

**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, 2024

OR

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

For the transition period from _____ to _____

COMMISSION FILE NUMBER: 001-40738

RENOVORX, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

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

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

94022
(Zip Code)

(650) 284-4433

(Registrant's telephone number, including area code)

N/A

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

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.0001 per share	RNXT	The Nasdaq Capital Market

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

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

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

Large accelerated filer
Non-accelerated filer

Accelerated filer
Smaller reporting company
Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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

As of May 8, 2024, the registrant had 23,951,825 shares of common stock, \$0.0001 par value per share, outstanding.

TABLE OF CONTENTS

<u>PART I. FINANCIAL INFORMATION</u>	1
<u>Item 1. Financial Statements (unaudited)</u>	1
<u>Condensed Balance Sheets as of March 31, 2024, and December 31, 2023</u>	1
<u>Condensed Statements of Operations for the three months ended March 31, 2024, and 2023</u>	2
<u>Condensed Statements of Convertible Preferred Stock and Stockholders' Equity for the three months ended March 31, 2024, and 2023</u>	3
<u>Condensed Statements of Cash Flows for the three months ended March 31, 2024, and 2023</u>	5
<u>Notes to the Unaudited Condensed Interim Financial Statements</u>	6
<u>Item 2: Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	13
<u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u>	22
<u>Item 4. Controls and Procedures</u>	22
<u>PART II. OTHER INFORMATION</u>	24
<u>Item 1. Legal Proceedings</u>	24
<u>Item 1A. Risk Factors</u>	24
<u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u>	25
<u>Item 3. Defaults Upon Senior Securities</u>	25
<u>Item 4. Mine Safety Disclosures</u>	25
<u>Item 5. Other Information</u>	25
<u>Item 6. Exhibits</u>	26
<u>SIGNATURES</u>	27

Cautionary Note Regarding Forward-Looking Statements

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

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

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

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

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

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

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

PART I – FINANCIAL INFORMATION

Item 1. Financial Statements

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

	March 31, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	\$ 4,389	\$ 1,173
Prepaid expenses and other current assets	271	192
Deferred offering costs	128	101
Total assets	\$ 4,788	\$ 1,466
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 356	\$ 561
Accrued expenses	737	614
Total current liabilities	1,093	1,175
Common stock warrant liability	1,928	3,291
Total liabilities	3,021	4,466
Commitments and contingencies		
Stockholders' equity:		
Convertible preferred stock, \$0.0001 par value; 15,000,000 shares authorized as of March 31, 2024, and December 31, 2023, respectively; no shares issued and outstanding at March 31, 2024, and December 31, 2023	-	-
Common stock, \$0.0001 par value, 250,000,000 shares authorized at March 31, 2024, and December 31, 2023; 16,865,975 and 10,693,580 shares issued and outstanding as of March 31, 2024, and December 31, 2023, respectively	2	1
Additional paid-in capital	44,246	38,404
Accumulated deficit	(42,481)	(41,405)
Total stockholders' equity	1,767	(3,000)
Total liabilities and stockholders' equity	\$ 4,788	\$ 1,466

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

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

	Three Months Ended	
	March 31,	
	2024	2023
Operating expenses:		
Research and development	\$ 1,257	\$ 1,338
General and administrative	1,219	1,923
Total operating expenses	2,476	3,261
Loss from operations	(2,476)	(3,261)
Other income/(expenses), net:		
Interest and dividend income	37	4
Change in fair value of common warrant liability	1,363	-
Total other income/(expenses), net	1,400	4
Net loss	(1,076)	(3,257)
Net loss per share, basic and diluted	\$ (0.07)	\$ (0.36)
Weighted-average shares of common stock outstanding, basic and diluted	14,947,500	9,089,989

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

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

	Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
Balance — December 31, 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	-	-	<u>16,865,975</u>	<u>2</u>	<u>44,246</u>	-	<u>(42,481)</u>	<u>1,767</u>

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

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

	Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
Balance — December 31, 2022	-	\$ -	9,097,701	\$ 1	\$ 37,318	\$ 17	\$ (31,173)	\$ 6,163
Issuance of common stock upon exercise of stock options	-	-	3,547	-	6	-	-	6
Issuance of restricted stock awards	-	-	30,000	-	117	-	-	117
Stock-based compensation expense	-	-	-	-	244	-	-	244
Other comprehensive loss	-	-	-	-	-	(17)	-	(17)
Net loss	-	-	-	-	-	-	(3,257)	(3,257)
Balance — March 31, 2023	-	-	9,131,248	1	37,685	-	(34,430)	3,256

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,	
	2024	2023
Cash flows from operating activities:		
Net loss	\$ (1,076)	\$ (3,257)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	423	361
Unrealized gain on change in fair value of common warrants classified as a liability	(1,362)	-
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(79)	233
Deferred offering costs	(27)	(246)
Accounts payable	(206)	294
Accrued expenses	123	(91)
Net cash used in operating activities	(2,204)	(2,706)
Cash flows from investing activities:		
Proceeds from maturities of marketable securities	-	2,032
Net cash provided by investing activities	-	2,032
Cash flows from financing activities:		
Proceeds from private placement offering, net of offering costs	5,378	-
Proceeds from exercise of stock options	42	6
Net cash provided by financing activities	5,420	6
Net increase (decrease) in cash and cash equivalents	3,216	(668)
Cash and cash equivalents:		
Beginning of period	1,173	4,391
End of period	\$ 4,389	\$ 3,723
Supplemental of non-cash 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.

