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 March 31, 2025

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	**27-1448452**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
2570 West El Camino Real, Suite 320 Mountain View, California	
(Address of principal executive offices)	**94040 (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, a 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 May 9, 2025, the registrant had 36,572,232 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 (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 significant risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control. All statements other than present and historical facts and conditions contained in this Report, including statements regarding our future revenues, our ongoing clinical trial and other 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," "would," "in the future" 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 significant 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;
- our estimates regarding future revenue, expenses, 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 Phase III TIGeR-PaC trial and potential future clinical trials;
- projections for the timing for enrollment of our clinical trials and our expectations relating to the timing of the provision of updates on, public announcements (if any) for interim or top line data from, and completion of our clinical trials (notably our ongoing Phase III TIGeR-PaC trial);
- 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 technology, devices and 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 our catheter on a standalone basis;
- 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 addressable market opportunities and our ability to successfully penetrate such market opportunities;

- the success of competing therapies or devices that are or may become available;
- developments relating to our competitors and our industry, including competing product candidates, therapies and devices;
- our plans relating to the further development and manufacturing of our devices and 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 significant risks, uncertainties, assumptions and other factors described in the section titled "Risk Factors" and elsewhere in this Report, in our Annual Report on Form 10-K for the year ended December 31, 2024 and our other SEC filings and public statements. 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*)

	March 31, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 14,582	$ 7,154
Accounts receivable	242	43
Prepaid expenses	477	328
Other current assets	444	303
Total current assets	15,745	7,828
Right-of-use operating asset	256	278
Property and equipment, net	13	12
Total assets	$ 16,014	$ 8,118
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 967	$ 586
Accrued expenses	769	1,323
Total current liabilities	1,736	1,909
Common stock warrant liability	935	1,519
Operating lease liability, net of current portion	186	212
Total liabilities	2,857	3,640
Commitments and contingencies (Note 6)		
Convertible preferred stock and stockholders' equity:		
Convertible preferred stock, $0.0001 par value; 15,000,000 shares authorized as of March 31, 2025, and December 31, 2024, respectively; no shares issued and outstanding at March 31, 2025, and December 31, 2024	-	-
Common stock, $0.0001 par value, 250,000,000 shares authorized at March 31, 2025, and December 31, 2024; 36,546,752 and 24,034,672 shares issued and outstanding as of March 31, 2025, and December 31, 2024, respectively	4	2
Additional paid-in capital	65,792	54,695
Accumulated deficit	(52,639)	(50,219)
Total convertible preferred stock and stockholders' equity	13,157	4,478
Total liabilities, convertible preferred stock and stockholders' equity	$ 16,014	$ 8,118

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 March 31,	
	2025	**2024**
Revenues	$ 197	$ -
Cost of revenues	94	-
Gross profit	103	-
Operating expenses:		
Research and development	1,642	1,257
Selling, general and administrative	1,571	1,219
Total operating expenses	3,213	2,476
Loss from operations	(3,110)	(2,476)
Other income:		
Interest and dividend income	106	37
Change in fair value of common warrant liability	584	1,363
Total other income	690	1,400
Net loss	$ (2,420)	$ (1,076)
Net loss per share, basic and diluted	$ (0.08)	$ (0.07)
Weighted-average shares of common stock outstanding, basic and diluted	31,395,888	14,947,500

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	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Deficit	Equity
Balance — December 31, 2024	-	$ -	24,034,672	$ 2	$ 54,695	$ (50,219)	$ 4,478
Issuance of common stock upon equity financing, net of issuance cost	-	-	11,523,810	2	10,801	-	10,803
Issuance of common stock upon exercise of pre-funded common warrants			951,500	-	-	-	-
Issuance of restricted stock awards	-	-	30,000	-	-	-	-
Issuance of common stock upon exercise of stock options			6,770	-	8	-	8
Stock-based compensation expense	-	-	-	-	288	-	288
Net loss	-	-	-	-	-	(2,420)	(2,420)
Balance — March 31, 2025	-	$ -	36,546,752	$ 4	$ 65,792	$ (52,639)	$ 13,157

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	Accumulated	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Capital	Deficit	(Deficit)
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

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

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

	Three Months Ended March 31,	
	2025	**2024**
Cash flows from operating activities:		
Net loss	$ (2,420)	$ (1,076)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	288	423
Noncash lease expense	22	-
Depreciation expense	1	-
Change in fair value of common warrants classified as a liability	(584)	(1,362)
Changes in operating assets and liabilities:		
Accounts receivable	(199)	-
Prepaid expenses	(149)	(53)
Other current assets	(141)	(26)
Deferred offering costs	-	(27)
Accounts payable	381	(206)
Accrued expenses	(580)	123
Net cash used in operating activities	(3,381)	(2,204)
Cash flows from investing activities:		
Purchase of property and equipment	(2)	-
Net cash used in investing activities	(2)	-
Cash flows from financing activities:		
Proceeds from equity financing, net of issuance cost	10,803	-
Proceeds from private placement offering, net of offering costs	-	5,378
Proceeds from exercise of stock options	8	42
Net cash provided by financing activities	10,811	5,420
Net increase in cash and cash equivalents	7,428	3,216
Cash and cash equivalents:		
Beginning of period	7,154	1,173
End of period	$ 14,582	$ 4,389
Supplemental Disclosure of Cash Flow Information:		
Cash paid for income taxes	$ 1	$ -
Cash paid for interest	$ 5	$ -
Supplemental Disclosure of Noncash Financing Activities:		
Fair value of common warrant classified as a liability	$ -	$ 1,928

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

1. Business and Principal Activities

Description of Business

RenovoRx, Inc. (the "Company") was incorporated in the state of Delaware in December 2012 and operates from its headquarters in Mountain View, California. The Company is a life sciences company offering RenovoCath®, a novel, U.S. Food and Drug Administration ("FDA")-cleared local drug-delivery device, targeting high unmet medical needs, with a present focus on difficult to treat cancers. The Company is both a clinical stage and a commercial stage enterprise. The Company's clinical stage lead product candidate is a novel drug-device combination product consisting of intra-arterial delivery of the chemotherapy gemcitabine via RenovoCath and which is referred to herein as "IAG." IAG is currently the subject of a pivotal Phase III clinical study (known as the TIGeR-PaC study) for the treatment of locally advanced pancreatic cancer ("LAPC"). At the same time, the Company is commercializing RenovoCath for standalone use by interventional radiologists, oncologists and other medical professionals who can use RenovoCath to treat patients within RenovoCath's FDA-cleared fields of use.

