

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

FORM 10-Q

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 2024

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

COMMISSION FILE NUMBER: 001-40738

RENOVORX, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

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

27-1448452
(I.R.S. Employer
Identification No.)

94022
(Zip Code)

(650) 284-4433

(Registrant's telephone number, including area code)

N/A

(Former name, former address and former fiscal year, if changed since last report)

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, par value \$0.0001 per share	RNXT	The Nasdaq Capital Market

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer
Non-accelerated filer

Accelerated filer
Smaller reporting company
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.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

As of November 7, 2024, the registrant had 24,001,339 shares of common stock, \$0.0001 par value per share, outstanding.

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Cautionary Note Regarding Forward-Looking Statements

This Quarterly Report on Form 10-Q, or Form 10-Q (this “Report”), particularly in the sections captioned “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the “Securities Act”), and Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), that are based on our management’s beliefs and assumptions and on information currently available to our management. Forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified. All statements other than present and historical facts and conditions contained in this Report, including statements regarding our future results of operations and financial position, business strategy, plans and our objectives for future operations, are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as “anticipate,” “believe,” “can,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “might,” “objective,” “ongoing,” “plan,” “potential,” “predict,” “project,” “should,” “will,” or “would,” or the negative of these terms or other comparable terminology. Actual events or results may differ from those expressed in these forward-looking statements, and these differences may be material and adverse. Forward-looking statements include, but are not limited to, statements about:

- the sufficiency of our existing cash, cash equivalents, and investments to fund our future operating expenses and capital expenditure requirements and our ability to operate as a going concern;
 - our estimates regarding expenses, future revenue, anticipated capital requirements to fund our future operating expenses, and our need for additional financing;
 - our financial performance;
 - our anticipated use of our existing cash, cash equivalents, and investments;
 - the ability of our clinical trials to demonstrate safety and efficacy of our product candidates and other positive results;
 - the progress and focus of our current and future clinical trials and the timing of reporting of data from those trials;
 - our continued reliance on third parties to conduct clinical trials of our product candidates and for the manufacture of our product candidates;
 - the beneficial characteristics, safety, efficacy, and therapeutic effects of our product candidates;
 - our ability to advance product candidates into and successfully complete clinical trials;
 - our ability to further develop and expand our therapy platform, both to use different chemotherapeutic agents, to include new indications, or to market and sell our FDA-cleared catheter drug-delivery device, RenovoCath[®], on a standalone basis;
 - enrollment timing and projections for our clinical trials and our expectations relating to the timing of the provision of updates on, data readouts for, and completion of our clinical trials;
 - our ability to obtain and maintain regulatory approval of our product candidates and the timing or likelihood of regulatory filings and approvals, including our expectation to seek special designations, such as orphan drug designation, for our product candidates for various diseases;
 - existing regulations and regulatory developments in the United States and other jurisdictions;
 - our plans relating to commercializing our product candidates, if approved, including the geographic areas of focus and our potential and ability to successfully commercialize our product candidates and generate revenue;
 - the implementation of our strategic plans for our business and product candidates;
 - the expected potential benefits of strategic collaborations with third parties and our ability to attract collaborators with relevant and complementary expertise;
 - our estimates of the number of patients in the United States who suffer from the diseases we target;
 - our estimates of potential market opportunities and our ability to successfully realize these opportunities;
 - the success of competing therapies that are or may become available;
 - developments relating to our competitors and our industry, including competing product candidates and therapies;
 - our plans relating to the further development and manufacturing of our product candidates, including for additional indications which we may pursue;
 - our plans and ability to obtain or protect intellectual property rights, including extensions of existing patent terms where available;
 - the scope of protection we are able to establish and maintain for intellectual property rights, including our therapy platform and product candidates;
 - our ability to successfully negotiate and enter into agreements with distribution, strategic and corporate partners;
 - our potential and ability to successfully manufacture and supply our product candidates for clinical trials and for commercial use, if approved;
 - our ability to retain the continued service of our key personnel and to identify, hire, and then retain additional qualified personnel;
-

- our ability to maintain compliance with the continuing listing requirements of The Nasdaq Stock Market LLC (“Nasdaq”); and
- our expectations regarding the impact of major domestic and geopolitical events on our business.

We have based the forward-looking statements contained in this Report primarily on our current expectations and projections about future events and trends that we believe may affect our business, financial condition, results of operations, prospects, business strategy and financial needs. The outcome of the events described in these forward-looking statements is subject to risks, uncertainties, assumptions and other factors described in the section titled “Risk Factors” and elsewhere in this Report. These risks are not exhaustive. Other sections of this Report include additional factors that could adversely affect our business and financial performance. Moreover, we operate in a very competitive and rapidly changing environment. New risks and uncertainties emerge from time to time and it is not possible for us to predict all risks and uncertainties that could have an impact on the forward-looking statements contained in this Report. We cannot assure you that the results, events and circumstances reflected in the forward-looking statements will be achieved or occur, and actual results, events or circumstances could differ materially from those described in the forward-looking statements. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame or at all.

In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Report, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements.

The forward-looking statements made in this Report relate only to events as of the date on which such statements are made. We undertake no obligation to update any forward-looking statements after the date of this Report or to conform such statements to actual results or revised expectations, except as required by law.

Unless the context otherwise indicates, “RenovoRx,” the “Company,” “we,” “our,” and “us” refer to RenovoRx, Inc., a Delaware corporation. All information presented herein is based on our fiscal calendar. Unless otherwise stated, references to particular years, quarters, months or periods refer to the Company’s fiscal years ended in December and the associated quarters, months and periods of those fiscal years.

PART I – FINANCIAL INFORMATION

Item 1. Financial Statements

RenovoRx, Inc.
Condensed Balance Sheets
(Unaudited)
(in thousands, except share and per share amounts)

	September 30, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	\$ 9,563	\$ 1,173
Prepaid expenses and other current assets	468	192
Deferred offering costs	-	101
Total assets	\$ 10,031	\$ 1,466
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	\$ 686	\$ 561
Accrued expenses	1,086	614
Total current liabilities	1,772	1,175
Common stock warrant liability	1,188	3,291
Total liabilities	2,960	4,466
Commitments and contingencies (Note 5)		
Stockholders' equity (deficit):		
Convertible preferred stock, \$0.0001 par value; 15,000,000 shares authorized as of September 30, 2024, and December 31, 2023, respectively; no shares issued and outstanding at September 30, 2024, and December 31, 2023	-	-
Common stock, \$0.0001 par value, 250,000,000 shares authorized at September 30, 2024, and December 31, 2023; 24,001,339 and 10,693,580 shares issued and outstanding as of September 30, 2024, and December 31, 2023, respectively	2	1
Additional paid-in capital	54,410	38,404
Accumulated deficit	(47,341)	(41,405)
Total stockholders' equity (deficit)	7,071	(3,000)
Total liabilities and stockholders' equity (deficit)	\$ 10,031	\$ 1,466

The accompanying notes are an integral part of these condensed interim financial statements.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Operating expenses:				
Research and development	\$ 1,650	\$ 1,629	\$ 4,449	\$ 4,892
General and administrative	1,178	1,354	3,889	4,727
Total operating expenses	<u>2,828</u>	<u>2,983</u>	<u>8,338</u>	<u>9,619</u>
Loss from operations	(2,828)	(2,983)	(8,338)	(9,619)
Other income/(expenses), net:				
Interest and dividend income	124	43	299	97
Change in fair value of common warrant liability	233	1,519	2,103	3,092
Transaction costs allocated to common warrant liability	-	-	-	(575)
Total other income/(expenses), net	<u>357</u>	<u>1,562</u>	<u>2,402</u>	<u>2,614</u>
Net loss	\$ (2,471)	\$ (1,421)	\$ (5,936)	\$ (7,005)
Net loss per share, basic and diluted	<u>\$ (0.10)</u>	<u>\$ (0.13)</u>	<u>\$ (0.28)</u>	<u>\$ (0.69)</u>
Weighted-average shares of common stock outstanding, basic and diluted	<u>24,940,746</u>	<u>10,693,080</u>	<u>21,325,695</u>	<u>10,154,914</u>

The accompanying notes are an integral part of these condensed interim financial statements.

RenovoRx, Inc.
Condensed Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)
(Unaudited)
(in thousands, except share amounts)

	Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount				
Balance — December 31, 2023	-	\$ -	10,693,580	\$ 1	\$ 38,404	\$ -	\$ (41,405)	\$ (3,000)
Issuance of common stock upon exercise of stock options	-	-	38,981	-	42	-	-	42
Proceeds from private placement offering, net of offering costs	-	-	6,133,414	1	5,377	-	-	5,378
Stock-based compensation expense	-	-	-	-	423	-	-	423
Net loss	-	-	-	-	-	-	(1,076)	(1,076)
Balance — March 31, 2024	-	\$ -	16,865,975	\$ 2	\$ 44,246	\$ -	\$ (42,481)	\$ 1,767
Issuance of common stock upon exercise of stock options	-	-	23,228	-	12	-	-	12
Issuance of restricted stock awards	-	-	120,000	-	-	-	-	-
Issuance of common stock upon the private placement offering	-	-	6,960,864	-	9,638	-	-	9,638
Stock-based compensation expense	-	-	-	-	244	-	-	244
Net loss	-	-	-	-	-	-	(2,389)	(2,389)
Balance — June 30, 2024	-	\$ -	23,970,067	\$ 2	\$ 54,140	\$ -	\$ (44,870)	\$ 9,272
Issuance of common stock upon exercise of stock options	-	-	31,272	-	15	-	-	15
Stock-based compensation expense	-	-	-	-	255	-	-	255
Net loss	-	-	-	-	-	-	(2,471)	(2,471)
Balance — September 30, 2024	-	\$ -	24,001,339	\$ 2	\$ 54,410	\$ -	\$ (47,341)	\$ 7,071

The accompanying notes are an integral part of these condensed interim financial statements.

RenovoRx, Inc.
Condensed Statements of Convertible Preferred Stock and Stockholders' Equity
(Unaudited)
(in thousands, except share amounts)

	Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
Balance — December 31, 2022	-	\$ -	9,097,701	\$ 1	\$ 37,318	\$ 17	\$ (31,173)	\$ 6,163
Issuance of common stock upon exercise of stock options	-	-	3,547	-	6	-	-	6
Issuance of restricted stock awards	-	-	30,000	-	117	-	-	117
Stock-based compensation expense	-	-	-	-	244	-	-	244
Other comprehensive loss	-	-	-	-	-	(17)	-	(17)
Net loss	-	-	-	-	-	-	(3,257)	(3,257)
Balance — March 31, 2023	-	\$ -	9,131,248	\$ 1	\$ 37,685	\$ -	\$ (34,430)	\$ 3,256
Issuance of common stock upon the registered direct offering	-	-	1,000,000	-	-	-	-	-
Issuance and exercise of pre-funded common warrants upon the registered direct offering	-	-	557,632	-	-	-	-	-
Issuance of common stock upon exercise of stock options	-	-	4,200	-	2	-	-	2
Stock-based compensation expense	-	-	-	-	257	-	-	257
Net loss	-	-	-	-	-	-	(2,327)	(2,327)
Balance — June 30, 2023	-	\$ -	10,693,080	\$ 1	\$ 37,944	\$ -	\$ (36,757)	\$ 1,188
Stock-based compensation expense	-	-	-	-	239	-	-	239
Net loss	-	-	-	-	-	-	(1,421)	(1,421)
Balance — September 30, 2023	-	\$ -	10,693,080	\$ 1	\$ 38,183	\$ -	\$ (38,178)	\$ 6

The accompanying notes are an integral part of these condensed interim financial statements.

RenovoRx, Inc.
Condensed Statements of Cash Flows
(Unaudited)
(in thousands)

	Nine Months Ended September 30,	
	2024	2023
Cash flows from operating activities:		
Net loss	\$ (5,936)	\$ (7,005)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	922	857
Change in fair value of common warrants classified as a liability	(2,103)	(3,092)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(276)	573
Deferred offering costs	101	(41)
Accounts payable	125	(184)
Accrued expenses	472	687
Net cash used in operating activities	(6,695)	(8,205)
Cash flows from investing activities:		
Proceeds from sale of investments	-	2,032
Net cash provided by investing activities	-	2,032
Cash flows from financing activities:		
Proceeds from private placement offering, net of offering costs	15,016	5,000
Proceeds from exercise of stock options	69	8
Net cash provided by financing activities	15,085	5,008
Net increase/(decrease) in cash and cash equivalents	8,390	(1,165)
Cash and cash equivalents:		
Beginning of period	1,173	4,391
End of period	\$ 9,563	\$ 3,226
Supplemental disclosure of non-cash financing activities:		
Fair value of common warrant classified as a liability	\$ 1,188	\$ 1,908

The accompanying notes are an integral part of these condensed interim financial statements.

RenovoRx, Inc.
Notes to the Unaudited Condensed Interim Financial Statements

1. Business and Principal Activities

Description of Business

RenovoRx, Inc. (the “Company,” “we,” “us,” “our” and similar terminology) was incorporated in the state of Delaware in December 2012 and operates from its headquarters in Los Altos, California. The Company is a life sciences company developing novel targeted oncology therapies and offering **RenovoCath®**, a novel U.S. Food and Drug Administration (“FDA”) cleared local drug delivery platform targeting high unmet medical needs.

The Company’s patented **Trans-Arterial Micro-Perfusion (“TAMP™”)** therapy platform is designed to ensure precise therapeutic delivery across the arterial wall near the tumor site to bathe the target tumor, while potentially minimizing a therapy’s toxicities versus systemic intravenous therapy. The Company’s novel approach to targeted treatment offers the potential for increased safety, tolerance, and improved efficacy, and its mission is to transform the lives of cancer patients by providing innovative solutions to enable targeted delivery of diagnostic and therapeutic agents.

The Company’s lead product candidate is a novel oncology drug-device combination product being investigated under a U.S. Investigational New Drug (“IND”) application that is regulated by the FDA’s 21 CFR 312 pathway. The investigational drug-device combination candidate utilizes **RenovoCath**, its FDA-cleared device, indicated for temporary vessel occlusion in applications including arteriography, preoperative occlusion, and chemotherapeutic drug infusion.

The intra-arterial infusion of the chemotherapy gemcitabine utilizing RenovoCath 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) in our ongoing Phase III TIGeR-PaC randomized multi-center clinical trial.

Liquidity and Capital Resources

From the Company’s inception through September 30, 2024, it has raised an aggregate of \$59.2 million, primarily from private placements of convertible preferred stock, convertible debt securities, the issuance of securities in the Company’s August 2021 initial public offering (the “IPO”), the sale of common stock and common stock warrants and the exercise of common stock warrants and common stock options. After deducting underwriting discounts and commissions, placement agent fees and other offering expenses, the Company’s net offerings were \$53.8 million. As of September 30, 2024, the Company had cash and cash equivalents of \$9.6 million. As used herein, the term “common stock” refers to the Company’s common stock, par value \$0.0001 per share.

The Company is in the pre-commercial stage and therefore has incurred significant losses and negative cash flows from operations since its inception. For the nine months ended September 30, 2024, the Company reported a net loss of \$5.9 million and an accumulated deficit of \$47.3 million and does not expect to generate positive cash flows from operations in the foreseeable future. The Company expects to incur significant and increasing losses until regulatory approval is granted for its first product candidate, RenovoGem™. Regulatory approval is not guaranteed and may never be obtained. The Company may also pursue other revenue-generating strategies such as licensing or collaboration agreements or marketing its proprietary catheter device on a standalone basis. No assurances can be made that the Company will pursue these strategies, and even if it does, there is a risk that the Company will be unable to generate revenue from such activities.

The Company believes it will be able to raise additional required capital through debt financings, private or public equity financings, license agreements, collaborative agreements or other arrangements with other companies, or other sources of financing. There can be no assurance that such financing will be available or will be at terms acceptable to the Company. The inability to raise capital as and when needed would have a negative impact on the Company’s liquidity, financial condition and its ability to pursue its business strategy. The Company will need to generate significant revenue to achieve profitability, and it may never do so.

On November 10, 2022, the Company filed an omnibus shelf registration statement on Form S-3 that provides for the aggregate offerings of up to \$50.0 million of the Company’s securities subject to various limitations, including limited sales in any twelve-month period while the Company is subject to the “baby-shelf” rules. As of September 30, 2024, and subject to the baby-shelf limitations rules, the aggregate offerings would be up to \$9.7 million. The Company has also filed a registration statement on Form S-1 to register the cash exercise of the Company’s outstanding IPO, underwriter and private warrants. Cash exercise of these outstanding warrants is only expected to occur (if at all) when the trading price of the common stock is in excess of the \$10.80 per share exercise price of such outstanding warrants.