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

1. Business and Principal Activities

Description of Business

RenovoRx, Inc. (the “Company,” “we,” “us,” “our” and similar terminology) was incorporated in the state of Delaware in December 2012 and operates from its headquarters in Los Altos, California. The Company is a clinical-stage biopharmaceutical company focused on developing novel precision oncology therapies based on a local drug delivery platform for high unmet medical need with a goal to improve therapeutic outcomes for cancer patients undergoing treatment. The Company is presently conducting a pivotal Phase III pancreatic cancer clinical trial for its lead product candidate RenovoGem™. The Company’s proprietary therapy platform, Trans-Arterial Micro-Perfusion, or TAMP™, is designed to ensure precise therapeutic delivery to directly target the tumor while potentially minimizing a therapy’s toxicities versus systemic (intravenous (known as IV) therapy). The Company’s novel approach to targeted treatment offers the potential for increased safety, tolerance, and improved efficacy.

Liquidity and Capital Resources

From the Company’s inception through March 31, 2024, it has raised an aggregate of \$48.0 million, primarily from private placements of convertible preferred stock, convertible debt securities, the issuance of securities in the Company’s August 2021 initial public offering (the “IPO”), the sale of common stock and common stock warrants and the exercise of common stock warrants and common stock options. As of March 31, 2024, the Company had cash and cash equivalents of \$4.4 million. As used herein, the term “common stock” refers to the Company’s common stock, par value \$0.0001 per share.

The Company is in the pre-revenue stage and therefore has incurred significant losses and negative cash flows from operations since its inception. For the three months ended March 31, 2024, the Company reported a net loss of \$1.1 million and an accumulated deficit of \$42.5 million and does not expect to generate positive cash flows from operations in the foreseeable future. The Company expects to incur significant and increasing losses until regulatory approval is granted for its first product candidate, RenovoGem™. Regulatory approval is not guaranteed and may never be obtained. The Company may also pursue other revenue-generating strategies such as licensing or collaboration agreements or marketing its proprietary catheter device on a standalone basis. No assurances can be made that the Company will pursue these strategies, and even if it does, there is a risk that the Company will be unable to generate revenue from such activities.

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

The Company has filed an omnibus shelf registration statement on Form S-3 that provides for the aggregate offerings of up to \$50.0 million of the Company’s securities subject to various limitations, including limited sales in any twelve-month period while the Company is subject to the “baby-shelf” rules. 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 a warrant to purchase up to 1,947,040 shares of common stock (the “April 2023 Warrant”). The aggregate gross proceeds from this offer were \$5.0 million, and the net offering proceeds were \$4.4 million after deducting placement agent fees and placement agent’s expenses of \$0.4 million and other professional expenses of \$0.2 million.

On January 26, 2024, 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 warrants to purchase up to an aggregate of 6,133,414 shares of common stock, which warrants expire five years from the issuance date, January 26, 2024. In connection with such private placement, the Company entered into a placement agent agreement and, as additional compensation to the placement agent, issued warrants to purchase up to an aggregate of 511,940 shares of common stock (the “January 2024 PA Warrants”), which warrants expire five years from the issuance date. The exercise price for the significant majority of the warrants issued in this private placement have an exercise price of \$0.99 per share; warrants purchased by directors, officers, employees and consultants of the Company in this private placement have an exercise price of \$1.22 per share.

See “Note 10. Subsequent Events” in Notes to the Unaudited Condensed Interim Financial Statements for information regarding an additional private placement closed by the Company subsequent to March 31, 2024.

The accompanying 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 the Company’s current operating plan, management believes that its existing cash and cash equivalents as of the issuance of the accompanying unaudited condensed interim financial statements will be sufficient to allow the Company to fund operating, investing and financing cash flow needs for at least twelve months from such date. The accompanying unaudited condensed interim financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. The accompanying unaudited condensed interim financial statements do not reflect any adjustments relating to the recoverability and reclassifications of assets and liabilities that might be necessary if the Company is unable to continue as a going concern.

2. Summary of Significant Accounting Policies

Basis of Presentation and Unaudited Condensed Interim Financial Information

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

Summary of Significant Accounting Policies

There have been no material changes to the significant accounting policies during the three months ended March 31, 2024 from those previously disclosed in the Company's Annual Report on Form 10-K for the year ended December 31, 2023 filed with the SEC on April 1, 2024 (the "2023 Annual Report").

Risks and Uncertainties

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

Use of Estimates

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

Emerging Growth Company and Smaller Reporting Company Status

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

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

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

Recent Accounting Pronouncement

Recently Adopted Accounting Pronouncements

In February 2016, the FASB issued Accounting Standards Updates 2016-02, “Leases (Topic 842)” (“ASU 2016-02”). The guidance requires lessees to recognize assets and liabilities related to long-term leases on the balance sheet and expands disclosure requirements regarding leasing arrangements. In July 2018, the FASB issued additional guidance, which offers a transition option to entities adopting the new lease standards, and a package of practical expedients an entity can elect to utilize to reduce the level of effort required for adoption. Under the transition option, entities can elect to apply the new guidance using a modified retrospective approach at the beginning of the year in which the new lease standard is adopted, rather than to the earliest comparative period presented in their financial statements. In November 2019, the FASB issued ASU 2019-10, “Leases (Topic 842),” deferring the effective date for the Company for fiscal years beginning after December 15, 2020, and interim periods within fiscal years beginning after December 15, 2021. In June 2020, the FASB issued ASU 2020-05, “Leases (Topic 842)” which further defers the effective date for the Company for fiscal years beginning after December 15, 2021, and interim periods within fiscal years beginning after December 15, 2021. Early adoption is permitted. The Company adopted ASU 2016-02 on January 1, 2022 and the adoption had no material impact to the Company’s financial statements.