Liquidity and Capital Resources

From the Company's inception through March 31, 2025, it has raised an aggregate of $71.4 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"), registered and unregistered sales 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 proceeds raised since inception were $64.3 million. As of March 31, 2025, the Company had cash and cash equivalents of $14.6 million. As used herein, the term "common stock" refers to the Company's common stock, par value $0.0001 per share.

The Company has incurred significant losses and negative cash flows from operations since its inception. For the three months ended March 31, 2025, the Company reported a net loss of $2.4 million and an accumulated deficit of $52.6 million and does not expect to generate positive cash flows from operations unless and until its commercialization activities for RenovoCath as a standalone device (which activities remain in the relatively early stages) generate sufficient revenues. The Company expects to continue to incur significant losses until regulatory approval is granted for its first drug-device combination product candidate, IAG, or until revenues from RenovoCath commercialization increase substantially. Regulatory approval is not guaranteed and may never be obtained, and the Company's plans to grow RenovoCath revenue may not be achieved at levels anticipated, or at all. The Company may also pursue other revenue-generating strategies such as licensing or collaboration agreements. 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 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.

The Company has filed an omnibus shelf registration statement on Form S-3 (No. 333-268302) (the "Shelf Registration Statement") 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.

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 offering 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, or January 26, 2029. 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, 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 offering 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.

On February 10, 2025, the Company closed an underwritten public offering of common stock, in connection with a takedown from the Shelf Registration Statement (the "February 2025 Offering"), and received gross proceeds of approximately $12.1 million. The net proceeds were $10.8 million after deducting underwriting fees of $0.8 million and other professional expenses of $0.5 million. The Company issued an aggregate 11,523,810 shares of its common stock in this offering and issued to the underwriters of this offering underwriter warrants to purchase 576,191 shares of common stock at $1.21 per share over a 5-year term.

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 its current cash and cash equivalents will be sufficient to fund its operations through at least the next 12 months from the issuance of this Report.

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, 2024, is derived from the Company's audited financial statements. The results of operations for the three months ended March 31, 2025, are not necessarily indicative of the results to be expected for the year ending December 31, 2025, 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 three months ended March 31, 2025 from those previously disclosed in the Company's Annual Report on Form 10-K for the year ended December 31, 2024 filed with the SEC on April 1, 2025 (the "2024 Annual Report"), other than the accounting policies adopted in connection with the Company's February 2025 Offering as described below.

February 2025 Offering

The Company evaluated the underwriter warrants Common issued in connection with the February 2025 Offering in accordance with ASC Topic 480, *Distinguishing Liabilities from Equity* and ASC 815-40, *Derivatives and Hedging – Contracts in Entity's Own Entity* and concluded that the underwriter warrants are freestanding financial instruments, meeting ASC Topic 480's criteria for legal detachment and separate exercisability from the common stock. The underwriter 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 underwriter warrants are dilutive but not participating securities before exercise, ensuring no impact on basic EPS until shares are issued.

Risks and Uncertainties

The Company and its business are subject to a number of significant risks associated with clinical-stage and early commercial stage life science companies, including the risks associated with (i) its relatively early stage commercialization efforts for RenovoCath, (ii) the development of IAG or other product candidates that must receive regulatory approval before market launch, (iii) possible failure of current or future preclinical studies or clinical trials, (iv) dependence on key third parties such as device manufacturers and providers of clinical trial administration services; (v) the need to obtain and maintain insurance coding for its products and product candidates, (vi) dependence on key officer and employees, (vii) competition from larger and more established companies, (viii) obtaining and maintaining intellectual property protections, (ix) changes in the Company's technology or industry, (x) volatility in the public capital markets, (xi) the Company's ability to obtain adequate financing when needed to support the Company's business plan, (xii) the ability to attract and retain additional qualified personnel to manage the anticipated growth of the Company and (xiii) general economic and political conditions.

Use of Estimates

The preparation of condensed interim financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, revenue, income and expenses as well as the disclosure of contingent assets and liabilities, at the date of the condensed interim financial statements during the reporting periods. In preparing these condensed interim financial statements, management has made its best estimates and judgments of certain amounts included in the condensed interim financial statements. Significant estimates and assumptions made in the accompanying condensed interim financial statements include, but are not limited to, accruals of certain liabilities, including clinical trial accruals and other contingences, 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 expects to lose its status as an emerging growth company status as of December 31, 2026, the last day of the fiscal year following the fifth anniversary of the closing its August 2021 initial public.

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

Accounting Pronouncements Not Yet Adopted

In December 2023, FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures* (ASU 2023-09). ASU 2023-09 modifies the rules on income tax disclosures to enhance the transparency and decision-usefulness of income tax disclosures, particularly in the rate reconciliation table and disclosures about income taxes paid. The amendments are intended to address investors' requests for income tax disclosures that provide more information to help them better understand an entity's exposure to potential changes in tax laws and the ensuing risks and opportunities and to assess income tax information that affects cash flow forecasts and capital allocation decisions. The guidance also eliminates certain existing disclosure requirements related to uncertain tax positions and unrecognized deferred tax liabilities. The guidance is effective for all entities for annual periods beginning after December 15, 2025. All entities should apply the guidance prospectively but have the option to apply it retrospectively. Early adoption is permitted. The Company is continuing to assess the timing of adoption and the potential impacts of ASU 2023-09 on the financial statements and related disclosures.

In November 2024, the FASB issued ASU 2024-03, *Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures (Subtopic 220-40)* (ASU 2024-03). ASU 2024-03 modifies the rules on income statement disclosures to enhance the transparency of and include more detailed information about the types of expenses, including purchases of inventory, employee compensation, depreciation, amortization, and depletion, in commonly presented expense captions such as cost of sales, research and development, and selling, general and administrative expenses. The amendments are intended to address investors' requests for income statement expense disclosures that provide more information to help them better understand the components of an entity's expenses, make their own judgments about the entity's performance, and more accurately forecast expenses, and enable investors to better assess an entity's prospects for future cash flows. It will also provide contextual information for an entity's presentation and consideration of management's discussion and analysis of financial position and results of operations. The guidance is effective for all entities for annual periods beginning after December 15, 2026. All entities should apply the guidance prospectively but have the option to apply it retrospectively. Early adoption is permitted. The Company is continuing to assess the timing of adoption and the potential impacts of ASU 2024-03 on the financial statements and related disclosures.

