

**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, 2023

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)

REGISTRANT'S TELEPHONE NUMBER, INCLUDING AREA CODE: (650) 284-4433

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	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
Emerging growth company

Accelerated filer
Smaller reporting 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 10, 2023, the registrant had 10,131,798 shares of common stock, \$0.0001 par value per share, outstanding.

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Forward-Looking Statements

This Quarterly Report on Form 10-Q, or Quarterly Report, and the information incorporated herein by reference, 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, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or 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 Quarterly 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 and to include new indications;
- 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, and enrollment timing and projections for our clinical trials;
- 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; and
- our expectations regarding the impact of the ongoing COVID-19 pandemic and geopolitical events on our business.

We have based the forward-looking statements contained in this Quarterly 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 Quarterly Report. These risks are not exhaustive. Other sections of this Quarterly 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 Quarterly 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 Quarterly 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 Quarterly 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 Quarterly 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.

PART I – FINANCIAL INFORMATION

Item 1. Financial Statements

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

	<u>March 31,</u> <u>2023</u>	<u>December 31,</u> <u>2022</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 3,723	\$ 4,391
Short-term marketable securities	-	2,049
Prepaid expenses and other current assets	592	825
Deferred offering costs	246	-
Total assets	\$ 4,561	\$ 7,265
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 828	\$ 534
Accrued expenses	477	568
Total liabilities	1,305	1,102
Commitments and contingencies		
Stockholders' equity:		
Convertible preferred stock, \$0.0001 par value; 15,000,000 shares authorized as of March 31, 2023, and December 31, 2022, respectively; none shares issued and outstanding at March 31, 2023, and December 31, 2022	-	-
Common stock, \$0.0001 par value, 250,000,000 shares authorized at March 31, 2023, and December 31, 2022; 9,131,248 and 9,097,701 shares issued and outstanding as of March 31, 2023, and December 31, 2022, respectively	1	1
Additional paid-in capital	37,685	37,318
Accumulated other comprehensive income	-	17
Accumulated deficit	(34,430)	(31,173)
Total stockholders' equity	3,256	6,163
Total liabilities and stockholders' equity	\$ 4,561	\$ 7,265

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

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

	Three Months Ended	
	March 31,	
	2023	2022
Operating expenses:		
Research and development	\$ 1,338	\$ 1,289
General and administrative	1,923	1,716
Total operating expenses	3,261	3,005
Loss from operations	(3,261)	(3,005)
Interest income, net	4	1
Other income, net	-	1
Total other income, net	4	2
Net loss	\$ (3,257)	\$ (3,003)
Net loss per share, basic and diluted	\$ (0.36)	\$ (0.33)
Weighted-average shares of common stock outstanding, basic and diluted	9,089,989	8,992,404

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 Income	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

	Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
Balance—December 31, 2021	-	\$ -	8,933,989	\$ 1	\$ 36,632	\$ -	\$ (21,284)	\$ 15,349
Issuance of common stock upon exercise of stock options	-	-	91,816	-	26	-	-	26
Issuance of restricted stock awards	-	-	3,500	-	14	-	-	14
Stock-based compensation expense	-	-	-	-	154	-	-	154
Net loss	-	-	-	-	-	-	(3,003)	(3,003)
Balance— March 31, 2022	-	\$ -	9,029,305	\$ 1	\$ 36,826	\$ -	\$ (24,287)	\$ 12,540

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,	
	2023	2022
Operating activities:		
Net loss	\$ (3,257)	\$ (3,003)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	361	168
Amortization on leasehold improvement	-	3
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	233	267
Deferred offering costs	(246)	
Accounts payable	294	204
Accrued expenses	(91)	264
Net cash used in operating activities	(2,706)	(2,097)
Investing activities:		
Proceeds from maturities of marketable securities	2,032	-
Net cash provided by investing activities	2,032	-
Financing activities:		
Proceeds from exercise of stock options	6	26
Net cash provided by financing activities	6	26
Decrease in cash and cash equivalents	(668)	(2,071)
Cash and cash equivalents, beginning of period	4,391	15,192
Cash and cash equivalents, end of period	\$ 3,723	\$ 13,121

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”) 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 therapies for the local treatment of solid tumors and conducting a Phase III pancreatic cancer clinical trial for its lead product candidate RenovoGem™. The Company’s therapy platform, RenovoRx Trans-Arterial Micro-Perfusion, or RenovoTAMP® utilizes approved chemotherapeutics with validated mechanisms of action and well-established safety and side effect profiles, with the goal of increasing their efficacy, improving their safety, and widening their therapeutic window.

Initial Public Offering

On August 25, 2021, the Company’s Registration Statement on Form S-1 (File No. 333-258071) relating to its initial public offering (“IPO”) was declared effective and its shares of common stock began trading on the Nasdaq Capital Market on August 26, 2021. In connection with the IPO, the Company issued and sold an aggregate of 1,850,000 units at a price of \$9.00 per unit. Each unit consisted of (a) one share of common stock and (b) one warrant to purchase one share of common stock at an exercise price equal to \$10.80 per share, which is exercisable for a period of five years after the issuance date. The underwriters exercised their over-allotment option to purchase 277,500 common stock warrants on August 30, 2021. In connection with the IPO, the underwriters were issued a five-year warrant, exercisable on or after February 25, 2022, to purchase up to 198,875 shares of the Company’s common stock at an exercise price of \$10.80.

The Company received aggregate gross proceeds of \$16.7 million from the IPO, paid underwriting discounts and commissions of \$1.3 million and incurred other expenses of \$0.8 million, resulting in net offering proceeds of \$14.6 million. Immediately prior to the closing of the IPO, all shares of convertible preferred stock then outstanding were converted into 3,535,469 shares of common stock after giving effect to the reverse stock split. In addition, all of the outstanding 2020 and 2021 Convertible Notes, representing principal and accrued but unpaid interest of \$5.3 million, converted at a 20% and 12.5% discount to the IPO price, respectively, into an aggregate of 708,820 units. Each unit consisted of (a) one share of common stock and (b) one five-year warrant to purchase one share of common stock at an exercise price equal to \$10.80 per share.

Reverse Stock Split

On August 5, 2021, the Company effected a 1-for-5 reverse stock split of its issued and outstanding preferred stock and common stock. The number of authorized shares and the par values of the common stock and convertible preferred stock were not adjusted as a result of the reverse stock split. Adjustments corresponding to the reverse stock split were made to the ratio at which the Company’s convertible preferred stock converted into the Company’s common stock. Accordingly, all share and per share amounts related to the common stock, stock options, warrants and restricted stock awards for all periods presented in the accompanying financial statements and notes thereto have been retroactively adjusted.

Liquidity and Capital Resources

Since inception, and through March 31, 2023, the Company has raised an aggregate of \$35.0 million from private placements of convertible preferred stock, convertible debt securities, the issuance of securities in the IPO, and the exercise of warrants and common stock options. As of March 31, 2023, the Company had cash and cash equivalents of \$3.7 million.

The Company has incurred significant losses and negative cash flows from operations since its inception. For the three months ended March 31, 2023, the Company reported a net loss of \$3.3 million and an accumulated deficit of \$34.4 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 for the foreseeable future until regulatory approval is granted for its first product candidate, RenovoGem™. Regulatory approval is not guaranteed and may never be obtained. The Company believes it will be able to raise additional capital through debt financings, private or public equity financings, license agreements, collaborative agreements or other arrangements with other companies, or other sources of financing. There can be no assurance that such financing will be available or will be at terms acceptable to the Company. The inability to raise capital as and when needed would have a negative impact on the Company's liquidity, financial condition and its ability to pursue its business strategy. The Company will need to generate significant revenue to achieve profitability, and it may never do so.

The Company has filed an omnibus shelf registration statement on Form S-3 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 the outstanding warrants is only expected to occur when the trading price of the Company's common stock is in excess of the \$10.80 per share exercise price of the outstanding warrants.

On March 30, 2023, the Company entered into a definitive securities purchase agreement under the shelf registration statement for the purchase and sale of common stock, including the issuance of pre-funded common stock warrants, for aggregate gross proceeds of approximately \$5 million before deducting placement fees and other offering expenses. See "Note 11. Subsequent Events" in Notes to the Financial Statements.

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 the effects of the ongoing novel coronavirus ("COVID-19") pandemic, cash requirements for the upcoming year, funding capacity, net working capital, total stockholders' equity and future access to capital. Based upon this review and the Company's current financial condition and operating plans as of March 31, 2023, the Company has concluded that substantial doubt exists as to the Company's ability to operate 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 or ("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, 2022, is derived from the Company's audited financial statements. The results of operations for the three months ended March 31, 2023, 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 ("ASC") and as amended by Accounting Standards Update ("ASU") of the Financial Accounting Standards Board ("FASB").

The accompanying unaudited condensed interim financial statements should be read in conjunction with the audited financial statements and the related notes thereto for the year ended December 31, 2022, which are included in the Company's Annual Report on Form 10-K for the year ended December 31, 2022, filed with the SEC on March 31, 2023.

Summary of Significant Accounting Policies

There have been no material changes to the significant accounting policies during the three months ended March 31, 2023 from those previously disclosed in the Company's Annual Report on Form 10-K for the year ended December 31, 2022.

Emerging Growth Company and Smaller Reporting Company Status

The Company is an emerging growth company ("EGC") 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 Pronouncement

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments—Credit Losses (Topic 326)*. 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 (CECL). 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 ("SRC") 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.

Recently Accounting Pronouncement Not Yet Adopted

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. Early adoption is permitted. The Company has not yet determined the impact that this new standard will have on its financial position and results of operations.

3. Fair Value Measurements

As of March 31, 2023, and December 31, 2022, the Company held \$3.6 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, 2023, and December 31, 2022 (in thousands):

Assets	Fair Value Measurements at March 31, 2023 using:			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	\$ 3,558	\$ -	\$ -	\$ 3,558
	<u>\$ 3,558</u>	<u>\$ -</u>	<u>\$ -</u>	<u>\$ 3,558</u>
	Fair Value Measurements at December 31, 2022 using:			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	\$ 4,300	\$ -	\$ -	\$ 4,300
Available-for-sale securities:				
U.S. Treasury bills	2,049	-	-	2,049
	<u>\$ 6,349</u>	<u>\$ -</u>	<u>\$ -</u>	<u>\$ 6,349</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.

4. Short-Term Marketable Securities

There were no short-term marketable securities as of March 31, 2023. The tables summarize the Company's short-term marketable securities as of December 31, 2022 (in thousands):

	Amortized Cost Basis	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. Treasury bills	\$ 2,032	\$ 17	\$ -	\$ 2,049
	<u>\$ 2,032</u>	<u>\$ 17</u>	<u>\$ -</u>	<u>\$ 2,049</u>

5. Accrued Expenses

The components of accrued expenses as of March 31, 2023, and December 31, 2022 are as follows (in thousands):

	March 31, 2023	December 31, 2022
Clinical trial	\$ 238	\$ 88
Employee benefits	204	475
Other	35	5
Total accrued expenses	<u>\$ 477</u>	<u>\$ 568</u>

6. 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, 2023, 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, 2023.

Operating Leases

The Company leases its headquarters in Los Altos, California under a month-to-month operating lease agreement. Rent expense was \$18,000 for the three months ended March 31, 2023, and 2022.

7. Equity Incentive Plan - Stock-Based Compensation Expense and Common Stock 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, 2023, the number of shares reserved and available for issuance increased by 272,931 shares.

A summary of the stock option activity for the three months ended March 31, 2023 is as follows:

	Number of Stock Options	Weighted- Average Exercise Price	Weighted- Average Remaining Contractual Life	Aggregate Intrinsic Value
Outstanding as of December 31, 2022	1,399,252	\$ 2.40	7.79	\$ 928
Granted	304,325	\$ 3.40	-	\$ -
Exercised	(3,547)	\$ 1.52	-	\$ -
Forfeited	(25,000)	\$ 1.82	-	\$ -
Expired	-	\$ -	-	\$ -
Outstanding as of March 31, 2023	<u>1,675,030</u>	<u>\$ 2.59</u>	7.95	\$ 2,131
Exercisable as of March 31, 2023	<u>743,247</u>	<u>\$ 1.92</u>	6.04	\$ 1,478
Vested and expected to vest as of March 31, 2023	<u>1,675,030</u>	<u>\$ 2.59</u>	7.95	\$ 2,131

As of March 31, 2023, there was \$0.7 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 3.25 years.

For the three months ended March 31, 2023, and 2022, 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,	
	2023	2022
Expected Volatility	99.49% – 103.76%	41.66% – 42.13%
Expected term (years)	6.02 – 10.0	6.44
Risk-free interest rate	3.51% – 4.28%	0.62% – 1.00%
Dividend rate	–%	–%

During the three months ended March 31, 2023, and 2022, the Company recognized \$244,000 and \$168,000, 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 and comprehensive loss 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 and Comprehensive Loss during the three months ended March 31, 2023, and 2022 (in thousands):

	Three Months Ended March 31,	
	2023	2022
Research and development	\$ 42	\$ 45
General and administrative	202	123
Total stock-based compensation expense	\$ 244	\$ 168

Restricted Stock

During the three months ended March 31, 2023, the Board approved the issuance of 30,000 shares of restricted stock to an entity as consideration for a commercial contract, vested immediately, in a private placement. The shares were issued outside the 2021 Plan and the Company recognized \$117,000 of stock-based compensation expense for the restricted stock.

Common Stock Warrants

In August 2021, in connection with the IPO, the Company issued warrants to purchase 3,035,195 shares of the Company's common stock. Warrants to purchase 198,875 shares of the Company's common stock expire on August 25, 2026 and warrants to purchase 2,588,120 shares of the Company's common stock expire on August 31, 2026.

The following is a summary of the common stock warrant activity during the three months ended March 31, 2023.

	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, 2022	2,786,995	\$ 10.80	3.67	\$ 30,100
Issued	-	\$ -	-	\$ -
Exercised	-	\$ -	-	\$ -
Expired	-	\$ -	-	\$ -
Outstanding as of March 31, 2023	2,786,995	\$ 10.80	3.42	\$ 30,100

8. Income Taxes

The Company had no income tax expense for the three months ended March 31, 2023, and 2022. During the three months ended March 31, 2023, and 2022, 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, 2023.

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, 2023, and 2022, the Company had no accrued interest or penalties related to uncertain tax positions.