In December 2019, the FASB issued ASU 2019-12, “Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes” (“ASU 2019-12”), which simplifies the accounting for income taxes, and is effective on a prospective basis for annual reporting periods beginning after December 15, 2021, and for interim periods within fiscal years beginning after December 15, 2022, with early adoption permitted. The Company adopted ASU 2019-12 on January 1, 2022, and the adoption had no significant impact to the Company’s financial statements.

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

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

3. Fair Value Measurements

As of March 31, 2024, and December 31, 2023, the Company held \$0.1 million and \$4.3 million, respectively, in a money market account.

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

Assets	Fair Value Measurements at March 31, 2024 using:			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	\$ 3,768	\$ -	\$ -	\$ 3,768
	<u>\$ 3,768</u>	<u>\$ -</u>	<u>\$ -</u>	<u>\$ 3,768</u>
Liabilities				
Common stock warrant liability	\$ -	\$ -	\$ 1,928	\$ 1,928
	<u>\$ -</u>	<u>\$ -</u>	<u>\$ 1,928</u>	<u>\$ 1,928</u>

Assets	Fair Value Measurements at December 31, 2023 using:			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	\$ 905	\$ -	\$ -	\$ 905
	<u>\$ 905</u>	<u>\$ -</u>	<u>\$ -</u>	<u>\$ 905</u>
Liabilities				
Common stock warrant liability	\$ -	\$ -	\$ 3,291	\$ 3,291
	<u>\$ -</u>	<u>\$ -</u>	<u>\$ 3,291</u>	<u>\$ 3,291</u>

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

Assumptions Used in Determining Fair Value of Warrant

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

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

A summary of the Black Scholes pricing model assumptions used to record the fair value of the April 2023 Warrant is as follows:

	March 31, 2024	December 31, 2023
Expected volatility	116% – 198%	116% – 177%
Expected term (years)	1.01 – 4.51	1.01 – 4.76
Risk-free interest rate	4.26% – 5.03%	3.86% – 4.78%
Dividend rate	–%	–%

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

The following table reflects the change in the Company's Level 3 liability associated with the April 2023 Warrant for the three months ended March 31, 2024 (in thousands):

Fair value as of December 31, 2023	\$ 3,291
Change in fair value	(1,363)
Fair value as of March 31, 2024	<u>\$ 1,928</u>

4. Accrued Expenses

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

	March 31, 2024	December 31, 2023
Clinical trial	\$ 540	\$ 470
Employee benefits	45	75
Other	152	69
Total accrued expenses	<u>\$ 737</u>	<u>\$ 614</u>

5. Commitments and Contingencies

Legal Proceedings

From time to time, the Company may become involved in legal proceedings arising in the ordinary course of business. The Company was not subject to any material legal proceedings during the three months ended March 31, 2024, and no material legal proceedings are subsequently outstanding or pending.

Guarantees and Indemnification

In the ordinary course of business, the Company enters into agreements that may include indemnification provisions. As permitted under Delaware law and in accordance with its bylaws, the Company indemnifies its officers and directors for certain events or occurrences while the officer or director is or was serving in such capacity. The Company is also party to indemnification agreements with its officers and directors. In some cases, the indemnification will continue after the termination of the agreement. The maximum potential amount of future payments that the Company could be required to make under these provisions is not determinable. The Company has never incurred material costs to defend lawsuits or settle claims related to these indemnification provisions. The Company is not currently aware of any indemnification claims. Accordingly, the Company has not recorded any liabilities for these indemnification rights and agreements as of March 31, 2024.

Operating Leases

The Company leases its headquarters in Los Altos, California under a month-to-month operating lease agreement. Rent expenses were \$20,300 and \$18,000 for the three months ended March 31, 2024, and 2023, respectively.

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

2021 Omnibus Equity Incentive Plan

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

A summary of the stock option activity for the three months ended March 31, 2024 is as follows:

	Number of Stock Options	Weighted- Average Exercise Price	Weighted- Average Remaining Contractual Life	Aggregate Intrinsic Value
Outstanding as of December 31, 2023	1,860,125	\$ 2.47	7.24	\$ 984
Granted	1,114,384	\$ 1.20	-	\$ -
Exercised	(38,981)	\$ 1.08	-	\$ -
Forfeited	(334,371)	\$ 1.97	-	\$ -
Expired	-	\$ -	-	\$ -
Outstanding as of March 31, 2024	2,601,157	\$ 2.01	7.56	\$ 547
Exercisable as of March 31, 2024	1,335,269	\$ 2.09	5.78	\$ 393
Vested and expected to vest as of March 31, 2024	2,601,157	\$ 2.01	7.56	\$ 547

As of March 31, 2024, there was \$2.0 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 2.98 years.

For the three months ended March 31, 2024, and 2023, the Company utilized the Black-Scholes option-pricing model for estimating the fair value of the stock option granted. The Company estimated the fair value of each option grant on the grant date using the Black-Scholes option pricing model with the following weighted-average assumptions:

	Three Months Ended March 31,	
	2024	2023
Expected volatility	123.76% – 143.10%	99.49% – 103.76%
Expected term (years)	6.02 – 10.00	6.02 – 10.00
Risk-free interest rate	4.03% – 4.16%	3.51% – 4.28%
Dividend rate	–%	–%

During the three months ended March 31, 2024, and 2023, the Company recognized \$423,000 and \$244,000, respectively, in stock-based compensation expense from stock option grants. The compensation expense is allocated on a departmental basis, based on the classification of the option holder. No income tax benefits have been recognized in the condensed statements of operations for stock-based compensation arrangements.