3. Fair Value Measurements

As of March 31, 2025, and December 31, 2024, the Company held cash equivalents of $14.4 million and $7.0 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 (in thousands):

	March 31, 2025			
Assets	**Level 1**	**Level 2**	**Level 3**	**Total**
Cash equivalents:				
Money market funds	$ 14,369	$ -	$ -	$ 14,369
	$ 14,369	$ -	$ -	$ 14,369

Liabilities	**Level 1**	**Level 2**	**Level 3**	**Total**
Common stock warrant liability	$ -	$ -	$ 935	$ 935
	$ -	$ -	$ 935	$ 935

	December 31, 2024			
Assets	**Level 1**	**Level 2**	**Level 3**	**Total**
Cash equivalents:				
Money market funds	$ 7,008	$ -	$ -	$ 7,008
	$ 7,008	$ -	$ -	$ 7,008

Liabilities	**Level 1**	**Level 2**	**Level 3**	**Total**
Common stock warrant liability	$ -	$ -	$ 1,519	$ 1,519
	$ -	$ -	$ 1,519	$ 1,519

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.

Common Stock Warrants Liability, 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 common stock warrant liability for the three months ended March 31, 2025 (in thousands):

Fair value as of December 31, 2024	$ 1,519
Change in fair value	(584)
Fair value as of March 31, 2025	$ 935

The Company remeasures the fair value of its common stock warrant liability at each reporting date. The fair value of the common stock warrants was determined using a probability weighted scenario method with a Monte Carlo simulation and Black-Scholes model. The scenario-based method estimates the fair value of the Company's common stock warrants by considering various outcomes as assessed by the Company. Quantitative elements associated with the inputs impacting the fair value measurement of the common stock warrants include the underlying fair value of common stock, timing of the expected scenarios, risk-free rate, and volatility of the Company's shares. The risk-free rate is determined by reference to the U.S. Treasury yield curve for the respective time periods based on the remaining contractual term of the warrants. The volatility is based on the historical volatility of the Company's stock. The Monte Carlo simulation projects the Company's volume weighted average stock price based on the various fundamental transaction scenarios considered and utilizes a Black-Scholes model to value the warrants within these scenarios.

The following table details the assumptions used in the Monte Carlo simulation to estimate the fair value of the common stock warrant liability:

	March 31, 2025	**December 31, 2024**
Stock price	$ 0.99	$ 1.29
Strike price	$ 3.21	$ 3.21
Expected volatility	100% – 106%	108.0%
Expected term (years)	0.00 – 3.51	3.76
Risk-free interest rate	3.91% – 4.32%	4.31%
Dividend rate	—%	—%

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.

4. Property and Equipment, Net

Property and equipment, net are as follows (in thousands):

	March 31, 2025	December 31, 2024
Property and equipment	$ 14	$ 12
Subtotal	14	12
Less accumulated depreciation	(1)	-
Property and equipment, net	$ 13	$ 12

Depreciation is computed on a straight-line basis over the estimated useful lives of the assets. The useful life for furniture and equipment is seven years.

Depreciation expense was approximately $1,000 and nil for the three months ended March 31, 2025 and 2024, respectively.

5. Accrued Expenses

The components of accrued expenses are as follows (in thousands):

	March 31, 2025	December 31, 2024
Clinical trial	$ 516	$ 432
Employee benefits	151	817
Lease liability — current	97	66
Other	5	8
Total accrued expenses	$ 769	$ 1,323

6. Leases, Commitments and Contingencies

Operating Leases

In October 2024, the Company entered into a 36-month non-cancelable operating lease, commencing on December 1, 2024, for approximately 1,900 rentable square feet of office space in Mountain View, California. The lease has a one-time option to renew the term for an extension period of 36 months. The office space lease has a remaining lease term of approximately three years. The option to renew the term was not included for purposes of determining the right-of-use asset and associated lease liabilities as the Company determined that the renewal of the lease is not reasonably certain so only the original lease term was taken into consideration. The accounting lease commencement in accordance with ASC Topic 842, *Leases*, occurred on December 1, 2024, and the Company recorded a total associated right-of-use asset and corresponding lease liability of $285,000.

Classification of the Company's operating lease on the condensed balance sheets are as follows (in thousands):

	March 31, 2025	December 31, 2024
Assets		
Right-of-use operating asset	$ 256	$ 278
Liability		
Operating lease liability – current	$ 97	$ 66
Operating lease liability – noncurrent	186	212
Total liability	$ 283	$ 278

The current operating lease of $97,000 is classified as an accrued expense on the condensed balance sheet, see "Note 5. Accrued Expenses" in Notes to Condensed Interim Financial Statements.

Lease expense and cash paid by lease type that was recognized during the three months ended March 31, 2025 and 2024 are as follows (in thousands):

	March 31,	
	2025	2024
Operating lease	$ 28	$ -
Short-term lease	-	20
Total lease expense	$ 28	$ 20

Short-term leases for three months ended March 31, 2024 of $20,000 were month-to-month lease arrangements where the Company recognized the lease payments as an expense in the period in which the obligation for those payments incurred. The Company made an election policy not to apply the recognition requirements under ASC Topic 842, *Leases*, for month-to-month lease agreements.

The minimum lease payments are expected to be as follows for the years ending December 31, (in thousands):

2025	$ 86
2026	118
2027	111
Total lease payments	$ 315
Less imputed interest	(32)
Present value of operating lease liability	$ 283

The interest rate implicit in lease contracts is typically not readily determinable and as such, the Company uses its incremental borrowing rate of 7.75% based on the information available at the lease commencement date, which represents an internally developed rate that would be incurred to borrow, on a collateralized basis, over a similar term, an amount equal to the lease payments in a similar economic environment. As of March 31, 2025, the Company had a remaining lease term of 2.67 years.

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 three months ended March 31, 2025, 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 had not recorded any liabilities for these indemnification rights and agreements as of March 31, 2025.

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

2021 Omnibus Equity Incentive Plan

On July 19, 2021, the Company's Board of Directors (the "Board") 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 continued to be governed by the 2013 Plan. In accordance with the terms of the 2021 Plan, on January 1, 2025, the number of shares reserved and available for issuance increased by 721,040 shares.

