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): **January 18, 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 January 18, 2023, RenovoRx, Inc. (the "Company") issued a press release announcing various information that is to be presented at the 2023 ASCO Gastrointestinal Cancers Symposium on January 19-21, 2023, in San Francisco, California. 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 January 18, 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: January 18, 2023

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

Exhibit 99.1

RenovoRx Announces Initial Results in Pharmacokinetic (PK) Substudy: Data on RenovoGem ™ Supports Potential for RenovoTAMP® Therapy Platform to Increase Local Gemcitabine (Chemotherapy) Delivery and Decrease Side Effects of Pancreatic Cancer Treatment

Researchers presenting four abstracts on different substudies, including the preliminary PK substudy, at the ASCO GI Cancers Symposium in San Francisco on January 19-21, 2023.

Los Altos, CA, January 18, 2023 - RenovoRx, Inc. (Nasdaq: RNXT), a biopharmaceutical company focused on the localized treatment of solid tumors, today announced initial results from a pharmacokinetic (PK) substudy within the phase III un-blinded randomized control TIGeR-PaC clinical trial to be presented at the 2023 ASCO Gastrointestinal (ASCO GI) Cancers Symposium this week. The TIGeR-PaC clinical trial is evaluating intra-arterial (IA) administration of gemcitabine (chemotherapy) using the proprietary RenovoRx Trans-Arterial Micro-Perfusion (RenovoTAMP) platform for targeted treatment of Locally Advanced Pancreatic Cancer (LAPC). The substudy provides clinical support that RenovoTAMP may increase local drug delivery and thus concentration at the tumor site while decreasing the debilitating side effects often associated with systemic intravenous (IV) delivery, which is the current standard of care.

Three additional abstracts supporting the use of RenovoTAMP with gemcitabine for treatment of LAPC will also be presented at the ASCO GI on January 19-21, 2023 in San Francisco, California, and available online.

"Intra-arterial Gemcitabine vs IV Gemcitabine PK Substudy in Patients with Locally Advanced Pancreatic Cancer," presented by Amer H. Zureikat, MD, et al., evaluates RenovoTAMP for IA delivery of gemcitabine (chemotherapy) directly into tumors for higher local drug concentration and decreased systemic drug concentration and associated side effects. The PK substudy evaluates a sample of LAPC patients (N=13) participating in the TIGeR-PaC study and demonstrates that the cohort had an average greater than 50% reduction in systemic drug exposure with IA delivery of gemcitabine using RenovoTAMP when compared with IV administration. The substudy concludes that RenovoTAMP may increase local gemcitabine concentration, which may be beneficial in decreasing gemcitabine-related systemic side effects. Five TIGeR-PaC clinical sites participated in this substudy.

"The upcoming presentation of our TIGeR-PaC clinical trial substudy at ASCO GI highlights significant potential benefits for patients with LAPC," said Ramtin Agah, MD, Chief Medical Officer and Founder of RenovoRx. "Targeted local delivery of standard dose gemcitabine via the RenovoTAMP therapy platform may be associated with significantly less systemic drug exposure. The clinical implications may be decreased side effects and enhanced chemotherapy delivery. Ongoing studies are quantifying the resulting impact on improving patients' quality of life and extending lifespan."

"This substudy data, and the additional three studies to be presented at ASCO GI, enhance the strong clinical momentum of our therapy platform as we prepare for our most significant milestone to date: the initial interim analysis for our randomized phase III TIGeR-PaC trial." said Shaun Bagai, CEO of RenovoRx.

Three additional clinical data abstracts presented by researchers at ASCO GI with data from the induction phase of the TIGeR-PaC study help to advance the science behind pancreatic cancer. In one abstract, Dr. Amer H. Zureikat, et al. investigates Mesenteric Venous Thrombosis (MVT), often identified on routine imaging studies performed with LAPC, and concludes that severe MVT is more prevalent in this patient population than previously reported. Anticoagulation is also underutilized in this cohort; however, chemotherapy may have a beneficial effect in downstaging MVT beyond anticoagulation. In a second abstract, Dr. Karyn A. Goodman, et al. performs an exploratory analysis to compare the toxicity and efficacy between patients receiving either stereotactic body radiation therapy (SBRT) or intensity-modulated radiation therapy (IMRT) during the induction phase (prior to randomization) of the TIGeR-PaC study. When compared to IMRT, SBRT demonstrates improved tolerability for treatment of patients with LAPC with comparable clinical efficacy. It was this finding that led to the modification of the TIGeR-PaC study design in 2021. Finally, a third abstract presented by Michael J. Pishvaian, et al. focuses on the TIGeR-PaC trial design and status.

The poster presentations for the four RenovoRx abstracts to be presented at the ASCO GI Symposium will be available on RenovoRx's website once available: https://renovorx.com/for-clinicians/.

About RenovoGem

RenovoGem™ (gemcitabine, an FDA-approved chemotherapy, delivered via the Company's proprietary delivery system), utilizes pressure-mediated delivery of drug across the arterial wall to bathe tumor tissue in chemotherapy via RenovoTAMP®. RenovoGem is currently being evaluated in a Phase III clinical trial in Locally Advanced Pancreatic Cancer (LAPC) patients, and the Company plans to investigate RenovoGem in extrahepatic Cholangiocarcinoma (eCCA), beginning in the first half of 2023.

About the Phase III TIGeR-PaC Clinical Trial

TIGeR-PaC is an un-blinded randomized multi-center Phase III study evaluating the use of RenovoRx's innovative therapy platform, RenovoTAMP ® (RenovoRx Trans-Arterial Micro-Perfusion), with gemcitabine as a potential treatment option for LAPC. The study is evaluating the Company's first product candidate, RenovoGem™, to treat locally advanced pancreatic cancer (LAPC) following stereotactic body radiation therapy (SBRT) 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. The study is designed to randomize 114 patients with all patients receiving up front SBRT and induction chemotherapy and 57 patients in each arm. Final analysis will be conducted after 86 deaths from the SBRT population. Additionally, the study includes two planned interim analyses, the first upon 30% (26 of 86) of the total and the second upon 60% (52 of 86) of the total.

To date, 47 out of 114 target post-SBRT/chemotherapy patients have been randomized in the TIGeR-PaC trial and the Company has received reports of 25 events (deaths) in this population.

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. Our 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 is designed to utilize approved chemotherapeutics with validated mechanisms of action and well-established safety and side effect profiles, with the goal of increasing local delivery of the chemotherapeutic, reducing side effects often associated with systemic delivery, 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 investigational oncology drug product, subject to ongoing clinical evaluation for treating 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 eight 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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