The following table summarizes the components of stock-based compensation expense recognized in the Company's Condensed Statements of Operations during the three months ended March 31, 2024, and 2023 (in thousands):

	Three Months Ended March 31,	
	2024	2023
Research and development	\$ 126	\$ 42
General and administrative	297	319
Total stock-based compensation expense	<u>\$ 423</u>	<u>\$ 361</u>

Restricted Stock Awards Issued for Services

In March 2024, the Company issued 120,000 shares of restricted stock awards outside the 2021 Plan for business advisory and investor relations services and recognized \$4,000 of stock-based compensation expense.

January 2024 Common Warrants

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

The following is a summary of the common stock warrant activity during the three months ended March 31, 2024.

	Shares Issuable Upon Exercise of Outstanding Warrants	Weighted- Average Exercise Price	Weighted- Average Remaining Contractual Life	Aggregate Intrinsic Value (In thousands)
Outstanding as of December 31, 2023	6,681,075	\$ 5.44	3.26	\$ 36,350
Issued to investors	5,961,286	\$ 0.99	4.82	\$ 5,901
Issued to placement agency	511,940	\$ 0.99	4.82	507
Issued to insiders	172,128	\$ 1.22	4.82	210
Exercised	-	\$ -	-	\$ -
Expired	-	\$ -	-	\$ -
Outstanding as of March 31, 2024	<u>13,326,429</u>	<u>\$ 3.22</u>	<u>3.88</u>	<u>\$ 42,968</u>

7. Income Taxes

The Company had no income tax expense for the three months ended March 31, 2024, and 2023. During the three months ended March 31, 2024, and 2023, the Company had a net operating loss (“NOL”) for each period that generated deferred tax assets for NOL carryforwards. Deferred income tax assets and liabilities are recognized for temporary differences between the financial statements and income tax carrying values using tax rates in effect for the years such differences are expected to reverse. Due to uncertainties surrounding our ability to generate future taxable income and consequently realize such deferred income tax assets, the Company has determined that it is more likely than not that these deferred tax assets will not be realized. Accordingly, the Company has established a full valuation allowance against its deferred tax assets as of March 31, 2024.

The Company’s policy is to recognize any interest and penalties related to unrecognized tax benefits as a component of income tax expense. For the three months ended March 31, 2024, and 2023, the Company had no accrued interest or penalties related to uncertain tax positions.

8. Net Loss Per Share

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

	Three Months Ended March 31,	
	2024	2023
Numerator:		
Net loss	\$ (1,076)	\$ (3,257)
Denominator:		
Weighted average shares used in computing net loss per share – basic and diluted	14,947,500	9,089,989
Net loss per share – basic and diluted	\$ (0.07)	\$ (0.36)

For the three months ended March 31, 2024, and 2023, the Company had a net loss and as such, all outstanding shares of potentially dilutive securities were excluded from the calculation of diluted net loss per share as the inclusion would be anti-dilutive.

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

	As of March 31,	
	2024	2023
Options to purchase common stock	663,785	1,416,884
Common stock warrants	6,645,354	-
Total	7,309,139	1,416,884

9. Related Party Transactions

The Company has a consulting agreement with one of the Company’s co-founders, Dr. Ramtin Agah, pursuant to which Dr. Agah provides consulting services as the Company’s Chief Medical Officer by overseeing Company-sponsored clinical trials. For the three months ending March 31, 2024, and 2023, consulting fees paid to Dr. Agah were \$63,200 and \$75,900, respectively.

10. Subsequent Events

On April 4, 2024, the Company entered into a series of subscription agreements, in connection with a private placement offering to approximately 170 accredited investors, which closed on April 11, 2024, and pursuant to which the Company raised aggregate gross proceeds of \$11.1 million before deducting placement agent fees and other offering expenses of approximately \$1.5 million. In connection with this offering, the Company issued 6,960,864 shares of common stock, a pre-funded warrant to purchase 951,500 shares of common stock, five-year Series A warrants to purchase up to 7,921,364 shares of common stock, two-year Series B warrants to purchase up to an aggregate of 3,956,182 shares of common stock and placement agent warrants to purchase up to an aggregate of 701,243 shares of common stock. All such warrants have an exercise price of \$1.22 per share, except the placement agent warrants have an exercise price of \$1.69 per share.

As previously disclosed in a Current Report on Form 8-K filed with the SEC on February 23, 2024, on February 21, 2024, the Company received a written notice from Nasdaq (the “Notice”) that the Company had, as of the date of the Notice, failed to meet the minimum stockholders’ equity requirement for continued listing on The Nasdaq Capital Market under Listing Rule 5550(b)(1) (the “Minimum Stockholders’ Equity Requirement”) and that Nasdaq would commence delisting proceedings against the Company unless the Company timely requests a hearing before the Nasdaq Hearings Panel (the “Hearings Panel”). On February 28, 2024, the Company provided written notice to request a hearing, which request will stay any delisting or suspension action by the Nasdaq staff at least pending the issuance of the Hearings Panel decision and the expiration of any extension that may be granted to the Company following the hearing. As a result of completion of two private placement offerings in early 2024, on April 17, 2024, the Company received a written notice from Nasdaq that the deficiency under Listing Rule 5550(b) has been cured, and that the Company is in compliance with all applicable continued listing standards. The Company’s stock will continue to be listed and traded on Nasdaq.