A summary of the stock option activity for the three months ended March 31, 2025 is as follows:

	Number of Stock Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life	Aggregate Intrinsic Value
Outstanding as of December 31, 2024	2,797,529	$ 1.84	7.82	$ 521
Granted	52,000	$ 1.10	-	$ -
Exercised	(6,770)	$ 1.08	-	$ -
Forfeited	(9,910)	$ 2.41	-	$ -
Expired	-	$ -	-	$ -
Outstanding as of March 31, 2025	2,832,849	$ 1.83	7.56	$ 167
Exercisable as of March 31, 2025	1,653,265	$ 2.03	6.66	$ 165
Vested and expected to vest as of March 31, 2025	2,832,849	$ 1.83	7.56	$ 167

As of March 31, 2025, there was $1.6 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 2.30 years.

For the three months ended March 31, 2025, and 2024, 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:

	Three Months Ended March 31,	
	2025	2024
Expected volatility	115.1% – 118.0%	123.76% – 143.10%
Expected term (years)	10.00	6.02 – 10.00
Risk-free interest rate	4.27% – 4.79%	4.03% – 4.16%
Dividend rate	–%	–%

During the three months ended March 31, 2025, and 2024, the Company recognized $288,000 and $423,000, 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 (in thousands):

	Three Months Ended March 31,	
	2025	2024
Research and development	$ 137	$ 126
General and administrative	151	297
Total stock-based compensation expense	$ 288	$ 423

Restricted Stock

In March 2025, the Board approved the issuance of 30,000 shares of restricted stock to an entity as consideration for a commercial contract, vested immediately, in a private placement. The shares were issued outside the 2021 Plan and the Company recognized $30,600 of stock-based compensation expense for the restricted stock.

2025 Underwriter Warrants

In connection with the Company's February 2025 Shelf Offering, the Company issued to the underwriter warrants to purchase up to 576,191 shares of common at $1.21 per share over a five year term. All such warrants expire on February 10, 2030.

The following is a summary of the common stock warrants activity during the three months ended March 31, 2025.

	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, 2024	25,558,845	$ 2.32	3.42	$ 59,298
Issued in February 2025 to:				
Underwriter	576,191	$ 1.21	4.87	$ 697
Exercised	(951,500)	$ 0.0001	-	-
Expired	(9,000)	$ 1.01	-	$ (9)
Outstanding as of March 31, 2025	25,174,536	$ 2.38	3.21	$ 59,986

8. Income Taxes

The Company had no income tax expense for the three months ended March 31, 2025, and 2024. The Company's effective income tax rate was 0% for the three ended March 31, 2025. During the three months ended March 31, 2025, and 2024, 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 March 31, 2025.

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 months ended March 31, 2025, and 2024, the Company had no accrued interest or penalties related to uncertain tax positions.

9. 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 March 31,	
	2025	2024
Numerator:		
Net loss	$ (2,420)	$ (1,076)
Denominator:		
Weighted average shares used in computing net loss per share – basic and diluted	31,395,888	14,947,500
Net loss per share – basic and diluted	$ (0.08)	$ (0.07)

For the three ended March 31, 2025, and 2024, 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 March 31,	
	2025	2024
Options to purchase common stock	398,223	663,785
Common stock warrants	6,439,893	6,645,354
Total	6,838,116	7,309,139

10. Segment Information

Operating segments are defined as components of an entity for which separate financial information is available and that is regularly reviewed by the Company's Chief Executive Officer ("CEO"), who for these purposes is the Company's Chief Operating Decision Maker ("CODM") in deciding how to allocate resources to an individual segment and in assessing performance. The Company operates as a single reporting segment, focused on developing novel targeted oncology therapies and offering RenovoCath delivery system as stand-alone device targeting high unmet medical needs. The Company's measure of segment profit or loss is net loss. The CODM is the CEO. The CODM manages and allocates resources to the operations of the Company on a total company basis. Managing and allocating resources on a company basis enables the CEO to assess the overall level of resources available and how to best deploy these resources across functions, clinical, manufacturing and research and development projects that are in line with the Company's long-term company-wide strategic goals. Consistent with this decision-making process, the CEO uses financial information for purposes of evaluating performance, forecasting future period financial results, allocating resources and setting incentive targets. Operating expenses are used to monitor budget versus actual results. The CODM also uses net loss in competitive analysis by benchmarking to the Company's peer group. The competitive analysis along with the monitoring of budgeted versus actual results are used in assessing performance of the segment. All the Company's assets are held in the United States and all the Company's revenues are derived from the United States.

The following table is representative of revenue and significant expense categories regularly provided to the CODM when managing the Company's single reporting segment (in thousands):

	Three Months Ended March 31,	
	2025	2024
Revenues	$ 197	$ -
Program expenses [1]		
Clinical trial studies	758	705
Manufacturing, RenovoCath	250	49
Other research and development expenses	127	3
Non-program expenses [2]	1,106	887
Personnel compensation and related expenses, including share-based compensation	1,067	832
Other segment items [3]	(691)	(1,400)
Net loss	$ (2,420)	$ (1,076)

(1) Includes external research expenses, clinical studies, manufacturing including manufacturing and non-recurring engineering costs, professional and consulting, regulatory, and trade shows.
(2) Includes selling, general and administrative expenses for professional and consulting expenses, audit fees, board fees, legal expenses, insurance expenses, travel, and other office expenses.
(3) Includes interest income and interest expense and gain recognized on the fair value of common stock warrant liability.

11. 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 assisting in, among other management items, the oversight of the Company-sponsored clinical trials. For the three months ended March 31, 2025, and 2024, consulting fees paid to Dr. Agah were $84,000 and $63,200, respectively. In addition, the Board approved a discretionary bonus of $121,000 paid in February 2025 to Dr. Agah in recognition of the Company's and individual performance achieved in 2024.

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 condensed 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, 2024, which is included in our 2024 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 2024 Annual Report.

As used herein, the term "common stock" refers to our common stock, par value $0.0001 per share.

Overview

We are a life sciences company offering **RenovoCath®**, a novel, U.S. Food and Drug Administration ("FDA")-cleared local drug delivery device, targeting high unmet medical needs, with a present focus on difficult to treat cancers. Our mission is to transform the lives of cancer patients by providing innovative solutions to enable targeted therapeutic delivery.

We are both a clinical stage and a commercial stage enterprise. Our clinical stage lead product candidate is a novel drug-device combination product consisting of intra-arterial delivery of the chemotherapy gemcitabine via RenovoCath -- we refer to our lead product candidate herein as "**IAG**." IAG is currently the subject of a Phase III clinical study for the treatment of locally advanced pancreatic cancer ("LAPC"). At the same time, we are commercializing RenovoCath for standalone use by interventional radiologists, oncologists, and other medical professionals who can use RenovoCath to treat patients within its FDA-cleared fields of use.

