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 14, 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 November 14, 2023, RenovoRx, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended September 30, 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 November 14, 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: November 14, 2023

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

Exhibit 99.1

RenovoRx Reports Third Quarter 2023 Financial Results and Operational Highlights

Collaboration with Imugene further validates TAMP™ (Trans-Arterial Micro-Perfusion) and will expand use of RenovoRx's delivery platform beyond chemotherapy to immunotherapy.

The TAMP therapy platform is in a Phase III clinical trial for the treatment of Pancreatic Cancer, interim analysis was completed in March 2023, and the Data Monitoring Committee recommended a continuation of the study.

TIGeR-PaC is prespecified to provide a primary endpoint of a 6-month Overall Survival (OS) benefit and secondary endpoints including reduced adverse events versus standard of care.

Los Altos, CA, November 14, 2023 - RenovoRx, Inc. ("RenovoRx" or the "Company") (Nasdaq: RNXT), a clinical-stage biopharmaceutical company developing targeted combination therapies, today announced financial results for the third quarter ended September 30, 2023.

"We remain focused on our core mission to improve the lives of patients diagnosed with difficult-to-treat cancers by delivering novel targeted combination therapies that have the potential to alter the current paradigm of oncology care," said Shaun Bagai, CEO of RenovoRx. "We are encouraged by the progress in our pivotal Phase III TIGeR-PaC study, and the recent completed interim analysis, along with our partnership with Imugene as we explore pipeline expansion opportunities using our TAMP therapy platform."

Key Business Highlights:

- Continued to advance Phase III TIGeR-PaC clinical trial for the treatment of LAPC. The first of two interim analyses was completed in March 2023, and the Data Monitoring Committee recommended a continuation of the study. The study is prespecified to provide a primary endpoint of a 6-month OS benefit and secondary endpoints including reduced adverse events versus standard of care. Additionally, Dr. Michael J. Pishvaian, Johns Hopkins Medicine and Principal Investigator of TIGeR-PaC, presented at the Global Summit on Gastrointestinal Malignancies in Bermuda. The presentation, "Increasing Local Gemcitabine Delivery Using TAMP in the Chemotherapy Advances in Pancreatic Cancer," highlighted the proprietary TAMP therapy platform and its design to ensure precise delivery for targeted treatment of cancer, and its potential for increased safety, tolerance, and improved efficacy.
- Ripal Gandhi, FSIR, FSVM, investigator in the TIGeR-PaC study, presented, "Advances in Pancreatic Cancer: Trans-arterial Therapy on the Horizon," at the Symposium on Clinical Interventional Oncology (CIO) on September 22-24, 2023, in Orlando, Florida. Dr. Gandhi highlighted the TAMP therapy platform as a potential targeted treatment option for patients diagnosed with locally advanced pancreatic cancer versus the standard of care. Dr. Gandhi is a member of the Miami Cancer Institute and Miami Cardiac and Vascular Institute physician team, a Clinical Professor at Florida International University Herbert Wertheim College of Medicine and Associate Professor at USF School of Medicine.
- Collaboration with Imugene Ltd (ASX: IMU) further validates the TAMP platform and will expand use of RenovoRx's delivery platform beyond chemotherapy to immunotherapy.

Financial Highlights for Third Quarter ended September 30, 2023:

- **Cash Position:** Cash and cash equivalents as of September 30, 2023, were $3.2 million.
- **R&D Expenses:** Research and development expenses were $1.6 million for the quarter ended September 30, 2023, compared to $0.8 million for the quarter ended September 30, 2022. The increase was primarily due to our ongoing Phase III clinical trial cost of $0.4 million, an increase in employee and related benefits costs of $0.3 million and general and administrative allocated costs of $0.2 million. This increase was partially offset by a decrease in costs associated with a secondary manufacturer of $0.1 million.
- **G&A Expenses:** General and administrative expenses were $1.3 million for the third quarter ended September 30, 2023, flat compared to the same period last year. Employee and related benefits costs increased $0.3 million compared to the same quarter last year. This increase was offset by a decrease in directors' and officers' insurance expenses of $0.1 million, including allocation of general and administrative expenses to research and development of $0.2 million.
- **Net Loss:** Net loss was $1.4 million for the quarter ended September 30, 2023, compared to net loss of $2.1 million for the quarter ended September 30, 2022. The decrease is primarily due to an increase in operating expenses of $0.8 million, offset by $1.5 million reported gain on the fair value of common warrants issued under our Registered Direct Offering in April 2023.
- **Shares Outstanding:** Shares of common stock outstanding, as of September 30, 2023, were 10,693,080.

About RenovoRx, Inc.

RenovoRx is a clinical-stage biopharmaceutical company developing proprietary targeted combination therapies for high unmet medical need with a goal to improve therapeutic outcomes for cancer patients undergoing treatment. The Company's proprietary Trans-Arterial Micro-Perfusion (TAMP™) therapy platform is designed to ensure precise therapeutic delivery to directly target the tumor while potentially minimizing a therapy's toxicities versus systemic (intravenous (IV) therapy). RenovoRx's unique approach is under investigation for targeted treatment with the potential for increased safety, tolerance, and improved efficacy. Our Phase III lead product candidate, RenovoGem™, a novel oncology drug-device combination product, is being investigated under a US IND that is regulated by FDA 21 CFR 312 pathway. RenovoGem is currently being evaluated for the treatment of locally advanced pancreatic cancer (LAPC) by the Center for Drug Evaluation and Research (the drug division of FDA.)

RenovoRx is committed to transforming the lives of patients by delivering innovative solutions to change the current paradigm of cancer care.RenovoGem is currently under investigation for TAMP therapeutic delivery of gemcitabine and has not been approved for commercial sale.

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 RenovoCath®, RenovoGem™ or TAMP™ 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 possibility that 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; our ability to comply with the continued listing standards of Nasdaq Stock Market LLC ("Nasdaq") or the continued listing of our securities on Nasdaq; 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 Condensed Balance Sheet Data
(Unaudited)
(in thousands)

	September 30, 2023	December 31, 2022
Cash, cash equivalents and marketable securities	$ 3,226	$ 6,440
Total assets	**$ 3,519**	**$ 7,265**
Current liabilities	$ 1,605	$ 1,102
Common warrant liability	1,908	-
Total liabilities	$ 3,513	$ 1,102
Total stockholders' equity	$ 6	$ 6,163
Total liabilities and stockholders' equity	**$ 3,519**	**$ 7,265**

RenovoRx, Inc.
Condensed Statements of Operations and Comprehensive Loss
(Unaudited)
(*in thousands, except share and per share amounts*)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Operating expenses:				
Research and development	$ 1,629	$ 846	$ 4,892	$ 3,525
General and administrative	1,354	1,315	4,727	4,255
Total operating expenses	2,983	2,161	9,619	7,780
Loss from operations	(2,983)	(2,161)	(9,619)	(7,780)
Other income/(expenses), net:				
Interest and dividend income	43	22	97	43
Other income, net	-	3	-	4
Change in fair value of common warrant liability	1,519	-	3,092	-
Transaction costs allocated to common warrant liability	-	-	(575)	-
Total other income/(expenses), net	1,562	25	2,614	47
Net loss	(1,421)	(2,136)	(7,005)	(7,733)
Other comprehensive loss:				
Unrealized gain on marketable securities	-	17	-	13
Comprehensive loss	$ (1,421)	$ (2,119)	$ (7,005)	$ (7,720)
Net loss per share, basic and diluted	$ (0.13)	$ (0.24)	$ (0.69)	$ (0.86)
Weighted-average shares of common stock outstanding, basic and diluted	10,693,080	9,067,509	10,154,914	9,039,308

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