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

Unless the context otherwise requires, all references in this section to the “Company,” “we,” “us,” or “our” refer to RenovoRx, Inc. You should read the following discussion and analysis of our financial condition and results of operations in conjunction with our unaudited interim condensed financial statements and related notes included elsewhere in this Report, our management’s discussion and analysis of financial condition and results of operations for the year ended December 31, 2023, included in our 2023 Annual Report and our final prospectus, dated August 25, 2021, filed with the SEC pursuant to Rule 424(b)(4) under the Securities Act.

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 titled “Cautionary Note Regarding Forward Looking Statements.” Our actual results and the timing of selected events could differ materially from those discussed below. Factors that could cause or contribute to such differences include, but are not limited to, those identified below and those set forth under the section titled “Risk Factors” included elsewhere in this Report and in the 2023 Annual Report.

Overview

We are a clinical-stage biopharmaceutical company developing novel precision oncology therapies based on a local drug delivery platform for high unmet medical need with a goal to improve therapeutic outcomes for cancer patients undergoing treatment. Our proprietary Trans-Arterial Micro-Perfusion (TAMPTM) therapy platform is designed to ensure precise therapeutic delivery to directly target the tumor while potentially minimizing a therapy’s toxicities versus systemic (intravenous (“IV”) therapy). Our novel approach to targeted treatment offers the potential for increased safety, tolerance, and improved efficacy.

Our novel and patented approach to targeted treatment offers the potential for increased safety, tolerance, and improved efficacy. Phase III lead product candidate, **RenovoGemTM**, an oncology drug-device combination product, is being investigated under a U.S. Investigational New Drug Application (“IND”) that is regulated by U.S. Food and Drug Administration (“FDA”) under the 21 CFR 312 pathway. RenovoGem is currently being evaluated for the treatment of locally advanced pancreatic cancer (“LAPC”) by the Center for Drug Evaluation and Research (the drug division of FDA). We also plan to evaluate RenovoGem as a potential therapy in other potential pipeline indication opportunities to follow including bile duct cancer, non-small cell lung cancer, uterine tumors, glioblastoma, and sarcoma. RenovoGem received Orphan Drug Designation for pancreatic cancer and bile duct cancer which provides 7 years of market exclusivity upon New Drug Application (“NDA”) approval.

We have completed our RR1 Phase I/II and RR2 observational registry studies, with 20 and 25 patients respectively, in LAPC. These studies demonstrated a median Overall Survival (“OS”) of 27.9 months in LAPC patients pre-treated with radiation followed by treatment with RenovoGem. Based on previous large randomized clinical trials, the expected survival of LAPC patients is 12 to 15 months in patients receiving only IV systemic chemotherapy or IV chemotherapy plus radiation (which are both considered standard of care). Unlike the randomized trials that established these standard of care results, our RR1 and RR2 clinical trials did not prospectively control the standard of care therapy received prior to administration of RenovoGem. Based on an FDA safety review of our Phase I/II study, the FDA allowed us to proceed to evaluate RenovoGem within our Phase III registrational clinical trial.

Our Phase III clinical trial of RenovoGem for the treatment of LAPC is called **TIGeR-PaC**. This trial is an ongoing randomized multi-center study using TAMP to evaluate RenovoGem. The study is evaluating trans-arterial delivery, a form of intra-arterial (“IA”) administration, of an FDA-approved chemotherapy, gemcitabine, to treat LAPC following stereotactic body radiation therapy (“SBRT”). The study is comparing treatment of an FDA-approved cancer drug, gemcitabine, with TAMP versus systemic IV administration of gemcitabine and nab-paclitaxel.

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

The first interim analysis in the TIGeR-PaC study at the 26th event of the specified events (deaths), was completed in March 2023, with the Data Monitoring Committee recommending a continuation of the study. The TIGeR-PaC study’s primary endpoint is a 6-month OS benefit with secondary endpoints including reduced side effects versus standard of care. The data was first presented at the 2023 American Association for Cancer Research Annual Meeting in April 2023 and then as a Late Breaker Oral Presentation with additional secondary endpoint data at the 2023 European Society of Medical Oncology World Congress on Gastrointestinal Cancer in June 2023. The second interim analysis for this study will be triggered by the 52nd event, which is estimated to occur in late 2024. The second interim data read out would follow thereafter, with the timing for such read out depending on customary factors such as time needed for analysis.

Our TAMP therapy platform is focused on optimizing drug concentration in solid tumors using approved small molecule chemotherapeutics. Our platform enables physicians to isolate segments of the vascular anatomy closest to tumors and force chemotherapy across the blood vessel wall to bathe these difficult-to-reach solid tumors in chemotherapy. Specifically, our patented approach allows physicians to combine, on the one hand, pre-treatment of the local blood vessels and tissue with standard-of-care radiation therapy to decrease chemotherapy washout and, on the other hand, local delivery via our patented **RenovoCath** delivery system which utilizes pressure to force small molecule chemotherapy into the tumor tissue. We believe there are many advantages to our TAMP therapy platform, including:

- *Application of Approved Small Molecule Chemotherapeutic Agents:* We use approved small molecule chemotherapeutic agents, such as gemcitabine, with well-known safety and efficacy profiles.