On April 3, 2023, the Company completed a registered direct offering (“RDO”) utilizing its shelf registration statement for the purchase and sale of 1,557,632 shares of common stock (or pre-funded common stock warrants) to a certain institutional investor. In a concurrent private placement, the Company issued to the investor unregistered common warrants to purchase up to 1,947,040 shares of common stock (the “April 2023 Warrant”). The aggregate gross proceeds from this offer were \$5.0 million, and the net offering proceeds were \$4.3 million after deducting placement agent fees and placement agent’s expenses of \$0.4 million and other professional expenses of \$0.3 million.

On January 26, 2024, the Company completed a private placement to 92 accredited investors with gross proceeds of \$6.1 million before deducting placement agent fees and other offering expenses of approximately \$0.7 million. In this private placement, the Company issued 6,133,414 shares of its common stock and common warrants to purchase up to an aggregate of 6,133,414 shares of common stock, which expire five years from the issuance date, January 26, 2024. In connection with such private placement, the Company entered into a placement agent agreement as additional compensation to the placement agent, and issued common warrants to purchase up to an aggregate of 511,940 shares of common stock (the “January 2024 PA Warrants”), which warrants expire five years from the issuance date. The significant majority of the warrants issued in this private placement have an exercise price of \$0.99 per share. The warrants purchased by directors, officers, employees and consultants of the Company in this private placement have an exercise price of \$1.22 per share.

On April 11, 2024, the Company completed another private placement offering to 172 accredited investors, issuing common stock, pre-funded warrants, Series A warrants, and Series B warrants. The aggregate gross proceeds from this offer were \$11.1 million, and the net offering proceeds were \$9.6 million after deducting placement agent fees of \$1.3 million and other professional expenses of \$0.2 million. In conjunction with the issuance of 6,960,864 shares of common stock, the Company bundled the offering with: (i) a pre-funded warrant exercisable for 951,500 shares of common stock at an exercise price of \$0.0001 per share, with an unlimited term and immediate exercisability upon issuance, subject to specific beneficial ownership limitations; (ii) Series A warrants exercisable for 7,912,364 shares of common stock at \$1.22 per share, valid for 5 years and immediately exercisable subject to customary adjustments and beneficial ownership limitations; (iii) Series B warrants exercisable for 3,956,182 shares of common stock at \$1.22 per share, valid for 2 years and immediately exercisable subject to customary adjustments and beneficial ownership limitations, with the Company retaining the right to call these warrants under certain conditions. Additionally, as compensation to the placement agent, the Company issued warrants on the same date, to purchase up to an aggregate of 701,243 shares of common stock (the “April 2024 PA Warrants”) at \$1.69 per share over a 5-year term, with provisions for cashless exercise if the shares are unregistered or no current prospectus is available for resale. The April 2024 PA Warrants become exercisable on October 11, 2024, subject to specific beneficial ownership limitations and customary adjustments.

The accompanying condensed interim financial statements have been prepared assuming that the Company will continue as a going concern and has reviewed the relevant conditions and events surrounding its ability to continue as a going concern including among others: historical losses, projected future results, negative cash flows from operations, including cash requirements for the upcoming year, funding capacity, net working capital, total stockholders’ equity and future access to capital. Based upon this review and the Company’s current financial condition and operating plans, the Company has concluded that these conditions raise substantial doubt regarding its ability to continue as a going concern for a period of at least one year from the date of issuance of these condensed interim financial statements.

As a result, the Company will require additional funding to support its continuing operations. Until such time, if ever, as the Company can generate product revenue through its commercialization strategy, the Company expects to finance its cash needs through private or public equity financings, debt financings and collaborations, licenses or other similar arrangements. The Company continues to attract potential investors on the novel approach of its TAMP therapy platform.

2. Summary of Significant Accounting Policies

Basis of Presentation and Unaudited Condensed Interim Financial Information

The accompanying unaudited condensed interim financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (“GAAP”) and applicable rules and regulations of the Securities and Exchange Commission (“SEC”) for interim reporting. As permitted under those rules and regulations, certain footnotes or other financial information normally included in unaudited condensed interim financial statements prepared in accordance with GAAP have been condensed or omitted. The unaudited condensed interim financial statements have been prepared on the same basis as the annual financial statements and, in the opinion of management, reflect all adjustments, which include only normal, recurring adjustments that are necessary to present fairly the Company’s results for the interim periods presented. The condensed balance sheet as of December 31, 2023, is derived from the Company’s audited financial statements. The results of operations for the three and nine months ended September 30, 2024, are not necessarily indicative of the results to be expected for the year ending December 31, 2024, or for any other future annual or interim period. Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as found in the Accounting Standards Codification (“ASC”) and as amended by Accounting Standards Update (“ASU”) of the Financial Accounting Standards Board (“FASB”).

There have been no material changes to the significant accounting policies during the nine months ended September 30, 2024 from those previously disclosed in the Company’s Annual Report on Form 10-K for the year ended December 31, 2023 filed with the SEC on April 1, 2024 (the “2023 Annual Report”) other than the accounting policies adopted in connection with the Company’s private placement offerings and the September Common Warrants as follows.

In January and April of this year, the Company completed two private placement offerings issuing Common Stock, Pre-funded Common Warrants, Common Warrants and Placement Agent Warrants or (“PA Warrants”). The Company has applied the following accounting policies as it relates to each offering.

January 2024 Private Placement

The Company evaluated the Common Warrants and the PA Warrants issued in connection with the January offering in accordance with ASC 480, *Distinguishing Liabilities from Equity* and ASC 815-40, *Derivatives and Hedging – Contracts in Entity’s Own Entity* and concluded that the Common Warrants and the PA Warrants are freestanding financial instruments, meeting ASC 480’s criteria for legal detachment and separate exercisability from the Common Stock. The Common Warrants and PA Warrants are classified as equity, not liabilities, as they do not embody obligations for cash settlement or issuance of variable shares. The initial recognition involves recording proceeds in Additional Paid-In Capital (“APIC”) with issuance costs as contra-equity. For diluted Earnings Per Share (“EPS”), the treasury stock method applies, as the Warrants are dilutive but not participating securities before exercise, ensuring no impact on basic EPS until shares are issued.

April 2024 Private Placement

The Company evaluated the Pre-funded Common Warrants, Common Warrants, (Series A and Series B), and the PA Warrants issued in connection with the April offering in accordance with ASC 480, *Distinguishing Liabilities from Equity* and ASC 815-40, *Derivatives and Hedging – Contracts in Entity’s Own Entity* to determine whether the Common Warrants and PA Warrants qualify as freestanding financial instruments under ASC 480. The Company concluded that the Common Warrants and the PA Warrants both meet the criteria due to their legal detachment and separate exercisability from the issued Common Stock. The Common Warrants, while sold as a bundled Unit, are legally detachable and separately exercisable, allowing them to qualify as freestanding. The PA Warrants, issued independently as compensation, are also freestanding. Neither the Common Warrants or the PA Warrants are classified as liabilities under ASC 480, as they do not embody obligations for cash settlement or variable shares linked to external indexes or fixed monetary amounts. Under ASC 815-40, both Series A and B Warrants meet the criteria for equity classification, being indexed solely to the Company’s stock and possessing fixed-for-fixed settlement terms. The Company will record these warrants as APIC based on relative fair value and allocate issuance costs as contra-equity. The PA Warrants’ issuance cost will be treated similarly to a deemed distribution, with fair value calculated through the Black-Scholes model. For EPS, under ASC 260-10, *Earnings Per Share*, the Company will treat Pre-funded Warrants as equivalent to outstanding shares in basic EPS since they are exercisable for minimal consideration. Series A, Series B, and PA Warrants will be considered in diluted EPS under the treasury stock method if dilutive, as they are non-participating securities and do not impact basic EPS until exercised.

September 2024 Contract Manufacturing Organization Warrants

In September 2024, the Company has issued a warrant to purchase up to 709,500 shares of the Company’s common stock (the “CMO Warrant”) as a performance incentive for the Company’s RenovoCath contract manufacturing organization, (“CMO”). The CMO Warrant vests and only becomes exercisable over time in tranches, and only if the CMO achieves certain manufacturing milestones. The Company evaluated the CMO Warrant in accordance with ASC 718, *Compensation – Stock Compensation*, and concluded the CMO Warrant constitutes share-based payments for goods used in the Company’s operations and the CMO Warrant is equity-classified, as it lacks characteristics that would require liability treatment, such as cash settlement provisions or obligations to repurchase shares. The fair value of the CMO Warrant will be measured using the Black-Scholes model, with grant date fair value determined by the award terms. As the CMO Warrant is an incentive under the Company’s commercial strategy for its RenovoCath device, the fair value of the CMO Warrant will be considered as part of the costs to produce the device as inventory and subsequently recognized as cost of sales upon the sale of associated goods. For the EPS treatment, management concluded that the CMO Warrant constitutes contingently issuable potential common shares. When shares are issued upon exercise

of the CMO Warrant, the Company will assess dilutive effects per ASC 260, Earnings Per Share. Following ASC 260-10-45-22, the treasury stock method will apply, assuming warrant exercise at the start of each period (or issuance if later), and calculating incremental shares based on proceeds hypothetically used to repurchase shares at the average market price. Since the holder of the CMO Warrant does not participate in dividends with common stock pre-exercise, the shares of common stock underlying the CMO Warrant does not affect basic EPS until exercised.

Risks and Uncertainties

The Company is subject to a number of risks associated with companies at a similar stage, including the risks associated with the development of products that must receive regulatory approval before market launch, dependence on key individuals, competition from larger and more established companies, volatility of the industry, ability to obtain adequate financing to support the Company's business plan, the ability to attract and retain additional qualified personnel to manage the anticipated growth of the Company and general economic conditions. The Company is subject to a number of risks similar to other clinical-stage biopharmaceutical companies, including, but not limited to, the need to obtain adequate additional funding, possible failure of current or future preclinical studies or clinical trials, its reliance on third parties to conduct its clinical trials, the need to obtain regulatory and marketing approvals and insurance coding for its product candidates, competitors developing new technological innovations, the need to successfully commercialize and gain market acceptance of the Company's product candidates, protection of its proprietary technology, and the need to secure and maintain adequate manufacturing arrangements with third parties.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, income and expenses as well as the disclosure of contingent assets and liabilities, at the date of the financial statements during the reporting periods. In preparing these financial statements, management has made its best estimates and judgments of certain amounts included in the financial statements. Significant estimates and assumptions made in the accompanying financial statements include, but are not limited to, accruals of certain liabilities, including clinical trial accruals and other contingencies, the valuation of financial instruments, the fair value of the Company's common stock and the fair value of options granted under the Company's equity incentive plan. On an ongoing basis, the Company evaluates its estimates, including those related to the fair values of assets, stock-based compensation, clinical trial accruals and other contingencies. Management bases its estimates on historical experience or on various other assumptions that it believes to be reasonable under the circumstances. Actual results could differ materially from these estimates.

Emerging Growth Company and Smaller Reporting Company Status

The Company is an emerging growth company as defined in the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act") and may take advantage of reduced reporting requirements that are otherwise applicable to public companies. Section 107 of the JOBS Act exempts emerging growth companies from complying with new or revised financial accounting standards until private companies are required to comply with those standards. The Company has elected to use the extended transition period for complying with new or revised accounting standards.

The Company is also a "smaller reporting company," as defined in Rule 12b-2 of the Exchange Act. If the Company is a smaller reporting company at the time the Company ceases to be an emerging growth company, the Company may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company, the Company may choose to present only the two most recent fiscal years of audited financial statements in its Annual Report on Form 10-K and, like emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

From time to time, new accounting pronouncements are issued by the FASB or other standard-setting bodies and adopted by the Company as of the specified effective date. Unless otherwise discussed, the impact of recently issued standards that are not yet effective will not have a material impact on the Company's financial position or results of operations upon adoption.

Recent Accounting Pronouncements

In November 2024, the FASB issued ASU 2024-03, Disaggregation of Income Statement Expenses. ASU 2024-03 requires additional disclosures and disaggregation of certain costs and expenses on an interim and annual basis in the notes to the financial statements. ASU 2024-03 is effective for the Company for fiscal years beginning after December 15, 2026, and interim periods within fiscal years beginning after December 15, 2027. Early adoption is permitted. The Company is currently evaluating the potential impact of adopting this new guidance on its financial statements and disclosures.

In December 2023, the FASB issued ASU 2023-09, "Improvement to income tax disclosures (Topic 740)". ASU 2023-09 requires consistent categories and greater disaggregation of information in the income tax rate reconciliation as well as a disaggregation of taxes paid by jurisdiction for the income taxes paid. ASU 2023-09 is required to be adopted by the Company for annual periods beginning after December 15, 2024. Early adoption is permitted for annual consolidated financial statements that have not yet been issued or made available for issuance. The Company is currently evaluating the impact of the ASU, but does not expect any material impact upon adoption.

In November 2023, the FASB issued ASU 2023-07, "Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures," ASU 2023-07 is intended to improve reportable segment disclosures, primarily through enhanced disclosures about significant segment expenses, as well as how the chief operating decision maker uses the reported measure(s) of segment profit or loss in assessing performance. The guidance is effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024. Early adoption is permitted. The guidance is to be applied retrospectively to all periods presented in the financial statements. The Company is currently evaluating the potential impact of adopting this new guidance on its financial statements and disclosures.

Recently Adopted Accounting Pronouncements

In June 2016, the FASB issued ASU 2016-13, "Financial Instruments—Credit Losses (Topic 326)" "ASU 2016-13"). The guidance represents a significant change in the accounting for credit losses model by requiring immediate recognition of management's estimates of current expected credit losses. Under the prior model, losses were recognized only as they were incurred. The Company has determined that it has met the criteria of a smaller reporting company as of November 15, 2019. As such, ASU 2019-10, "Financial Instruments—Credit Losses (Topic 326)", "Derivatives and Hedging (Topic 815)", and "Leases (Topic 842)—Effective Dates" amended the effective date for the Company to be for reporting periods beginning after December 15, 2022. The Company adopted ASU 2016-13 on January 1, 2023 and the adoption had no significant impact to the Company's condensed interim financial statements.

In August 2020, the FASB issued ASU 2020-06, "Debt – Debt with Conversion and Other Options (Subtopic 470-20)" and "Derivatives and Hedging – Contracts in Entity's Own Equity (Subtopic 815-40) (ASU 2020-06): Accounting for Convertible Instruments and Contracts in an Entity," which simplifies the accounting for certain financial instruments with characteristics of liabilities and equity, including convertible instruments and contracts on an entity's own equity. The updated guidance is effective on a prospective basis for annual reporting periods beginning after December 15, 2023 and for interim periods within those periods. The Company early adopted this guidance as of January 1, 2022 and the pronouncement did not have any material impact on the Company's financial position or results of operations.

3. Fair Value Measurements

As of September 30, 2024, and December 31, 2023, the Company held \$9.1 million and \$0.9 million, respectively, in a money market account.

The following tables summarize the Company's financial assets and liabilities, measured at fair value on a recurring basis by level within the fair value hierarchy, as of September 30, 2024, and December 31, 2023 (in thousands):

September 30, 2024				
Assets	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	\$ 9,099	\$ -	\$ -	\$ 9,099
	<u>\$ 9,099</u>	<u>\$ -</u>	<u>\$ -</u>	<u>\$ 9,099</u>
Liabilities				
Common stock warrant liability	\$ -	\$ -	\$ 1,188	\$ 1,188
	<u>\$ -</u>	<u>\$ -</u>	<u>\$ 1,188</u>	<u>\$ 1,188</u>
December 31, 2023				
Assets	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	\$ 905	\$ -	\$ -	\$ 905
	<u>\$ 905</u>	<u>\$ -</u>	<u>\$ -</u>	<u>\$ 905</u>
Liabilities				
Common stock warrant liability	\$ -	\$ -	\$ 3,291	\$ 3,291
	<u>\$ -</u>	<u>\$ -</u>	<u>\$ 3,291</u>	<u>\$ 3,291</u>

There were no transfers between Level 1, Level 2 or Level 3 during the periods presented. The Company had no other financial assets or liabilities that were required to be measured at fair value on a recurring basis.

Assumptions Used in Determining Fair Value of Warrant

The terms of the April 2023 Warrant provide that in the event of certain fundamental transactions involving the Company, the warrant holder may require the Company to make a payment based on a Black-Scholes valuation of the April 2023 Warrant, using specified inputs. Therefore, the April 2023 Warrants are accounted for as liabilities.

The Company recorded the fair value of the April 2023 Warrant using the Monte Carlo simulation model. It is also required to revalue the April 2023 Warrant at each reporting date, with any changes in fair value recorded on the Company's statement of operations. The valuation of the April 2023 Warrant is considered under Level 3 of the fair value hierarchy and influenced by the fair value of the underlying common stock.

