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): **August 17, 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 2.02 Results of Operations and Financial Condition.

On August 17, 2023, RenovoRx, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended June 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 August 17, 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: August 17, 2023

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

Exhibit 99.1

RenovoRx Reports Second Quarter 2023 Financial Results and Operational Highlights

Presented positive Phase III TIGeR-PaC interim study results observing 8-month delay in cancer progression, concordant with 6-month overall survival benefit and 65% reduction in adverse effects over standard of care.

Announced collaboration with Imugene to explore delivery of oncolytic virus therapy using proprietaryTrans-Arterial Micro-Perfusion (TAMP™) platform, expanding use from targeting locally advanced disease to treating metastatic disease.

Los Altos, CA, August 17, 2023 - RenovoRx, Inc. ("RenovoRx" or the "Company") (Nasdaq: RNXT), a clinical-stage biopharmaceutical company developing targeted combination therapies, today announced financial results for the second quarter ended June 30, 2023.

"We made strong progress this quarter and have continued momentum in our commitment to transform the lives of patients by delivering innovative solutions to change the current paradigm of cancer care," said Shaun Bagai, CEO of RenovoRx. "This quarter marked significant milestones including positive interim data presented from our pivotal Phase III TIGeR-PaC study, a strategic collaboration to potentially utilize immunotherapy to expand our platform to help metastatic patients, and key additions to our leadership team, Board of Directors and Scientific Advisory Board. We are also excited for the upcoming year, when we expect our secondary interim analysis data readout"

Key Business Highlights:

- • Presented positive Phase III data demonstrating RenovoGem delays cancer progression by 8-months, while providing a 6-month overall survival benefit and 65% reduction in adverse effects over standard of care in locally advanced pancreatic cancer patients, at 2023 ESMO World Congress in Gastrointestinal Cancer and American Association for Cancer Research Annual Meeting.
- Initiated patient enrollment at the University of Texas Southwestern Medical Center for pivotal Phase III TIGeR-PaC clinical trial.
- • Launched collaboration with Imugene Ltd (ASX: IMU) to explore a better way to deliver oncolytic immunotherapy in difficult to access to tumors, such as metastatic pancreatic cancer, using RenovoRx's proprietary TAMP therapy platform. This collaboration potentially expands the market for the TAMP platform beyond locally advanced to metastatic pancreatic cancer.
- Appointed Margaret A. Tempero, M.D., Director, UCSF Pancreas Center and Leader of the UCSF Pancreas Cancer Program, to the Company's Scientific Advisory Board (SAB).
- Appointed Robert J. Spiegel, MD to the Company's Board of Directors. Dr. Spiegel is former Chief Medical Officer of Schering-Plough ($41B merger with Merck MSD). His experience includes involvement involved in more than 30 successful New Drug Application (NDA) approvals by the FDA and the development and launch of multiple products with annual sales exceeding $1B.
- Appointed Leesa Gentry as Senior Vice President of Clinical Operations *to lead RenovoRx's expansive clinical programs*. Ms. Gentry is *an industry expert in clinical trials management with prior senior leadership experience at Evotec, PPD, Quintiles and Otsuka America Pharmaceutical.*
- Closed a registered direct offering and a concurrent private placement for aggregate gross proceeds of $5 million.

Second Quarter 2023 Financial Results:

- **Cash Position:** Cash and cash equivalents as of June 30, 2023, were $6.0 million.
- **R&D Expenses:** Research and development expenses were $1.9 million for the quarter ended June 30, 2023, compared to $1.4 million for the quarter ended June 30, 2022. The increase was primarily due to our ongoing Phase III clinical trial costs and an increase in employee and related benefits costs. This increase was partially offset by a decrease in costs associated with a secondary manufacturer.
- **G&A Expenses:** General and administrative expenses were $1.4 million for the second quarter ended June 30, 2023, compared to $1.2 million for the quarter ended June 30, 2022. This increase was primarily due to higher employee and related benefits costs due to an increased in headcount. This increase was partially offset by a decrease in professional and consulting fees compared to the same period last year.
- **Net Loss:** Net loss was $2.3 million for the quarter ended June 30, 2023, compared to net loss of $2.6 million for the quarter ended June 30, 2022.
- **Shares Outstanding:** Shares of common stock outstanding, as of June 30, 2023, were 10,693,080.

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 the IND 21 CFR 312 pathway. RenovoGem is currently in a Phase III clinical trial (TIGeR-PaC) for the treatment of locally advanced pancreatic cancer, where it observed a 6-month median Overall Survival benefit, 8-month progression-free survival (PFS) and 65% reduction in adverse events at its interim analysis. 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; 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)

	June 30, 2023	December 31, 2022
Cash, cash equivalents and marketable securities	$ 5,954	$ 6,440
Total assets	**$ 6,314**	**$ 7,265**
Current liabilities	$ 1,699	$ 1,102
Common warrant liability	3,427	-
Total liabilities	$ 5,126	$ 1,102
Total stockholders’ equity	$ 1,188	$ 6,163
Total liabilities and stockholders’ equity	**$ 6,314**	**$ 7,265**

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Operating expenses:				
Research and development	$ 1,925	$ 1,390	$ 3,263	$ 2,679
General and administrative	1,450	1,224	3,373	2,940
Total operating expenses	3,375	2,614	6,636	5,619
Loss from operations	(3,375)	(2,614)	(6,636)	(5,619)
Other income/(expenses), net:				
Interest and dividend income	50	20	54	21
Other income, net	-	-	-	1
Change in fair value of common warrant liability	1,573	-	1,573	-
Transaction costs allocated to common warrant liability	(575)	-	(575)	-
Total other income/(expenses), net	1,048	20	1,052	22
Net loss	(2,327)	(2,594)	(5,584)	(5,597)
Other comprehensive loss:				
Unrealized loss on marketable securities	-	(4)	-	(4)
Comprehensive loss	$ (2,327)	$ (2,598)	$ (5,584)	$ (5,601)
Net loss per share, basic and diluted	$ (0.22)	$ (0.29)	$ (0.57)	$ (0.62)
Weighted-average shares of common stock outstanding, basic and diluted	10,655,155	9,057,185	9,881,371	9,024,973

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