- *Targeted Approach:* In a preclinical study using our therapy platform, we demonstrated up to 100 times higher local drug concentration compared to systemic chemotherapy. We believe our TAMP therapy platform allows for a targeted approach that can decrease systemic exposure and improve patient outcomes.
- *Delivery Method Independent of Tumor Vascularity:* Our therapy platform is designed to deliver small molecule chemotherapeutic agents to solid tumors resistant to systemic chemotherapy due to lack of tumor feeder blood vessels. If approved, our product candidates have the potential to treat tumors that are not directly supported by blood vessels.
- *Broad Application for Solid Tumor Indications:* Our therapy platform is not restricted to a single small molecule chemotherapeutic agent or solid tumor type. As such, it may be applied for use in additional solid tumor indications, including in solid tumors without identifiable tumor feeder blood vessels.

In a further validation of our TAMP platform, in July 2023, we announced a collaboration with Imugene (ASX: IMU) to explore expansion of our TAMP product pipeline with Imugene's CF33 oncolytic virus therapy for the treatment of difficult-to-access tumors. We are constantly in discussions regarding similar collaborations and potentially out-licenses of RenovoGem as we gear up for the NDA filing (assuming we meet our study endpoints) and commercialization of RenovoGem (if approved by FDA) as well as other collaborations with our TAMP platform.

Since our inception, we have devoted substantially all of our efforts to developing our cancer therapy platform and product candidates, raising capital and organizing and staffing our Company. As of December 31, 2023, we have received over \$41.8 million in gross proceeds and have financed our operations primarily through issuance of convertible preferred stock, convertible notes, securities in our IPO, common stock purchase warrants, an RDO in April 2023 and a loan pursuant to the Paycheck Protection Program under the Coronavirus Aid, Relief and Economic Security Act (the "CARES Act"). After deducting underwriting discounts, commissions, placement fees, legal fees, and other professional expenses of \$3.5 million, our net offering proceeds were \$38.3 million.

Subsequent to December 31, 2023, we have raised additional funding from two private placements, in January and April 2024, of shares of common stock and warrants to purchase shares of common stock for gross proceeds of \$17.2 million.

We have incurred significant operating losses and generated negative cash flows from operations since our inception. As of March 31, 2024, we had cash and cash equivalents of \$4.4 million. As of March 31, 2024, we had an accumulated deficit of \$42.5 million. We expect to continue to incur significant expenses, increasing operating losses and negative cash flows for the foreseeable future. We do not expect to generate revenues from product sales unless and until we successfully complete development and obtain regulatory approval for one or more product candidates or engage in other activities that generate revenue sooner (including collaborations, licensing arrangements or other strategic or commercial activities relating to our technology). Given economic and market conditions and timing of regulatory approval, we expect that our expenses will increase in connection with our ongoing research and development activities, particularly if and when we decide to:

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

In addition to the variables described above, if and when any of our product candidates successfully complete development, we will incur substantial additional costs associated with establishing a sales, marketing, medical affairs and distribution infrastructure to commercialize our products for which we may obtain marketing approval, regulatory filings, marketing approval, and post-marketing requirements, in addition to other commercial costs. We cannot reasonably estimate these costs at this time.

Components of Our Results of Operations

Revenue

We have not generated any revenue from product sales and do not currently expect to generate any revenue for the foreseeable future, if at all. If our development efforts for our current or future product candidates are successful and result in marketing approval or collaboration or license agreements with third parties, we may generate revenue in the future from a combination of product sales or payments from collaboration or license agreements. We may also pursue a strategy of commercializing our proprietary catheter delivery device, called RenovoCath, as a standalone device as a means of generating revenue.

Operating Expenses

Research and Development

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

Our research and development expenses include:

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

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

General and Administrative

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

Other Income (Expenses), Net

Interest and Dividend Income (Expense), Net

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

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

Change in Fair Value of Common Warrant Liability

Change in fair value of warrant liability represents the gain or loss reported from the change in the fair value of the warrant liability associated with the April 2023 Warrant. The fair value per share of the April 2023 Warrant was \$0.99 and \$1.69 on March 31, 2024 and December 31, 2023, respectively. The decrease in the fair value was primarily due to the decrease in our stock price.

Income Tax Expense

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

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

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

Results of Operations

Comparison of the Three Months Ended March 31, 2024, and 2023

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

	Three Months Ended		Increase / (Decrease)	
	2024	2023	\$	%
	(unaudited)			
Operating expenses:				
Research and development	\$ 1,257	\$ 1,338	\$ (81)	(6)%
General and administrative	1,219	1,923	(704)	(37)%
Total operating expenses	2,476	3,261	(785)	(24)%
Loss from operations	(2,476)	(3,261)	785	(24)%
Other income/(expense), net				
Interest and dividend income	37	4	33	825%
Change in fair value of common warrant liability	1,363	-	1,363	n/a
Total other income/(expense), net	1,400	4	1,396	34,900%
Net loss	\$ (1,076)	\$ (3,257)	\$ 2,181	(67)%

Research and Development

Research and development expenses were \$1.3 million for the three months ended March 31, 2024, remaining flat compared to the same period last year. Higher clinical costs due to our ongoing Phase III clinical trial cost of \$0.1 million, and an increase in employee and related benefits costs of \$0.1 million, partially offset by a decrease in costs associated with clinical and regulatory consulting of \$0.1 million. Allocated general and administrative support costs for personnel, facility and office supply expenses decreased by \$0.1 million compared to the same period last year. We anticipate research and development expenses to increase as we increase manufacturing costs for our device and continue advancing our lead programs throughout the year.