Our RenovoCath device utilize our patented **Trans-Arterial Micro-Perfusion ("TAMP™")** therapy platform, which is designed to ensure targeted 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, including chemotherapy. Our novel approach to targeted treatment offers the potential for increased safety, tolerance, and improved efficacy. RenovoCath is indicated for temporary vessel occlusion in applications including arteriography, preoperative occlusion, and chemotherapeutic drug infusion. We hold a robust portfolio of 19 issued patents and 12 pending patents covering our TAMP technology.

Commercialization of RenovoCath

For the past several years, we have focused our efforts on progressing IAG through clinical trials. However, based on organic demand from doctors in the field who have become familiar with our technology, in 2024, we made the decision to launch an effort to commercialize our RenovoCath delivery device as a standalone device within its FDA cleared uses. Commenced in the field in the fourth quarter of 2024, this commercial effort has already begun to achieve positive results, including our first commercial sales revenue. To accommodate increased need for RenovoCath supply, we expanded our relationship with our U.S.-based third-party RenovoCath manufacturer, Medical Murray, Inc.

We are encouraged by the strong organic demand we are seeing for RenovoCath. In December 2024, we announced that over ten medical institutions had initiated the process for RenovoCath purchase orders, and in February 2025, we announced additional purchase orders received from several esteemed, high volume National Cancer Institute-designated centers and that utilization of RenovoCath devices by our initial customers led to repeat purchase orders. Further, we believe the approximately twenty cancer centers that have used RenovoCath as part of our ongoing Phase II trial could also be potential customers for RenovoCath after completion of trial enrollment, anticipated for later in 2025.

We have begun to generate revenue through sales of our RenovoCath devices, and our goal is to significantly increase these revenues over time. Importantly, we believe our current commercial strategy can be accomplished without a material increase in our capital expenditures, regardless of whether we self-commercialize or choose to partner with a larger organization with an existing sales force. We are actively exploring potential commercial sales partners for RenovoCath, which will allow us to determine in the coming quarters which RenovoCath sales strategy, or combination of strategies, will be most beneficial to us.

Following our late 2024 commercial launch, we continued to generate revenues from RenovoCath sales. In the first quarter ended March 31, 2025 we generated revenue of $197,000 from RenovoCath sales and anticipate sequential quarter over quarter increases in revenue during the remainder of 2025.

However, we are at the beginning of our RenovoCath commercialization efforts and have not had to recognize revenue from our operations in the past. A primary goal from these efforts is to generate and recognize revenue from RenovoCath sales. Revenue recognition under generally accepted accounting principles requires subjective judgements to be made by our management and could otherwise be complex and create uncertainties, including uncertainties arising from varying terms of sale we may offer to different customers. We may also be required to defer recognition of revenues until certain conditions are met. See “Components of Our Results of Operations – Revenue” below for further information.

Based on our internal assumptions, we believe that our initial total U.S. addressable market based solely on the initial clinical interest we have received for RenovoCath could represent an estimated $400 million peak annual U.S. sales opportunity. Our current assumptions regarding our initial addressable market include: (i) pressure-mediated delivery catheters on the market today, which are analogous to RenovoCath, have an average selling price of $6,500-$8,500 per unit; (ii) approximately 7,000 initial target patients at peak market penetration(meaning patients with whom we have experience through our clinical work, without the potential to expand indications beyond LAPC); and (iii) an average of approximately 8 annual procedures per patient. Beyond this initial market, we believe there are expansion opportunities across other indications that could create a several billion-dollar market potential for RenovoCath over time.

Our Ongoing Pivotal Phase III Trial for IAG

In parallel to our RenovoCath commercialization efforts, we are completing enrolment in our ongoing Phase III randomized multi-center clinical trial (called TIGeR-PaC) to investigate IAG for the treatment of LAPC. This trial is being conducted under a U.S. Investigational New Drug (“IND”) application that is regulated by the FDA’s 21 CFR 312 pathway. IAG has received Orphan Drug Designation for pancreatic cancer and bile duct cancer, which provides 7 years of market exclusivity upon approval by the FDA.

Our initial interim data from the TIGeR-PaC study, announced in March 2023, showed that patients experienced a median overall survival of 16 months, compared to 10 months from the time of randomization following a 5.5 month induction phase prior to randomization, for patients receiving standard systemic chemotherapy. Moreover, we observed a 65% reduction in adverse events such as nausea and fatigue, significantly improving patient quality of life. These results strengthen our conviction that TAMP can redefine outcomes for patients facing some of the most difficult-to-treat cancers.

The current protocol and statistical analysis plan for the TIGeR-PaC trial requires 114 randomized patients, with 86 events (deaths) necessary to complete the final analysis. As of May 2, 2025, 91 patients have been randomized and 56 events have occurred, triggering the second pre-planned interim analysis per the statistical analysis plan. We expect the study’s Data Monitoring Committee to review the data in the third quarter of 2025 and look forward to their recommendation regarding the continuation of the study and their guidance on interpretation and data-sharing of the second interim analysis.

We may also evaluate RenovoCath with gemcitabine and other agents as a potential therapy in other indications.

Cash Resources, History of Losses and Planned Activities

We have incurred significant operating losses and generated negative cash flows from operations since our inception. As of March 31, 2025, we had cash and cash equivalents of $14.6 million. We reported net losses of $2.4 million and $1.1 million for the three months ended March 31, 2025, and 2024, respectively. As of March 31, 2025, we had an accumulated deficit of $52.6 million. We expect to continue to incur significant expenses, operating losses and negative cash flows while we seek to grow our revenues from RenovoCath commercial sales. We will not generate revenues from IAG sales unless and until we successfully complete development and obtain regulatory approval for IAG or another product candidate. Given economic and market conditions and timing of regulatory approval, we expect that our expenses will increase in connection with our ongoing commercial, research and development activities, particularly if and when we decide to:

- Advance clinical development of IAG and our platform technology by continuing to enroll patients in our ongoing Phase III TIGeR-PaC clinical trial, expand the number of clinical trials, and advance IAG through other preclinical and clinical pipeline indication opportunities beyond LAPC;
- Make investments we need necessary to expand our commercial sales operation for RenovoCath;
- Hire additional research, development, sales and marketing, and selling, 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.

In addition to the variables described above, if and when IAG or any of our other potential future product candidates successfully complete development and receive regulatory approval, we will incur substantial additional costs associated with establishing a sales, marketing, medical affairs and distribution infrastructure to commercialize 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.