The fair value of the warrants was measured using a combination of Black-Scholes option pricing and Monte Carlo Simulation models that take into consideration probability factors of the various outcomes related to the exercise terms of the warrants using the following inputs:

	September 30, 2024	December 31, 2023
Expected volatility	100% – 111%	116% – 177%
Expected term (years)	0 – 4.01	1.01 – 4.76
Risk-free interest rate	3.58% – 4.73%	3.86% – 4.78%
Dividend rate	–%	–%

Changes on Level 3 Liabilities Measured at Fair Value on a Recurring Basis

The following table reflects the change in the Company’s Level 3 liability associated with the April 2023 Warrant for the nine months ended September 30, 2024 (in thousands):

Fair value as of December 31, 2023	\$ 3,291
Change in fair value	(2,103)
Fair value as of September 30, 2024	<u>\$ 1,188</u>

4. Accrued Expenses

The components of accrued expenses as of September 30, 2024, and December 31, 2023 are as follows (in thousands):

	September 30, 2024	December 31, 2023
Clinical trial	\$ 495	\$ 470
Employee benefits	568	75
Other	23	69
Total accrued expenses	<u>\$ 1,086</u>	<u>\$ 614</u>

5. Commitments and Contingencies

Legal Proceedings

From time to time, the Company may become involved in legal proceedings arising in the ordinary course of business. The Company was not subject to any material legal proceedings during the nine months ended September 30, 2024, and no material legal proceedings are subsequently outstanding or pending.

Guarantees and Indemnification

In the ordinary course of business, the Company enters into agreements that may include indemnification provisions. As permitted under Delaware law and in accordance with its bylaws, the Company indemnifies its officers and directors for certain events or occurrences while the officer or director is or was serving in such capacity. The Company is also party to indemnification agreements with its officers and directors. In some cases, the indemnification will continue after the termination of the agreement. The maximum potential amount of future payments that the Company could be required to make under these provisions is not determinable. The Company has never incurred material costs to defend lawsuits or settle claims related to these indemnification provisions. The Company is not currently aware of any indemnification claims. Accordingly, the Company has not recorded any liabilities for these indemnification rights and agreements as of September 30, 2024.

Operating Leases

The Company leases its headquarters in Los Altos, California under a month-to-month operating lease agreement. Rent expenses were \$21,000 and \$18,000 for the three months ended September 30, 2024, and 2023, respectively. Rent expenses were \$62,000 and \$55,000 for the nine months ended September 30, 2024, and 2023, respectively.

6. Equity Incentive Plan – Stock-Based Compensation Expense and Warrants

2021 Omnibus Equity Incentive Plan

On July 19, 2021, the Company's Board of Directors adopted the RenovoRx, Inc. 2021 Omnibus Equity Incentive Plan (the "2021 Plan"). The 2021 Plan, which became effective immediately prior to the closing of the IPO, initially reserved 2,185,832 shares of common stock, which included 10,832 shares of common shares reserved but unissued under the Amended and Restated 2013 Equity Incentive Plan (the "2013 Plan"). The Company's 2013 Plan was terminated immediately prior to the closing of the IPO; however, shares subject to awards granted under the 2013 Plan will continue to be governed by the 2013 Plan. In accordance with the terms of the 2021 Plan, on January 1, 2024, the number of shares reserved and available for issuance increased by 320,807 shares.

A summary of the stock option activity for the nine months ended September 30, 2024 is as follows:

	Number of Stock Options	Weighted- Average Exercise Price	Weighted- Average Remaining Contractual Life	Aggregate Intrinsic Value
Outstanding as of December 31, 2023	1,860,125	\$ 2.47	7.24	\$ 984
Granted	1,393,634	\$ 1.18	-	\$ -
Exercised	(93,481)	\$ 0.74	-	\$ -
Forfeited	(334,371)	\$ 1.97	-	\$ -
Expired	(107,278)	\$ 2.50	-	\$ -
Outstanding as of September 30, 2024	2,718,629	\$ 1.93	7.76	\$ 195
Exercisable as of September 30, 2024	1,446,266	\$ 2.12	6.56	\$ 193
Vested and expected to vest as of September 30, 2024	2,718,629	\$ 1.93	7.76	\$ 195

As of September 30, 2024, there was \$1.8 million of unrecognized stock-based compensation expense related to options granted but not yet amortized, which will be recognized over a weighted-average period of approximately 2.90 years.

For the nine months ended September 30, 2024, and 2023, the Company utilized the Black-Scholes option-pricing model for estimating the fair value of the stock option granted. The Company estimated the fair value of each option grant on the grant date using the Black-Scholes option pricing model with the following weighted-average assumptions:

	Nine Months Ended September 30,	
	2024	2023
Expected volatility	123.76% – 143.10%	99.49% – 106.69%
Expected term (years)	6.02 – 10.00	6.02 – 10.00
Risk-free interest rate	3.63% – 4.30%	3.40% – 4.28%
Dividend rate	–%	–%

During the three months ended September 30, 2024, and 2023, the Company recognized \$255,000 and \$239,000, respectively, in stock-based compensation expense from stock option grants. During the nine months ended September 30, 2024, and 2023, the Company recognized \$922,000 and \$857,000, respectively, in stock-based compensation expense from stock option grants. The compensation expense is allocated on a departmental basis, based on the classification of the option holder. No income tax benefits have been recognized in the condensed statements of operations for stock-based compensation arrangements.

The following table summarizes the components of stock-based compensation expense recognized in the Company's Condensed Statements of Operations during the three and nine months ended September 30, 2024, and 2023 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Research and development	\$ 87	\$ 46	\$ 294	\$ 155
General and administrative	168	193	628	702
Total stock-based compensation expense	\$ 255	\$ 239	\$ 922	\$ 857

Restricted Stock Units and Restricted Stock Awards Issued for Services

Restricted stock units ("RSU") are valued based on the closing price of the Company's common stock on the date of the grant. The fair value of RSU is recognized and amortized on a straight-line basis over the requisite service period of the award.

The following table summarizes RSU activity during the nine months ended September 30, 2024:

	Shares	Weighted-Average Exercise Price
Outstanding as of December 31, 2023	-	\$ -
Granted	5,000	\$ 1.47
Vested	(5,000)	\$ 1.47
Forfeiture	-	\$ -
Outstanding as of September 30, 2024	-	\$ -

In March 2024, the Company issued 120,000 shares of restricted stock awards outside the 2021 Plan for business advisory and investor relations services and recognized \$27,000 of stock-based compensation expense.

2024 Common Warrants

In connection with the Company's January 2024 private placement offering, the Company issued warrants to purchase up to 6,133,414 shares of common stock and January 2024 PA Warrants to purchase up to 511,940 shares of common stock. All such warrants expire on January 26, 2029.

In connection with the Company's April 2024 private placement offering, the Company issued pre-funded warrants to purchase 951,500 shares of common stock, Series A warrants to purchase up to 7,912,364 shares of common stock, Series B warrants to purchase up to 3,956,182 shares of common stock and April 2024 PA Warrants to purchase up to 701,243 shares of common stock. Series B Warrants expire on April 11, 2026, and all other such warrants expire on April 10, 2029.

The following is a summary of the common stock warrant activity during the three months ended September 30, 2024.

	Shares Issuable Upon Exercise of Outstanding Warrants	Weighted- Average Exercise Price	Weighted- Average Remaining Contractual Life	Aggregate Intrinsic Value (In thousands)
Outstanding as of December 31, 2023	4,734,035	\$ 7.68	3.51	\$ 36,350
Issued in January 2024 to:				
Investors	5,961,286	\$ 0.99	4.32	\$ 5,901
Placement agency	511,940	\$ 0.99	N/A	\$ 507
Insiders	172,128	\$ 1.22	4.32	\$ 210
Issued in April 2024 to:				
Investors	11,868,546	\$ 1.22	3.53	\$ 14,480
Investors (Pre-funded)	951,500	\$ 0.0001	N/A	\$ -
Placement agency	701,243	\$ 1.69	4.53	\$ 1,185
Exercised	-	\$ -	-	\$ -
Expired	-	\$ -	-	\$ -
Outstanding as of September 30, 2024	24,900,678	\$ 2.35	3.61	\$ 58,633

7. Income Taxes

The Company had no income tax expense for the three and nine months ended September 30, 2024, and 2023. The Company's effective income tax rate was 0% for the three and nine months ended September 30, 2024. During the three months ended September 30, 2024, and 2023, the Company had a net operating loss ("NOL") for each period that generated deferred tax assets for NOL carryforwards. Deferred income tax assets and liabilities are recognized for temporary differences between the financial statements and income tax carrying values using tax rates in effect for the years such differences are expected to reverse. Due to uncertainties surrounding our ability to generate future taxable income and consequently realize such deferred income tax assets, the Company has determined that it is more likely than not that these deferred tax assets will not be realized. Accordingly, the Company has established a full valuation allowance against its deferred tax assets as of September 30, 2024.

The Company's policy is to recognize any interest and penalties related to unrecognized tax benefits as a component of income tax expense. For the three and nine months ended September 30, 2024, and 2023, the Company had no accrued interest or penalties related to uncertain tax positions.

8. Net Loss Per Share

Basic and diluted net loss per common share was calculated as follows (in thousands except per share amounts):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Numerator:				
Net loss	\$ (2,471)	\$ (1,421)	\$ (5,936)	\$ (7,005)
Denominator:				
Weighted average shares used in computing net loss per share – basic and diluted	24,940,746	10,693,080	21,325,695	10,154,914
Net loss per share – basic and diluted	\$ (0.10)	\$ (0.13)	\$ (0.28)	\$ (0.69)

For the three and nine months ended September 30, 2024, and 2023, the Company had a net loss and as such, all outstanding shares of potentially dilutive securities were excluded from the calculation of diluted net loss per share as the inclusion would be anti-dilutive.

Potentially dilutive securities not included in the computation of diluted net loss per share because to do so would be antidilutive are as follows (in common stock equivalent shares):

	As of September 30,	
	2024	2023
Options to purchase common stock	397,025	453,346
Common stock warrants	6,473,226	-
Total	6,870,251	453,346

9. Related Party Transactions

The Company has a consulting agreement with one of the Company's co-founders, Dr. Ramtin Agah, pursuant to which Dr. Agah provides consulting services as the Company's Chief Medical Officer by overseeing Company-sponsored clinical trials. For the three months ended September 30, 2024, and 2023, consulting fees paid to Dr. Agah were \$76,000, respectively. For the nine months ended September 30, 2024, and 2023, consulting fees paid to Dr. Agah were \$228,000, respectively. In addition, the Board approved a discretionary bonus of \$49,000 and \$91,000, paid in May 2024 and February 2023, respectively, to Dr. Agah in recognition of the Company's and individual performance.

10. Subsequent Events

On October 24, 2024, the Company entered into a lease agreement for new headquarters office space located in Mountain View, California, consisting of approximately 1,900 rentable square feet, with a monthly base rent of approximately \$10,000 per month. The term of the lease agreement is for 36 months, commencing on December 1, 2024 and ending on November 30, 2027. The new lease agreement will replace the Company's current month-to-month office space lease agreement in Los Altos, California, for which the Company pays approximately \$7,000 per month.

Item 2: Management’s Discussion and Analysis of Financial Condition and Results of Operations

Unless the context otherwise requires, all references in this section to the “Company,” “we,” “us,” or “our” refer to RenovoRx, Inc. You should read the following discussion and analysis of our financial condition and results of operations in conjunction with our unaudited interim condensed financial statements and related notes included elsewhere in this Report, our management’s discussion and analysis of financial condition and results of operations for the year ended December 31, 2023, which is included in our 2023 Annual Report.

This discussion contains forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act that reflect our plans, estimates, and beliefs that involve risks and uncertainties, including those described in the section of this Report titled “Cautionary Note Regarding Forward Looking Statements.” Our actual results and the timing of selected events could differ materially from those discussed below. Factors that could cause or contribute to such differences include, but are not limited to, those identified below and those set forth under the section titled “Risk Factors” included elsewhere in this Report and in the 2023 Annual Report.

Overview

We are a life sciences company developing novel targeted oncology therapies and offering **RenovoCath**, a novel, U.S. Food and Drug Administration (“FDA”)-cleared local drug-delivery platform, targeting high unmet medical needs. Our patented **TAMP** therapy platform is designed to ensure precise therapeutic delivery across the arterial wall near the tumor site to bathe the target tumor, while potentially minimizing a therapy’s toxicities versus systemic intravenous therapy. Our novel approach to targeted treatment offers the potential for increased safety, tolerance, and improved efficacy, and our mission is to transform the lives of cancer patients by providing innovative solutions to enable targeted delivery of diagnostic and therapeutic agents.

Our lead product candidate is a novel oncology drug-device combination product and is being investigated under a U.S. Investigational New Drug (“IND”) application that is regulated by the FDA’s 21 CFR 312 pathway. The investigational drug-device combination candidate utilizes RenovoCath[®], our FDA-cleared device, indicated for temporary vessel occlusion in applications including arteriography, preoperative occlusion, and chemotherapeutic drug infusion.

The intra-arterial infusion of the chemotherapy, gemcitabine, utilizing RenovoCath 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) in our ongoing Phase III TIGeR-PaC randomized multi-center clinical trial.

We may also evaluate RenovoCath with gemcitabine as a potential therapy in other indications. RenovoCath with gemcitabine received Orphan Drug Designation for pancreatic cancer and bile duct cancer, which provides 7 years of market exclusivity upon NDA approval by the FDA.

Further, as described further below under “Other Potential Opportunities for RenovoCath,” we are also actively exploring other commercialization strategies utilizing our TAMP technology and FDA-cleared RenovoCath delivery system as a stand-alone device.

Intra-arterial Infusion of Gemcitabine with RenovoCath: Clinical Process to Date

Systemic (IV gemcitabine and nab-paclitaxel) chemotherapy is currently the standard of care for pancreatic cancer treatment. However, it is known to cause debilitating side effects for patients diagnosed with this disease. Unlike other tumors with extensive blood supply, pancreatic tumors have poor blood supply so systemic chemotherapy may not adequately reach the tumor. Thus, the standard of care may be less effective in treating this type of cancer because the blood vessels are critical for transporting systemic administration of chemotherapy to the tumor.

We have completed our RR1 Phase I/I and RR2 observational registry studies for RenovoCath with gemcitabine, with 20 and 25 patients respectively, in LAPC. In the 35 pooled patients evaluable in these two studies, 9 patients pretreated with radiation followed by treatment with RenovoCath with gemcitabine experienced a median Overall Survival (“OS”) of 27.1 months. Based on previous large randomized clinical trials, the expected survival of LAPC patients is 12.0 to 18.8 months in patients receiving only IV systemic chemotherapy or IV chemotherapy plus radiation (which are both considered standard of care). Unlike the randomized trials that established these standard of care results, our RR1 and RR2 clinical trials did not prospectively control the standard of care therapy received prior to administration of RenovoCath with gemcitabine. Based on FDA safety review of our Phase I/II study, the FDA allowed us to proceed to evaluate RenovoCath with gemcitabine within our Phase III TIGeR-PaC clinical trial.

Our ongoing Phase III TIGeR-PaC clinical trial, a randomized, multi-center study, is evaluating RenovoRx’s first product candidate, using TAMP, a novel investigational oncology drug-device combination utilizing the Company’s FDA-cleared RenovoCath device for the intra-arterial administration of gemcitabine to treat LAPC following stereotactic body radiation therapy (“SBRT”). The study compares the treatment of LAPC using RenovoCath with gemcitabine versus systemic IV administration of gemcitabine and nab-paclitaxel.

Our protocol for TIGeR-PaC involves systemic chemotherapy and SBRT during the induction phase of the study (prior to randomization). Patients receiving SBRT during the induction phase are required to complete 5 treatments, over 5 consecutive days, and do not receive oral chemotherapy vs. previously utilized intensity-modulated radiation therapy (“IMRT”) where patients must complete 25 radiation treatments in combination with oral chemotherapy during the induction phase of the study, which takes between 35 and 56 days to complete. In December 2021, we amended our protocol and statistical analysis plan for TIGeR-PaC (the “Modified SAP”) to (i) enroll and analyze only patients receiving SBRT during the induction phase, (ii) include a second interim analysis, (iii) change the total number of patients randomized in the study to 114 with a total of 86 deaths from SBRT patients, and (iv) repower the study from 90% to 80%. The change to the 80% power calculation aligns with common practice for clinical trials and, we believe this design will shorten the timeframe needed to complete the study, as well as significantly decrease our costs. We have not discussed the protocol amendment or the Modified SAP with the FDA, and we cannot provide any assurance that the FDA will agree with these modifications, but these modifications have been submitted to the FDA.