General and Administrative

General and administrative expenses were \$1.2 million for the three months ended March 31, 2024, a decrease of \$0.7 million compared to \$1.9 million in the same period last year. This decrease was primarily due to lower costs in employee and related benefits costs due to decreased headcount of \$0.1 million, legal, professional and consulting fees of \$0.2 million, investor and public relations of \$0.3 million, directors' and officers' liability insurance expense of \$0.1 million, were partially offset by in lower allocated general and administrative costs of \$0.1 million compared to the same period last year. We anticipate general and administrative expenses to increase somewhat throughout the year as we progress with our lead program.

Other Income/(Expense), Net

Other income/(expense), net was \$1.4 million for the three months ended March 31, 2024, compared to nil in the same prior period. The increase was primarily due to a \$1.4 million change in the fair value of the common warrant liability due to a decrease in our common stock price during the period.

Liquidity and Capital Resources

For the three months ended March 31, 2024, we incurred a net loss of \$1.1 million. As of March 31, 2024, our accumulated deficit stood at \$42.5 million. We anticipate incurring further losses and increasing operating expenses in future periods.

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

On January 26, 2024, we completed a private placement to 92 accredited investors with gross proceeds of \$6.1 million. The private placement included issuing 6,133,414 shares of our common stock and common stock warrants to purchase 6,133,414 million 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.

As of March 31, 2024, we have received over \$48.0 million in gross proceeds through various financial arrangements to include the issuance of preferred stock, convertible debt, securities in our IPO, the RDO, private placements and various loans. After deducting underwriting discounts, commissions, placement fees, legal fees, and other professional expenses of \$4.9 million, our net offering proceeds from these activities were \$43.1 million.

Based upon our current operating plan, management believes that its existing cash and cash equivalents as of March 31, 2024, will be sufficient to allow us to fund operating, investing and financing cash flow needs for at least twelve months from the date of issuance of these unaudited condensed interim financial statements. Given our financing activities subsequent to March 31, 2024 (see “Note 10. Subsequent Events” in Notes to the Unaudited Condensed Interim Financial Statements), as of the date of this Report we believe that we have sufficient cash resources to allow us to fund our operating, investing and financing cash flow needs at least through 12 months. The accompanying unaudited condensed interim financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. The accompanying unaudited condensed interim financial statements do not reflect any adjustments relating to the recoverability and reclassification of assets and liabilities that might be necessary if the Company is unable to continue as a going concern.

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

Sources of Liquidity

Since our inception, we have not generated any revenue from product sales and we have incurred significant operating losses and negative cash flows from operations. We anticipate that we will continue to incur net losses for the foreseeable future. We do not have any products that have achieved regulatory marketing approval and we do not expect to generate revenue from sales of any product candidates for several years, if ever.

On April 11, 2024, we completed a private placement to approximately 170 accredited investors with gross proceeds of approximately \$11.1 million before deducting placement agent fees and other offering expenses of approximately \$1.1 million. The private placement included issuing 6,960,864 shares of our common stock, a prefunded common stock warrant to purchase 951,500 shares of common stock, five-year Series A warrants to purchase 7,921,364 shares of common stock, two-year Series B warrants to purchase 3,956,182 shares of common stock and placement agent warrants to purchase 701,243 shares of common stock (see “Note 10. Subsequent Events” in Notes to the Unaudited Condensed Interim Financial Statements).

We have financed our operations through the date of this Report primarily through the issuance and sale of convertible preferred stock and convertible debt. Through the date of this report, we have raised an aggregate of \$59.2 million from private placements of our convertible preferred stock, convertible debt securities, the issuance of securities in our IPO, RDO and other private placement offerings, various loans and the exercise of warrants and common stock options. During the first four months of 2024 alone, we raise new capital for aggregate gross proceeds of \$17.2 million, which provides us with a cash runway at least through 12 months.

Cash Flows

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

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

	Three Months Ended March 31,	
	2024	2023
Net cash provided by (used in):		
Operating activities	\$ (2,204)	\$ (2,706)
Investing activities	-	2,032
Financing activities	5,420	6
Increase (decrease) in cash and cash equivalents	\$ 3,216	\$ (668)

Net Cash Used in Operating Activities

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 net change in our operating assets and liabilities of \$0.2 million.

Cash used in operating activities for the three months ended March 31, 2023, reflected a net loss of \$3.3 million, offset by non-cash charges of \$0.4 million, consisting of stock-based compensation expense and a net change in our operating assets and liabilities of \$0.2 million.

Cash Provided by Investing Activities

Cash provided by investing activities for the three months ended March 31, 2023, consisted of U.S. Treasury bills held to maturity.

Cash Provided by Financing Activities

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.

Net cash provided by financing activities for the three months ended March 31, 2023 was \$6,000, consisting of proceeds from the exercise of stock options.

Contractual Obligations and Other Commitments

There have been no significant changes in our contractual obligations or other commitments as of March 31, 2024.

Critical Accounting Policies and Significant Judgments and Estimates

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

There have been no significant changes to our critical accounting policies or significant judgments and estimates for the three months ended March 31, 2024, from those previously disclosed in our 2023 Annual Report.

Convertible Instruments and Embedded Derivatives

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

April 2023 Warrants

We evaluate pre-funded warrant and April 2023 Warrant issued in connection with registered direct financing in April 2023 to determine where 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 other expenses, including other professional expenses incurred. We evaluate the terms under the financing agreement to determine the classification of direct costs in the accompanying Condensed Statements of Operations.

