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): **May 15, 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 (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 Condition.

On May 15, 2023, RenovoRx, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended March 31, 2023. 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 May 15, 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: May 15, 2023

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

Exhibit 99.1

RenovoRx Reports First Quarter 2023 Financial Results and Operational Highlights

Announced Phase III Interim Study Analysis Results: 60% Survival Benefit and Greater than 65% Reduction in Side Effects with RenovoGem™ Compared to Systemic Chemotherapy in Pancreatic Cancer

Los Altos, CA, May 15, 2023 - RenovoRx, Inc. ("RenovoRx" or the "Company") (Nasdaq: RNXT), a biopharmaceutical company focused on the localized treatment of cancers, today announced financial results for the first quarter ended March 31, 2023.

"We are off to a strong start in 2023, as we build upon the recent positive interim data analysis announced at the American Association of Cancer Research (AACR) from our open-label Phase III TIGeR-PaC clinical trial with RenovoGem," said Shaun Bagai, CEO, RenovoRx. "Results of the analysis highlight a trend in median overall survival by 24-weeks and reduced side effects for patients with locally advanced pancreatic cancer (LAPC) with RenovoGem versus systemic chemotherapy. We're also thrilled to welcome industry veteran Robert J. Spiegel to our Board of Directors, and, clinical trials expert, Leesa Gentry, as our new Senior Vice President of Clinical Operations. We are well positioned to build on our success and momentum, and plan to advance our pipeline of innovative therapies to address unmet medical needs for patients with solid tumor cancers."

Operational Highlights for the First Quarter Ended March 31, 2023:

- Announced positive new data from Phase III clinical trial interim analysis. Data suggests a 60% survival benefit and greater than 65% reduction in side effects compared to systemic chemotherapy.
- Announced initial results in pharmacokinetic (PK) substudy: data on RenovoGem supports potential for the RenovoTAMP® therapy platform to increase local gemcitabine (chemotherapy) delivery and decrease side effects of pancreatic cancer treatment.
- Issued 8th U.S. patent extending the intellectual property coverage of the RenovoTAMP therapy platform.
- Acceptance of four clinical data abstracts at the 2023 ASCO Gastrointestinal Cancer Symposium.

Highlights Subsequent to the First Quarter Ended March 31, 2023:

- Appointed Robert J. Spiegel, MD, FACP, former Chief Medical Officer of Schering-Plough, to the Board of Directors.
- Appointed Leesa Gentry as Senior Vice President of Clinical Operations.
- Presented Phase III interim analysis data of the TIGeR-PaC study at the 2023 American Association for Cancer Research (AACR) in Orlando, Florida.
- Closed $5 million registered direct offering.

Financial Highlights for the First Quarter Ended March 31, 2023:

- Cash and cash equivalents as of March 31, 2023, were $3.7 million.
- Research and development expenses were $1.3 million for the quarter ended March 31, 2023, compared to $1.3 million, relatively flat compared to the quarter ended March 31, 2022. Clinical consulting support for the ongoing Phase III clinical trial increased $0.1 million, which was offset by a decrease in our Phase III clinical trial costs of $0.1 million primarily due to suspending the European Phase III clinical trial.
- General and administrative expenses were $1.9 million for the quarter ended March 31, 2023, compared to $1.7 million for the quarter ended March 31, 2022. The increase was primarily due to higher employee and related benefit costs of $0.3 million, and an increase in professional and consulting fees of $0.2 million. This increase was partially offset by an increase of $0.2 million in allocated general and administrative expenses to research and development including other miscellaneous general and administrative costs of $0.1 million.
- Net loss was $3.3 million for the quarter March 31, 2023, compared to net loss of $3.0 million for year ended March 31, 2022.
- As of March 31, 2023, the Company had 9,097,701 common shares outstanding.

About RenovoGem

RenovoGem™ is the first drug-device combination product candidate that utilizes the RenovoTAMP® 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. RenovoGem™ is currently under investigation for the intra-arterial delivery of gemcitabine and has not been approved for commercial sale.

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, or systemic delivery methods, thus improving patient well-being and, potentially 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 clinical use, with the goal of improving their safety, tolerance, and widening their therapeutic window by providing more targeted delivery at the location of the tumor tissue. 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 open label, randomized Phase III TIGeR-PaC clinical 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 study 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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