The first interim analysis in the TIGeR-PaC study at the 26th event of the specified events (deaths), was completed in March 2023, with the Data Monitoring Committee recommending a continuation of the study. The TIGeR-PaC study’s primary endpoint is an OS benefit with secondary endpoints including reduced side effects versus standard of care. The second interim analysis for this study will be triggered by the 52nd event, which is estimated to occur in late 2024 or early 2025. The second interim data readout would follow thereafter, with the timing for such readout depending on customary factors such as time needed for analysis. We are also aiming to complete patient enrollment in the TIGeR-PaC study in the first half of 2025.

Our TAMP Therapy Platform

Our patented TAMP therapy platform is focused on optimizing drug concentration in solid tumors by delivering oncology therapies with our RenovoCath delivery system. TAMP is designed to enable physicians to isolate segments of the vascular anatomy closest to tumors and ensure precise therapeutic delivery, while potentially minimizing a therapy’s toxicities versus systemic intravenous therapy. Specifically, our patented approach enables physicians to pre-treat patients with standard-of-care radiation therapy and utilize our RenovoCath delivery system to use pressure to force chemotherapy across the arterial wall near the tumor site to bathe the target tumor.

We believe there are many advantages to our TAMP therapy platform, including:

- *Application of Approved Chemotherapeutic Agents:* Approved chemotherapeutic agents, with well-known safety and efficacy profiles have been used with our RenovoCath delivery system. These include small molecule chemotherapy agents, and based on more recent animal studies, we believe that larger molecule agents could be utilized as well.
- *Targeted Approach:* In a preclinical study using our therapy platform, we demonstrated up to 100 times higher local drug concentration compared to systemic chemotherapy. We believe our TAMP therapy platform allows for a targeted approach that can decrease systemic exposure and improve patient outcomes.
- *Delivery Method Independent of Tumor Vascularity:* Our therapy platform is designed to deliver chemotherapeutic agents to solid tumors resistant to systemic chemotherapy due to lack of tumor feeder blood vessels. If approved, our product candidates utilizing our FDA-cleared RenovoCath delivery system have the potential to treat tumors that are not directly supplied by large blood vessels.
- *Broad Application for Solid Tumor Indications:* Our therapy platform is not restricted to a single chemotherapeutic agent or solid tumor type. As such, it may be applied for use with additional therapeutic agents and/or in additional solid tumor indications, including in solid tumors with and without identifiable tumor feeder blood vessels.

We received our first FDA 510(k) clearance for RenovoCath in 2014, a second clearance to use the RenovoCath for infusion of chemotherapy agents in 2017, a further clearance to use RenovoCath with a power-injector in 2019, and a fourth clearance in 2021 to expand vessel diameter range to 3-11 mm, implement certain changes in the Instructions for Use, change the recommended saline to contrast solution ratio, among other changes and improvements.

In a further validation of our TAMP platform, last year, we announced a collaboration with Imugene (ASX: IMU) to explore expansion of our TAMP product pipeline with Imugene's CF33 oncolytic virus therapy for the treatment of difficult-to-access tumors. We are continually in discussions regarding similar collaborations and potentially out-licenses of RenovoCath with gemcitabine as we prepare for the NDA filing (assuming we meet our study endpoints) and commercialization of RenovoCath (if approved by FDA) as well as other collaborations with our TAMP platform.

For further information regarding our RenovoCath Instructions for Use ("IFU"), please see: [IFU-10004-Rev.-F-Universal-IFU.pdf](#)

Other Potential Commercial Opportunities for RenovoCath

In recent years, we have focused our efforts primarily on progressing RenovoCath with gemcitabine through our ongoing Phase III TIGeR-PaC study for LAPC. During this process, we have begun to explore other opportunities for our TAMP therapy platform.

As a result of the introduction of our FDA-cleared RenovoCath delivery system as part of the TIGeR-PaC study and the resulting unsolicited (and subsequently solicited) feedback we have received from oncologists, surgeons, and interventional radiologists indicating increased demand for targeted delivery of diagnostic and/or therapeutic agents, during the first half of 2024, we began to actively explore a new opportunity to market and sell RenovoCath as a standalone device. RenovoCath is FDA-cleared and indicated for temporary vessel occlusion in applications including arteriography, preoperative occlusion, and chemotherapeutic drug infusion. We will engage in this potential revenue-generating activity either on our own or, more likely, in tandem with a commercial partner.

In September 2024, we announced the signing of a new project work order with our RenovoCath contract manufacturing organization partner, Medical Murray Inc. of North Barrington, IL (the “CMO”), for an expanded relationship as we continue our exploration of commercial opportunities for RenovoCath beyond our currently ongoing clinical programs. To create performance incentives for our CMO, we have issued a warrant to purchase up to 709,500 shares of our common stock. This warrant vests and is only exercisable over time in tranches and only if the CMO achieves certain manufacturing milestones.

Beyond LAPC, we believe there are many clinical applications for RenovoCath to improve targeted delivery of diagnostic and therapeutic agents. This leads us to a business development opportunity that would also likely engage in Phase IV post-market “registry” clinical studies of the RenovoCath delivery system to gather additional data to support both our clinical and commercial efforts. Securing the manufacturing capacity for this strategy with our CMO partner is a great first step. We are also in active discussions with many interested customers to purchase supplies of RenovoCath as well as potential distribution partners.

We are increasing production of RenovoCath supplies through our CMO, and if we launch our commercial strategy as planned, we anticipate potential for near-term revenue in 2025. Without incremental revenues from this commercial strategy, we maintain sufficient cash on hand to achieve both our next interim read-out of our Phase III TIGeR-PaC study, which will be triggered by the 52nd event, estimated to occur in late 2024 or early 2025, and fund our current efforts for our RenovoCath go to market activities. The second interim data readout would follow thereafter, with the timing for such readout depending on customary factors such as time needed for analysis. We are also aiming to complete patient enrollment in the TIGeR-PaC study in the first half of 2025.

In parallel, we remain fully engaged and committed to the ongoing pivotal Phase III TIGeR-PaC clinical trial in LAPC. During 2024, we announced that additional renowned clinical oncology sites are now participating in the study with the goal of accelerating patient enrollment. We are progressing towards data, which could allow for a second interim readout in the trial and the potential filing of NDA with the FDA for RenovoCath with gemcitabine as a drug-device treatment in LAPC.

Previous Fundraising and Anticipated Future Spending

Since our inception, we have devoted substantially all our efforts to developing our cancer therapy platform and product candidates, raising capital and organizing and staffing our company. In January and April 2024, we raised additional funding in two private placements, offering shares of common stock and warrants to purchase shares of common stock for aggregate gross proceeds of \$17.2 million. As of September 30, 2024, we have received over \$59.2 million in aggregate gross proceeds and have financed our operations primarily through issuance of convertible preferred stock and convertible notes prior to our initial public offering, and securities issued in our August 2021 initial public offering, a registered direct offering with a single institutional investor in April 2023 (the “RDO”), common stock purchase warrants, the aforementioned January and April 2024 private placements, and a loan pursuant to the Paycheck Protection Program under the Coronavirus Aid, Relief and Economic Security Act (the “CARES Act”). After deducting underwriting discounts, commissions, placement fees, legal fees, and other professional expenses of \$5.8 million, our net offering proceeds to date are \$53.4 million.

We have incurred significant operating losses and generated negative cash flows from operations since our inception. As of September 30, 2024, we had cash and cash equivalents of \$9.6 million. As of September 30, 2024, we had an accumulated deficit of \$47.3 million. We expect to continue to incur significant expenses, increasing operating losses and negative cash flows for the foreseeable future. At the time we launch our commercial strategy, we anticipate to generate revenue from RenovoCath device sales via either on our own or, more likely, in tandem with a commercial partner our direct channel and/or collaborations, licensing arrangements or other strategic or commercial activities. Given economic and market conditions and the timing of regulatory approval, we expect that our expenses will increase in connection with our ongoing research, development and potential commercialization activities, particularly if and when we decide to:

- Advance clinical development of the TAMP therapy platform with the RenovoCath delivery system by continuing to enroll patients in our ongoing Phase III TIGeR-PaC clinical trial, and advancing our technology through preclinical and clinical pipeline indication opportunities;
- Hire additional research, development, engineering, and general and administrative personnel;
- Pursue collaborations, licensing arrangements or other strategic or commercial activities relating to our technology;
- Maintain, expand, enforce, defend, and protect our intellectual property portfolio; and
- Expand our operational, financial and management systems and increase personnel, including personnel to support our clinical development, manufacturing and commercialization efforts and our operations.

As a result, we will require significant additional funding to support our continuing operations. If and when any of our product candidates successfully complete development, we will incur substantial additional costs associated with establishing a sales, marketing, medical affairs and distribution infrastructure to commercialize our products for which we may obtain marketing approval, regulatory filings, marketing approval, and post-marketing requirements, in addition to other commercial costs. We cannot reasonably estimate these costs at this time.

Our ability to obtain additional financing will be subject to a number of factors, including market conditions, fluctuations in interest rates, our operating performance and investor sentiment. If we are unable to raise additional capital when required or on acceptable terms, we may have to significantly delay, scale back or discontinue the development and/or commercialization of our product candidates, restrict or cease our operations or obtain funds by entering into agreements on unfavorable terms. Failure to obtain additional capital on acceptable terms, or at all, would result in a material and adverse impact on our operations. As a result, there is substantial doubt about our ability to operate as a going concern.

Our financial statements as of September 30, 2024 have been prepared on a going concern basis and do not include any adjustments that may result from the outcome of this uncertainty. Based on our operating plans, we do not expect that our current cash and cash equivalents as of the date of this filing, will be sufficient to fund our operating, investing and financing cash flow needs, assuming our programs advance as currently contemplated.

Components of Our Results of Operations

Revenue

Currently, we have not generated any revenue from product sales of our patented RenovoCath device or as a result of our TIGeR-PaC clinical study or any other clinical or sales efforts. If our development efforts for our current or future product candidates are successful and result in marketing approval or collaboration or license agreements with third parties, we may generate revenue in the future from a combination of product sales or payments from collaboration or license agreements. We may also pursue a strategy of commercializing our RenovoCath, as a standalone device as a means of generating revenue.

Operating Expenses

Research and Development

Research and development expenses consist of costs related to the research and development of our platform technology. Clinical trial costs are a significant component of research and development expenses and include costs associated with third-party contractors and consultants. We outsource a substantial portion of our clinical trial activities, utilizing the service of third-party clinical trial sites and third-party vendors to assist us with the execution of our clinical trials. In addition, we have FDA 510(k) clearance for our proprietary catheter delivery device RenovoCath, which comprises part of the RenovoGem product. Accordingly, we are able to charge our clinical trial sites for the RenovoCath delivery device. To date, payments from clinical trial sites in consideration for RenovoCath delivery devices have been adequate to cover our direct manufacturing costs. Any payments we receive from clinical trial sites as consideration for use of RenovoCath delivery devices offset a portion of our research and development expenses. We expect our research and development expenses to increase for the foreseeable future as we continue the development of our product candidates and enroll subjects in our ongoing Phase III clinical trial, initiate new clinical trials and pursue regulatory approval of our product candidates. It is difficult to predict with any certainty the duration and costs of completing our current or future clinical trials of our product candidates or if, when or to what extent we will achieve regulatory approval and generate revenue from the commercialization and sale of our product candidates. The duration, costs and timing of clinical trials and other development of our product candidates will depend on a variety of factors, including uncertainties in clinical trial enrollment, timing and extent of future clinical trials, development of new product candidates and significant and changing government regulation. We may never succeed in achieving regulatory approval for any of our product candidates.

Our research and development expenses include:

- expenses incurred under agreements with clinical trial sites, third-party vendors, and consultants that are involved in conducting our clinical trials;
- costs of acquiring and developing clinical trial materials;
- personnel costs, including salaries, benefits, bonuses, and stock-based compensation for employees engaged in preclinical and clinical research and development;
- costs related to compliance with regulatory requirements;
- third-party vendor costs related to manufacturing materials and testing of our RenovoCath catheter delivery device;
- costs related to preclinical studies and pilot testing;
- travel expenses; and
- allocated general and administrative expenses which includes facilities and other indirect administrative expenses to support research and development activities, including employees' salaries and benefits.

Research and development costs are expensed as incurred. Costs for certain development activities, such as clinical trials and preclinical studies, are recognized based on evaluation of progress to completion of specific tasks using data such as subject enrollment, clinical site activations or information provided to us by third party vendors.

General and Administrative

General and administrative expenses consist of salaries, benefits, and stock-based compensation for personnel in executive, finance and administrative functions, professional services and associated costs related to accounting, tax, audit, legal, intellectual property other matters, consulting costs, conferences, travel, and allocated expenses for rent, insurance, and other general overhead costs. We expect to continue to incur additional expenses as a result of operating as a public company, including costs to comply with the rules and regulations of the Securities and Exchange Commission, or SEC, and Nasdaq listing standards and increased expenses in the areas of insurance, professional services and investor relations. As a result, we expect our general and administrative expenses to increase in the foreseeable future. General and administrative expenses are expensed as incurred.

Other Income (Expenses), Net

Interest and Dividend Income (Expense), Net

Interest expense consists of financing interest for the Directors and Officers liability insurance premiums.

Interest income and dividend income are earned from cash deposited in our short-term marketable securities and money market accounts.

Change in Fair Value of Common Warrant Liability

Change in fair value of warrant liability represents the gain or loss reported from the change in the fair value of the warrant liability associated with the April 2023 Warrant. The fair value per share of the April 2023 Warrant was \$0.61 and \$1.69 on September 30, 2024 and December 31, 2023, respectively. The decrease in the fair value was primarily due to the decrease in our stock price.

Income Tax Expense

We account for income taxes using the asset and liability method. Under this method, deferred income tax assets and liabilities are recorded based on the estimated future tax effects of differences between the financial statement and income tax basis of existing assets and liabilities. Deferred income tax assets and liabilities are recorded net and classified as noncurrent on the balance sheets. A valuation allowance is provided against our deferred income tax assets when their realization is more likely than not.

We are subject to income taxes in the federal and state jurisdictions. Tax regulations within each jurisdiction are subject to the interpretation of the related tax laws and regulations and require significant judgment to apply. In accordance with the authoritative guidance on accounting for uncertainty in income taxes, we recognize tax liabilities for uncertain tax positions when it is more likely than not that a tax position will not be sustained upon examination and settlement with various taxing authorities. Liabilities for uncertain tax positions are measured based upon the largest amount of benefit that is more-likely-than-not (greater than 50%) of being realized upon settlement. Our policy is to recognize interest and/or penalties related to income tax matters in income tax expense.

On March 27, 2020, the CARES Act was enacted. The CARES Act includes several significant provisions for corporations, including the usage of net operating losses (“NOLs”), interest deductions and payroll benefits. Corporate taxpayers may carryback NOLs originating during 2018 through 2020 for up to five years.

Results of Operations

Comparison of the Three Months Ended September 30, 2024, and 2023

The following table summarizes the significant components of our results of operations for the periods presented (in thousands, except percentages):

	Three Months Ended September 30,		Increase / (Decrease)	
	2024	2023	\$	%
	(unaudited)			
Operating expenses:				
Research and development	\$ 1,650	\$ 1,629	\$ 21	1%
General and administrative	1,178	1,354	(176)	(13)%
Total operating expenses	2,828	2,983	(155)	(5)%
Loss from operations	(2,828)	(2,983)	155	(5)%
Other income/(expense), net				
Interest and dividend income	124	43	81	188%
Change in fair value of common warrant liability	233	1,519	(1,286)	(85)%
Transaction costs allocated to warrant liabilities	-	-	-	-%
Total other income/(expense), net	357	1,562	(1,205)	(77)%
Net loss	\$ (2,471)	\$ (1,421)	\$ (1,050)	74%

Research and Development

Research and development expenses were approximately \$1.7 million for the three months ended September 30, 2024, remaining relatively flat compared to the same period last year. Employee and related benefit costs increased \$0.1 million including an increase of \$0.1 million in clinical conferences and trade shows activities. This increase was partially offset by lower regulatory and clinical consulting costs and manufacturing for our proprietary catheter delivery device. We anticipate research and development expenses to increase as we increase manufacturing costs for our device and continue advancing our Phase III clinical trial study throughout the remainder of the year.

General and Administrative

General and administrative expenses were approximately \$1.2 million for the three months ended September 30, 2024, a decrease of approximately \$0.2 million compared to approximately \$1.4 million for the same period last year. The decrease was primarily due to decreases of \$0.2 million in professional and consulting fees, and legal fees, partially offset by an increase of \$0.1 million in investor and public relations costs. We anticipate general and administrative expenses increasing moderately throughout the remaining year as we progress our commercialization activities for our RenovoCath device.