9. Net Loss Per Share

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

	Three Months Ended March 31,	
	2023	2022
Numerator:		
Net loss	\$ (3,257)	\$ (3,003)
Denominator:		
Weighted average shares used in computing net loss per share – basic and diluted	9,089,989	8,992,404
Net loss per share – basic and diluted	\$ (0.36)	\$ (0.33)

For the three months ended March 31, 2023, and 2022, 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):

	March 31,	
	2023	2022
Options to purchase common stock	1,416,884	589,885
Total	1,416,884	589,885

10. Related Party Transactions

In January 2018, the Company entered into 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. The agreement, which was amended on September 1, 2019, and November 11, 2021, respectively, continues in force for as long as Dr. Agah is providing consulting services and may be terminated by either party on 30 days’ notice. Dr. Agah was awarded (i) options to purchase 60,000 shares of the Company’s common stock in May 2017, which have vested, (ii) options to purchase 40,000 shares of the Company’s common stock in July 2018, which have vested, (iii) options to purchase 20,000 shares of the Company’s common stock in June 2021, which vest ratably over 24 months from the vesting commencement date of May 14, 2021, (iv) options to purchase of 52,203 shares of the Company’s common stock in September 2021, which vest ratably over 48 months from the vesting commencement date of August 26, 2021, and (v) options to purchase 21,398 shares of the Company’s common stock in March 2022, which vest ratably over 48 months from the vesting commencement date of August 26, 2021. In December 2018, Dr. Agah’s agreement was amended to provide that he would receive cash compensation of \$4,000 per month for certain proctoring services, and in September 2019, his compensation was increased to \$10,000 per month to compensate for additional services he was providing. In November 2021, we entered into a third amendment to the Consulting Agreement with Dr. Agah which provides for a monthly consulting fee of \$21,667.67, based on Dr. Agah spending no less than 24 hours per week on Company matters. Dr. Agah’s monthly consulting fee was increased to \$25,000, effective January 1, 2023. The Company may, in its discretion, proportionally adjust the monthly consulting fee if Dr. Agah’s time commitment decreases. The amendment also provides for Dr. Agah’s eligibility for an annual target cash incentive bonus equal to 35% of his annualized base consulting fee. In November 2021, we entered into a Change in Control and Severance Agreement with Dr. Agah. For the three months ending March 31, 2023, and 2022, consulting fees paid to Dr. Agah were \$75,900 and \$72,000, respectively. In addition, the Board approved a discretionary bonus of \$91,000 paid in February 2023 to Dr. Agah in recognition of Company and individual performance during the year ended December 31, 2022.

11. Subsequent Events

On March 30, 2023, the Company entered into a securities purchase agreement (“Securities Purchase Agreement”) with a certain institutional investor (“Purchaser”). Pursuant to the Securities Purchase Agreement, the Company agreed to sell in a registered direct offering 1,000,000 shares (“Shares”) of the Company’s common stock, par value \$0.0001 (“Common Stock”), and purchase contracts issued as pre-funded warrants (“Pre-Funded Warrants”) to purchase up to 557,632 shares of Common Stock, which Pre-Funded Warrants are issued to the extent that the Purchaser determines, in its sole discretion, that such Purchaser would beneficially own in excess of 4.99% (or at the Purchaser’s election, 9.99%). The Pre-Funded Warrants have an exercise price of \$0.0001 per share and are immediately exercisable and can be exercised at any time after their original issuance until such Pre-Funded Warrants are exercised in full. Each Share is being sold at an offering price of \$3.21 and each Pre-Funded Warrant is being sold at an offering price of \$3.2099 (equal to the purchase price per Share minus the exercise price of the Pre-Funded Warrant).

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 Quarterly Report on Form 10-Q, our management’s discussion and analysis of financial condition and results of operations for the year ended December 31, 2022, included in our Annual Report on Form 10-K that was filed with the SEC on March 31, 2023 (the “Annual Report”), and our final prospectus, dated August 25, 2021, filed with the SEC pursuant to Rule 424(b)(4) under the Securities Act of 1933, as amended (the “Securities Act”).

This discussion contains forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Securities Exchange Act of 1934, as amended, that reflect our plans, estimates, and beliefs that involve risks and uncertainties, including those described in the section titled “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 Quarterly Report and in the Annual Report.

Overview

We are a clinical-stage biopharmaceutical company with a vision to disrupt the current paradigm of cancer treatment. Our mission is to lead a revolution in oncology therapy by delivering its innovative and targeted intra-arterial (IA) delivery of chemotherapy directly to solid tumors. The proprietary RenovoRx Trans-Arterial Micro-Perfusion (RenovoTAMP®) therapy platform aims to avoid the harsh side effects typical of the current standard of care, or systemic delivery methods, thus improving patient well-being and, potentially extension of life, so more time may be enjoyed with loved ones. RenovoTAMP utilizes approved chemotherapeutics with validated mechanisms of action and well-established safety and clinical use, with the goal of improving their safety, tolerance, and widening their therapeutic window by providing more targeted delivery at the location of the tumor tissue. RenovoRx’s lead product candidate, RenovoGem™, is a combination of gemcitabine and its patented delivery system, RenovoCath®. The FDA has determined that RenovoGem will be regulated as, and if approved we expect will be reimbursed as, a new oncology drug product. We have secured FDA Orphan Drug Designation for RenovoGem in two rare diseases: pancreatic cancer and cholangiocarcinoma (bile duct cancer, or eCCA).

We have completed the first of two planned interim analyses of the ongoing open label Phase III TIGeR-PaC clinical trial. TIGeR-PaC is a randomized multi-center Phase III open label clinical trial designed to investigate the Company’s first product candidate, RenovoGem, which utilizes RenovoRx’s proprietary therapy platform, RenovoTAMP, to provide targeted intra-arterial delivery of FDA-approved chemotherapy, gemcitabine, to treat locally advanced pancreatic cancer (“LAPC”) following stereotactic body radiation therapy (“SBRT”). The study is comparing treatment with RenovoGem versus standard of care treatment. In this interim analysis, the control and treatment arms demonstrated divergence in median overall survival for patients. The study is designed to randomize 114 patients (57 in each arm) with all patients receiving upfront induction chemotherapy and SBRT. This first of two planned interim analysis occurred upon the discovery of the 26th event (death) which equates to 30% of the total events required (96) for the final analysis. The TIGeR-PaC Data Monitoring Committee (“DMC”) met and determined the interim data warrants continuation of this pivotal trial without modification and no safety concerns were observed. The interim analysis shows a 6-month median overall survival benefit for patients: approximately a 60% improvement versus the study control arm and current standard of care: intravenous (IV) administration of gemcitabine and nab-paclitaxel for - LAPC. RenovoGem patients also had greater than 65% reduction in adverse events. These can include nausea, fatigue, and a decline in white blood cells.

In December 2021, we amended the protocol for the TIGe-PaC Phase III clinical trial to only allow for SBRT during the induction phase of the study (prior to randomization). We had previously permitted both SBRT and intensity-modulated radiation therapy (“IMRT”). Patients receiving IMRT 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 comparison, patients receiving SBRT during the induction phase are only required to complete 5 treatments, over 5 consecutive days, and do not receive oral chemotherapy. The decision to modify the study population was based on the observation in the Phase III TIGeR-PaC study that IMRT patients had a higher dropout rate during the induction phase of the study due to the high frequency of hospital visits and side effects from the required concurrent chemotherapy. As part of the pre-randomization, induction phase change made to the protocol, we initiated a review of the statistical considerations for the study and in June 2022, submitted a modified Statistical Analysis Plan (the “Modified SAP”) to FDA. As part of the Modified SAP, we now plan to (i) analyze only patients receiving SBRT, consistent with the protocol change made in December 2021, (ii) include a second interim analysis, (iii) change the total number of SBRT patients randomized in the study to 114 (a reduction from the original 200 patients) with a total of 86 deaths from SBRT patients, including all deaths from SBRT patients enrolled in the study before the submission of the Modified SAP, and (iv) repower the study from 90% to 80%, which is commonly used in clinical trials. We believe these changes 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. The first planned interim analysis was triggered when 30%, or 26 of 86, of the total number of deaths occurred (and announced in March 2023), and the second interim analysis at 60%, or 52 of 86, of the total number of deaths have occurred and is estimated to be mid-2024. Given that the timing of the interim analysis is predicated on a specific number of deaths, it is difficult to predict the exact timing of the interim analysis or when we will be able to complete the study. As of April 25, 2023, the Phase III TIGeR-PaC trial has randomized 50 SBRT patients out of 114 total needed under the Modified SAP. At this rate, we anticipate that all patients will be enrolled and randomized in 2024, with the final study readout in 2025.

We are also planning to evaluate RenovoGem in a second indication in a Phase II/III trial in extrahepatic (or outside the liver) cholangiocarcinoma (or eCCA), cancer that occurs in the bile ducts that lead out of the liver and join with the gallbladder. After significant input from key opinion leaders across the spectrum of relevant medical specialties and feedback from the FDA, we submitted the protocol for a Phase II/III eCCA clinical trial to FDA, and after receiving feedback, we are finalizing the protocol and also including incorporating a recently approved drug, durvalumab into the study protocol with guidance from the Steering Committee. We anticipate launching this study mid this year. We have also secured FDA Orphan Drug Designation for RenovoGem for the treatment of cholangiocarcinoma, which would provide us with seven years of orphan exclusivity to market RenovoGem for our eCCA indication upon NDA approval, provided that we are the first sponsor to obtain FDA approval for intra-arterial gemcitabine for the eCCA indication.

We intend to explore applications of our RenovoTAMP platform in additional indications, locally advanced lung cancer, locally advanced uterine cancer, and glioblastoma. We have completed and presented data on a lung cancer application in preclinical studies, and additional preclinical experiments in lung cancer may be conducted.

We are using gemcitabine in our initial anti-cancer product candidate, RenovoGem. However, multiple small molecule therapeutics are compatible with our RenovoTAMP platform. We intend to opportunistically develop additional anti-cancer product candidates using small molecule therapeutics in combination with our therapy 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. To date, we have financed our operations primarily through issuance of convertible preferred stock with net proceeds of \$11.8 million, convertible notes with net proceeds of \$15.0 million, and a loan of \$140,000 pursuant to the Paycheck Protection Program (“PPP”) under the Coronavirus Aid, Relief and Economic Security Act (the “CARES Act”), which was forgiven in February 2021. In August 2021, we completed our IPO with aggregate gross proceeds of \$16.7 million. We paid underwriting discounts and commissions of \$1.3 million, and incurred expenses of \$0.8 million in connection with the offering. As a result, the net offering proceeds to us, after deducting underwriting discounts and commissions and offering expenses were \$14.6 million.

We have incurred significant operating losses and generated negative cash flows from operations since our inception. As of March 31, 2023, we had cash and cash equivalents of \$3.7 million. For the three months ended March 31, 2023, we reported net losses of \$3.3 million. As of March 31, 2023, we had an accumulated deficit of \$34.4 million. We expect to continue to incur significant expenses, increasing operating losses and negative cash flows from operations in 2023 and 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. We expect that our expenses will increase substantially in connection with our ongoing research and development activities, particularly as we:

- 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 planned clinical trial in HCCA, and advancing RenovoGem through preclinical and clinical development in additional indications;
- Hire additional research, development, engineering, and general and administrative personnel;
- 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 products for which we may obtain marketing approval, regulatory filings, marketing approval, and post-marketing requirements, in addition to other commercial costs. We cannot reasonably estimate these costs at this time.

Due to our recurring operating losses and the expectation that we will continue to incur net losses in the future, we will be required to raise additional capital to complete the development and commercialization of our product candidates. We have historically financed our operations primarily through private sales of our equity, debt financing and the sale of common stock and warrants in our initial public offering, or IPO. To raise additional capital, we may seek to sell additional equity and/or debt securities, obtain a credit facility or other loan or enter into collaborations, licenses or other similar arrangements, which we may not be able to do on favorable terms, or at all. For example, we have filed an omnibus shelf registration statement on Form S-3 that provides for aggregate offerings of up to \$50 million of the Company's securities subject to various limitations, including limited sales in any twelve-month period while we are subject to the "baby-shelf" rules. On April 3, 2023, we completed a registered direct offering 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 stock warrants) at a purchase price of \$3.21 per share of common stock (or pre-funded common stock warrants) to a certain institutional investor (the "Registered Direct Offering"). Additionally, in a concurrent private placement, we issued to the investor unregistered warrants to purchase up to 1,947,040 shares of common stock (together with the Registered Direct Offering, the "March 2023 Offering"). The aggregate gross proceeds from the March 2023 Offering were approximately \$5 million before deducting placement fees and other offering expenses. We also have filed a registration statement on Form S-1 to register the cash exercise of our outstanding warrants, with such cash exercise only expected to occur when the trading price of our common stock is in excess of the \$10.80 per share exercise price of our outstanding warrants. Our ability to obtain additional financing will be subject to a number of factors, including market conditions, fluctuations in interest rates, our operating performance and investor sentiment. If we are unable to raise additional capital when required or on acceptable terms, we may have to significantly delay, scale back or discontinue the development and/or commercialization of our product candidates, restrict or cease our operations or obtain funds by entering into agreements on unfavorable terms. Failure to obtain additional capital on acceptable terms, or at all, would result in a material and adverse impact on our operations. As a result, there is substantial doubt about our ability to operate as a going concern.

Our financial statements as of March 31, 2023 have been prepared on a going concern basis and do not include any adjustments that may result from the outcome of this uncertainty. Based on our operating plans, we do not expect that our current cash and cash equivalents as of March 31, 2023, will be sufficient to fund our operating, investing and financing cash flow needs, assuming our programs advance as currently contemplated.

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

Impact of COVID-19

The ongoing COVID-19 global and national health emergency has caused significant disruption in the international and U.S. economies and financial markets. The continued spread of COVID-19, and its variants, has caused illness, quarantines, cancellation of events and travel, business and school shutdowns, reduction in business activity and financial transactions, labor shortages, supply chain interruptions and overall economic and financial market instability.

In response to public health directives and orders and to help minimize the risk of the virus to employees, we have taken precautionary measures, including implementing hybrid work policies for certain employees. The ongoing COVID-19 global pandemic also has negatively affected, and we expect will continue to negatively affect, our clinical studies. For example, we have faced challenges in conducting our clinical trials, including recruiting subjects and accommodating patient visits. Additionally, our service providers and their operations may be disrupted, temporarily closed or experience worker or supply shortages, which could result in additional disruptions or delays in shipments of purchased materials or the continued development of our product candidates. To date, we have not suffered material supply chain disruptions.