Emerging Growth Company and Smaller Reporting Company Status

We are an “emerging growth company” as defined in the Jumpstart Our Business Startups Act of 2012, as amended, or the JOBS Act. Under the JOBS Act, companies have extended transition periods available for complying with new or revised accounting standards. We have elected this exemption to delay adopting new or revised accounting standards. We will remain an emerging growth company until the earlier of (1) December 31, 2026, (2) the last day of the fiscal year in which we have total annual gross revenues of at least \$1.07 billion, (3) the date on which we are deemed to be a “large accelerated filer” as defined in Rule 12b-2 under the Exchange Act, or (4) the date on which we have issued more than \$1.0 billion in non-convertible debt securities during the prior three-year period. An emerging growth company may take advantage of specified reduced reporting requirements and is relieved of certain other significant requirements that are otherwise generally applicable to public companies. As an emerging growth company,

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

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

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

Recently Issued and Adopted Accounting Pronouncements

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

Item 3. Quantitative and Qualitative Disclosures about Market Risk

The disclosures in this section 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-151 and 15d-15(e) under the Exchange Act) as of the end of the fiscal quarter ended March 31, 2023. Based on this evaluation, our Chief Executive Officer and Principal Accounting Officer have concluded that, during the period covered by this Report, our disclosure controls and procedures were not effective due to our previously identified material weaknesses in internal control over financial reporting. As a result, we have performed additional analysis as deemed necessary to ensure that our financial statements were prepared in accordance with GAAP. Accordingly, notwithstanding the identified material weaknesses, management, including our Chief Executive Officer and Principal Accounting Officer, believes the financial statements included in this Report are fairly presented, in all material respects, in accordance with GAAP.

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

Management's Report on Internal Control over Financial Reporting

For the fiscal quarter ended March 31, 2024, our management identified a material weakness in our internal control over financial reporting related to our control environment. A material weakness is a deficiency, or combination of significant deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected and corrected on a timely basis.

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

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

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

We intend to complete the implementation of our remediation plan when we have sufficient cash to remediate our material weakness. 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 weakness.

This Report does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of the Company's registered public accounting firm due to a transition period established by SEC rules for newly public companies. For as long as we remain an emerging growth company under the JOBS Act, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal control over financial reporting. When we lose our status as an emerging growth company and reach an accelerated filer threshold, our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the last fiscal quarter ended March 31, 2024 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II – OTHER INFORMATION

Item 1. Legal Proceedings

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

Item 1A. Risk Factors

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

Risk Factors Summary

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

- We are a clinical stage biopharmaceutical company, have a limited operating history and have no drug/device combination products approved for commercial sale, which makes it difficult to evaluate our current business and predict our future success and viability.
- We have incurred significant net losses in each period since inception, and we expect to continue to incur net losses for the foreseeable future.
- We will need to raise substantial additional capital to develop and commercialize RenovoGem, and our failure to obtain funding when needed may force us to delay, reduce or eliminate our product development programs or collaboration efforts.
- 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, regulatory approvals, and the risks generally inherent in the development of a pharmaceutical product candidate. If we are unable to successfully advance or develop our product candidates, our business will be materially harmed.
- If we do not achieve our projected development goals in the timeframes we announce and expect, our stock price may decline.
- Our product candidates may exhibit undesirable side effects when used alone or in combination with other approved pharmaceutical products or investigational new drugs, which may delay or preclude further development or regulatory approval or limit their use if approved.
- If the results of preclinical studies or clinical trials for our product candidates are negative, we could be delayed or precluded from the further development or commercialization of our product candidates, which could materially harm our business.

- If we are unable to satisfy regulatory requirements, we may not be able to commercialize our product candidates.
- If our product candidates are unable to compete effectively with marketed drugs targeting similar indications as our product candidates, our commercial opportunity will be reduced or eliminated.
- We may delay or terminate the development of our product candidates at any time if we believe the perceived market or commercial opportunity does not justify further investment, which could materially harm our business.
- Our future success depends on our ability to retain our key personnel and to attract, retain, and motivate qualified personnel, especially in light of an acute workforce shortage and hyper-competitive compensation environment.
- If we are unable to protect our intellectual property effectively, we may be unable to prevent third parties from using our technologies, which would impair our competitive advantage.
- The patents issued to us may not be broad enough to provide any meaningful protection, one or more of our competitors may develop more effective technologies, designs, or methods without infringing our intellectual property rights and one or more of our competitors may design around our proprietary technologies.
- The market price of our common stock may be volatile and fluctuate substantially, which could result in substantial losses for our investors.
- We issued a large number of shares of common stock and warrants to purchase common stock in connection with our 2024 financing activities. Substantial future sales of such shares of our common stock could cause the market price of our common stock to decline or have other adverse effects on our company.

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

Unregistered Sales of Equity Securities

Not applicable.

Use of Proceeds from Public Offering of Common Stock

Not applicable.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

None.

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
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			

* Indicates management contract or compensatory plan.

† 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 10, 2024

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

Date: May 10, 2024

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

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

I, 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 10, 2024

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

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

I, Ronald B. Kocak, certify that:

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

Date: May 10, 2024

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

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

In connection with the Quarterly Report of RenovoRx, Inc. (the "Company") on Form 10-Q for the period ended March 31, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Shaun R. Bagai, hereby certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that:

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

Date: May 10, 2024

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

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

In connection with the Quarterly Report of RenovoRx, Inc. (the "Company") on Form 10-Q for the period ended March 31, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Ronald B. Kocak, hereby certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that:

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

Date: May 10, 2024

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