Other Income/(Expense), Net

Other income/(expense), net was approximately \$0.4 million for the three months ended September 30, 2024, a decrease of approximately \$1.2 million compared to approximately \$1.6 million for the in the same period last year. The decrease was primarily due to a \$1.3 million change in the fair value of the common warrant liability offset by interest and dividend income of \$0.1 million.

Comparison of the Nine Months Ended September 30, 2024, and 2023

The following table summarizes the significant components of our results of operations for the periods presented (in thousands, except percentages):

	Nine Months Ended September 30,		Increase / (Decrease)	
	2024	2023	\$	%
	(unaudited)			
Operating expenses:				
Research and development	\$ 4,449	\$ 4,892	\$ (443)	(9)%
General and administrative	3,889	4,727	(838)	(18)%
Total operating expenses	8,338	9,619	(1,281)	(13)%
Loss from operations	(8,338)	(9,619)	1,281	(13)%
Other income/(expense), net				
Interest income and dividend income	299	97	202	208%
Change in fair value of common warrant liability	2,103	3,092	(989)	(32)%
Transaction costs allocated to warrant liabilities	-	(575)	575	(100)%
Total other income/(expense), net	2,402	2,614	(212)	(8)%
Net loss	\$ (5,936)	\$ (7,005)	\$ 1,069	(15)%

Research and Development

Research and development expenses were approximately \$4.4 million for the nine months ended September 30, 2024, a decrease of approximately \$0.5 million, compared to approximately \$4.9 million for the prior year period. The decrease was primarily due lower costs of \$0.6 million on clinical, regulatory and clinical consulting costs from our ongoing Phase III clinical trial cost as we reduced expenses to conserve our cash runway in the first quarter and a decrease of \$0.1 million in clinical conferences and trade shows, partially offset by an increase of \$0.3 million in employee and related benefits costs. Our primary manufacturer company of our RenovoCath device commenced production this year as we implemented our commercialization and sale of our product candidate's strategy. Allocated general and administrative support costs for personnel, facility and office supply expenses decreased by \$0.1 million compared to the same period last year. We anticipate research and development expenses to increase as we progress our commercialization strategy, including our ongoing Phase III clinical trial study throughout the remainder of the year.

General and Administrative

General and administrative expenses were approximately \$3.9 million for the nine months ended September 30, 2024, a decrease of approximately \$0.8 million compared to approximately \$4.7 million for the prior year period. The decrease was primarily due to a \$0.3 million reduction in professional and consulting fees, a \$0.1 million decrease in recruitment fees, a \$0.2 million decrease in investor and public relations costs, a \$0.2 million decrease in directors' and officers' liability insurance expense and a \$0.1 million decrease in legal fees. The decrease was partially offset by lower allocated general and administration expenses to research and development of \$0.1 million. We anticipate general and administrative expenses to increase slightly throughout the remaining year as we progress with our commercialization activities for our RenovoCath device.

Other Income/(Expense), Net

Other income/(expense), net was approximately \$2.4 million for the nine months ended September 30, 2024, a decrease of approximately \$0.2 million compared to approximately \$2.6 million for the prior year period. The decrease was primarily due to a \$1.0 million change in the fair value of the common warrant liability due to a decline in our common stock price during the nine months ended September 30, 2023 as compared to September 30, 2024. The decrease was offset by a \$0.2 million increase in interest and dividend income from an increase in cash and cash equivalents related to the completion of two private placement financings completed earlier in the year and \$0.6 million of transaction costs allocated to common warrant liability in the previous period.

Liquidity and Capital Resources

For the nine months ended September 30, 2024, we incurred a net loss of \$5.9 million. As of September 30, 2024, our accumulated deficit stood at \$47.3 million. We anticipate incurring further losses and increasing operating expenses in future periods.

On April 3, 2023, we completed a RDO under our shelf registration statement on Form S-3 for the purchase and sale of 1,557,632 shares of common stock (or pre-funded common warrants) at a purchase price of \$3.21 per share of common stock (or pre-funded warrants) to a certain institutional investor. Additionally, in a concurrent private placement, we issued to the investor common warrants to purchase up to 1,947,040 shares of our common stock. The aggregate gross proceeds from this RDO were \$5.0 million, and the net offering proceeds were \$4.4 million after deducting placement agent fees and placement agent's expenses of \$0.4 million and other professional expenses of \$0.2 million.

On January 26, 2024, we completed a private placement to 92 accredited investors with gross proceeds of \$6.1 million. The private placement included issuing 6,133,414 shares of our common stock and common stock warrants to purchase 6,133,414 shares of common stock, which expire five years from the date of issuance. In connection with the private placement, we entered into a placement agent agreement as additional compensation to the placement agent, and issued common stock warrants to purchase 511,940 shares of common stock, which expire five years from the issuance date.

On April 11, 2024, we completed a second private placement offering, issuing common stock, pre-funded warrants, Series A warrants, and Series B warrants. The aggregate gross proceeds from this offer were \$11.1 million, and the net offering proceeds were \$9.7 million after deducting placement agent fees of \$1.2 million and other professional expenses of \$0.2 million. In conjunction with the issuance of 6,960,864 shares of common stock, we bundled the offering with: (i) a pre-funded warrant exercisable for 951,500 shares of common stock at an exercise price of \$0.0001 per share, with an unlimited term and immediate exercisability upon issuance, subject to specific beneficial ownership limitations; (ii) Series A warrants exercisable for 7,912,364 shares of common stock at \$1.22 per share, valid for 5 years and immediately exercisable subject to customary adjustments and beneficial ownership limitations; (iii) Series B warrants exercisable for 3,956,182 shares of common stock at \$1.22 per share, valid for 2 years and immediately exercisable subject to customary adjustments and beneficial ownership limitations, with us retaining the right to call these warrants under certain conditions. Additionally, we issued the April 2024 PA Warrants on the same date, exercisable for 701,243 shares of common stock at \$1.69 per share over a 5-year term, with provisions for cashless exercise if the shares are unregistered or no current prospectus is available for resale. The April 2024 PA Warrants become exercisable on October 11, 2024, subject to specific beneficial ownership limitations and customary adjustments.

As of September 30, 2024, we have received over \$59.2 million in gross proceeds through various financial arrangements to include the issuance of preferred stock, convertible debt, securities in our IPO, the RDO, private placements and various loans. After deducting underwriting discounts, commissions, placement fees, legal fees, and other professional expenses of \$5.8 million, our net offering proceeds from these activities were \$53.4 million.

Based on our operational plans, we do not expect that our current cash and cash equivalents as of the date of this filing, will be sufficient to fund our operating, investing and financing cash flow needs for at least the next twelve months, assuming our programs advance as currently contemplated. Based upon this review and the Company's current financial condition, the Company has concluded that substantial doubt exists as to the Company's ability to continue as a going concern. We believe we will continue to be able to raise additional capital through debt financing, private or public equity financings, license agreements, obtain a credit facility or other loan or at-the-market offering, collaborative agreements or other arrangements with other companies, or other sources of financing.

Our ability to obtain additional required financing will be subject to a number of factors, including market conditions, fluctuations in interest rates, our operating performance and investor sentiment. However, there can be no assurances that such financing will be available or will be at terms acceptable to us, or at all. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our clinical trials, discontinue the development and/or commercialization of our product candidates, restrict or cease our operations or obtain funds by entering into agreements on unfavorable terms. If any of these events occur, our ability to achieve our operational goals would be adversely affected. Our future capital requirements and the adequacy of available funds will depend on many factors, including those described in the section titled "Risk Factors in Part I item 1A on Form 10-K on our 2023 Annual Report." Depending on the severity and direct impact of these factors on us, we may be unable to secure additional financing to meet our operating requirements on commercially acceptable terms favorable to us, or at all.

Sources of Liquidity

Since our inception, we have not generated any revenue from product sales and we have incurred significant operating losses and negative cash flows from operations. We anticipate that we will continue to incur net losses for the foreseeable future. We do not have any drug-device combination products that have achieved regulatory marketing approval and we do not expect to generate revenue from sales of any drug-device combination product candidates for several years, if ever. While we are actively, in parallel to our clinical efforts, exploring commercialization of our FDA-cleared RenovoCath delivery system on a standalone basis, which could generate revenues over the nearer term, our plans in this regard may not lead to meaningful revenue generation or cash liquidity for us over the next 12 months, if at all.

We have financed our operations from inception through the date of this Report primarily through the issuance and sale of an aggregate of \$59.2 million from private placements of our convertible preferred stock, convertible debt securities prior to our August 2021 initial public offering, and the issuance of securities in our initial public offering, our RDO and other private placement offerings, various loans and the exercise of warrants and common stock options. After deducting underwriting discounts and commissions, placement agent fees and other offering expenses, net offerings were \$53.8 million. During the first four months of 2024 alone, we raised new capital for aggregate gross proceeds of \$17.2 million, to further advance our programs.

Cash Flows

Our primary uses of cash are to fund our operations including research and development and general and administrative expenses. We will continue to incur operating losses in the future and expect that our research and development and general and administrative expenses will continue to increase as we continue our research and development efforts with respect to clinical development of our product candidates, further develop our therapy platform and ensure that we are complying with the requirements of being a public company. The cash used to fund operating expenses is impacted by the timing of when we pay expenses, as reflected in the change in our outstanding accounts payable and accrued expenses.

The following table summarizes our cash flows for the period indicated (in thousands):

	Nine Months Ended September 30,	
	2024	2023
Net cash provided by (used in):		
Operating activities	\$ (6,695)	\$ (8,205)
Investing activities	-	2,032
Financing activities	15,085	5,008
Increase/decrease in cash and cash equivalents	<u>\$ 8,390</u>	<u>\$ (1,165)</u>

Net Cash Used in Operating Activities

Cash used in operating activities for the nine months ended September 30, 2024, reflected a net loss of \$5.9 million and non-cash charges of \$1.2 million, and offset by net change in our operating assets and liabilities of \$0.4 million.

Cash used in operating activities for the nine months ended September 30, 2023, reflected a net loss of \$7.0 million and non-cash charges of \$2.2 million, offset by a net change in our operating assets and liabilities of \$1.0 million.

Cash Provided by Investing Activities

Cash provided by investing activities for the nine months ended September 30, 2023, consisted of \$2.0 million from the sale of investments.

Cash Provided by Financing Activities

Net cash provided by financing activities for the nine months ended September 30, 2024 was \$15.1 million, consisting primarily of net proceeds from two private placement offerings.

Net cash provided by financing activities for the nine months ended September 30, 2023 was \$5.0 million, consisting primarily of proceeds from common stock and pre-funded common warrants.

Contractual Obligations and Other Commitments

There have been no significant changes in our contractual obligations or other commitments as of September 30, 2024.

Critical Accounting Policies and Significant Judgments and Estimates

The accompanying management's discussion and analysis of our financial condition and results of operations are based upon our unaudited condensed interim financial statements and the related disclosures, which have been prepared in accordance with GAAP. The preparation of these unaudited condensed interim financial statements requires us to make estimates, assumptions and judgments that affect the reported amounts in our unaudited condensed interim financial statements and accompanying notes. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. To the extent that there are material differences between these estimates and actual results, our future financial statement presentation, financial condition, results of operations and cash flows will be affected. Our critical accounting policies and estimates are detailed in our 2023 Annual Report.

There have been no significant changes to our critical accounting policies or significant judgments and estimates for the nine months ended September 30, 2024, from those previously disclosed in our 2023 Annual Report.

Convertible Instruments and Embedded Derivatives

We evaluate all of our agreements to determine whether such instruments have derivatives or contain features that qualify as embedded derivatives. We account for certain redemption features that are associated with the terms of convertible notes as liabilities at fair value and adjust the instruments to their fair value at the end of each reporting period. For derivative financial instruments that are accounted for as liabilities, the derivative instrument is initially recorded at its fair value and is then re-valued at each reporting date, with changes in the fair value reported in other income (expenses), net in the statements of operations. Derivative instrument liabilities are classified in the balance sheets as current or non-current based on whether or not net-cash settlement of the derivative instrument could be required within 12 months of the balance sheet date.

April 2023 Warrants

We evaluate pre-funded warrants and April 2023 Warrant issued in connection with registered direct financing in April 2023 to determine whether such warrants qualify for equity classification, or meet the definition of a derivative instrument, classified as a liability on the Condensed Balance Sheets and measured at fair value at inception and at each reporting date with changes in fair value recognized in the Condensed Statements of Operations in the period of change.

Direct Offering Costs

Direct offering costs consist principally of commissions, placement fees and legal fees, including other professional expenses incurred. We evaluate the terms under the financing agreement to determine the classification of direct costs in the accompanying Condensed Statements of Operations.

Emerging Growth Company and Smaller Reporting Company Status

We are an “emerging growth company” as defined in the Jumpstart Our Business Startups Act of 2012, as amended, or the JOBS Act. Under the JOBS Act, companies have extended transition periods available for complying with new or revised accounting standards. We have elected this exemption to delay adopting new or revised accounting standards. We will remain an emerging growth company until the earlier of (1) December 31, 2026, (2) the last day of the fiscal year in which we have total annual gross revenues of at least \$1.235 billion, (3) the date on which we are deemed to be a “large accelerated filer” as defined in Rule 12b-2 under the Exchange Act, or (4) the date on which we have issued more than \$1.0 billion in non-convertible debt securities during the prior three-year period. An emerging growth company may take advantage of specified reduced reporting requirements and is relieved of certain other significant requirements that are otherwise generally applicable to public companies. As an emerging growth company,

- we may present only two years of audited financial statements, plus unaudited interim condensed financial statements for any interim period, and related Management’s Discussion and Analysis of Financial Condition and Results of Operations;
- we may avail ourselves of the exemption from the requirement to obtain an attestation and report from our auditors on the assessment of our internal control over financial reporting pursuant to the Sarbanes-Oxley Act;
- we may provide reduced disclosure about our executive compensation arrangements; and
- we do not require stockholder non-binding advisory votes on executive compensation or golden parachute arrangements.

We have elected to take advantage of certain of the reduced disclosure obligations in this Quarterly Report on Form 10-Q and may elect to take advantage of other reduced reporting requirements in future filings. As a result, the information that we provide to our stockholders may be different than you might receive from other public reporting companies in which you hold equity interests.

We are also a “smaller reporting company,” meaning that the market value of our stock held by non-affiliates plus the proposed aggregate amount of gross proceeds to us is less than \$700.0 million and our annual revenue is less than \$100.0 million during the most recently completed fiscal year. We may continue to be a smaller reporting company if either (1) the market value of our stock held by nonaffiliates is less than \$250.0 million or (2) our annual revenue is less than \$100.0 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than \$700.0 million. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and, like emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

Recently Issued and Adopted Accounting Pronouncements

There were no new accounting pronouncements that were issued or became effective since the issuance of our 2023 Annual Report that had, or are expected to have, a material impact on our unaudited condensed balance sheets, unaudited condensed statement of operations or unaudited condensed statement of cash flows.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

The disclosures in this Item are not required because we qualify as a smaller reporting company under federal securities laws.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including our Chief Executive Officer and Principal Accounting Officer, we conducted an evaluation of the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15I and 15d-15(e) under the Exchange Act) as of the end of the fiscal quarter ended September 30, 2024. Based on this evaluation, our Chief Executive Officer and Principal Accounting Officer have concluded that, during the period covered by this Report, our disclosure controls and procedures were not effective due to our previously identified material weaknesses in internal control over financial reporting. As a result, we have performed additional analysis as deemed necessary to ensure that our financial statements were prepared in accordance with GAAP. Accordingly, notwithstanding the identified material weaknesses, management, including our Chief Executive Officer and Principal Accounting Officer, believes the financial statements included in this Report are fairly presented, in all material respects, in accordance with GAAP.

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed by us in our Exchange Act reports is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated, communicated and discussed with our management, including our Chief Executive Officer and Principal Accounting Officer or persons performing similar functions, as appropriate, to allow timely decisions regarding required disclosure. Management recognizes that controls and procedures, no matter how well designed and operated, can only provide reasonable, not absolute, assurance the desired control objectives will be met. In reaching a reasonable level of assurance, management has weighed the cost of contemplated controls against their intended benefits. The design of any system of controls is based on management's assumptions about the likelihood of future events. We cannot assure you that our controls will achieve their stated goals under all possible conditions. Changes in future conditions may render our controls inadequate or may cause our degree of compliance with them to deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

For the fiscal quarter ended September 30, 2024, our management identified material weaknesses in our internal control over financial reporting related to our control environment. A material weakness is a deficiency, or combination of significant deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected and corrected on a timely basis.

