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): March 2, 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)	(I.R.S. Employer Identification No.)

4546 El Camino Real, Suite B1
Los Altos, California 94022
(Address of principal executive offices) (zip code)

Registrant's telephone number, including area code: (650) 284-4433

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:

☐ 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))

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.0001 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 March 2, 2023, RenovoRx, Inc. (the "Company") issued a press release announcing its financial results for the year ended December 31, 2022. The full text of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 8.01. Other Events.

In addition to announcing certain financial results, the Company's press release provides certain updates related to the expected interim analysis of the Company's clinical trial as described in such press release. 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 March 2, 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, as amended, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

RENOVORX, INC.

Date: March 2, 2023

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

Exhibit 99.1

RenovoRx Reports Full Year 2022 Financial Results and Achievement of Important Phase III Clinical Study Milestone

First of Two Planned Interim Analyses Triggered

Company and Data Monitoring Committee Conducting Review

Results of Analysis Forthcoming

Los Altos, CA, March 2, 2023 - RenovoRx, Inc. ("RenovoRx" or the "Company") (Nasdaq: RNXT), a biopharmaceutical company focused on the localized treatment of solid tumors, today is reporting its financial results for the year ended December 31, 2022, and a pipeline update including the status of the interim analysis of for the Company's Phase III TIGeR-PaC clinical trial**.**

RenovoRx anticipates finalizing the interim analysis for the TIGeR-PaC Phase III trial and releasing the results within the next week or so. To date, 47 out of 114 target post-SBRT/chemotherapy patients have been randomized in the TIGeR-PaC clinical trial, and the Company has received reports of 26 events (deaths) in this population. This 26th event represents 30% of the 86 events and thus triggered the first planned interim analysis and a meeting of the study's Data Monitoring Committee ("DMC") to evaluate the ongoing progression of the Phase III clinical trial. Upon completion of the analysis and assessment of the data by the DMC, and RenovoRx's subsequent review of their findings, the Company will report the first interim analysis.

TIGeR-PaC is a randomized multi-center Phase III open label clinical trial designed to investigate the Company's first product candidate, RenovoGem™, which utilizes RenovoRx's proprietary therapy platform, RenovoTAMP®, to provide targeted intra-arterial delivery of FDA-approved chemotherapy, gemcitabine, to treat locally advanced pancreatic cancer (LAPC) following stereotactic body radiation therapy (SBRT). The study is comparing treatment with RenovoTAMP versus standard of care systemic intravenous (IV) administration of gemcitabine and nab-paclitaxel. The study is designed to randomize 114 patients (57 in each arm) with all patients receiving upfront induction chemotherapy and SBRT. Final analysis will be conducted after 86 protocol-specified events have occurred in the SBRT population with two planned interim analyses: the first analysis when 30% of the specified events have been reported (data announcement forthcoming) and the second analysis when 60% of the events have been reported (expected in 2024).

"RenovoRx has continued to grow in 2022 as we have focused on advancing our innovative therapy platform with the vision of disrupting the current standard of care," said Shaun Bagai, CEO of RenovoRx. "Over the past year, we have advanced our mission to transform oncology therapy with our TIGeR-PaC Phase III study, treating pancreatic cancer, and expanding our clinical pipeline to treat other solid tumors. We have also built a strong internal team, and we look forward to continued progress as we strive to give our patients not just more time but more quality time that they can spend with their loved ones."

Fiscal Year 2022 and Subsequent Operational Highlights:

- Announced Initial Results in Pharmacokinetic Substudy at the 2023 ASCO Gastrointestinal Cancer Symposium: Data on RenovoGem supports potential for RenovoTAMP therapy platform to increase local gemcitabine delivery and decrease side effects of pancreatic cancer treatment
- Eighth U.S. patent issued extending the intellectual property coverage of the RenovoTAMP therapy platform
- Acceptance of four clinical data abstracts at the 2023 ASCO Gastrointestinal Cancer Symposium
- Presented RenovoTAMP therapy platform at the Advanced Interventional Management Symposium
- Presented at Symposium on Clinical Interventional Oncology
- Appointed Angela Gill Nelms as Chief Operating Officer
- Appointed James Ahlers as Chief Financial Officer
- Participated in University of Cambridge Academy of Therapeutic Sciences Gateway to Translation Seminar Series
- Presented preclinical research data demonstrating potential utility for treatment of bile duct cancer
- Enrolled first pancreatic cancer patient at Columbia University's New York-Presbyterian Hospital Irving Medical Center in TIGeR-PaC clinical trial study
- Presented at 2022 SPECTRUM Conference

Financial Highlights for the Fiscal Year Ended December 31, 2022

- Cash, cash equivalents and marketable securities as of December 31, 2022, were $6.4 million. We estimate that our current capital resources will be sufficient to fund our operating expenses and capital expenditure requirements into the third quarter of 2023.
- Total assets and total liabilities as of December 31, 2022, were $7.3 million and $1.1 million, respectively.
- Total operating expenses were $10.0 million for the year ended December 31, 2022, compared to $5.7 million for the year ended December 31, 2021. The increase was related to higher research and development expenses and general and administrative expenses.
- Research and development expenses were $4.3 million for the year ended December 31, 2022, compared to $3.0 million for the year ended December 31, 2021. The increase was primarily related to higher costs for contracted research development and consulting, including employee related costs and costs associated with a secondary manufacturer for the RenovoCath® delivery system. In addition, allocated general administrative support costs increased during the year.
- General and administrative expenses were $5.6 million for the year ended December 31, 2022, compared to $2.6 million for the year ended December 31, 2021. The increase was primarily related to higher professional and consulting costs, including legal expenses, employee-related costs and D&O and liability insurance and other expenses. The increase was partially offset by general and administrative support costs allocated to research and development expenses.

- Net loss was $9.9 million for the ended December 31, 2022, compared to net loss of $6.3 million for year ended December 31, 2021.
- Net loss per share, basic and diluted were ($1.09) for the year ended December 31, 2022, compared to ($1.21) for the year ended December 31, 2021.
- As of December 31, 2022 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 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 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 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).

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.

RenovoRx, Inc.
Selected Balance Sheet Data
(in thousands)

	December 31,	
	2022	**2021**
	(unaudited)	
Cash, cash equivalents and marketable securities	$ 6,440	$ 15,192

Total assets	**$ 7,265**	**$ 16,287**
Total liabilities	$ 1,102	$ 938
Total stockholders' equity	$ 6,163	$ 15,349
Total liabilities and stockholders' equity	**$ 7,265**	**$ 16,287**

RenovoRx, Inc.
Selected Statement of Operations Data
(in thousands, execpt for share and per share amount)

	Year Ended December 31,	
	2022	**2021**
	(unaudited)	
Operating expenses:		
Research and development	$ 4,301	$ 3,039
General and administrative	5,649	2,632
Total Operating expenses	9,950	5,671
Loss from operations	(9,950)	(5,671)
Other income (expenses), net	61	(653)
Net loss	(9,889)	(6,324)
Other comprehensive income	17	-
Comprehensive loss	**$ (9,872)**	**$ (6,324)**
Net loss per share, basic and diluted	$ (1.09)	$ (1.21)
Weighted-average shares of common stock outstanding, basic and diluted	9,051,726	5,217,000

Investor Contact:

KCSA Strategic Communications
Valter Pinto or Jack Perkins
T:212-896-1254
renovorx@kcsa.com

Media Contact:

Kevin Knight
T: 214-732-9392
kknightpr@gmail.com