Although the public health emergency declaration related to COVID-19 will end on May 11, 2023, the extent of COVID-19's effect on our operational and financial performance will depend in large part on future developments, which cannot be predicted and are out of our control. As the COVID-19 global pandemic continues to evolve, it could result in significant long-term disruption of global financial markets, including a period of a rising rate of inflation, reducing our ability to raise additional capital when needed and on acceptable terms, if at all, which could negatively affect our liquidity. The extent to which the COVID-19 pandemic impacts our clinical development and regulatory efforts will depend on future developments that are highly uncertain and cannot be predicted with confidence, such as the duration of the continued outbreak, new travel restrictions, quarantines and social distancing requirements in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the virus. We will continue to monitor the COVID-19 situation closely.

Components of Our Results of Operations

Revenue

We have not generated any revenue from product sales and do not expect to generate any revenue from the sale of products for several years, 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.

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 contract research organizations to assist us with the execution of our clinical trials. In addition, we have FDA 510(k) clearance for the RenovoCath delivery device, which comprises part of 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 our research and development expenses. We expect our research and development expenses to increase for the foreseeable future as we continue the development of our product candidates and enroll subjects in our ongoing Phase III clinical trial, initiate new clinical trials and pursue regulatory approval of our product candidates. It is difficult to predict with any certainty the duration and costs of completing our current or future clinical trials of our product candidates or if, when or to what extent we will achieve regulatory approval and generate revenue from the commercialization and sale of our product candidates. The duration, costs and timing of clinical trials and other development of our product candidates will depend on a variety of factors, including uncertainties in clinical trial enrollment, timing and extent of future clinical trials, development of new product candidates and significant and changing government regulation. We may never succeed in achieving regulatory approval for any of our product candidates.

Our research and development expenses include:

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

Due to the ongoing impact of the COVID-19 pandemic and work-from-home policies and other operational limitations mandated by federal, state, and local governments as a result of the pandemic, certain of our research and development activities delayed and may be further delayed until we and our vendors return to pre-pandemic capacity.

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 and other matters, consulting costs, conferences, travel and allocated expenses for rent, insurance and other general overhead costs. We expect to continue to incur additional expenses as a result of operating as a public company, including costs to comply with the rules and regulations of the Securities and Exchange Commission, or SEC, and Nasdaq listing standards and increased expenses in the areas of insurance, professional services and investor relations. As a result, we expect our general and administrative expenses to increase in the foreseeable future. General and administrative expenses are expensed as incurred.

Other Income, Net

Interest Income, Net

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

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, 2023, and 2022

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

	Three Months Ended March 31,		Increase / (Decrease)	
	2023	2022	\$	%
	(unaudited)			
Operating expenses:				
Research and development	\$ 1,338	\$ 1,289	\$ 49	4%
General and administrative	1,923	1,716	207	12%
Total operating expenses	<u>3,261</u>	<u>3,005</u>	<u>256</u>	<u>9%</u>
Loss from operations	(3,261)	(3,005)	(256)	9%
Other income, net				
Interest income, net	4	1	3	300%
Other income, net	-	1	(1)	(100)%
Total other income, net	<u>4</u>	<u>2</u>	<u>2</u>	<u>100%</u>
Net loss	<u>\$ (3,257)</u>	<u>\$ (3,003)</u>	<u>\$ (254)</u>	<u>8%</u>

Research and Development

Research and development expenses were \$1.3 million for the three months ended March 31, 2023, remaining relatively flat compared to the same period last year. Clinical consulting to support the ongoing Phase III clinical trial increased \$0.1 million which was partially offset by a decrease in our Phase III clinical trial costs of \$0.1 million primarily due to suspending the European Phase III clinical trial. Expenses associated with pre-development manufacturing for our RenovCath delivery device decreased by \$0.2 million as we established a secondary manufacturer for the devices upon completion of manufacturing testing. We anticipate the secondary manufacturer device company will commence production run later this year. Allocated general and administrative support costs for personnel, facility and office supply costs increased by \$0.2 million compared to the prior year quarter. We expect research and development expenses to increase during the year as we continue to advance our lead programs.

General and Administrative

General and administrative expenses were \$1.9 million for the three months ended March 31, 2023, an increase of \$0.2 million, compared to \$1.7 million for the same period last year. This increase was due to higher employee and related benefits costs of \$0.3 million due to an increase in personnel, and an increase in professional and consulting fees of \$0.2 million, in each case, as compared to the prior year quarter. This increase was partially offset by an increase of \$0.2 million in general and administrative expenses allocated to research and development including other miscellaneous general and administrative costs of \$0.1 million. We expect general and administrative expenses to increase during the fiscal year as we continue to advance our lead programs.

Interest Income, Net

Interest income for the three months ended March 31, 2023 was \$4,000, compared to \$1,000 in the same period last year.

Other Income, Net

Other income, net for the three months ended March 31, 2023 was nil, compared to \$1,000 in the same period last year.

Liquidity and Capital Resources

For the three months ended March 31, 2023, we incurred a net loss of \$3.3 million. As of March 31, 2023, we had an accumulated deficit of \$34.4 million. We expect to incur additional losses and increase operating expenses in future periods. Since our inception, our primary sources of liquidity have been the sale and issuance of convertible preferred stock, convertible notes and common stock, including in our IPO and the March 2023 Offering, and from the exercise of warrants.

As of March 31, 2023 and December 31, 2022, we had \$3.7 million and \$6.4 million in cash and cash equivalents and short-term marketable securities, respectively. During the three months ended March 31, 2023, we used \$2.7 million of cash in operations. Our primary requirements for liquidity have been to fund our clinical trial activity and general corporate and working capital needs. In August 2021, we completed our IPO and received aggregate gross proceeds of \$16.7 million. We paid underwriting discounts and commissions of \$1.3 million, and we also incurred expenses of \$0.8 million in connection with the offering. As a result, the net offering proceeds to us, after deducting underwriting discounts and commissions and offering expenses, were \$14.6 million. In February 2021, we received notification and confirmation from Silicon Valley Bank that our PPP loan of \$140,000 was forgiven in its entirety and automatically cancelled by the U.S. Small Business Administration.

Based on our operating plans, we do not expect that our current cash and cash equivalents as of the date of this filing, will be sufficient to fund our operating, investing and financing cash flow needs for at least the next twelve months, assuming our programs advance as currently contemplated. Based upon this review and the Company's current financial condition, the Company has concluded that substantial doubt exists as to the Company's ability to continue as a going concern. We believe we will be able to raise additional capital through debt financing, 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 us. 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 or other operations. 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." 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.

We filed an omnibus shelf registration statement on Form S-3 that provides for the aggregate offerings of up to \$50 million of our securities subject to various limitations, including limited sales in any twelve-month period while we are subject to the "baby-shelf" rules. On April 3, 2023, we completed the Registered Direct Offering 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 stock warrants) at a purchase price of \$3.21 per share of common stock (or pre-funded common stock warrants) to a certain institutional investor. Additionally, in a concurrent private placement, we issued to the investor unregistered warrants to purchase up to 1,947,040 shares of its common stock. The aggregate gross proceeds from the March 2023 Offering were approximately \$5 million before deducting placement fees and other offering expenses. We have 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 the outstanding warrants is only expected to occur when the trading price of the Company's common stock is in excess of the \$10.80 per share exercise price of the outstanding warrants.

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 our operations. 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.

We have financed our operations 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 \$35.0 million of gross proceeds from private placements of our equity and convertible debt securities, the issuance of securities in our IPO and the exercise of warrants and common stock options. This amount also includes a loan under the PPP, which was forgiven in February 2021.

On March 30, 2023, the Company entered into a definitive securities purchase agreement under the shelf registration statement for the purchase and sale of common stock, including the issuance of pre-funded common stock warrants, for aggregate gross proceeds of approximately \$5 million before deducting placement fees and other offering expenses. See “Note 11. Subsequent Events” in Notes to the Financial Statements.

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,	
	2023	2022
Net cash provided by (used in):		
Operating activities	\$ (2,706)	\$ (2,097)
Investing activities	2,032	-
Financing activities	6	26
Decrease in cash and cash equivalents	<u>\$ (668)</u>	<u>\$ (2,071)</u>

Net Cash Used in Operating Activities

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

Cash used in operating activities for the three months ended March 31, 2022, reflected a net loss of \$3.0 million, offset by a net change in our operating assets and liabilities of \$0.7 million, and non-cash charges of \$0.2 million, consisting primarily of stock-based compensation expense.

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, 2023 was \$6.0 million, consisted of proceeds from the exercise of stock options.

Net cash provided by financing activities for the three months ended March 31, 2022 was \$26.0 million, consisted 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, 2023.

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 accounting principles generally accepted in the United States or 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 Annual Report on Form 10-K for the year ended December 31, 2022.

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

Emerging Growth Company and Smaller Reporting Company Status

We are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act ("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 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.

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 Annual Report on Form 10-K for the year ended December 31, 2022 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.

Off-Balance Sheet Arrangements

During the periods presented, we did not have, nor do we currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

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 Chief Financial and Accounting Officer, we conducted an evaluation of the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of the end of the fiscal quarter ended March 31, 2023. Based on this evaluation, our Chief Executive Officer and Chief Financial and Accounting Officer have concluded that, during the period covered by this Quarterly 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 U.S. GAAP. Accordingly, notwithstanding the identified material weaknesses, management, including our Chief Executive Officer and Chief Financial and Accounting Officer, believes the financial statements included in this Quarterly Report on Form 10-Q are fairly presented, in all material respects, in accordance with U.S. 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 Chief Financial Officer, or persons performing similar functions, as appropriate, to allow timely decisions regarding required disclosure. Management recognizes that controls and procedures, no matter how well designed and operated, can only provide reasonable, not absolute, assurance the desired control objectives will be met. In reaching a reasonable level of assurance, management has weighed the cost of contemplated controls against their intended benefits. The design of any system of controls is based on management's assumptions about the likelihood of future events. We cannot assure you that our controls will achieve their stated goals under all possible conditions. Changes in future conditions may render our controls inadequate or may cause our degree of compliance with them to deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

Previously Identified Material Weakness and Plans to Remediate

In preparation for our IPO, we identified a material weakness in our internal control over financial reporting related to our control environment. 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. 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.

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 U.S. 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 during 2023. 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.

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 quarter ended March 31, 2023 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Limitations on the Effectiveness of Controls

In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints, and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

PART II – OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, we may become involved in legal proceedings arising in the ordinary course of our business. We are not currently a party to any material legal proceedings. Regardless of the outcome, litigation can have an adverse impact on us due to defense and settlement costs, diversion of management resources, negative publicity, reputational harm and other factors.

Item 1A. Risk Factors

An investment in our securities involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this Quarterly Report on Form 10-Q, 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. The occurrence of any of the events or developments described below 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

Investing in shares of our common stock involves a high degree of risk because our business is subject to numerous risks and uncertainties, including those outside of our control, that could cause our actual results to be harmed. The 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, among others:

- 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. As a result, there is substantial doubt about our ability to operate as a going concern.
- 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.

In addition, we face other risks and uncertainties that may materially affect our business prospects, financial condition, and results of operations. You should consider the risks discussed in “Risk Factors” and in our other public filings before investing in our securities.

Risks Related to Our Business, Financial Condition and Capital Requirements

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 are a clinical stage biopharmaceutical company with a limited operating history upon which you can evaluate our business and prospects. While RenovoCath, a drug delivery medical device, has been separately cleared by the FDA for the isolation of blood flow and delivery of fluids, including diagnostic and/or therapeutic agents, to selected sites in the peripheral vascular system, and for temporary vessel occlusion in applications including arteriography, preoperative occlusion, and chemotherapeutic drug infusion, we are focused on developing and commercializing drug product candidates in combination with our delivery platform technology. We have no drug/device combination products approved for commercial sale and have not generated any revenue from product sales. We are developing a novel therapy platform, which is an unproven and highly uncertain undertaking and involves a substantial degree of risk. Our first product candidate, RenovoGem, is a drug/device combination product consisting of intra-arterial gemcitabine and RenovoCath. The FDA has determined that RenovoGem will be regulated as, and if approved we expect will be reimbursed as, a new oncology drug product. To date, we have not obtained marketing approval for any drug/device combination product candidates, manufactured a commercial scale product or arranged for a third-party to do so on our behalf, or conducted sales and marketing activities necessary for successful product commercialization. Our limited operating history as a company makes any assessment of our future success and viability subject to significant uncertainty. As a result, it may be more difficult for investors to accurately predict our likelihood of success and viability than it could be if we had a longer operating history.

We will encounter expenses, difficulties, complications, delays, and other known and unknown factors and risks frequently experienced by clinical stage biopharmaceutical companies in rapidly evolving fields. We also may need to transition from a company with a research and clinical development focus to a company capable of supporting commercial activities. We have not yet demonstrated an ability to successfully overcome such risks and difficulties, or to make such a transition. If we do not adequately address these risks and difficulties or successfully make such a transition, our business will suffer.

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 are a clinical stage company and have incurred significant losses since our formation. As of March 31, 2023, we have an accumulated deficit of approximately \$34.4 million. For the three months ended March 31, 2023, we had a net loss of approximately \$3.3 million. For the fiscal years ended December 31, 2022, and 2021, we had net losses of approximately \$9.9 million and \$6.3 million, respectively. To date, we have experienced negative cash flow from the development of our product candidate, RenovoGem, our platform technology, RenovoTAMP, and our RenovoCath delivery system. We have not generated any revenue from operations, and we expect to incur substantial net losses for the foreseeable future as we seek to further develop and commercialize RenovoGem and expand our pipeline of product candidates. Because of the numerous risks and uncertainties associated with developing and commercializing RenovoGem, we are unable to predict the extent of any future losses or when we will attain profitability, if ever. Investors in our common stock must carefully consider the substantial challenges, risks and uncertainties inherent in the attempted development and commercialization of RenovoGem. We may never successfully commercialize RenovoGem, and our business may not be successful.