Specifically, we have determined that we have not maintained adequate formal accounting policies, processes and controls related to complex transactions as a result of a lack of finance and accounting staff with the appropriate GAAP technical expertise needed to identify, evaluate and account for complex and non-routine transactions. We also determined that we have not maintained sufficient staffing or written policies and procedures for accounting and financial reporting, which contributed to the lack of a formalized process or controls for management's timely review and approval of financial information. More specifically, we have determined that our financial statement close process includes significant control gaps mainly driven by the small size of our accounting and finance staff and, as a result, a significant lack of appropriate segregation of duties. This includes the ability of users to create and post journal entries without adequate compensating review controls as well as review of system rights on the journal entry and financial close process. In addition, we did not have proper information technology general controls related to user access, including the performance of user access reviews, access to edit data in applications was not properly restricted, and formal approval of application access was not documented and retained.

We are in the process of implementing a number of measures to address the material weaknesses that has been identified including: (i) engaging additional accounting and financial reporting personnel with GAAP and SEC reporting experience, (ii) developing, communicating and implementing an accounting policy manual for our accounting and financial reporting personnel for recurring transactions and period-end closing processes, and (iii) establishing effective monitoring and oversight controls for non-recurring and complex transactions to ensure the accuracy and completeness of our financial statements and related disclosures.

These additional resources and procedures are designed to enable us to broaden the scope and quality of our internal review of underlying information related to financial reporting and to formalize and enhance our internal control procedures. With the oversight of senior management and our Audit Committee, we have begun taking steps and plan to take additional measures to remediate the underlying causes of the material weaknesses.

We intend to complete the implementation of our remediation plan when we have sufficient cash to remediate our material weaknesses. Although we believe that our remediation plan will improve our internal control over financial reporting, additional time may be required to fully implement it and to make conclusions regarding the effectiveness of our internal control over financial reporting. Our management will closely monitor and modify, as appropriate, the remediation plan to eliminate the identified material weaknesses.

Changes in Internal Control over Financial Reporting

Except for the material weaknesses noted above, during the quarter ended September 30, 2024, there were no changes in our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II – OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, we are engaged in various legal actions, claims and proceedings arising in the ordinary course of business, none of which are expected to be material. The Company is not currently engaged in any material legal proceedings.

Item 1A. Risk Factors

An investment in our securities is speculative and involves a high degree of risk. You should carefully consider the risk factors below, as well as the other information in this Report, including our unaudited interim condensed financial statements and the related notes and the section titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” and in our other public filings in evaluating our business, including those risk factors included in our 2023 Annual Report. The occurrence of any of the events or developments described in our 2023 Annual Report, or summarized below or described elsewhere in this Report could harm our business, financial condition, results of operations, growth prospects or stock price. In such an event, the market price of our common stock could decline, and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations and the market price of our common stock.

Risk Factors Summary

The following is a summary of principal factors and uncertainties that make investing in shares of our common stock risky and impact our ability to execute on our business strategy include risks regarding the following. This summary is not exhaustive, and readers are therefore encouraged to review the “Risk Factors” section and the “Risk Factors” section in our 2023 Annual Report in their entirety:

- We are a clinical stage biopharmaceutical company, have a limited operating history and have no drug/device combination products approved for commercial sale, which makes it difficult to evaluate our current business and predict our future success and viability.
- We have incurred significant net losses in each period since inception, and we expect to continue to incur net losses for the foreseeable future.
- We will need to raise substantial additional capital to develop and fully commercialize RenovoGem and/or RenovoCath, and our failure to obtain funding when needed may force us to delay, reduce or eliminate our product development programs or collaboration efforts. As a result, there is substantial doubt about our ability to operate as a going concern.
- We may consider strategic alternatives in order to maximize stockholder value, including financing, strategic alliances, and licensing arrangements, particularly in connection with our proposal commercialization of RenovoCath should we utilize a commercial collaboration. We may not be able to identify or consummate any suitable strategic alternatives and any consummated strategic alternatives may not be successful.
- Our product candidates’ commercial viability remains subject to current and future preclinical studies, clinical trials, regulatory approvals, and the risks generally inherent in the development of a pharmaceutical product candidate. If we are unable to successfully advance or develop our product candidates, our business will be materially harmed.
- If we do not achieve our projected development goals in the timeframes we announce and expect, our stock price may decline.
- Our product candidates may exhibit undesirable side effects when used alone or in combination with other approved pharmaceutical products or investigational new drugs, which may delay or preclude further development or regulatory approval or limit their use if approved.
- If the results of preclinical studies or clinical trials for our product candidates are negative, we could be delayed or precluded from the further development or commercialization of our product candidates, which could materially harm our business.
- If we are unable to satisfy any applicable regulatory requirements, we may not be able to commercialize our product candidates.
- If our product candidates are unable to compete effectively with marketed drugs targeting similar indications as our product candidates, our commercial opportunity will be reduced or eliminated.
- We may delay or terminate the development of our product candidates at any time if we believe the perceived market or commercial opportunity does not justify further investment, which could materially harm our business.
- Our future success depends on our ability to retain our key personnel and to attract, retain, and motivate qualified personnel, especially in light of an acute workforce shortage and hyper-competitive compensation environment.
- If we are unable to protect our intellectual property effectively, we may be unable to prevent third parties from using our technologies, which would impair our competitive advantage.
- The patents issued to us may not be broad enough to provide any meaningful protection, one or more of our competitors may develop more effective technologies, designs, or methods without infringing our intellectual property rights and one or more of our competitors may design around our proprietary technologies.
- The market price of our common stock may be volatile and fluctuate substantially, which could result in substantial losses for our investors.
- We issued a large number of shares of common stock and warrants to purchase common stock in connection with our 2024 financing activities. Substantial future sales of such shares of our common stock could cause the market price of our common stock to decline or have other adverse effects on our company.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

Unregistered Sales of Equity Securities

January 2024 Private Placement

On January 26, 2024, we entered into a series of subscription agreements (the “January 2024 Subscription Agreements”) in connection with a private placement offering to 92 accredited investors (the “January 2024 Investors”), which was also closed on January 26, 2024, and pursuant to which we raised aggregate gross proceeds of \$6,111,695 (the “January 2024 Offering”). Under the provisions of the January 2024 Subscription Agreements, the minimum amount of subscriptions required to close the January 2024 Offering was \$5 million, which minimum amount was satisfied, and the maximum offering amount was \$15 million. In connection with the January 2024 Offering, we sold to the January 2024 Investors an aggregate of 6,133,414 shares (the “January 2024 Shares”) of our common stock and common stock purchase warrants (the “January 2024 Investor Warrants”) to purchase an aggregate of up to 6,133,414 shares of common stock (the “January 2024 Investor Warrant Shares” and collectively with the January 2024 Shares and the January 2024 Investor Warrants, the “Investor Securities”).

The January 2024 Investors paid a purchase price of \$0.99 for each January 2024 Share and related January 2024 Investor Warrant, which represents a 10% discount to the intraday volume weighted average price of \$1.10 for our shares of common stock on the Nasdaq Capital Market on January 23, 2024, which was the date that the January 2024 Offering was priced (the “Pricing Date”). The exercise price of the January 2024 Investor Warrants is also \$0.99 per share. Notwithstanding the foregoing the five January 2024 Investors who are either officers, directors, employees or consultants to the Company paid a purchase price of \$1.22 for each January 2024 Share and related January 2024 Investor Warrant, which represents the average of the official Nasdaq closing price for our shares of common stock on the Nasdaq Capital Market for the five trading days immediately preceding the Pricing Date, plus an attributed price of \$0.125 per warrant as required by Nasdaq. The exercise price of these January 2024 Investor Warrants is also \$1.22 per share.

The Investor Securities may not be offered or sold in the United States absent registration or an applicable exemption from registration requirements. We relied on the private placement exemption from registration provided by Section 4(a)(2) of the Securities Act and by Rule 506(c) of Regulation D promulgated thereunder by the SEC.

As additional compensation for Paulson Investment Company, LLC, the placement agent for the January 2024 Offering (“Paulson”), we issued common stock purchase warrants to Paulson and its designees to purchase an aggregate of up to 511,940 shares of common stock at an exercise price of \$0.99 per share.

April 2024 Private Placement

On April 11, 2024, we closed a previously announced private placement offering (the “April 2024 Offering”) of an aggregate of (i) 6,960,864 shares (the “April 2024 Shares”) of common stock, (ii) a pre-funded warrant, with an unlimited term, exercisable for a total of 951,500 shares of common stock, at an exercise price of \$0.0001 per share (the “Pre-Funded Warrant”) subject to customary adjustments thereunder, which Pre-Funded Warrant is immediately exercisable upon issuance, subject to certain beneficial ownership limitations, (iii) Series A warrants, with a term of 5 years, exercisable for a total of 7,912,364 shares of common stock (the “Series A Warrant Shares”) with an exercise price of \$1.22 per share, subject to customary adjustments thereunder, which Series A Warrants are immediately exercisable upon issuance, subject to certain beneficial ownership limitations, (iv) Series B warrants, with a term of 2 years, exercisable for a total of 3,956,182 shares of common stock (the “Series B Warrant Shares”) with an exercise price of \$1.22 per share, subject to customary adjustments thereunder, which Series B Warrants are immediately exercisable upon issuance, subject to certain beneficial ownership limitations, and may be called by the Company under certain conditions, and (v) the April 2024 PA Warrants, with a term of 5 years, exercisable for a total of 701,243 shares of common stock (the “PA Warrant Shares”) with an exercise price of \$1.69 per share and may also be exercised on a cashless basis, if the PA Warrant Shares are not registered for resale under an effective registration statement or no current prospectus is available for the resale of the PA Warrant Shares, are subject to customary adjustments thereunder, and which April 2024 PA Warrants are first exercisable on October 11, 2024, subject to certain beneficial ownership limitations. The purchase price paid by investors for each April 2024 Share and related Series A warrant and Series B warrant was \$1.4075.

We raised gross proceeds of approximately \$11.1 million in the April 2024 Offering, before deducting placement agent fees and other offering expenses. The Company intends to use the net proceeds from this April 2024 Offering for working capital purposes. The net proceeds from the April 2024 Offering was approximately \$9.6 million.

The April 2024 Shares, Series A warrants, Series B warrants, Series A Warrant Shares, and Series B Warrant Shares may not be offered or sold in the United States absent registration or an applicable exemption from registration requirements. We relied on the private placement exemption from registration provided by Section 4(a)(2) of the Securities Act and by Rule 506(b) of Regulation D (“Rule 506(b)”) promulgated thereunder by the SEC. We accepted subscriptions for the April 2024 Shares, Series A Warrants, and Series B Warrants only from accredited investors who have submitted fully completed and signed subscription agreements, along with appropriate supporting documentation verifying their accredited investor status in accordance with Rule 506(b).

CMO Warrants

In September 2024, we announced the signing of a new project work order with our CMO. To create performance incentives for our CMO, we have issued a warrant to the CMO to purchase up to 709,500 shares of our common stock. This warrant vests and is only exercisable over time in tranches and only if the CMO achieves certain manufacturing milestones. In issuing this warrant, we relied on the private placement exemption from registration provided by Section 4(a)(2) of the Securities Act.

Use of Proceeds from Public Offering of Common Stock

Not applicable.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

Not applicable.

Item 6. Exhibits

Exhibit Number	Exhibit Description	Incorporated by Reference			
		Form	File No.	Exhibit	Filing Date
3.1	Sixth Amended and Restated Certificate of Incorporation of RenovoRx, Inc.	8-K	001-40738	3.1	August 31, 2021
3.2	Amended and Restated Bylaws of RenovoRx, Inc.	8-K	001-40738	3.1	September 11, 2023
4.1	Form of Private Common Stock Warrant (related to the 2020 Convertible Notes and 2021 Convertible Notes)	10-Q	001-40738	4.1	November 15, 2021
4.2	Form of Underwriter's Warrant	S-1	258071-333-	4.1	August 25, 2021
4.3	Form of Warrant Agent Agreement (including the terms of the Warrants)	S-1	258071-333-	4.2	August 25, 2021
4.4	Specimen Stock Certificate evidencing the Shares of Common Stock	S-1	258071-333-	4.4	August 25, 2021
4.5	Form of Warrant Certificate	S-1	258071-333-	4.5	August 25, 2021
4.6	Form of Pre-Funded Common Stock Purchase Warrant	8-K	40738-001-	4.1	April 3, 2023
4.7	Form of Common Stock Purchase Warrant	8-K	40738-001-	4.2	April 3, 2023
4.8	Warrant to Purchase Common Stock of RenovoRx, Inc.	8-K	40738-001-	10.3	January 29, 2024
4.9	RenovoRx Placement Agent Warrant	8-K	40738-001-	10.5	January 29, 2024
4.10	Form of Pre-Funded Common Stock Purchase Warrant of RenovoRx, Inc.	8-K	001-40738	10.2	April 15, 2024
4.11	Form of Series A Warrant to Purchase Common Stock of RenovoRx, Inc.	8-K	001-40738	10.3	April 15, 2024
4.12	Form of Series B Warrant to Purchase Common Stock of RenovoRx, Inc.	8-K	001-40738	10.4	April 15, 2024
4.13	Form of Placement Agent Warrant to Purchase Common Stock of RenovoRx, Inc.	8-K	001-40738	10.5	April 15, 2024
4.14 [^]	Common Stock Purchase Warrant Issued to Medical Murray, Inc., dated September 25, 2024	Filed herewith			
31.1	Certification of Principal Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	Filed herewith			
31.2	Certification of Principal Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	Filed herewith			
32.1 [†]	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	Furnished herewith			
32.2 [†]	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	Furnished herewith			
101.INS	Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document	Filed herewith			
101.SCH	Inline XBRL Taxonomy Extension Schema Document	Filed herewith			
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document	Filed herewith			
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document	Filed herewith			
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document	Filed herewith			
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document (embedded within the Inline XBRL document)	Filed herewith			
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in the Interactive Data Files submitted as Exhibit 101)	Filed herewith			

[^] Certain portions of this exhibit are omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K because they are not material and are the type that the Company treats as private or confidential. The Company hereby agrees to furnish a copy of any omitted portion to the SEC upon request.

[†] The certifications attached as Exhibits 32.1 and 32.2 that accompany this Quarterly Report on Form 10-Q are deemed furnished and not filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of the Registrant under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Quarterly Report on Form 10-Q, irrespective of any general incorporation language contained in such filing.

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 thereunto duly authorized.

RenovoRx, Inc.

Date: November 13, 2024

By: /s/ Shaun R. Bagai
Shaun R. Bagai
Chief Executive Officer

Date: November 13, 2024

By: /s/ Ronald B. Kocak
Ronald B. Kocak
VP Controller and Principal Accounting Officer

CERTAIN IDENTIFIED INFORMATION (INDICATED BY “**”) HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS BOTH NOT MATERIAL AND WOULD LIKELY CAUSE COMPETITIVE HARM TO THE REGISTRANT IF PUBLICLY DISCLOSED.

NEITHER THIS SECURITY NOR THE SECURITIES FOR WHICH THIS SECURITY IS EXERCISABLE HAVE BEEN REGISTERED WITH THE SECURITIES AND EXCHANGE COMMISSION OR THE SECURITIES COMMISSION OF ANY STATE IN RELIANCE UPON AN EXEMPTION FROM REGISTRATION UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE “SECURITIES ACT”), AND, ACCORDINGLY, MAY NOT BE OFFERED OR SOLD EXCEPT PURSUANT TO AN EFFECTIVE REGISTRATION STATEMENT UNDER THE SECURITIES ACT OR PURSUANT TO AN AVAILABLE EXEMPTION FROM, OR IN A TRANSACTION NOT SUBJECT TO, THE REGISTRATION REQUIREMENTS OF THE SECURITIES ACT AND IN ACCORDANCE WITH APPLICABLE STATE SECURITIES LAWS. THIS SECURITY AND THE SECURITIES ISSUABLE UPON EXERCISE OF THIS SECURITY MAY BE PLEDGED IN CONNECTION WITH A BONA FIDE MARGIN ACCOUNT WITH A REGISTERED BROKER-DEALER OR OTHER LOAN WITH A FINANCIAL INSTITUTION THAT IS AN “ACCREDITED INVESTOR” AS DEFINED IN RULE 501(A) UNDER THE SECURITIES ACT OR OTHER LOAN SECURED BY SUCH SECURITIES.

COMMON STOCK PURCHASE WARRANT

RENOVORX, INC.