Due to our recurring operating losses and the expectation that we will continue to incur net losses in the future, we will likely be required to raise additional capital at some point to continue the commercialization of RenovoCath and complete the development of and gain regulatory approval for IAG or any other of our future potential product candidates. We have historically financed our operations primarily through private and public sales of our equity (including warrants to purchase common stock). To raise additional capital, we may seek to sell additional equity and/or debt securities, obtain a credit facility or other loan or enter into collaborations, licenses or other similar arrangements, which we may not be able to do on favorable terms, or at all.

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.

Our condensed interim financial statements as of March 31, 2025 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 expect that our current cash and cash equivalents as of the date of this Report will be sufficient to fund our operating, investing and financing cash flow needs through the second half of 2026, assuming our commercial strategy and our development programs advance as currently contemplated.

As a result, we are faced with the risk of requiring significant additional funding to support our continuing operations. Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through private or public equity financings, debt financings and collaborations, licenses or other similar arrangements. We currently have no credit facility or committed sources of capital. To the extent that we raise additional capital through the future sale of equity or debt, the ownership interests of our stockholders will be diluted and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our existing common stockholders. If we raise additional funds through the issuance of debt securities, these securities could contain covenants that could restrict our operations. We may require additional capital beyond our currently anticipated amounts and additional capital may not be available on reasonable terms, or at all. If we raise additional funds through collaboration arrangements or other strategic transactions in the future, we may have to relinquish valuable rights to our technologies or future revenue streams or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through private or public equity financings or debt financings when needed, we may be required to delay, limit, reduce or terminate development or future commercialization efforts, and we may be unable to continue as a going concern. If we are unable to continue as a going concern, we might have to liquidate our assets and the value we receive for our assets in liquidation or dissolution could be significantly lower than the values reflected in our condensed interim financial statements, and our shareholders may lose their entire investment in our common stock.

Components of Our Results of Operations

Revenue

In December of 2024, we began to derive revenue through the sale of our RenovoCath device on a standalone basis directly to end users (i.e., hospitals and cancer treatment centers). We consider customer purchase orders, which in some cases are governed by master sales agreements or standard terms and conditions, to be the contracts with a customer. Our contracts with customers typically contain a single performance obligation, which is the delivery of the RenovoCath device. We recognize revenue from sales of products at the point in time that the customer obtains control, which is typically based upon the terms of delivery. In determining the transaction price, we evaluate whether the price is subject to refund or adjustment to determine the net consideration to which it expects to be entitled. The only type of variable consideration we offer is limited return rights relating primarily to product damage or defects identified upon receipt, and therefore we expect minimal returns. Returns are estimated taking into consideration several factors including these limited product return rights, historical return activity, and other relevant factors. We have not experienced any commercial product returns to date, and accordingly no allowance for returns was recorded for the period ended March 31, 2025.

Cost of Revenue

Cost of revenue consist of costs associated with the sales of RenovoCath devices and were disaggregated between the cost of devices expensed in prior periods as part of our clinical trial as research and development and the cost from our primary third-party manufacturer, Medical Murray, Inc. (the "CMO"). Prior to our commercialization strategy, all costs of manufacturing to produce the devices were allocated to our TIGeR-PaC Phase III clinical trial study in prior periods and expensed as research and development. The cost of revenue associated with the TIGeR-PaC study was recorded at zero-costs. The cost of revenue for devices not associated with the TIGeR-PaC study represents the total costs to manufacture the device based on time and materials to produce the devices including shipping and handling fees when applicable.

Operating Expenses

Research and Development

Research and development expenses consist of costs related to the research and development of our TAMP technology and our ongoing clinical trial. 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 several clinical research vendors and consultants to assist us with the execution of our clinical trials. In addition, we have FDA 510(k) clearance for the RenovoCath delivery device, which comprises part of our IAG product candidate. 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 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, contract research organizations, 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;
- costs related to preclinical studies and pilot testing;
- travel expenses; and
- allocated selling, general and administrative expenses which includes facilities and other indirect administrative expenses to support research and development activities.

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.

Selling, General and Administrative

Selling, general and administrative expenses consist of salaries, benefits, and stock-based compensation for personnel in executive, finance, commercial and administrative functions, professional services and associated costs related to accounting, tax, audit, legal, intellectual property and 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 selling, general and administrative expenses to increase in the foreseeable future. Selling, general and administrative expenses are expensed as incurred.

Other Income

Interest income is earned from cash deposited in our short-term marketable securities and money market account.

Change in Fair Value of Warrant Liability

Change in fair value of warrant liability represents the gain or loss reported from the change in the fair value of the common stock warrant liability for warrants issued under the registered direct offering. On April 3, 2023, we completed a registered direct offering financing issuing common shares and common stock warrants. The fair value of the common stock warrant per share was $0.48 and $0.99 on March 31, 2025 and 2024, 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.

Results of Operations

Comparison of the Three Months Ended March 31, 2025 and 2024

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

	Three Months Ended March 31,		Increase / (Decrease)	
	2025	2024	$	%
	(unaudited)			
Revenues	$ 197	$ -	$ 197	n/a
Cost of revenues	94	-	94	n/a
Gross profit	103	-	103	n/a
Operating expenses:				
Research and development	1,642	1,257	385	31%
General and administrative	1,571	1,219	352	29%
Total operating expenses	3,213	2,476	737	30%
Loss from operations	(3,110)	(2,476)	(634)	26%
Other income				
Interest and dividend income	106	37	69	186%
Change in fair value of common warrant liability	584	1,363	(779)	(57)%
Total other income, net	690	1,400	(710)	(51)%
Net loss	$ (2,420)	$ (1,076)	$ (1,344)	(125)%

Revenue

We recognized approximately $197,000 of revenue from sales of RenovoCath for the three months ended March 31, 2025, compared to no revenue for the same period last year as we only launched initial commercial sales activity for RenovoCath during the latter part of 2024. The quarter ended March 31, 2025 marked our first full quarter of revenue generation from RenovoCath sales, following an initial recognition of approximately $43,000 of RenovoCath-related revenue in the fourth quarter of 2024. We expect to grow revenue from RenovoCath sales on a sequential quarter-by-quarter basis for the remainder of 2025.