Our product candidates will require substantial additional development time and resources before we will be able to receive regulatory approvals, if any, and, if approved, to begin generating revenue from product sales. As a result, we expect that will be several years, if ever, before we receive approval to commercialize a product and generate revenue from product sales. Even if we succeed in receiving marketing approval for and commercializing one or more of our product candidates, we expect that we will continue to incur substantial expenses and increasing operating losses in the foreseeable future. The amount of our future net losses will depend, in part, on the level of our future expenditure and revenue. Moreover, our net losses may fluctuate significantly from quarter to quarter and year to year, such that a period-to-period comparison of our results of operations may not be a good indication of our future performance. If we are unable to generate significant revenue from RenovoGem or attain profitability, we will not be able to sustain operations.

We anticipate that our expenses will increase substantially if and as we:

- continue our research and discovery activities;
- continue the development of our proprietary technology platform;
- progress our current and any future product candidates through preclinical and clinical development;
- initiate and conduct additional preclinical, clinical, or other studies for our product candidates;
- work with our contract manufacturing organizations to manufacture RenovoCath and our other product candidates for our clinical trials;
- change or add additional contract manufacturers or suppliers;
- seek regulatory approvals and marketing authorizations for our product candidates;
- establish sales, marketing, and distribution infrastructure to commercialize any products for which we obtain approval;
- take steps to seek protection of our intellectual property and defend our intellectual property against challenges from third parties;
- obtain, expand, maintain, protect, and enforce our intellectual property portfolio;
- pursue any licensing or collaboration opportunities;
- attract, hire, and retain key and qualified personnel including clinical, scientific, management, and administrative personnel;
- provide additional internal infrastructure to support our continued research and development operations and any planned commercialization efforts in the future;
- experience any delays or encounter other issues related to our operations;
- implement operations, financial, and management information systems;
- meet the requirements and demands of being a public company; and
- defend against any product liability claims or other lawsuits related to our products.

Our prior operating losses and expected future net losses have had and will continue to have an adverse effect on our stockholders' equity, working capital, and our ability to fund our development efforts and achieve and maintain profitability. In any particular period, our operating results could be below the expectations of securities analysts or investors, or such analysts or investors could perceive these results to be negative, which could have a substantial adverse effect on the price of our common stock.

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. If we do not obtain adequate and timely funding, we may not be able to continue as a going concern.

As of March 31, 2023, we had cash and cash equivalents of \$3.7 million. Due to our recurring operating losses and the expectation that we will continue to incur net losses in the future, we will be required to raise additional capital to complete the development and commercialization of our product candidates. We have historically financed our operations primarily through private sales of our equity, debt financing and the sale of common stock and warrants in our initial public offering, or IPO. To raise additional capital, we may seek to sell additional equity and/or debt securities, obtain a credit facility or other loan or enter into collaborations, licenses or other similar arrangements, which we may not be able to do on favorable terms, or at all. For example, we have filed an omnibus shelf registration statement on Form S-3 that provides for aggregate offerings of up to \$50 million of the Company's securities subject to various limitations, including limited sales in any twelve-month period while we are subject to the "baby-shelf" rules. On April 3, 2023, we completed the Registered Direct Offering under its shelf registration statement on Form S-3 for the purchase and sale of 1,557,632 shares of the Company's common stock (or pre-funded common stock warrants) at a purchase price of \$3.21 per share of common stock (or pre-funded common stock warrants) to a certain institutional investor. Additionally, in a concurrent private placement, we issued to the investor unregistered warrants to purchase up to 1,947,040 shares of its common stock. The aggregate gross proceeds from the March 2023 Offering were approximately \$5 million before deducting placement fees and other offering expenses. We also have filed a registration statement on Form S-1 to register the cash exercise of our outstanding warrants, with such cash exercise only expected to occur when the trading price of our common stock is in excess of the \$10.80 per share exercise price of our outstanding warrants. Our ability to obtain additional financing will be subject to a number of factors, including market conditions, fluctuations in interest rates, our operating performance and investor sentiment. If we are unable to raise additional capital when required or on acceptable terms, we may have to significantly delay, scale back or discontinue the development and/or commercialization of our product candidates, restrict or cease our operations or obtain funds by entering into agreements on unfavorable terms. Failure to obtain additional capital on acceptable terms, or at all, would result in a material and adverse impact on our operations. As a result, there is substantial doubt about our ability to operate as a going concern.

Our financial statements as of March 31, 2023 have been prepared on a going concern basis and do not include any adjustments that may result from the outcome of this uncertainty. If we fail to raise additional working capital, or do so on commercially unfavorable terms, it would materially and adversely affect our business, prospects, financial condition and results of operations, and we may be unable to continue as a going concern. As a result, there is substantial doubt about our ability to operate as a going concern. If we seek additional financing to fund our business activities in the future and there remains substantial doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide additional funding to us on commercially reasonable terms, if at all. If we are unable to continue as a going concern, we might have to liquidate our assets and the value we receive for our assets in liquidation or dissolution could be significantly lower than the values reflected in our financial statements, and our shareholders may lose their entire investment in our ordinary shares.

Risks Related to the Discovery, Development, and Commercialization of Our Product Candidates

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 candidate, our business will be materially harmed.

In the near-term, failure to successfully advance the development of any of our product candidates may have a material adverse effect on us. To date, we have not successfully developed or commercially marketed, distributed, or sold any product candidate. The success of our business depends primarily upon our ability to successfully advance the development of our current and future product candidates through preclinical studies and clinical trials, have the product candidates approved for sale by the FDA or regulatory authorities in other countries, and ultimately have the product candidates successfully commercialized by us or a commercial partner. We cannot assure you that the results of our ongoing preclinical studies or clinical trials will support or justify the continued development of our product candidates, or that we will receive regulatory approval from the FDA, or similar regulatory authorities in other countries, to advance the development of our product candidates.

Our product candidates must satisfy rigorous regulatory standards of safety and efficacy before we can advance or complete their clinical development, or before they can be approved for sale. To satisfy these standards, we must engage in expensive and lengthy preclinical studies and clinical trials, develop acceptable manufacturing processes, and obtain regulatory approval. Despite these efforts, the FDA could delay, limit or deny approval of a product candidate for many reasons, including because the FDA:

- may not deem our product candidate to be safe and effective;
- determines that the product candidate does not have an acceptable benefit-risk profile;
- may not agree that the data collected from preclinical studies and clinical trials are acceptable or sufficient to support the submission of an NDA or other submission or to obtain regulatory approval, and may impose requirements for additional preclinical studies or clinical trials;
- may determine that adverse events experienced by participants in our clinical trials represent an unacceptable level of risk;
- may determine that population studied in the clinical trial may not be sufficiently broad or representative to assure safety in the full population for which we seek approval;
- may disagree regarding the formulation, labeling and/or the specifications;
- may not approve the manufacturing processes associated with our product candidate or may determine that a manufacturing facility does not have an acceptable compliance status;
- may conclude there are CMC issues that preclude approval of the NDA;
- may conclude that the drug substance or drug product manufacturing process is not in a state of control or does not meet cGMP or all the regulatory requirements;
- may conclude that the medical device manufacturing process for the drug/device combination product candidate is not in a state of control or does not meet all the regulatory requirements;
- may not be able to timely conduct the necessary pre-approval inspection or devote sufficient resources to NDA review on a timely basis due to the ongoing COVID-19 pandemic;
- may change approval policies or adopt new regulations; or
- may not file a submission due to, among other reasons, the content or formatting of the submission.

If we experience delays in obtaining approval or if we fail to obtain approval of RenovoGem, our commercial prospects will be harmed and our ability to generate revenues will be materially impaired which would adversely affect our business, prospects, financial condition and results of operations.

We cannot assure you that the results of late-stage clinical trials will be favorable enough to support the continued development of our product candidates. A number of companies in the pharmaceutical and biopharmaceutical industries have experienced significant delays, setbacks and failures in all stages of development, including late-stage clinical trials, even after achieving promising results in preclinical testing or early-stage clinical trials. Accordingly, results from completed preclinical studies and early-stage clinical trials of our product candidates may not be predictive of the results we may obtain in later-stage trials. Furthermore, even if the data collected from preclinical studies and clinical trials involving our product candidates demonstrate a favorable safety and efficacy profile, such results may not be sufficient to support the submission of an NDA to obtain regulatory approval from the FDA in the U.S., or other similar regulatory agencies in other jurisdictions, which is required to market and sell the product. Even if we are successful in obtaining approval in one jurisdiction, we may not be successful in obtaining approval in any other jurisdictions. If we are unable to obtain approval for our product candidates in multiple jurisdictions, our business, financial condition, results of operations and our growth prospects could be negatively affected.

Our product candidates will require significant additional research and development efforts, the commitment of substantial financial resources, and regulatory approvals prior to advancing into further clinical development or being commercialized by us or collaborators. Additionally, changes in regulations as part of a response to the COVID-19 pandemic, including the effects of recent variants, may require us to change the ways in which our clinical trials are conducted, or to discontinue clinical trials altogether, or which may result in unexpected costs. We cannot assure you that our product candidates will successfully progress through the drug development process or will result in commercially viable products. We do not expect our product candidates to be commercialized by us or collaborators for at least several years.

If we do not achieve our projected development goals in the timeframes we announce and expect, our stock price may decline.

From time to time, we estimate the timing of the anticipated accomplishment of various scientific, clinical, regulatory and other product development goals, which we sometimes refer to as milestones. These milestones may include the commencement or completion of scientific studies and clinical trials and the submission of regulatory filings. From time to time, we may publicly announce the expected timing of some of these milestones. All of these milestones are and will be based on numerous assumptions. The actual timing of these milestones can vary dramatically compared to our estimates, in some cases for reasons beyond our control. If we do not meet these milestones as publicly announced, 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.

Throughout the drug development process, we must continually demonstrate the efficacy, safety and tolerability of our product candidates to obtain regulatory approval to further advance clinical development or to market them. Even if our product candidates demonstrate clinical efficacy, any unacceptable, adverse side effects or toxicities, when administered alone or in the presence of other pharmaceutical products, which can arise at any stage of development, may outweigh the potential benefits. In preclinical studies and clinical trials we have conducted to date, each of our product candidate's tolerability profile is based on studies and trials that have involved a small number of subjects or patients over a limited period of time. We may observe adverse or significant adverse events or drug-drug interactions in future preclinical studies or clinical trial candidates, which could result in the delay or termination of development, prevent regulatory approval, or limit market acceptance if ultimately approved.

If the results of preclinical studies or clinical trials for our product candidates, including those that are subject to existing or future license or collaboration agreements, are unfavorable or delayed, we could be delayed or precluded from the further development or commercialization of our product candidates, which could materially harm our business.

To further advance the development of, and ultimately receive regulatory approval to sell, our product candidates, we must conduct extensive preclinical studies and clinical trials to demonstrate their safety and efficacy to the satisfaction of the FDA or similar regulatory authorities in other countries, as the case may be. Preclinical studies and clinical trials are expensive, complex, can take many years to complete, and have highly uncertain outcomes. Delays, setbacks, or failures can occur at any time, or in any phase of preclinical or clinical testing, and can result from concerns about safety or toxicity, a lack of demonstrated efficacy or superior efficacy over other similar products that have been approved for sale or are in more advanced stages of development, poor study or trial design, and issues related to the formulation or manufacturing process of the materials used to conduct the trials. The results of prior preclinical studies or clinical trials are not necessarily predictive of the results we may observe in later stage clinical trials. In many cases, product candidates in clinical development may fail to show desired safety, efficacy or tolerability characteristics despite having favorably demonstrated such characteristics in preclinical studies or earlier stage clinical trials.

In addition, we may experience numerous unforeseen events during, or as a result of, preclinical studies and the clinical trial process, which could delay or impede our ability to advance the development of, receive regulatory approval for, or commercialize our product candidate, including, but not limited to:

- communications with the FDA, or similar regulatory authorities in different countries, regarding the scope or design of a trial or trials;
- regulatory authorities, including an Institutional Review Board (“IRB”) or Ethical Committee (“EC”), not authorizing us to commence or conduct a clinical trial at a prospective trial site;
- enrollment in our clinical trials being delayed, or proceeding at a slower pace than we expected, because our clinical trial sites have staffing shortages or are unable to recruit/retain qualified staff, or we have difficulty recruiting patients, including as a result of competing clinical trials, or participants dropping out of our clinical trials at a higher rate than we anticipated;
- our third-party contractors, upon whom we rely for conducting preclinical studies, clinical trials and manufacturing of our trial materials, may fail to comply with regulatory requirements, fail to meet their contractual obligations to us in a timely manner, or terminate their relationship with us;
- having to suspend or ultimately terminate our clinical trials if participants are being exposed to unacceptable health or safety risks;
- IRBs, ECs, or regulators requiring that we hold, suspend or terminate our preclinical studies and clinical trials for various reasons, including non-compliance with regulatory requirements or due to the effects of the COVID-19 pandemic, including the effects of recent variants; and
- the supply or quality of drug material or the supply of our RenovoCath device necessary to conduct our preclinical studies or clinical trials being insufficient, inadequate, or unavailable, especially in light of the supply chain issues caused by the effects of the COVID-19 pandemic.

Even if the data collected from preclinical studies or clinical trials involving our product candidates demonstrate a favorable safety and efficacy profile, such results may not be sufficient to support the submission of an NDA to obtain regulatory approval from the FDA in the U.S., or other similar foreign regulatory authorities in foreign jurisdictions, which is required to market and sell the product.

We may be required to perform additional or unanticipated clinical trials to obtain approval or be subject to additional post-marketing testing requirements to maintain regulatory approval. In addition, regulatory authorities may withdraw their approval of a product or impose restrictions on our distribution, such as in the form of a Risk Evaluation and Mitigation Strategy, or REMS. The failure to obtain timely regulatory approval of product candidates, any product marketing limitations or a product withdrawal would materially and adversely affect our business, results of operations and financial condition.

Interim, preliminary or topline data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publish interim, preliminary or topline data from clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data becomes available. Preliminary or topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary or topline data previously published. As a result, interim, preliminary and topline data should be viewed with caution until the final data are available. Adverse differences between interim, preliminary or topline data and final data could significantly harm our reputation and business prospects. Moreover, preliminary, interim and topline data are subject to the risk that one or more of the clinical outcomes may materially change as more patient data become available when patients mature on study, patient enrollment continues or as other ongoing or future clinical trials with a product candidate further develop. Past results of clinical trials may not be predictive of future results. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically more extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure. Any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product candidate or our business. Similarly, even if we are able to complete our planned and ongoing preclinical studies and clinical trials of our product candidates according to our current development timeline, the positive results from such preclinical studies and clinical trials of our product candidates may not be replicated in subsequent preclinical studies or clinical trial results.