Warrant Shares: 709,500

Original Issuance Date: September 25, 2024

THIS COMMON STOCK PURCHASE WARRANT (the “Warrant”) certifies that, for value received, **MEDICAL MURRAY, INC.** or its assigns (the “Holder”) is entitled, upon the terms and subject to the limitations on exercise and the conditions hereinafter set forth, at any time on or after the applicable Initial Exercise Date (as defined and provided for below), and on or prior to 5:00 p.m. (New York City time) on the five year anniversary of the Original Issuance Date (the “Termination Date”) but not thereafter, to subscribe for and purchase from **RENOVORX, INC.**, a Delaware corporation (the “Company”), up to **709,500 shares** (as subject to adjustment and exercisability as provided for herein, the “Warrant Shares”) of the Company’s common stock, par value \$0.0001 per share (the “Common Stock”). The purchase price of one share of Common Stock under this Warrant shall be equal to the Exercise Price, as defined in Section 2(b).

This Warrant is being issued pursuant to the terms of the Supply Agreement.

Section 1. Definitions.

a) “** Lot 1 Finished Goods” means the initial lot of Finished Goods to be produced by Medical Murray for the Company on or before **, in accordance with the terms set forth in the Development Agreement.

b) “** Lot 2 Finished Goods” means the second lot of Finished Goods to be produced by Medical Murray for the Company on or before **, in accordance with the terms set forth in the Development Agreement.

c) “Development Agreement” means all of the following, as applicable: the Medical Murray Quotation dated April 4, 2024 for the RenovoRX T&M Clinical Catheter Build (Proposal Number D07595-80); Medical Murray Quotation dated March 27, 2024 for the RenovoRX T&M Clinical Catheter Build (Proposal Number D07595-90); Medical Murray Quotation dated July 22, 2024 for the RenovoRX T&M Clinical Catheter Build (Proposal Number D0811-30); and RenovoRx Purchase Orders RXT 2024-124, RXT 2024-125 and RXT 2024-126 issued by Company to Medical Murray.

d) “Finished Goods” means the Company products identified by Medical Murray’s Part Number identified in Annex A hereto, which shall strictly conform to the Company’s then-current Specifications and shall be merchantable and fit for Company’s intended purposes for a period equal to the greater of six (6) months from the original date of shipment or such longer warranty period as set forth in the Supply Agreement. Company shall have a right to inspect and accept or reject the Finished Goods upon delivery thereof, and to make a warranty claim or initiate a recall or market withdrawal as set forth in the Supply Agreement, in which case this Warrant becomes non-exercisable with respect to all such products.

e) “Initial Exercise Date” as reflected in the Medical Murray Accelerated Milestones – RNXT Equity Proposal attached hereto as Annex B, means:

- (i) if Medical Murray has delivered at least *** units of the *** Lot 1 Finished Goods on or prior to ***, then ***, with respect to the number of shares ***, but in no case greater than *** Warrant Shares;
- (ii) if Medical Murray has delivered at least *** units of the *** Lot 2 Finished Goods on or prior to ***, then ***, with respect to the number of shares ***, but in no case greater than *** Warrant Shares;
- (iii) if Medical Murray has delivered at least *** units of Finished Goods during the period from ***, through ***, then ***, with respect to the number of shares ***, but in no case greater than *** Warrant Shares;
- (iv) if Medical Murray has delivered at least *** units of Finished Goods during the period from ***, through ***, then ***, with respect to the number of shares ***, but in no case greater than *** Warrant Shares;
- (v) if Medical Murray has delivered at least *** units of Finished Goods during the period from ***, through ***, then ***, with respect to the number of shares ***, but in no case greater than *** Warrant Shares; and
- (vi) if Medical Murray has delivered at least *** units of Finished Goods during the period from ***, through ***, then ***, with respect to the number of shares ***, but in no case greater than *** Warrant Shares.

f) “Medical Murray” means Medical Murray, Inc., an Illinois corporation, the Company’s counterparty to the Supply Agreement.

g) “Person” means an individual or corporation, partnership, trust, incorporated or unincorporated association, joint venture, limited liability company, joint stock company, government (or an agency or subdivision thereof) or other entity of any kind.

h) “Trading Day” means a day on which the principal Trading Market is open for trading.

i) “Specifications” means the functional specifications, drawings and other requirements for the Finished Goods as set forth in the Supply Agreement (which may be modified from time to time by mutual written agreement of the Parties as contemplated therein).

j) “Supply Agreement” means the agreement between Company and Medical Murray for the manufacture and supply of the Finished Goods.

k) “Trading Market” means any of the following markets or exchanges on which the Common Stock is listed or quoted for trading on the date in question: The Nasdaq Capital Market, The Nasdaq Global Market, The Nasdaq Global Select Market, the NYSE American or the New York Stock Exchange (or any successors to the foregoing).

l) “Transfer Agent” means Pacific Stock Transfer Company, the current transfer agent of the Company, with a mailing address of 6725 Via Austi Pkwy, Suite 300, Las Vegas, Nevada 89119, and any successor transfer agent of the Company.

Section 2. Exercise.

a) Exercise of Warrant. Subject to the terms and conditions hereof, exercise of the purchase rights represented by this Warrant may be made, in whole or in part, at any time or times on or after the Initial Exercise Date and on or before the Termination Date (but subject in all instances to the occurrence of a Initial Exercise Date with respect to the Warrant Shares being exercised for) by delivery to the Company of a duly executed facsimile copy or PDF copy submitted by e-mail (or e-mail attachment) of the Notice of Exercise in the form attached hereto as Exhibit A (the “Notice of Exercise”). Within the earlier of (i) two (2) Trading Days and (ii) the number of Trading Days comprising the Standard Settlement Period (as defined in Section 2(d)(i) herein) following the date of exercise as aforesaid, the Holder shall deliver the aggregate Exercise Price for the Warrant Shares specified in the applicable Notice of Exercise by wire transfer or cashier’s check drawn on a United States bank. No ink-original Notice of Exercise shall be required, nor shall any medallion guarantee (or other type of guarantee or notarization) of any Notice of Exercise be required. Notwithstanding anything herein to the contrary, the Holder shall not be required to physically surrender this Warrant to the Company until the Holder has purchased all of the Warrant Shares available hereunder and the Warrant has been exercised in full, in which case, the Holder shall surrender this Warrant to the Company for cancellation within three (3) Trading Days of the date on which the final Notice of Exercise is delivered to the Company. Partial exercises of this Warrant resulting in purchases of a portion of the total number of Warrant Shares available hereunder shall have the effect of lowering the outstanding number of Warrant Shares purchasable hereunder in an amount equal to the applicable number of Warrant Shares purchased. The Holder and the Company shall maintain records showing the number of Warrant Shares purchased and the date of such purchases. The Company shall deliver any objection to any Notice of Exercise within two (2) Trading Days of receipt of such notice. For the avoidance of doubt, if the Company elects to exercise its right to inspect and accept or reject the Finished Goods upon delivery thereof, and to make a warranty claim or initiate a recall or market withdrawal as set forth in the Supply Agreement, then this Warrant may not be exercised with respect to any Warrant Shares which became exercisable as a result of the delivery of such Finished Goods. **The Holder and any assignee, by acceptance of this Warrant, acknowledge and agree that, by reason of the provisions of this paragraph, following the purchase of a portion of the Warrant Shares hereunder, the number of Warrant Shares available for purchase hereunder at any given time may be less than the amount stated on the face hereof.**

b) Exercise Price. The exercise price per share of Common Stock under this Warrant shall be **\$1.01**, subject to adjustment hereunder (the "Exercise Price").

c) Exercisability of Warrant. Notwithstanding anything in this Warrant to the contrary, the Holder shall not have any rights to purchase Warrant Shares hereunder, and such Warrant Shares shall remain unvested, until the performance milestone associated with such Warrant Shares contained within the definition of Initial Exercise Date herein has been achieved by Medical Murray under the Supply Agreement.

d) Mechanics of Exercise.

- i. Delivery of Warrant Shares Upon Exercise. The Company shall cause the Warrant Shares purchased hereunder to be transmitted by the Transfer Agent to the Holder by crediting the account of the Holder's or its designee's balance account with The Depository Trust Company through its Deposit or Withdrawal at Custodian system ("DWAC") if the Company is then a participant in such system and either there is an effective registration statement permitting the public resale of the Warrant Shares, and otherwise by physical delivery of a certificate, registered in the Company's share register in the name of the Holder or its designee, for the number of Warrant Shares to which the Holder is entitled pursuant to such exercise to the address specified by the Holder in the Notice of Exercise by the date that is the earlier of (A) the earlier of (i) two (2) Trading Days and (ii) the number of days comprising the Standard Settlement Period, in each case after the delivery to the Company of the Notice of Exercise and (B) one (1) Trading Day after delivery of the aggregate Exercise Price to the Company (such date, the "Warrant Share Delivery Date"). Upon delivery of the Notice of Exercise, the Holder shall be deemed for all corporate purposes to have become the holder of record of the Warrant Shares with respect to which this Warrant has been exercised, irrespective of the date of delivery of the Warrant Shares, provided that payment of the aggregate Exercise Price is received by the Warrant Share Delivery Date. As used herein, "Standard Settlement Period" means the standard settlement period, expressed in a number of Trading Days, on the Company's primary Trading Market with respect to the Common Stock as in effect on the date of delivery of the Notice of Exercise.
- ii. Delivery of New Warrants Upon Exercise. If this Warrant shall have been exercised in part, the Company shall, at the request of a Holder and upon surrender of this Warrant certificate, at the time of delivery of the Warrant Shares, deliver to the Holder a new Warrant evidencing the rights of the Holder to purchase the unpurchased Warrant Shares called for by this Warrant, which new Warrant shall in all other respects be identical with this Warrant.
- iii. Rescission Rights. If the Company fails to cause the Transfer Agent to transmit to the Holder the Warrant Shares pursuant to Section 2(d)(i) by the Warrant Share Delivery Date, then the Holder will have the right to rescind such exercise.
- iv. No Fractional Shares or Scrip. No fractional shares or scrip representing fractional shares shall be issued upon the exercise of this Warrant. As to any fraction of a share which the Holder would otherwise be entitled to purchase upon such exercise, the Company shall, at its election, either pay a cash adjustment in respect of such final fraction in an amount equal to such fraction multiplied by the Exercise Price or round up to the next whole share.
- v. Charges, Taxes and Expenses. Issuance of Warrant Shares shall be made without charge to the Holder for any issue or transfer tax or other incidental expense in respect of the issuance of such Warrant Shares, all of which taxes and expenses shall be paid by the Company, and such Warrant Shares shall be issued in the name of the Holder or in such name or names as may be directed by the Holder; provided, however, that in the event that Warrant Shares are to be issued in a name other than the name of the Holder, this Warrant when surrendered for exercise shall be accompanied by the Assignment Form attached hereto duly executed by the Holder and the Company may require, as a condition thereto, the payment of a sum sufficient to reimburse it for any transfer tax incidental thereto. The Company shall pay all Transfer Agent fees required for same-day processing of any Notice of Exercise and all fees to the Depository Trust Company (or another established clearing corporation performing similar functions) required for same-day electronic delivery of the Warrant Shares.

- vi. Closing of Books. The Company will not close its stockholder books or records in any manner which prevents the timely exercise of this Warrant, pursuant to the terms hereof.

e) Holder's Exercise Limitations. The Company shall not affect any exercise of this Warrant, and a Holder shall not have the right to exercise any portion of this Warrant, pursuant to Section 2 or otherwise, to the extent that after giving effect to such issuance after exercise as set forth on the applicable Notice of Exercise, the Holder (together with the Holder's Affiliates, and any other Persons acting as a group together with the Holder or any of the Holder's Affiliates (such Persons, "Attribution Parties")), would beneficially own in excess of the Beneficial Ownership Limitation (as defined below). For purposes of the foregoing sentence, the number of shares of Common Stock beneficially owned by the Holder and its Affiliates and Attribution Parties shall include the number of shares of Common Stock issuable upon exercise of this Warrant with respect to which such determination is being made, but shall exclude the number of shares of Common Stock which would be issuable upon (i) exercise of the remaining, nonexercised portion of this Warrant beneficially owned by the Holder or any of its Affiliates or Attribution Parties and (ii) exercise or conversion of the unexercised or nonconverted portion of any other securities of the Company (including, without limitation, any other Common Stock Equivalents) subject to a limitation on conversion or exercise analogous to the limitation contained herein beneficially owned by the Holder or any of its Affiliates or Attribution Parties. Except as set forth in the preceding sentence, for purposes of this Section 2(e), beneficial ownership shall be calculated in accordance with Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder, it being acknowledged by the Holder that the Company is not representing to the Holder that such calculation is in compliance with Section 13(d) of the Exchange Act and the Holder is solely responsible for any schedules required to be filed in accordance therewith. To the extent that the limitation contained in this Section 2(e) applies, the determination of whether this Warrant is exercisable (in relation to other securities owned by the Holder together with any Affiliates and Attribution Parties) and of which portion of this Warrant is exercisable shall be in the sole discretion of the Holder, and the submission of a Notice of Exercise shall be deemed to be the Holder's determination of whether this Warrant is exercisable (in relation to other securities owned by the Holder together with any Affiliates and Attribution Parties) and of which portion of this Warrant is exercisable, in each case subject to the Beneficial Ownership Limitation, and the Company shall have no obligation to verify or confirm the accuracy of such determination and shall have no liability for exercises of the Warrant that are not in compliance with the Beneficial Ownership Limitation, except to the extent the Holder relies on a number of outstanding shares of Common Stock that was provided by the Company. In addition, a determination as to any group status as contemplated above shall be determined in accordance with Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder, and the Company shall have no obligation to verify or confirm the accuracy of such determination and shall have no liability for exercises of the Warrant that are not in compliance with the Beneficial Ownership Limitation, except to the extent the Holder relies on the number of outstanding shares of Common Stock that was provided by the Company. For purposes of this Section 2(e), in determining the number of outstanding shares of Common Stock, a Holder may rely on the number of outstanding shares of Common Stock as reflected in (A) the Company's most recent periodic or annual report filed with the Commission, as the case may be, (B) a more recent public announcement by the Company or (C) a more recent written notice by the Company or the Transfer Agent setting forth the number of shares of Common Stock outstanding. Upon the written request of a Holder, the Company shall within two (2) Trading Days confirm orally and in writing to the Holder the number of shares of Common Stock then outstanding. In any case, the number of outstanding shares of Common Stock shall be determined after giving effect to the conversion or exercise of securities of the Company, including this Warrant, by the Holder or its Affiliates or Attribution Parties since the date as of which such number of outstanding shares of Common Stock was reported. The "Beneficial Ownership Limitation" shall be 9.99% of the number of shares of the Common Stock outstanding immediately after giving effect to the issuance of shares of Common Stock issuable upon exercise of this Warrant. The Holder, upon written notice to the Company, may increase or decrease the Beneficial Ownership Limitation provisions of this Section 2(e), provided that the Beneficial Ownership Limitation in no event exceeds 9.99% of the number of shares of the Common Stock outstanding immediately after giving effect to the issuance of shares of Common Stock upon exercise of this Warrant held by the Holder and the provisions of this Section 2(e) shall continue to apply. Any increase in the Beneficial Ownership Limitation will not be effective until the 61st day after such notice is delivered to the Company. The provisions of this paragraph shall be construed and implemented in a manner otherwise than in strict conformity with the terms of this Section 2(e) to correct this paragraph (or any portion hereof) which may be defective or inconsistent with the intended Beneficial Ownership Limitation herein contained or to make changes or supplements necessary or desirable to properly give effect to such limitation. In addition, the limitations contained in this paragraph shall apply to a successor holder of this Warrant. If the Warrant is unexercisable as a result of the Holder's Beneficial Ownership Limitation, no alternate consideration is owing to the Holder.