Cost of Revenue

Cost of revenue was approximately $94,000 for the three months ended March 31, 2025, compared to no cost of revenue for the same period last year. Cost of revenue consist of costs associated with the sales of RenovoCath devices and were disaggregated between the cost of devices expensed in prior periods as part of our clinical trial as research and development and the cost from our third-party CMO. Prior to our commercialization strategy, all costs of manufacturing to produce the devices were allocated to our TIGeR-PaC clinical trial study in prior periods and expensed as research and development. The cost of revenue associated with the TIGeR-PaC study were recorded at zero-costs. The cost of revenue for devices not associated with the TIGeR-PaC study represents the total costs to manufacture the device based on time and materials to produce the devices at approximately $90,000 including shipping and handling fees of $4,000.

Research and Development

Research and development expenses were approximately $1.7 million for the three months ended March 31, 2025, compared to $1.3 million for the same period last year, an increase of $0.4 million. The period-over-period increase in research and development expenses is primarily driven by an increase in employee and related benefit costs of $0.1 million primarily due to an increase in salaries due to cost-of-living allowance. Manufacturing and non-recurring engineering costs to scale manufacturing increased by $0.1 million to support the commercial effort on our RenovoCath delivery system. Clinical, oncology and interventional radiology conferences and other scientific trade shows activities increased by $0.1 million including other research and development activities of $0.1 million. We expect research and development expenses to increase during 2025 as we continue our commercialization activities for our RenovoCath device and progress our Phase III TIGeR-PaC clinical trial study for IAG.

Selling, General and Administrative

Selling, general and administrative expenses were approximately $1.6 million for the three months ended March 31, 2025, compared to $1.2 million for the same period last year, an increase of approximately $0.4 million. The period-over-period increase in selling, general and administrative expenses is primarily driven by an increase in head count and employee and related benefit costs of $0.1 million. Professional and consulting increased by $0.2 million compared to the same period last year, primarily due to support of the commercialization strategy including other selling, general and administrative expenses of $0.1 million. We anticipate selling, general and administrative expenses to increase during 2025 as we progress with our commercialization activities for our RenovoCath device.

Other Income

Other income was approximately $0.7 million for the three months ended March 31, 2025, a decrease of approximately $0.7 million compared to approximately $1.4 million for the same period last year. The decrease was primarily due to a $0.8 million in the fair value of the common warrant liability offset by an increase in interest and dividend income of $0.1 million.

Liquidity and Capital Resources

From our inception through March 31, 2025, we have raised an aggregate of $71.4 million, primarily from private placements of convertible preferred stock, convertible debt securities, the issuance of securities in public and private placement offerings and the exercise of common stock warrants and common stock options. After deducting underwriting discounts and commissions, placement agent fees and other offering expenses, our net proceeds from these offerings were $64.3 million. As of March 31, 2025, we had cash and cash equivalents of $14.6 million. Based on our operational plans, we expect that our current cash and cash equivalents as of the date of this Report 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, including fully funding both our RenovoCath scale-up and the continued progress of our Phase III TIGeR-PaC clinical trial.

We have incurred significant losses and negative cash flows from operations since our inception. For the three months ended March 31, 2025, we recorded a net loss of $2.4 million and an accumulated deficit of $52.6 million. Depending on our commercialization efforts with RenovoCath, we do not expect to generate positive cash flows from operations until we generate sufficient revenues from RenovoCath sales, which we may be unable to achieve. We also expect to incur losses from our clinical activities until regulatory approval is granted for our first product candidate, IAG. Regulatory approval is not guaranteed and may never be obtained. We may also pursue other revenue-generating strategies such as licensing or collaboration agreements or commercializing RenovoCath on a standalone basis. No assurances can be made that we will pursue these strategies, and even if it does, there is a risk that we will be unable to generate revenue from such activities.

We believe we will be able to raise additional required capital when needed 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 when needed or will be at terms acceptable to us. The inability to raise capital as and when needed would have a negative impact on our liquidity, financial condition and its ability to pursue its business strategy. We will need to generate significant revenue from commercial sales of RenovoCath or otherwise to achieve positive cash flow or profitability, and we may never do so.

On April 3, 2023, we completed a registered direct offering ("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 $4.3 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, 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 offering 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, 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.

On February 10, 2025, we closed the February 2025 Offering and received gross proceeds of approximately $12.1 million. The net proceeds were $10.8 million after deducting underwriting fees of $0.8 million and other professional expenses of $0.5 million. In connection with the offering, we issued an aggregate 11,523,810 shares of common stock and underwriter warrants to purchase 576,191 shares of common stock at $1.21 per share over a 5-year term.

Our ability to obtain additional financing we may need in the future 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 our 2024 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 been primarily a clinical stage company on our clinical development stage lead product candidate, novel drug-device combination product consists of IAG via RenovoCath for the treatment of LAPC. In 2024, we made the decision to launch an effort to commercialize our RenovoCath device as a standalone product within its FDA-cleared fields of use and upon our initial commercialization launch of RenovoCath, we started to generate revenue in the fourth quarter of 2024. We anticipate continuing to generate revenue from RenovoCath sales in 2025 with anticipated sequential quarter over quarter increases in revenue during the year, which would support our liquidity. However, we have incurred significant operating losses and negative cash flows from operations and we anticipate that we will continue to incur net losses until our RenovoCath commercial efforts generates meaningful revenues, of which no assurances can be given.

Cash Flows

Our primary uses of cash are to fund our operations, including research and development and selling, general and administrative expenses. We will continue to incur operating losses in the future and expect that our research and development and selling, 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 periods indicated (in thousands):

	Three Months Ended March 31,	
	2025	**2024**
Net cash provided by (used in):		
Operating activities	$ (3,381)	$ (2,204)
Investing activities	(2)	-
Financing activities	10,811	5,420
Increase in cash and cash equivalents	$ 7,428	$ 3,216

Net Cash Used in Operating Activities

Cash used in operating activities for the three months ended March 31, 2025, reflected a net loss of $2.4 million, non-cash charges of $0.3 million, and a net change in our operating assets and liabilities of $0.7 million.

Cash used in operating activities for the three months ended March 31, 2024, reflected a net loss of $1.1 million, offset by non-cash charges of $0.9 million, and a net change in our operating assets and liabilities of $0.2 million.

Cash Used in Investing Activities

Cash used in investing activities for the three months ended March 31, 2025, consisted of $0.2 million for the purchase of property and equipment.

Cash Provided by Financing Activities

Net cash provided by financing activities for the three months ended March 31, 2025 was $10.8 million, consisting primarily of net proceeds from the public equity offering.

Net cash provided by financing activities for the three months ended March 31, 2024 was $5.4 million, consisting primarily of net proceeds from private placement offering.