If third party vendors upon whom we intend to rely on to conduct our preclinical studies or clinical trials do not perform or fail to comply with strict regulations, these studies or trials of our product candidate may be delayed, terminated, or fail, or we could incur significant additional expenses, which could materially harm our business.

We have limited resources dedicated to designing, conducting, and managing preclinical studies and clinical trials. We intend to rely on third parties, including clinical research organizations, consultants, and principal investigators, to assist us in designing, managing, monitoring and conducting our preclinical studies and clinical trials. We intend to rely on these vendors and individuals to perform many facets of the drug development process, including certain preclinical studies, the recruitment of sites and patients for participation in our clinical trials, maintenance of good relations with the clinical sites, and ensuring that these sites are conducting our trials in compliance with the trial protocol, including safety monitoring and applicable regulations. If these third parties fail to perform satisfactorily, do not adequately fulfill their obligations under the terms of our agreements with them, or terminate their relationship with us, we may not be able to enter into alternative arrangements without undue delay or additional expenditures, and therefore the preclinical studies and clinical trials of our product candidate may be delayed or prove unsuccessful. For example, the investigators we currently use for our clinical trials are not our employees and we cannot control the amount or timing of resources that they devote to our programs. If these investigators fail to devote sufficient time and resources to our clinical trial, fail to enroll patients as rapidly as expected, or otherwise do not perform in a satisfactory manner, we may have to close such clinical trial site, which may increase our expenses, require additional attention from our clinical team and delay our clinical trial timeline and regulatory approval. Further, the FDA, or other similar foreign regulatory authorities, may inspect some of the clinical sites participating in our clinical trials in the U.S., or our third-party vendors' sites, to determine if our clinical trials are being conducted according to good clinical practice, or GCP. If we or the FDA determine that our third-party vendors are not in compliance with, or have not conducted our clinical trials according to, applicable regulations we may be forced to delay, repeat, or terminate such clinical trials. Additionally, certain third parties with whom we engage or may engage for preclinical studies or clinical studies may have to adjust their operations or limit their capacity in light of the effects of the COVID-19 pandemic, including the effects of recent variants.

We have limited capacity for recruiting and managing clinical trials, which could impair our timing to initiate or complete clinical trials of our product candidate and materially harm our business.

We have limited capacity to recruit and manage the clinical trials necessary to obtain FDA approval or approval by other regulatory authorities. By contrast, larger pharmaceutical and biopharmaceutical companies often have substantial staff with extensive experience in conducting clinical trials with multiple product candidates across multiple indications. In addition, they may have greater financial resources to compete for the same clinical investigators and patients that we are attempting to recruit for our clinical trials. If potential competitors are successful in completing drug development for their product candidates and obtain approval from the FDA, they could limit the demand to participate in clinical trials of our product candidates. As a result, we may be at a competitive disadvantage that could delay the initiation, recruitment, timing, and completion of our clinical trials, as well as obtaining regulatory approvals, if at all, for our product candidates.

We, and our collaborators, if any, must comply with extensive government regulations in order to advance our product candidates through the development process and ultimately obtain and maintain marketing approval for our products in the U.S. and abroad.

The product candidates that we, or our collaborators, are developing or may develop require regulatory approval to advance through clinical development and to ultimately be marketed and sold and are subject to extensive and rigorous domestic and foreign government regulation. In the U.S., the FDA regulates, among other things, the development, testing, manufacture, safety, efficacy, record-keeping, labeling, storage, approval, advertising, promotion, sale, and distribution of pharmaceutical and biopharmaceutical products. Our product candidates are also subject to similar regulation by foreign governments to the extent we seek to develop or market them in those countries. We, or our collaborators, must provide the FDA and foreign regulatory authorities, if applicable, with preclinical and clinical data, as well as data supporting an acceptable manufacturing process, that appropriately demonstrate each of our product candidate's safety and efficacy before it can be approved for the targeted indications. Our product candidates have not been approved for sale in the U.S. or any foreign market, and we cannot predict whether we or our collaborators will obtain regulatory approval for any product candidates we are developing or plan to develop. The regulatory review and approval process can take many years, is dependent upon the type, complexity, novelty of, and medical need for the product candidate, requires the expenditure of substantial resources, and involves post-marketing surveillance and vigilance and potentially post-marketing studies or Phase IV clinical trials. In addition, we or our collaborators may encounter delays in, or fail to gain, regulatory approval for any of our product candidates based upon additional governmental regulation resulting from future legislative, administrative action or changes in FDA's or other similar foreign regulatory authorities' policy or interpretation during the period of product development. Delays or failures in obtaining regulatory approval to advance any of our product candidates through clinical development, and ultimately to commercialize them, may:

- adversely impact our ability to raise sufficient capital, if at all, to fund the development of our product candidates;
- adversely affect our ability to further develop or commercialize our product candidates;
- diminish any competitive advantages that we or our collaborators may have or attain; or
- adversely affect the receipt of potential milestone payments and royalties from collaborators, if any, from the sale of our products or product revenues in the future.

Furthermore, any regulatory approvals, if granted, may later be withdrawn. If we or our collaborators fail to comply with applicable regulatory requirements at any time, or if post-approval safety concerns arise, we or our collaborators may be subject to restrictions or a number of actions, including:

- delays, suspension, or termination of clinical trials related to our product candidates;
- refusal by regulatory authorities to review pending applications or supplements to approved applications;
- product recalls or seizures;
- suspension of manufacturing;
- withdrawals of previously approved marketing applications; or
- fines, civil penalties, and criminal prosecutions.

Additionally, at any time we or our collaborators may voluntarily suspend or terminate the preclinical or clinical development of a product candidate or withdraw any approved product from the market if we believe that it may pose an unacceptable safety risk to patients, or if the product candidate or approved product no longer meets our business objectives. The ability to develop or market a pharmaceutical product outside of the U.S. is contingent upon receiving appropriate authorization from the respective foreign regulatory authorities. Foreign regulatory approval processes typically include many, if not all, of the risks and requirements associated with the FDA regulatory process for drug development and may include additional risks. Additionally, results acceptable to support approval in one jurisdiction may be deemed inadequate by another regulatory authority to support regulatory approval in that other jurisdiction.

Clinical trials involve a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results.

Our product candidates may not prove to be safe and efficacious in clinical trials and may not meet all the applicable regulatory requirements needed to receive regulatory approval. To receive regulatory approval for the commercialization of our product candidates, we must conduct, at our own expense, extensive preclinical testing and clinical trials to demonstrate safety and efficacy of our product candidate for the intended indication of use. Clinical testing is expensive, can take many years to complete, if at all, and its outcome is uncertain. Failure can occur at any time during the clinical trial process.

The results of preclinical studies and early clinical trials of new drugs do not necessarily predict the results of later-stage clinical trials. The design of our clinical trials is based on many assumptions about the expected effects of our product candidate, and if those assumptions are incorrect, they may not produce statistically significant results. Preliminary results may not be confirmed on full analysis of the detailed results of a clinical trial. Product candidates in later stages of clinical development may fail to show safety and efficacy sufficient to support intended use claims despite having progressed through earlier clinical testing. The data collected from clinical trials of our product candidates may not be sufficient to support the filing of an NDA or to obtain regulatory approval in the United States or elsewhere. Because of the uncertainties associated with drug development and regulatory approvals, we cannot determine if or when we will have an approved product for commercialization or achieve sales or profits.

Delays in clinical testing could result in increased costs to us and delay our ability to generate revenue.

We may experience delays in clinical testing of our product candidates. We do not know whether planned clinical trials will begin on time, will need to be redesigned or will be completed on schedule, if at all, especially in light of the effects of the COVID-19 pandemic, including the effects of recent variants. From time to time, based on our experience with a clinical trial, we may amend the clinical trial protocol to address any issues that we observe as the trial is progressing, including in response to COVID-19 related factors or other factors impacting safety and the data collected, or we may be required to make certain changes in response to issues raised by the FDA, IRB, other regulatory authorities, investigators or clinical sites. Protocol amendments are subject to IRB and regulatory approval before we implement material changes, can result in additional costs, require additional data or participants, and may negatively impact the timelines for the trial. For example, in December 2021, we amended the protocol for our Phase III clinical trial to only allow SBRT patients during the induction phase of the study, as we observed a higher drop-out rate for patients on IMRT. As part of this change, we initiated a review of the statistical considerations for the study and in June 2022, submitted a Modified SAP to FDA. We submitted a protocol amendment to FDA in the second half of 2022 to reflect the changes in the Modified SAP. Under the modified Phase III clinical trial protocol and the Modified SAP, we plan to (i) analyze only patients receiving SBRT, consistent with the protocol change made in December 2021, (ii) include a second interim analysis, (iii) change the total number of SBRT patients randomized in the study to 114 (a reduction from the original 200 patients), with a total of 86 deaths from SBRT patients, including all deaths from SBRT patients enrolled in the study before the submission of the Modified SAP, and (iv) repower the study from 90% to 80%, which is commonly used in clinical trials. To date, we have not received any comments or objections from the FDA on the Modified SAP, which we submitted to the FDA in June 2022. We cannot provide assurance that the FDA will not raise any objections or disagree with our Modified SAP or the protocol amendments. We can provide no assurance on the timing of any of our interim analyses or when we will complete our Phase III study, if at all, or the outcome of the study. Disclosure of findings from our interim analyses before the completion of the trial may also impact the enrollment or retention of patients in our ongoing clinical trial. The changes in our study protocol may limit the clinical trial sites that can participate in our study, impact enrollment, and delay regulatory approval. If the FDA objects to our protocol amendments or Modified SAP, we may be required to expand the size of our study, increase the power level, or make other changes that can delay our clinical timelines and delay regulatory approval. Further, to the extent protocol amendments impact the data needed to support our proposed indication, the indication that is ultimately approved by the FDA or other regulatory authorities may be narrower than the indication initially sought. The FDA and other regulatory authorities may also impose other restrictions in our proposed labeling, which could have a material adverse effect on the prospects of our product candidates, if approved, and our business.

Clinical trials can be delayed for a variety of reasons, including pandemics, delays in obtaining regulatory approval to commence a clinical trial, in securing clinical trial agreements with prospective sites with acceptable terms, in obtaining IRB approval to conduct a clinical trial at a prospective site, in recruiting patients to participate in a clinical trial or in obtaining sufficient supplies of clinical trial materials, including RenovoCath. Many factors affect patient enrollment, including the size of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the clinical trial, the existing body of safety and efficacy data with respect to the study drug, competing clinical trials, new drugs approved for the conditions we are investigating, clinicians' and patients' perceptions of the potential advantages and side effects of the product candidates being studied in relation to other available therapies and product candidates, and health epidemics such as the COVID-19 pandemic. Clinical investigators will need to decide whether to offer their patients enrollment in clinical trials of our product candidate versus treating these patients with commercially available drugs that have established safety and efficacy profiles. Any delays in completing our clinical trials will increase our costs, slow down our product development, timeliness and approval process, and delay our ability to generate revenue.

The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.

The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable, but it typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. We have not obtained regulatory approval for any product candidate, and it is possible that any of our existing product candidates, or any product candidate we may seek to develop in the future, may never obtain regulatory approval.

Our product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required for approval by the FDA or comparable foreign regulatory authorities;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of an NDA or other submission or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; or
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

This lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market our product candidates, which would significantly harm our business, results of operations, prospects and our underlying stock price.

In addition, even if we were to obtain approval, regulatory authorities may approve our product candidates for fewer or more limited indications than we request, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for any of our product candidates.

We have not previously submitted an NDA to the FDA, nor similar drug approval filings to comparable foreign authorities, for our product candidates, and we cannot be certain that our product candidates will be successful in clinical trials or receive regulatory approval. Further, our product candidates may not receive regulatory approval even if they are successful in clinical trials. If we do not receive regulatory approvals for our product candidates, we may not be able to continue our operations. Even if we successfully obtain regulatory approvals to market one or more of our product candidates, our revenues will be dependent on many factors including the size of the markets in the territories for which we gain regulatory approval and have commercial rights. If the markets for patients that we are targeting for our product candidates are not as significant as we estimate, we may not generate significant revenues from sales of such products, if approved.

We plan to seek regulatory approval and to commercialize our product candidates, directly or with collaborators in the United States, the European Union, and other foreign countries which we have not yet identified. While the scope of regulatory approval is similar in other countries, to obtain separate regulatory approval in many other countries we must comply with numerous and varying regulatory requirements of such countries regarding the safety and efficacy, among other things, of clinical trials and commercial sales, pricing, and distribution of our product candidates, and we cannot predict success in these jurisdictions.

We may be required to suspend or discontinue clinical trials due to unexpected side effects or other safety risks that could preclude approval of our product candidates.

Our clinical trials may be suspended at any time for a number of reasons. For example, we may voluntarily suspend or terminate our clinical trials if at any time we believe that they present an unacceptable risk to the clinical trial patients. In addition, the FDA or other regulatory agencies may order the temporary or permanent discontinuation of our clinical trials at any time if they believe that the clinical trials are not being conducted in accordance with applicable regulatory requirements or that they present an unacceptable safety risk to the clinical trial patients.

Administering our product candidates to humans may produce undesirable side effects. These adverse side effects could interrupt, delay or halt clinical trials of our product candidates and could result in the FDA or other regulatory authorities denying further development or approval of any of our product candidates for any or all targeted indications. Ultimately, our product candidates may prove to be unsafe for human use. Moreover, we could be subject to significant liability if any volunteer or patient suffers, or appears to suffer, adverse health effects as a result of participating in our clinical trials. Prosecution, enforcement actions, damages or adverse media coverage related to such events, if any, will likely result in a materially significant diversion of management's attention and resources and significant defense costs and other professional fees. As a general matter, such events could damage our reputation, brand, international activities, business, prospects, operating results and financial condition.

If we fail to comply with healthcare regulations, we could face substantial enforcement actions, including civil and criminal penalties and our business, operations and financial condition could be adversely affected.

Our business operations and activities may be directly or indirectly subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act. The product candidates that we are developing are highly regulated, and there can be no assurance that the regulatory environment in which we operate will not change significantly and adversely in the future. If we begin commercializing any products cleared or approved by the FDA in the United States, our exposure under such laws will increase significantly, and our costs associated with compliance with such laws are also likely to increase. Our current and future arrangements with healthcare professionals, clinical investigators, CROs, third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our products for which we obtain marketing approval. In addition, we may be subject to laws of the federal government and state governments in which we conduct our business relating to privacy, data protection and data security with respect to patient information.