Section 3. Certain Adjustments.

a) Stock Dividends and Splits. If the Company, at any time while this Warrant is outstanding: (i) pays a stock dividend or otherwise makes a distribution or distributions on shares of its Common Stock or any other equity or equity equivalent securities payable in shares of Common Stock (which, for avoidance of doubt, shall not include any shares of Common Stock issued by the Company upon exercise of this Warrant), (ii) subdivides outstanding shares of Common Stock into a larger number of shares, (iii) combines (including by way of reverse stock split) outstanding shares of Common Stock into a smaller number of shares, or (iv) issues by reclassification of shares of the Common Stock any shares of capital stock of the Company, then in each case the Exercise Price shall be multiplied by a fraction of which the numerator shall be the number of shares of Common Stock (excluding treasury shares, if any) outstanding immediately before such event and of which the denominator shall be the number of shares of Common Stock outstanding immediately after such event, and the number of shares issuable upon exercise of this Warrant shall be proportionately adjusted such that the aggregate Exercise Price of this Warrant shall remain unchanged. Any adjustment made pursuant to this Section 3(a) shall become effective immediately after the record date for the determination of stockholders entitled to receive such dividend or distribution and shall become effective immediately after the effective date in the case of a subdivision, combination or re-classification.

b) Fundamental Transaction. If, at any time while this Warrant is outstanding, (i) the Company, directly or indirectly, in one or more related transactions effects any merger or consolidation of the Company with or into another Person, (ii) the Company (or any Subsidiary), directly or indirectly, effects any sale, lease, license, assignment, transfer, conveyance or other disposition of all or substantially all of the Company's assets in one or a series of related transactions, (iii) any, direct or indirect, purchase offer, tender offer or exchange offer (whether by the Company or another Person) is completed pursuant to which holders of Common Stock are permitted to sell, tender or exchange their shares for other securities, cash or property and has been accepted by the holders of more than 50% of the aggregate voting power of the common equity of the Company, (iv) the Company, directly or indirectly, in one or more related transactions effects any reclassification, reorganization or recapitalization of shares of Common Stock or any compulsory share exchange pursuant to which the shares of Common Stock are effectively converted into or exchanged for other securities, cash or property, or (v) the Company, directly or indirectly, in one or more related transactions consummates a stock or share purchase agreement or other business combination (including, without limitation, a reorganization, recapitalization, spin-off, merger or scheme of arrangement) with another Person or group of Persons whereby such other Person or group acquires more than 50% of the aggregate voting power of the common equity of the Company (not including any shares of Common Stock held by the other Person or other Persons making or party to, or associated or affiliated with the other Persons making or party to, such stock or share purchase agreement or other business combination) (each a "Fundamental Transaction"), then, upon any subsequent exercise of this Warrant, the Holder shall have the right to receive, for each Warrant Share that would have been issuable upon such exercise immediately prior to the occurrence of such Fundamental Transaction, which, for the avoidance of doubt does not include any Warrant Shares subject to an Initial Exercise Date that has not yet occurred, at the option of the Holder (without regard to any limitation in Section 2(e) on the exercise of this Warrant), the number of shares of Common Stock of the successor or acquiring corporation or of the Company, if it is the surviving corporation, and any additional consideration (the "Alternate Consideration") receivable as a result of such Fundamental Transaction by a holder of the number of shares of Common Stock for which this Warrant is exercisable immediately prior to such Fundamental Transaction (without regard to any limitation in Section 2(e) on the exercise of this Warrant, but excluding any Warrant Shares subject to an Initial Exercise Date that has not yet occurred). For purposes of any such exercise, the determination of the Exercise Price shall be appropriately adjusted to apply to such Alternate Consideration based on the amount of Alternate Consideration issuable in respect of one share of Common Stock in such Fundamental Transaction, and the Company shall apportion the Exercise Price among the Alternate Consideration in a reasonable manner reflecting the relative value of any different components of the Alternate Consideration. If holders of Common Stock are given any choice as to the securities, cash or property to be received in a Fundamental Transaction, then the Holder shall be given the same choice as to the Alternate Consideration it receives upon any exercise of this Warrant following such Fundamental Transaction.

c) Calculations. All calculations under this Section 3 shall be made to the nearest cent or the nearest 1/100th of a share, as the case may be. For purposes of this Section 3, the number of shares of Common Stock deemed to be issued and outstanding as of a given date shall be the sum of the number of shares of Common Stock (excluding treasury shares, if any) issued and outstanding.

d) Voluntary Adjustment by Company. Subject to the rules and regulations of the Trading Market, the Company may at any time during the term of this Warrant, subject to the prior written consent of the Holder, reduce the then current Exercise Price to any amount and for any period of time deemed appropriate by the board of directors of the Company.

Section 4. Transfer of Warrant

a) Transferability. This Warrant and all rights hereunder are transferable, in whole or in part, with the prior written consent of the Company, upon surrender of this Warrant at the principal office of the Company or its designated agent, together with a written assignment of this Warrant substantially in the form attached hereto duly executed by the Holder or its agent or attorney and funds sufficient to pay any transfer taxes payable upon the making of such transfer. Any such request for assignment must be accompanied by the name of the proposed assignee and the number of Warrant Shares subject to such assignment, together with such other reasonable information the Company may request to ensure the assignment complies with applicable law. Upon such surrender and, if required, such payment, the Company shall execute and deliver a new Warrant or Warrants in the name of the assignee or assignees, as applicable, and in the denomination or denominations specified in such instrument of assignment, and shall issue to the assignor a new Warrant evidencing the portion of this Warrant not so assigned, and this Warrant shall promptly be cancelled. Notwithstanding anything herein to the contrary, the Holder shall not be required to physically surrender this Warrant to the Company unless the Holder has assigned this Warrant in full, in which case, the Holder shall surrender this Warrant to the Company within three (3) Trading Days of the date on which the Holder delivers an assignment form to the Company assigning this Warrant in full. The Warrant, if properly assigned in accordance herewith, may be exercised by a new holder for the purchase of Warrant Shares without having a new Warrant issued.

b) Upon the written consent the Company as required by Section 4(a), subject to the Holder's compliance with the restrictive legend on this Warrant and the transfer restrictions set forth herein, this Warrant and all rights hereunder are transferable, in whole or in part, upon surrender of this Warrant at the principal office of the Company or its designated agent, together with a written assignment of this Warrant substantially in the form attached hereto as Exhibit B duly executed by the Holder or its agent or attorney and funds sufficient to pay any transfer taxes payable upon the making of such transfer. Upon such surrender and, if required, such payment, the Company shall execute and deliver a new Warrant or Warrants in the name of the assignee or assignees, as applicable, and in the denomination or denominations specified in such instrument of assignment, and shall issue to the assignor a new Warrant evidencing the portion of this Warrant not so assigned, and this Warrant shall promptly be cancelled. Notwithstanding anything herein to the contrary, the Holder shall not be required to physically surrender this Warrant to the Company unless the Holder has assigned this Warrant in full, in which case, the Holder shall surrender this Warrant to the Company within three (3) Trading Days of the date on which the Holder delivers an assignment form to the Company assigning this Warrant in full. The Warrant, if properly assigned in accordance herewith, may be exercised by a new holder for the purchase of Warrant Shares or Exchange Warrants without having a new Warrant issued.

c) New Warrants. This Warrant may be divided or combined with other Warrants upon presentation hereof at the aforesaid office of the Company, together with a written notice specifying the names and denominations in which new Warrants are to be issued, signed by the Holder or its agent or attorney. Subject to compliance with Section 4(a), as to any transfer which may be involved in such division or combination, the Company shall execute and deliver a new Warrant or Warrants in exchange for the Warrant or Warrants to be divided or combined in accordance with such notice. All Warrants issued on transfers or exchanges shall be dated the Issue Date of this Warrant and shall be identical with this Warrant except as to the number of Warrant Shares issuable pursuant thereto.

d) Warrant Register. The Company shall register this Warrant, upon records to be maintained by the Company for that purpose (the "Warrant Register"), in the name of the record Holder hereof from time to time. The Company may deem and treat the registered Holder of this Warrant as the absolute owner hereof for the purpose of any exercise hereof or any distribution to the Holder, and for all other purposes, absent actual notice to the contrary.

e) Representation by the Holder. The Holder, by the acceptance hereof, represents and warrants that it is acquiring this Warrant and, upon any exercise hereof, will acquire the Warrant Shares issuable upon such exercise, for its own account and not with a view to or for distributing or reselling such Warrant Shares or any part thereof in violation of the Securities Act or any applicable state securities law, except pursuant to sales registered or exempted under the Securities Act.

Section 5. Miscellaneous.

a) No Rights as Stockholder Until Exercise; No Settlement in Cash. This Warrant does not entitle the Holder to any voting rights, dividends or other rights as a stockholder of the Company prior to the exercise hereof as set forth in Section 2(d)(i), except as expressly set forth in Section 3. Without limiting the rights of a Holder to receive the cash payments contemplated pursuant to Section 2(d)(iv), in no event will the Company be required to net cash settle an exercise of this Warrant.

b) Loss, Theft, Destruction or Mutilation of Warrant. The Company covenants that upon receipt by the Company of evidence reasonably satisfactory to it of the loss, theft, destruction or mutilation of this Warrant or any stock certificate relating to the Warrant Shares, and in case of loss, theft or destruction, of indemnity or security reasonably satisfactory to it (which, in the case of the Warrant, shall not include the posting of any bond), and upon surrender and cancellation of such Warrant or stock certificate, if mutilated, the Company will make and deliver a new Warrant or stock certificate of like tenor and dated as of such cancellation, in lieu of such Warrant or stock certificate.

c) Saturdays, Sundays, Holidays, etc. If the last or appointed day for the taking of any action or the expiration of any right required or granted herein shall not be a Trading Day, then, such action may be taken or such right may be exercised on the next succeeding Trading Day.

d) Authorized Shares. The Company covenants that, at all times during the period the Warrant is outstanding, it will reserve from its authorized and unissued Common Stock a sufficient number of shares to provide for the issuance of the Warrant Shares upon the exercise of any purchase rights under this Warrant. The Company further covenants that its issuance of this Warrant shall constitute full authority to its officers who are charged with the duty of issuing the necessary Warrant Shares upon the exercise of the purchase rights under this Warrant. The Company will take all such reasonable action as may be necessary to assure that such Warrant Shares may be issued as provided herein without violation of any applicable law or regulation, or of any requirements of the Trading Market upon which the Common Stock may be listed. The Company covenants that all Warrant Shares which may be issued upon the exercise of the purchase rights represented by this Warrant will, upon exercise of the purchase rights represented by this Warrant and payment for such Warrant Shares in accordance herewith, be duly authorized, validly issued, fully paid and nonassessable and free from all taxes, liens and charges created by the Company in respect of the issue thereof (other than taxes in respect of any transfer occurring contemporaneously with such issue).

Except and to the extent as waived or consented to by the Holder, the Company shall not by any action, including, without limitation, amending its certificate of incorporation or through any reorganization, transfer of assets, consolidation, merger, dissolution, issue or sale of securities or any other voluntary action, avoid or seek to avoid the observance or performance of any of the terms of this Warrant, but will at all times in good faith assist in the carrying out of all such terms and in the taking of all such actions as may be necessary or appropriate to protect the rights of Holder as set forth in this Warrant against impairment (it being understood that this Warrant shall not in any case prevent the Company from effecting any such amendment, reorganization, transfer, consolidation, merger, dissolution, issuance or sale). Without limiting the generality of the foregoing, the Company will (i) not increase the par value of any Warrant Shares above the amount payable therefor upon such exercise immediately prior to such increase in par value, (ii) take all such action as may be necessary or appropriate in order that the Company may validly and legally issue fully paid and nonassessable Warrant Shares upon the exercise of this Warrant and (iii) use commercially reasonable efforts to obtain all such authorizations, exemptions or consents from any public regulatory body having jurisdiction thereof, as may be, necessary to enable the Company to perform its obligations under this Warrant.

Before taking any action, which would result in an adjustment in the number of Warrant Shares for which this Warrant is exercisable or in the Exercise Price, the Company shall obtain all such authorizations or exemptions thereof, or consents thereto, as may be necessary from any public regulatory body or bodies having jurisdiction thereof.

e) Jurisdiction. All questions concerning the construction, validity, enforcement and interpretation of this Warrant shall be determined in accordance with the provisions of the Supply Agreement.

f) Restrictions. The Holder acknowledges that the Warrant Shares acquired upon the exercise of this Warrant, if not registered, will have restrictions upon resale imposed by state and federal securities laws.

g) Nonwaiver and Expenses. No course of dealing or any delay or failure to exercise any right hereunder on the part of Holder shall operate as a waiver of such right or otherwise prejudice the Holder's rights, powers or remedies, notwithstanding the fact that the right to exercise this Warrant terminates on the Termination Date. Without limiting any other provision of this Warrant, if the Company willfully and knowingly fails to comply with any provision of this Warrant, which results in any material damages to the Holder, the Company shall pay to the Holder such amounts as shall be sufficient to cover any costs and expenses including, but not limited to, reasonable attorneys' fees, including those of appellate proceedings, incurred by the Holder in collecting any amounts due pursuant hereto or in otherwise enforcing any of its rights, powers or remedies hereunder.

h) Notices. Any notice, request or other document required or permitted to be given or delivered to the Holder by the Company shall be delivered in accordance with the notice provisions of the Supply Agreement.

i) Limitation of Liability. No provision hereof, in the absence of any affirmative action by the Holder to exercise this Warrant to purchase Warrant Shares, and no enumeration herein of the rights or privileges of the Holder, shall give rise to any liability of the Holder for the purchase price of any Common Stock or as a stockholder of the Company, whether such liability is asserted by the Company or by creditors of the Company.

j) Remedies. The Holder, in addition to being entitled to exercise all rights granted by law, including recovery of damages, will be entitled to specific performance of its rights under this Warrant. The Company agrees that monetary damages would not be adequate compensation for any loss incurred by reason of a breach by it of the provisions of this Warrant and hereby agrees to waive and not to assert the defense in any action for specific performance that a remedy at law would be adequate.

k) Successors and Assigns. Subject to applicable securities laws, this Warrant and the rights and obligations evidenced hereby shall inure to the benefit of and be binding upon the successors and permitted assigns of the Company and the successors and permitted assigns of Holder. The provisions of this Warrant are intended to be for the benefit of any Holder from time to time of this Warrant and shall be enforceable by the Holder or holder of Warrant Shares.

l) Amendment. This Warrant may only be modified or amended, or the provisions hereof waived, with the written consent of the Company, on the one hand, and the Holder of this Warrant, on the other hand.

m) Severability. Wherever possible, each provision of this Warrant shall be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Warrant shall be prohibited by or invalid under applicable law, such provision shall be ineffective to the extent of such prohibition or invalidity, without invalidating the remainder of such provisions or the remaining provisions of this Warrant.

n) Headings. The headings used in this Warrant are for the convenience of reference only and shall not, for any purpose, be deemed a part of this Warrant.

(Signature Page Follows)

IN WITNESS WHEREOF, the Company has caused this Warrant to be executed by its officer thereunto duly authorized as of the date first above indicated.

RENOVORX, INC.

By: /s/ Shaun R. Bagai

Name: Shaun R. Bagai

Title: Chief Executive Officer

[SIGNATURE PAGE TO COMMON STOCK PURCHASE WARRANT, RENOVORX INC.]

NOTICE OF EXERCISE

TO: **RENOVORX, INC.**

(1) The undersigned hereby elects to purchase _____ Warrant Shares of the Company pursuant to the terms of the attached Warrant (only if exercised in full), and tenders herewith payment of the exercise price in full, together with all applicable transfer taxes, if any.

(2) Please issue said Warrant Shares in the name of the undersigned or in such other name as is specified below:

The Warrant Shares shall be delivered to the following DWAC Account Number:

[SIGNATURE OF HOLDER]

Name of Investing Entity: _____

Signature of Authorized Signatory of Investing Entity: _____

Name of Authorized Signatory: _____

Title of Authorized Signatory: _____

Date: _____

ASSIGNMENT FORM

(To assign the foregoing Warrant, execute this form and supply required information. Do not use this form to exercise the Warrant to purchase shares.)

FOR VALUE RECEIVED, the foregoing Warrant and all rights evidenced thereby are hereby assigned to

Name: _____
(Please Print)

Address: _____
(Please Print)

Phone Number: _____

Email Address: _____

Dated: _____, _____

Holder's Signature: _____

Holder's Address: _____

Annex A
Finished Goods

RenovoCath

Annex B

Medical Murray Accelerated Milestone - RNXT Equity Proposal

	<u>Year</u>	<u>Unit Targets</u>	<u>Deliver by Date</u>	<u>Goal</u>	<u>Min Max Units</u>	<u>Shares/ Unit to FG</u>	<u>Max Shares Achievable</u>
***	***	***	***	***	***	***	***

					Total		709,500

Note: FG = finished goods

**CERTIFICATION PURSUANT TO
RULES 13A-14(A) AND 15D-14(A) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Shaun R. Bagai, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of RenovoRx, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 13, 2024

By: /s/ Shaun R. Bagai
Chief Executive Officer

**CERTIFICATION PURSUANT TO
RULES 13A-14(A) AND 15D-14(A) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Ronald B. Kocak, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of RenovoRx, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 13, 2024

By: /s/ Ronald B. Kocak
VP Controller and Principal Accounting Officer

**CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of RenovoRx, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Shaun R. Bagai, hereby certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that:

- 1) The Report of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- 2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 13, 2024

By: /s/ Shaun R. Bagai
Chief Executive Officer

**CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of RenovoRx, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Ronald B. Kocak, hereby certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that:

- 1) The Report of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- 2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 13, 2024

By: */s/ Ronald B. Kocak*

VP Controller and Principal Accounting Officer