Contractual Obligations and Other Commitments

There have been no material changes in our contractual obligations or other commitments since we filed our 2024 Annual Report.

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 2024 Annual Report.

There have been no significant changes to our critical accounting policies or significant judgments and estimates for the three months ended March 31, 2025, from those previously disclosed in our 2024 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 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 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 what 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 2024 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-15(e) and 15d-15(e) under the Exchange Act) as of the end of the fiscal quarter ended March 31, 2025. 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 condensed interim 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.

Previously Identified Material Weakness

As previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 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 have 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.

The previously identified material weakness has not been remediated but 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, 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 since we filed our 2024 Annual Report.

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 2024 Annual Report. The occurrence of any of the events or developments described in our 2024 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 2024 Annual Report in their entirety:

- We have no drug/device combination products approved for commercial sale, only limited experience as a company in the commercialization of standalone medical devices, and no operating history as a revenue generating company. These factors make 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 until we receive FDA approval for our product candidate or until our commercial strategy for RenovoCath generates sufficient revenues.

- We are executing on a commercial strategy for selling our RenovoCath device on a standalone basis, which is a new activity for our company and subject to significant inherent risks.

- Our estimates of total addressable market, potential revenues and similar metrics related to our commercialization efforts for RenovoCath may prove inaccurate, particularly given that our commercialization efforts are relatively new and are evolving.

- Revenue recognition from our RenovoCath commercialization activities could be complex and uncertain. We may also be required to defer recognition of revenues under policies which we develop. Our inability to properly recognize revenue could have a material adverse effect on our estimates of our future revenue performance and on our actual financial results.

- Our revenues and results of operations may be difficult to predict and may fluctuate from quarter to quarter, which could adversely affect our business and the market price of our common stock.

- If the manufacturers upon whom we rely fail to produce RenovoCath or product candidates in the volumes that we require on a timely basis or fail to comply with stringent regulations applicable to life science manufacturers, we may face delays in the development and commercialization of RenovoCath and our product candidates.

- We will likely need to raise substantial additional capital to both develop and commercialize IAG (assuming FDA approval) and to separately engage in sales and marketing activities for RenovoCath as a standalone device. Our failure to obtain funding when needed (even following this offering) may force us to delay, reduce or eliminate our product development programs, commercial efforts or collaboration efforts. Moreover, if we do not obtain adequate and timely funding, we may not be able to continue as a going concern.

- We may consider strategic alternatives in order to maximize stockholder value, including financing, strategic alliances, and licensing arrangements. 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 (notably our Phase III TIGeR-PaC study), 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.

- As our ongoing Phase III TIGeR-PaC trial is evaluating our most advanced drug-device combination product candidate to date, the failure of the trial to achieve results conducive to progressing the trial or filing and receiving NDA approval could cause our company significant harm.

- 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 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.

- If we fail to maintain compliance with or meet all applicable Nasdaq requirements, we could be delisted from Nasdaq, which would seriously harm the liquidity of our stock and our ability to raise capital.

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

Unregistered Sales of Equity Securities

February 2025 Offering

On February 10, 2025, the Company closed the February 2025 Offering in connection with a takedown from the Shelf Registration Statement (No. 333-268302), and received gross proceeds of approximately $12.1 million. The net proceeds were $10.8 million after deducting underwriting fees of $0.8 million and other professional expenses of $0.5 million. In connection with the offering, the Company issued to underwriters of this offering underwriter warrants to purchase 576,191 shares of common stock at $1.21 per share over a 5-year term. Such underwriter warrants were issued in a private placement through an exemption from registration provided by Section 4(a)(2) of the Securities Act. There has been no material change in the planned use of proceeds from the February 2025 Offering as described in our prospectus supplement dated February 6, 2025 filed with the SEC on February 10, 2025 pursuant to Rule 424(b)(5).

MDM Worldwide Solutions, Inc Restricted Stock

In March 2025, we amended our engagement letter with MDM Worldwide Solutions, Inc. to provide business and advisory consulting services. In addition to a monthly consulting fee, we issued 30,000 restricted common stock for services performed. The restricted common shares were fully vested upon execution of the amended agreement. In issuing these restricted common shares, we relied on the private placement exemption from registration provided by Section 4(a)(2) of the Securities Act.

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	333-258071	4.1	August 25, 2021
4.3	Form of Warrant Agent Agreement (including the terms of the Warrants)	S-1	333-258071	4.2	August 25, 2021
4.4	Specimen Stock Certificate evidencing the Shares of Common Stock	S-1	333-258071	4.4	August 25, 2021
4.5	Form of Warrant Certificate	S-1	333-258071	4.5	August 25, 2021
4.6	Form of Pre-Funded Common Stock Purchase Warrant	8-K	001-40738	4.1	April 3, 2023
4.7	Form of Common Stock Purchase Warrant	8-K	001-40738	4.2	April 3, 2023
4.8	Warrant to Purchase Common Stock of RenovoRx, Inc.	8-K	001-40738	10.3	January 29, 2024
4.9	RenovoRx Placement Agent Warrant	8-K	001-40738	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	10-Q	001-40738	4.14	November 13, 2024
4.15	Form of Underwriter Warrant issued in February 2025 Public Offering	8-K	001-40738	4.1	February 10, 2025
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			

† 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: May 15, 2025

By: */s/ Shaun R. Bagai*
Shaun R. Bagai
Chief Executive Officer
(Principal Executive Officer)

Date: May 15, 2025

By: */s/ Ronald B. Kocak*
Ronald B. Kocak
VP Controller and Principal Accounting Officer
(Principal Financial Officer)

Exhibit 31.1

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: May 15, 2025

By: */s/ Shaun R. Bagai*
Shaun R. Bagai
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

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: May 15, 2025

By: */s/ Ronald B. Kocak*
Ronald B. Kocak
VP Controller and Principal Accounting Officer
(Principal Financial Officer)

Exhibit 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

In connection with the Quarterly Report of RenovoRx, Inc. (the "Company") on Form 10-Q for the period ended March 31, 2025 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: May 15, 2025

By: */s/ Shaun R. Bagai*
Shaun R. Bagai
Chief Executive Officer
(Principal Executive Officer)

Exhibit 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

In connection with the Quarterly Report of RenovoRx, Inc. (the "Company") on Form 10-Q for the period ended March 31, 2025 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: May 15, 2025

By: */s/ Ronald B. Kocak*
Ronald B. Kocak
VP Controller and Principal Accounting Officer
(Principal Financial Officer)