As a developer of drug/device combination products and a proprietary drug delivery device, certain federal and state healthcare laws and regulations pertaining to fraud and abuse, false claims, transparency and patients' privacy rights are and will be applicable to our business. We could be subject to healthcare fraud and abuse laws, transparency and privacy laws of both the federal government and the states in which we conduct our business and private "qui tam" actions brought by individual whistleblowers on behalf of the federal or state governments. The scope and enforcement of each of the laws applicable to our business and products are uncertain and subject to rapid change in the current environment of healthcare reform. The laws include:

- the federal healthcare program anti-kickback law, which prohibits, among other things, persons from soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs;
- federal false claims laws which prohibit, among other things, individuals, or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent, and which may apply to entities like us which provide coding and billing information to customers;
- the federal Health Insurance Portability and Accountability Act of 1996, which prohibits executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters and which also imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information;

- the federal Open Payments program under the Physician Payments Sunshine Act, created under Section 6002 of the ACA and its implementing regulations, which requires certain manufacturers of covered drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program (with certain exceptions) and applicable group purchasing organizations to report annually to CMS information related to payments or other transfers of value made in the previous year to covered recipients, including physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician healthcare professionals (such as physician assistants and nurse practitioners, among others), and teaching hospitals, and information regarding ownership and investment interests held by physicians (as defined above) and their immediate family members;
- the federal Food, Drug, and Cosmetic Act, which among other things, strictly regulates drug manufacturing and product marketing, prohibits manufacturers from marketing drug products for off-label use and regulates the distribution of drug samples;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- federal government drug price reporting laws, changed by the ACA to, among other things, increase the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program and offer such rebates to additional populations, that require us to calculate and report complex pricing metrics to government programs, where such reported prices may be used in the calculation of reimbursement or discounts on our marketed drugs (participation in these programs and compliance with the applicable requirements may subject us to potentially significant discounts on our product candidates, increased infrastructure costs, and potentially limit our ability to offer certain marketplace discounts);
- the Foreign Corrupt Practices Act, a United States law which regulates certain financial relationships with foreign government officials (which could include, for example, certain medical professionals);
- analogous state and foreign laws and regulations, including: state anti-kickback and false claims laws which may apply to our business practices, including, but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by state governmental and non-governmental third-party payors, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry’s voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government; state laws that require drug manufacturers to track gifts and other remuneration and items of value provided to healthcare professionals and entities; state and local laws that require the registration of pharmaceutical sales representatives; and state laws that require drug manufacturers to report information relating to pricing and marketing information; and
- state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by federal laws, thus complicating compliance efforts.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws may involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws. If our operations are found to be in violation of any of the laws described above or any governmental regulations that apply to us, we may be subject to greater liabilities, penalties, including civil and criminal penalties, damages, fines, and the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment or restructuring of our operations could adversely affect our ability to operate our business and our financial results. Although compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert management’s attention from the operation of our business.

If any of the physicians or other providers or entities with whom we expect to do business, is found not to be in compliance with applicable laws, it may be subject to significant criminal, civil or administrative sanctions, including exclusions from participation in government healthcare programs, which could also materially affect our business.

We are also subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws, and anti-money laundering laws and regulations. Compliance with these legal standards could impair our ability to compete in domestic and international markets. We can face criminal liability and other serious consequences for violations which can harm our business. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors, and other partners from authorizing, promising, offering, or providing, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We may engage third parties for clinical trials outside of the United States, to sell our products abroad once we enter a commercialization phase, or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals. We may have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors, and other partners, even if we do not explicitly authorize or have actual knowledge of such activities. Any violation of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences.

If we are unable to satisfy regulatory requirements, we may not be able to commercialize our product candidates.

We need FDA approval prior to marketing our product candidates in the United States. This approval process is lengthy and subject to extensive governmental regulations and given the unpredictability of the results of clinical trials, our failure to obtain regulatory approval from the FDA to market any of our product candidates would significantly harm our business, results of operations and prospects. Any delay or failure in seeking or obtaining required approvals from the FDA to market any of our product candidates would have a material and adverse effect on our ability to sell our product candidates in the United States and to generate revenue from any such candidates we are developing and for which we are seeking approval.

The FDA's review and approval process, including among other things, evaluation of preclinical studies and clinical trials of a product candidate as well as the manufacturing process and facility, is lengthy, expensive, and uncertain. To receive approval, we must, among other things, demonstrate with substantial evidence from well-designed and well-controlled preclinical testing and clinical trials that the product candidates are both safe and effective for each indication for which approval is sought. Satisfaction of these requirements typically takes several years, and the time needed to satisfy them may vary substantially, based on the type, complexity and novelty of the pharmaceutical product. We cannot predict if or when we will submit an NDA for approval for any of our product candidates currently under development. Any approvals we may obtain may not cover all of the clinical indications for which we are seeking approval or may contain significant limitations on the conditions of use.

The FDA has substantial discretion in the NDA review process and may either refuse to file our NDA for substantive review or may decide that our data is insufficient to support approval of our product candidates for the claimed intended uses. Following any regulatory approval of our product candidates, we will be subject to continuing regulatory obligations such as safety reporting, required and additional post marketing obligations, and regulatory oversight of promotion and marketing. Even if we receive regulatory approvals for any of our product candidates, the FDA may subsequently seek to withdraw approval of our NDA if we determine that new data or a reevaluation of existing data show the product is unsafe for use under the conditions of use upon the basis of which the NDA was approved, or based on new evidence of adverse effects or adverse clinical experience, or upon other new information. If the FDA does not file or approve our NDA or withdraws approval of our NDA, the FDA may require that we conduct additional clinical trials, preclinical or manufacturing studies and submit that data before it reconsiders our application. Depending on the extent of these or any other requested studies, approval of any applications that we submit may be delayed by several years, may require us to expend more resources than we have available, or may never be obtained at all. In addition, we have obtained FDA clearance for our RenovoCath delivery system, which is subject to FDA medical device regulations, including the Quality System Regulation. In the event adverse events arise with respect to the RenovoCath delivery system, the FDA could revoke its clearance which would have a material adverse effect on our business.

We will also be subject to a wide variety of foreign regulations governing the development, manufacture, and marketing of our products to the extent we seek regulatory approval to develop and market any of our product candidates in a foreign jurisdiction. As of the date hereof we have not identified any foreign jurisdictions which we intend to seek approval from. Whether or not FDA approval has been obtained, approval of a product candidate by the comparable regulatory authorities of foreign countries must still be obtained prior to marketing the product candidate in those countries. The approval process varies, and the time needed to secure approval in any region such as the European Union or in a country with an independent review procedure may be longer or shorter than that required for FDA approval. We cannot assure you that clinical trials conducted in one country will be accepted by other countries or that an approval in one country or region will result in approval elsewhere.

Even after approval, we are subject to extensive regulations. The regulations to which we are subject are complex and have tended to become more stringent over time. Regulatory changes could result in restrictions on our ability to carry on or expand our operations, higher than anticipated costs or lower than anticipated sales. The FDA and foreign counterparts enforce these regulatory requirements through, among other means, periodic unannounced inspections and periodic reviews of public marketing and promotion materials. We do not know whether we will be found compliant in connection with any future FDA or foreign counterparts' inspections or reviews. Failure to comply with applicable regulations could jeopardize our ability to sell our products and result in enforcement actions such as: warning letters; untitled letters; fines; injunctions; civil penalties; termination of distribution; recalls or seizures of products; delays in the introduction of products into the market; total or partial suspension of production; refusal to grant future clearances, approvals, or certifications; withdrawals or suspensions of current approvals or certifications, resulting in prohibitions on sales of our products; and in the most serious cases, criminal penalties.

We have received Orphan Drug Designation for RenovoGem for two rare diseases: pancreatic cancer and cholangiocarcinoma. We may seek Orphan Drug Designation for future product candidates, but we may be unable to obtain such designation or to maintain the benefits associated with Orphan Drug Designation, including market exclusivity, which may cause our revenue, if any, to be reduced.

To date, we have secured FDA Orphan Drug Designation for RenovoGem in two rare diseases: pancreatic cancer and cholangiocarcinoma. Although we may seek Orphan Drug Designation for some or all of our other product candidates, we may never receive such designations. Under the Orphan Drug Act, the FDA may designate a drug product as an orphan drug if it is intended to treat a rare disease or condition, defined as a patient population of fewer than 200,000 in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. Orphan Drug Designation must be requested before submitting an NDA. In the United States, Orphan Drug Designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages, and application fee waivers. After the FDA grants Orphan Drug Designation, the generic identity of the drug and its potential orphan use are disclosed publicly by the FDA.

In addition, if a drug product receives the first FDA approval for an indication for which it has orphan designation, the drug product is entitled to orphan drug exclusivity, which means the FDA may not approve any other application to market the same drug for the same indication for a period of seven years, except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity or where the manufacturer is unable to assure sufficient product quantity for the orphan patient population. Exclusive marketing rights in the United States may also be unavailable if we seek approval for an indication broader than the orphan designation and may be lost if the FDA later determines that the request for designation was materially defective.

Even if we obtain Orphan Drug Designation, we may not be the first to obtain marketing approval for any particular indication within the orphan designation due to uncertainties associated with developing pharmaceutical products, which would have a material adverse effect on our operations, regulatory approval and ability to commercialize our product candidate. Further, even if we obtain orphan drug exclusivity for a product candidate, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties can be approved for the same condition. Even after an orphan drug is approved, the FDA can subsequently approve the same drug with the same active moiety for the same indication or use if the FDA concludes that the later drug is clinically superior or makes a major contribution to patient care. Orphan Drug Designation neither shortens the development time or regulatory review time of a product candidate nor gives the product candidate any advantage in the regulatory review or approval process or entitles the product candidate to priority review.

Further, in *Catalyst Pharms., Inc. v. Becerra*, 14 F.4th 1299 (11th Cir. 2021), the court disagreed with the FDA's longstanding position that the orphan drug exclusivity only applies to the approved use or indication within an eligible disease. This decision created uncertainty in the application of the orphan drug exclusivity. On January 24, 2023, the FDA published a notice in the Federal Register to clarify that while the agency complies with the court's order in *Catalyst*, the FDA intends to continue to apply its longstanding interpretation of the regulations to matters outside of the scope of the *Catalyst* order – that is, the agency will continue tying the scope of orphan-drug exclusivity to the uses or indications for which a drug is approved, which permits other sponsors to obtain approval of a drug for new uses or indications within the same orphan designated disease or condition that have not yet been approved. It is unclear how future litigation, legislation, agency decisions, and administrative actions will impact the scope of the orphan drug exclusivity.

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 face competition generally from established pharmaceutical and biotechnology companies, as well as from academic institutions, government agencies and private and public research institutions. Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Small or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. We are aware of a number of companies in Phase III clinical trials for the treatment of LAPC including Angiodynamics, Bausch Health, FibroGen, Novocure, and SynCore Biotechnology. In addition, we are aware of a number of companies in Phase I and Phase II clinical trials for the treatment of LAPC including one interventional company, TriSalus Lifesciences. Our commercial opportunity will be reduced or eliminated if our competitors develop and commercialize any products that are safer, more effective, have fewer side effects or are less expensive than our product candidates. These potential competitors compete with us in recruiting and retaining key and qualified scientific and management personnel, establishing clinical trial sites, and patient enrollment for clinical trials, as well as in acquiring technologies and technology licenses complementary to our programs or advantageous to our business.

If approved and commercialized, RenovoGem would compete with several currently approved prescription therapies for the treatment of LAPC and cholangiocarcinoma. To our knowledge, other potential competitors are in the earlier stages of development. If potential competitors are successful in completing drug development for their product candidates and obtain approval from the FDA, they could limit the demand for RenovoGem.

We expect that our ability to compete effectively will depend upon our ability to:

- successfully identify and develop key points of product differentiation from currently available therapies;
- successfully and timely complete clinical trials and submit for and obtain all requisite regulatory approvals in a cost-effective manner;
- maintain a proprietary position for our products and manufacturing processes and other related product technology;
- attract and retain key and qualified personnel;
- develop relationships with physicians prescribing these products; and
- build an adequate sales and marketing infrastructure for our products, if approved.

Because we will be competing against significantly larger companies with established track records, we will have to demonstrate that, based on experience, clinical data, side-effect profiles and other factors, our products, if approved, are competitive with other products. If we are unable to compete effectively and differentiate our products from other marketed drugs, we may never generate meaningful revenue.

We may expend our limited resources to pursue one or more product candidates or indications within our product development strategy, which has and may continue to change over time, and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we intend to focus on developing product candidates for specific indications that we identify as most likely to succeed, in terms of their potential both to gain regulatory approval and to achieve commercialization. As a result, we may forego or delay the pursuit of opportunities with other product candidates or in other indications with greater commercial potential. Such resource allocation and strategic decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable product candidates. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing, or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to the product candidate.

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

We do not currently possess internal manufacturing capacity. We plan to utilize the services of cGMP manufacturers, FDA inspected contract manufacturers to formulate and manufacture our preclinical and clinical supplies. Any curtailment in the availability of gemcitabine, or RenovoCath, the drug delivery device, however, could result in production or other delays with consequent adverse effects on us. In addition, because regulatory authorities must generally approve raw material sources for pharmaceutical products, changes in raw material suppliers may result in production delays or higher raw material costs.

We obtain our RenovoCath delivery system from a single source, which must be manufactured in accordance with the FDA Quality System Regulation (QSR). Gemcitabine is supplied from our clinical sites' pharmacies and used off-label for intra-arterial use within our clinical study. We continue to pursue supply agreements for gemcitabine and our RenovoCath delivery system. We may be required to agree to minimum volume requirements, exclusivity arrangements or other restrictions with the contract manufacturers. We may not be able to enter into long-term agreements on commercially reasonable terms, or at all. If we change or add manufacturers, the FDA and comparable foreign regulators may require approval of the changes. Approval of these changes could require new testing by the manufacturer and compliance inspections to ensure the manufacturer is conforming to all applicable laws and regulations and cGMP.

