, however, has advanced to the point where it cannot be surgically removed. LAPC is typically associated with patients in Stage 3 of the disease as determined by the TNM (tumor, nodes and metastasis) grading system.

About RenovoGem

RenovoGem™ is the first drug-device combination product candidate that utilizes the TAMP™ therapy platform via pressure-mediated delivery technology to deliver gemcitabine, an FDA-approved systemic chemotherapy, locally across the arterial wall to bathe tumor

tissue in the chemotherapy. RenovoGem is currently being evaluated in the Phase III TIGeR-PaC clinical trial study in Locally Advanced Pancreatic Cancer (LAPC) patients. The Company plans to investigate RenovoGem in extrahepatic Cholangiocarcinoma (eCCA) in a clinical trial, which is anticipated to begin in the first half of 2023.

About RenovoRx, Inc.

RenovoRx is a clinical-stage biopharmaceutical company developing targeted combination therapies for high unmet medical needs. The Company's proprietary Trans-Arterial Micro-Perfusion (TAMP™) therapy platform is designed to bypass traditional systemic delivery methods and ensure precise therapeutic delivery to a target tissue, while minimizing a therapy's systemic toxicities. RenovoRx's unique approach to drug delivery offers the potential for increased treatment safety, tolerance, and wider therapeutic windows. The Company's lead product candidate, RenovoGem™, combines gemcitabine with the company's patented delivery system and is regulated by FDA under its 505(b)2 pathway. RenovoGem is currently in a Phase III clinical trial (TIGeR-PaC) for the treatment of LAPC. RenovoRx is committed to transforming the lives of patients by delivering innovative solutions to change the current paradigm of cancer care. For more information, visit www.renovorx.com. Follow 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 study in LAPC, statements regarding the potential for our product candidates to treat or provide clinically meaningful outcomes for certain medical conditions or diseases, and our preliminary financial results, cash position and related ability to continue as a going concern. 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; the interim results may not be predictive of the outcome of our clinical trial, which may not demonstrate sufficient safety and efficacy to support regulatory approval of our product candidate, or the regulatory

authority may disagree with our interpretation of the data; research and clinical development plans and timelines, and the regulatory process for our product candidates; future potential regulatory milestones for our product candidates, including those related to current and planned clinical studies; 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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https://www.businesswire.com/news/home/20230629226701/en/

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