The manufacture of pharmaceutical products, including drug/device combination products, requires significant expertise and capital investment, including the development of an acceptable formulation to support later-stage trials for our product candidates, advanced manufacturing techniques and process controls. Manufacturers of pharmaceutical products may encounter difficulties in production, particularly in scaling up production and reformulating the form of any of our product candidates. For drug/device combination products, ensuring compliance with both medical device and drug regulations exposes us to additional risks. These problems include difficulties with production costs and yields, quality control, including stability of the product and quality assurance testing, shortages of qualified personnel, as well as compliance with federal, state, and foreign regulations. Our contract manufacturers may also place a priority on the manufacture of their own products, or other customers' products. In addition, any delay or interruption in the supply of clinical trial supplies, due to the effects of the COVID-19 pandemic or otherwise, could delay the completion of our clinical trials, increase the costs associated with conducting our clinical trials and, depending upon the period of delay, require us to commence new clinical trials at significant additional expense or to terminate a clinical trial.

We will be responsible for ensuring that our future contract manufacturers comply with the cGMP requirements of the FDA and other regulatory authorities from which we seek to obtain product approval. These requirements include, among other things, quality control, quality assurance and the maintenance of records and documentation. The approval process for NDAs includes an inspection of the manufacturer's compliance with cGMP requirements. We will be responsible for regularly assessing a contract manufacturer's compliance with cGMP requirements through record reviews and periodic audits and for ensuring that the contract manufacturer takes responsibility and corrective action for any identified deviations. Manufacturers of our product candidates may be unable to comply with these cGMP requirements and with other FDA and foreign regulatory requirements, if any.

While we will oversee compliance of our contract manufacturers, ultimately, we will not have control over our manufacturers' compliance with these regulations and standards. A failure to comply with these requirements may result in fines and civil penalties, suspension of production, suspension or delay in product approval, product seizure or recall, or withdrawal of product approval. If the safety of any of our product candidates is compromised due to a manufacturers' failure to adhere to applicable laws or for other reasons, we may not be able to obtain regulatory approval for or successfully commercialize any of our product candidates, and we may be held liable for any injuries sustained as a result. Any of these factors could cause a delay of clinical trials, regulatory submissions, approvals, or commercialization of RenovoGem or other product candidates, entail higher costs or result in us being unable to effectively commercialize any of our product candidates. Furthermore, if our manufacturers fail to deliver the required commercial quantities on a timely basis and at commercially reasonable prices, we may be unable to meet demand for any approved products and would lose potential revenues. There are also risks of our contract manufacturers failing to perform as agreed, terminating their relationship with us, experiencing the effects of any strikes or other work stoppages, or not remaining in the contract manufacturing business.

Our dependence on third-party suppliers subjects us to a number of risks that could negatively impact our ability to manufacture products and harm our business, including:

- interruption of supply resulting from modifications to, or discontinuation of, a supplier's operations;
- delays in product shipments resulting from uncorrected defects, reliability issues, or a supplier's failure to produce components that consistently meet our quality specifications;
- price fluctuations due to a lack of long-term supply arrangements with our suppliers for key components;
- inability to obtain adequate supply in a timely manner or on commercially reasonable terms;
- difficulty identifying and qualifying alternative suppliers for components in a timely manner;
- inability of suppliers to comply with applicable provisions of the FDA's QSR, cGMP regulations or other applicable laws or regulations enforced by the FDA or state regulatory authorities and foreign regulatory authorities;
- inability to ensure the quality of products or components manufactured by third parties;
- production delays related to the evaluation and testing of products and components from alternative suppliers and corresponding regulatory qualifications;
- delays in delivery by our suppliers due to changes in demand from us or their other customers, or our suppliers prioritizing their other customers over us; and
- an outbreak of disease or similar public health threat, such as the existing threat of COVID-19 pandemic, particularly as it may impact our supply chain.

Although we require that our third-party suppliers provide our manufacturing partners with components that meet our specifications and comply with applicable provisions of the QSR, cGMP and other applicable legal and regulatory requirements in our agreements and contracts, there is a risk that our suppliers will not always act with our best interests in mind, and they may not always supply components that meet our requirements or supply components in a timely manner. Any interruption or delay in the supply of components or materials, or our inability to obtain components or materials from alternate sources at acceptable prices in a timely manner, could impair our ability to meet the demand of our customers and cause them to cancel orders or switch to competitive procedures. These events could harm our business and our operating results.

We may not be able to manufacture our product candidates in commercial quantities, which would prevent us from commercializing our product candidates.

To date, our product candidates have been manufactured in small quantities for preclinical studies and clinical trials. If any of our product candidates are approved by the FDA or comparable regulatory authorities in other countries for commercial sale, we will need to manufacture such product candidates in larger quantities. We may not be able to successfully increase the manufacturing capacity for our product candidates in a timely or economic manner, or at all. A significant scale-up of manufacturing may require additional validation studies, which the FDA must review and approve. If we are unable to successfully increase the manufacturing capacity for a product candidate, the clinical trials as well as the regulatory approval or commercial launch of that product candidate may be delayed or there may be a shortage in supply. Our product candidates require precise, high-quality manufacturing in accordance with cGMP. Our failure to achieve and maintain these high-quality manufacturing standards in collaboration with our third-party manufacturers, including the incidence of manufacturing errors, could result in patient injury or death, product recalls or withdrawals, delays or failures in product testing or delivery, cost overruns or other problems that could harm our business, financial condition and results of operations.

Our product candidates, if approved for sale, may not gain acceptance among physicians, patients, and the medical community, thereby limiting our potential to generate revenues.

If our product candidates are approved for commercial sale by the FDA or other regulatory authorities, the degree of market acceptance of any approved product by physicians, healthcare professionals and third-party payors and our profitability and growth will depend on a number of factors, including:

- demonstration of safety and efficacy;
- perceived advantages of our product candidates over alternative treatments;
- the indications for which the product candidates are approved and the labeling approved by regulatory authorities for use with the product candidates, including any warnings, limitations or contraindications contained in a product's approved labeling;
- approval of other new therapies for the same indications;
- acceptance by physicians and patients of the product candidate as a safe and effective treatment;
- the cost, safety and efficacy of treatment in relation to alternative treatments, including generic versions of the product candidates;
- the extent to which our product candidates are included on formularies of hospitals and managed care organizations;
- changes in the practice guidelines and the standard of care for the targeted indication;
- relative convenience and ease of administration;
- the prevalence and severity of any adverse side effects;
- budget impact of adoption of our product on relevant drug formularies and the availability, cost, and potential advantages of alternative treatments, including less expensive generic drugs;
- pricing, reimbursement, and cost effectiveness, which may be subject to regulatory control;
- effectiveness of our or any of our partners' sales and marketing strategies;
- the product labeling or product insert required by the FDA or regulatory authority in other countries; and
- the availability of adequate third-party insurance coverage or reimbursement.

If any product candidate that we develop does not provide a treatment regimen that is as beneficial as, or is perceived as being as beneficial as, the current standard of care or otherwise does not provide patient benefit, that product candidate, if approved for commercial sale by the FDA or other regulatory authorities, likely will not achieve market acceptance. Our ability to effectively promote and sell any approved products will also depend on pricing and cost-effectiveness, including our ability to produce a product at a competitive price and our ability to obtain sufficient third-party coverage or reimbursement. If any product candidate is approved but does not achieve an adequate level of acceptance by physicians, patients and third-party payors, our ability to generate revenues from that product would be substantially reduced. In addition, our efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources, may be constrained by FDA rules and policies on product promotion, and may never be successful.

Guidelines and recommendations published by various organizations can impact the use of our products.

Government agencies promulgate regulations and guidelines directly applicable to us and to our product. In addition, professional societies, practice management groups, private health and science foundations and organizations involved in various diseases from time to time may also publish guidelines or recommendations to the healthcare and patient communities. Recommendations of government agencies or these other groups or organizations may relate to such matters as usage, dosage, route of administration and use of concomitant therapies. Recommendations or guidelines suggesting the reduced use of our products or the use of competitive or alternative products that are followed by patients and healthcare providers could result in decreased use of our proposed products.

The market for RenovoGem and our other product candidates may not be as large as we expect.

Our estimates of the potential market opportunity for RenovoGem and our other product candidates include several key assumptions based on our industry knowledge, industry publications, third-party research reports and other surveys, including surveys commissioned by us. These assumptions include the size of our target populations, the prevalence and incidence of each of our target indications, the number of patients receiving current treatment, the percentage of patients unsatisfied with the current treatments, the number of diagnosed but untreated patients, the compliance and adherence of patients in our target populations, the number of treatment centers and prescribing physicians and the percentage of payer acceptance. While we believe that our internal assumptions are reasonable, if any of these assumptions proves to be inaccurate, then the actual market for our product candidates could be smaller than our estimates of our potential market opportunity. If the actual market for any of our product candidates is smaller than we expect, our product revenue may be limited, and it may be more difficult for us to achieve or maintain profitability.

In the event that we need to change our third-party contract manufacturers, our preclinical studies, clinical trials or the commercialization of our product candidates could be delayed, adversely affected or terminated, or such a change may result in significantly higher costs.

Due to regulatory restrictions inherent in an IND or NDA, or for economic reasons, various steps in the manufacture of any of our product candidates may need to be sole-sourced. We currently obtain our RenovoCath delivery system, subject to requirements under the QSR, from a single supplier. In accordance with cGMP regulations and QSR, changing manufacturers may require the re-validation of manufacturing processes and procedures, and may require further preclinical studies or clinical trials to show comparability between the materials produced by different manufacturers, and further regulatory review and approval. Changing our current or future contract manufacturers may be difficult for us and could be costly, which could result in our inability to manufacture our product candidate for an extended period of time and therefore a delay in the development of any of our product candidates. While we intend to find alternative suppliers to mitigate the risk, our efforts may not be successful. Further, to maintain our development timelines in the event of a change in our third-party contract manufacturer, we may incur significantly higher costs to manufacture any of our product candidates.

We currently do not have any internal drug discovery capabilities, and therefore we are dependent on identifying drugs that are off patent or on in-licensing or acquiring development programs from third parties in order to obtain additional product candidates.

If in the future we decide to further expand our pipeline of product candidates, we will be dependent on identifying drugs that are off patent or on in-licensing or acquiring product candidates as we do not have significant internal discovery capabilities at this time. We may face substantial competition from other biotechnology and pharmaceutical companies, many of which may have greater resources than we have, in obtaining in-licensing, sponsored research or acquisition opportunities. In-licensing or acquisition opportunities may not be available to us on terms we find acceptable, if at all. In-licensed compounds that appear promising in research or in preclinical studies may fail to progress into further preclinical studies or clinical trials.

If a product liability claim is successfully brought against us for uninsured liabilities, or such a claim exceeds our insurance coverage, we could be forced to pay substantial damage awards that could materially harm our business.

The use of any of our existing or future product candidates in clinical trials and the sale of any approved pharmaceutical products may expose us to significant product liability claims. We have product liability insurance coverage for our proposed clinical trials; however, such insurance coverage may be inadequate and may not protect us against any or all of the product liability claims that may be brought against us now or in the future. We may not be able to acquire or maintain adequate product liability insurance coverage at a commercially reasonable cost or in sufficient amounts or scope to protect us against potential losses. In the event a product liability claim is brought against us, we may be required to pay legal and other expenses to defend the claim, as well as uncovered damage awards resulting from a claim brought successfully against us. In the event that any of our product candidates are approved for sale by the FDA and commercialized, we may need to substantially increase the amount of our product liability coverage. Defending any product liability claim or claims could require us to expend significant financial and managerial resources, which could have a material adverse effect on our business.

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.

Even though the results of preclinical studies and clinical trials that have been conducted or may be conducted in the future may support further development of our product candidates, we may delay, suspend or terminate the future development of a product candidate at any time for strategic, business, financial or other reasons, including the determination or belief that the emerging profile of the product candidate is such that it may not receive FDA approval, gain meaningful market acceptance, generate a significant return to stockholders, or otherwise provide any competitive advantages in its intended indication or market.

Risks Related to Our Operations

Our future success depends on our ability to retain our key personnel and to attract, retain and motivate qualified personnel.

We are highly dependent on the development, regulatory, commercialization, and business development expertise of Shaun Bagai, our Chief Executive Officer, as well as the other principal members of our management, scientific and clinical teams. Although we have employment agreements, offer letters or consulting agreements with our executive officers, these agreements do not prevent them from terminating their services at any time.

If we lose one or more of our executive officers or key employees, our ability to implement our business strategy successfully could be seriously harmed. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop product candidates, gain regulatory approval, and commercialize new products. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these additional key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition, including a recent hyper-competitive compensation environment, for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be engaged by entities other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. One such key consultant is Dr. Ramtin Agah, our Chief Medical Officer. If we are unable to continue to attract and retain highly qualified personnel, our ability to develop and commercialize product candidates will be limited.

We will need to increase the size of our organization, and we may experience difficulties in managing growth.

We are a small company with less than 10 employees. The future growth of our company will impose significant additional responsibilities on members of management, including the need to identify, attract, retain, motivate and integrate highly skilled personnel. We may increase the number of employees in the future depending on the progress of our development and commercialization of our product candidates. Our future financial performance and our ability to commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to:

- manage our clinical studies effectively;
- integrate additional and future management, administrative, manufacturing, sales and marketing, and regulatory personnel;
- maintain sufficient administrative, accounting and management information systems and controls; and
- hire and train additional qualified personnel.

There is no guarantee that we will be able to accomplish these tasks, and our failure to accomplish any of them could materially adversely affect our business, prospects, and financial condition.

Business disruptions could seriously harm future revenue and financial condition and increase our costs and expenses.

Our operations, and those of our third-party manufacturers, contract research organizations (“CROs”), and other contractors and consultants, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or man-made disasters or business interruptions beyond our control, for which we are predominantly self-insured. The occurrence of any of these business disruptions could delay our clinical trials, seriously harm our operations and financial condition and increase our costs and expenses. In addition, our ability to obtain clinical supplies for our clinical trials and materials for our product candidates could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster or other business interruptions.

Our corporate headquarters are located in Silicon Valley, California, an area prone to wildfires and earthquakes. These and other natural disasters could severely disrupt our operations, and have a material adverse effect on our business, results of operations, financial condition and prospects. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as the manufacturing facilities of our third-party contract manufacturers, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. Any disaster recovery and business continuity plans we have in place may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material adverse effect on our business.

Catastrophic events and man-made problems, such as terrorism, war, or climate change may disrupt our business.

A significant natural disaster, such as an earthquake, fire, flood, hurricane, or significant power outages, water shortages and the risks associated with climate change could have an adverse impact on our business, results of operations, and financial condition. Our employees and executive officers are located in the San Francisco Bay Area, a region known for seismic activity, drought, and wildfires, and the resultant air quality impacts and power outages associated with such wildfires.

In addition, acts of terrorism, pandemics, such as the ongoing COVID-19 pandemic or another public health crisis, protests, riots, and the increasing frequency and impact of extreme weather events on critical infrastructure in the U.S. and elsewhere have the potential to disrupt our business and the business of our third-party suppliers, and may cause us to experience higher attrition, losses, and additional costs to maintain or resume operations. All of the aforementioned risks may be further increased if our course of action in response to catastrophic events proves to be inadequate. For example, if a catastrophic event occurred that prevented us from using all or a significant portion of our facility, that damaged critical infrastructure, such as the manufacturing facilities of our third-party contract manufacturers, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. Any disaster recovery and business continuity plan we have in place may prove inadequate in the event of a serious disaster or similar event and we may incur substantial expenses as a result of the limited nature of these plans, which could have a material adverse effect on our business.

In February 2022, armed conflict escalated between Russia and Ukraine. The sanctions announced by the U.S. and other countries against Russia, following Russia’s invasion of Ukraine, to date include restrictions on selling or importing goods, services, or technology in or from affected regions, and travel bans and asset freezes impacting connected individuals and political, military, business, and financial organizations in Russia. The United States and other countries could impose wider sanctions and take other actions should the conflict further escalate. It is not possible to predict the broader consequences of this conflict, which could include further sanctions, embargoes, regional instability, prolonged periods of higher inflation, geopolitical shifts, and adverse effects on macroeconomic conditions, currency exchange rates, and financial markets, all of which could have a material adverse effect on our business, financial condition, and results of operations.

Security threats to our information technology infrastructure and/or our physical buildings could expose us to liability and damage our reputation and business.

It is essential to our business strategy that our and our vendors, partners, clinical trial sites, and third-party providers' technology and network infrastructure and physical buildings remain secure and are perceived by our customers and corporate partners to be secure. Despite our implementation of security measures, any of the internal computer systems and networks belonging to or used by us or our employees and our third-party service providers are vulnerable to damage and disruption from computer viruses, ransomware and other malicious code, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failure, as well as security breaches and incidents from inadvertent or intentional actions, or from cyber-attacks by malicious third parties (including supply chain cyber-attacks, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information), which may compromise system infrastructure or lead to the loss, destruction, alteration, prevention of access to, disclosure, or dissemination of, or damage or unauthorized access to, our data (including trade secrets or other confidential information, intellectual property, proprietary business information, and personal information) or data that is processed or maintained on our behalf, or other assets, which could result in financial, legal, business and reputational harm to us. Any system failure, accident or security breach or incident that causes interruptions in our own or in our third-party service providers' operations could result in a material disruption of our development programs or other aspects of our operations. As a result of the ongoing COVID-19 pandemic, with many of our employees working from home from time to time and accessing our corporate network via remote devices, the potential for such events to occur is even greater. Despite security measures, we also cannot guarantee the security of our physical buildings. Physical building penetration or any cyber-attacks could negatively affect our reputation, damage our network infrastructure and our ability to deploy our products and services, harm our relationship with customers and partners that are affected, and expose us to financial liability, including the possibility of consequential damages resulting from cyber-attacks and other security threats.

Additionally, there are a number of state, federal, and international laws protecting the privacy and security of health information and personal data. For example, the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") imposes limitations on the use and disclosure of an individual's healthcare information by healthcare providers, healthcare clearinghouses, and health insurance plans, or, collectively, covered entities, and also grants individuals rights with respect to their health information. HIPAA also imposes compliance obligations and corresponding penalties for non-compliance on individuals and entities that provide services to healthcare providers and other covered entities. As part of the American Recovery and Reinvestment Act of 2009 ("ARRA"), the privacy and security provisions of HIPAA were amended. ARRA also made significant increases in the penalties for improper use or disclosure of an individual's health information under HIPAA and extended enforcement authority to state attorneys general. As amended by ARRA and subsequently by the final omnibus rule adopted in 2013, HIPAA also imposes notification requirements on covered entities in the event that certain health information has been inappropriately accessed or disclosed, including notification requirements to individuals, federal regulators, and in some cases, notification to local and national media. Notification is not required under HIPAA if the health information that is improperly used or disclosed is deemed secured in accordance with encryption or other standards developed by the U.S. Department of Health and Human Services. Most states have laws requiring notification of affected individuals and/or state regulators in the event of a breach of personal information, which is a broader class of information than the health information protected by HIPAA. Many state laws impose significant data security requirements, such as encryption or mandatory contractual terms, to ensure ongoing protection of personal information. Activities outside of the U.S. implicate local and national data protection standards, impose additional compliance requirements, and generate additional risks of enforcement for non-compliance. We may be required to expend significant capital and other resources to ensure ongoing compliance with applicable privacy and data security laws, to protect against security breaches and hackers or to alleviate problems caused by such breaches.

We and our third-party contract manufacturers must comply with environmental, health and safety laws and regulations, and failure to comply with these laws and regulations could expose us to significant costs or liabilities.

We and our third-party manufacturers are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the use, generation, manufacture, distribution, storage, handling, treatment, remediation and disposal of hazardous materials and wastes. Hazardous chemicals, including flammable and biological materials, are involved in certain aspects of our business, and we cannot eliminate the risk of injury or contamination from the use, generation, manufacture, distribution, storage, handling, treatment or disposal of hazardous materials and wastes. In the event of contamination or injury, or failure to comply with environmental, health and safety laws and regulations, we could be held liable for any resulting damages and any such liability could exceed our assets and resources. We could also incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

Environmental, health and safety laws and regulations are becoming increasingly more stringent. We may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Our failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Further, with respect to the operations of our third-party contract manufacturers, it is possible that if they fail to operate in compliance with applicable environmental, health and safety laws and regulations or properly dispose of wastes associated with our products, we could be held liable for any resulting damages, suffer reputational harm or experience a disruption in the manufacture and supply of our product candidates or products.

A variety of risks associated with operating internationally could materially adversely affect our business.

Doing business internationally involves a number of risks, including but not limited to:

- multiple, conflicting and changing laws and regulations, such as privacy regulations, tax laws, export and import restrictions, employment laws, regulatory requirements and other governmental approvals, permits and licenses;
- failure by us to obtain and maintain regulatory approvals for the use of our products in various countries;
- additional potentially relevant third-party patent rights;
- complexities and difficulties in obtaining protection and enforcing our intellectual property;
- difficulties in staffing and managing foreign operations;
- complexities associated with managing multiple payor reimbursement regimes, government payors or patient self-pay systems;
- limits in our ability to penetrate international markets;
- financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises on demand and payment for our products, exposure to foreign currency exchange rate fluctuations, and a rising rate of inflation;
- natural disasters, political and economic instability, including wars, terrorism and political unrest, outbreak of disease, boycotts, curtailment of trade and other business restrictions;
- certain expenses including, among others, expenses for travel, translation, and insurance; and
- regulatory and compliance risks that relate to maintaining accurate information and control over sales and activities that may fall within the purview of the U.S. Foreign Corrupt Practices Act, its books and records provisions, or its anti-bribery provisions.

Any of these factors could significantly harm any current or future international operations and, consequently, our results of operations.

General economic or business conditions may have a negative impact on our business.

Continuing concerns over U.S. healthcare reform legislation and energy costs, geopolitical issues, fluctuations in inflation rates, market volatility, the availability and cost of credit and government stimulus programs in the U.S. and other countries, including those related to the COVID-19 pandemic, as well as recent and potential future disruptions in access to bank deposits or lending commitments due to bank failure, have contributed to increased volatility and could materially and adversely affect our liquidity, our business and financial condition. The recent closures of Silicon Valley Bank and Signature Bank and their placement into receivership with the Federal Deposit Insurance Corporation (“FDIC”) created bank-specific and broader financial institution liquidity risk and concerns. Although the Department of the Treasury, the Federal Reserve, and the FDIC jointly released a statement that depositors at Silicon Valley Bank and Signature Bank would have access to their funds, even those in excess of the standard FDIC insurance limits, future adverse developments with respect to specific financial institutions or the broader financial services industry may lead to market-wide liquidity shortages. The failure of any bank in which we deposit our funds could reduce the amount of cash we have available for our operations or delay our ability to access such funds. Any such failure may increase the possibility of a sustained deterioration of financial market liquidity, or illiquidity at clearing, cash management and/or custodial financial institutions. In the event we have a commercial relationship with a bank that has failed or is otherwise distressed, we may experience delays or other issues in meeting our financial obligations. If other banks and financial institutions enter receivership or become insolvent in the future in response to financial conditions affecting the banking system and financial markets, our ability to access our cash and cash equivalents and investments may be threatened and could have a material adverse effect on our business and financial condition.

If the economic climate deteriorates or is poor, our business, as well as the financial condition of our suppliers and our third-party payors, could be negatively impacted, which could materially adversely affect our business, prospects and financial condition.

Our operations are subject to the effects of a rising rate of inflation.

The United States has recently experienced historically high levels of inflation. If the inflation rate continues to increase, for example due to increases in the costs of labor and supplies, it will affect our expenses, such as employee compensation and research and development charges. Additionally, the United States is experiencing an acute workforce shortage, which in turn, has created a very competitive wage environment that may increase the Company’s operating costs. To the extent inflation results in rising interest rates and has other adverse effects on the market, it may adversely affect our financial condition and results of operations.

Healthcare reform measures could adversely affect our business. The impact of recent healthcare reform legislation and other changes in the healthcare industry and in healthcare spending on us is currently unknown and may adversely affect our business model.

Existing regulatory policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

In the United States and foreign jurisdictions, there have been, and continue to be, a number of legislative and regulatory changes and proposed changes to the healthcare system that could affect our future results of operations. In particular, there have been and continue to be a number of initiatives at the federal and state levels in the United States that seek to reduce healthcare costs. In 2010, the Patient Protection and Affordable Care Act (the “PPACA”) was enacted, which includes measures to significantly change the way healthcare is financed by both governmental and private insurers. Among the provisions of the PPACA of greatest importance to the pharmaceutical and biotechnology industry are the following:

- an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;
- implementation of the federal physician payment transparency requirements, sometimes referred to as the “Physician Payments Sunshine Act”;
- a licensure framework for follow-on biologic products;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;
- establishment of a Center for Medicare Innovation at the Centers for Medicare & Medicaid Services to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending;

- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program, to 23.1% and 13% of the average manufacturer price for most branded and generic drugs, respectively and capped the total rebate amount for innovator drugs at 100% of the AMP;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for certain drugs and biologics, including our product candidates, that are inhaled, infused, instilled, implanted or injected;
- extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for individuals with income at or below 133% of the federal poverty level, thereby potentially increasing manufacturers' Medicaid rebate liability;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D; and
- expansion of the entities eligible for discounts under the Public Health program.

Since its enactment, there remain judicial and Congressional challenges to certain aspects of the PPACA. For example, in June 2021 the U.S. Supreme Court held that Texas and other challengers had no legal standing to challenge the PPACA, dismissing the case on procedural grounds without specifically ruling on the constitutionality of the PPACA. Thus, the PPACA will remain in effect in its current form. In addition, other legislative changes have been proposed and adopted since the PPACA was enacted. These changes include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year pursuant to the Budget Control Act of 2011, which began in 2013 due to subsequent legislative amendments will remain in effect through 2031, with the exception of a temporary suspension implemented under various COVID-19 relief legislation from May 1, 2020 through March 31, 2022, unless additional Congressional action is taken. Under current legislation, the actual reduction in Medicare payments can vary from 1% in 2022 to up to 4% in the final fiscal year of this sequester.

Moreover, there has recently been heightened governmental scrutiny over the manner in which drug manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. For example, under the American Rescue Plan Act of 2021, effective January 1, 2024, the statutory cap on Medicaid Drug Rebate Program rebates that manufacturers pay to state Medicaid programs will be eliminated. Elimination of this cap may require pharmaceutical manufacturers to pay more in rebates than it receives on the sale of products, which could have a material impact on our business. In August 2022, Congress passed the Inflation Reduction Act of 2022, which includes prescription drug provisions that have significant implications for the pharmaceutical industry and Medicare beneficiaries, including allowing the federal government to negotiate a maximum fair price for certain high-priced single source Medicare drugs, imposing penalties and excise tax for manufacturers that fail to comply with the drug price negotiation requirements, requiring inflation rebates for all Medicare Part B and Part D drugs, with limited exceptions, if their drug prices increase faster than inflation, and redesigning Medicare Part D to reduce out-of-pocket prescription drug costs for beneficiaries, among other changes. The impact of these legislative, executive, and administrative actions and any future healthcare measures and agency rules on us and the pharmaceutical industry as a whole is unclear. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our product candidates if approved. Complying with any new legislation and regulatory changes could be time-intensive and expensive, resulting in a material adverse effect on our business.

Individual states have become increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access, and marketing cost disclosure and transparency measures, and to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, results of operations, financial condition and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our products or put pressure on our product pricing, which could negatively affect our business, results of operations, financial condition and prospects.

In addition, given recent federal and state government initiatives directed at lowering the total cost of healthcare, Congress and state legislatures will likely continue to focus on healthcare reform, the cost of prescription drugs and biologics and the reform of the Medicare and Medicaid programs. While we cannot predict the full outcome of any such legislation, it may result in decreased reimbursement for drugs and biologics, which may further exacerbate industry-wide pressure to reduce prescription drug prices. This could harm our ability to generate revenue. Further, a number of states are considering or have recently enacted state drug price transparency and reporting laws that could substantially increase our compliance burdens and expose us to greater liability under such state laws once we begin commercialization.

Increases in importation or re-importation of pharmaceutical products from foreign countries into the United States could put competitive pressure on our ability to profitably price our products, which, in turn, could adversely affect our business, results of operations, financial condition and prospects. We might elect not to seek approval for or market our products in foreign jurisdictions in order to minimize the risk of re-importation, which could also reduce the revenue we generate from product sales. It is also possible that other legislative proposals having similar effects will be adopted.

Furthermore, regulatory authorities' assessment of the data and results required to demonstrate safety and efficacy can change over time and can be affected by many factors, such as the emergence of new information, including on other products, changing policies and agency funding, staffing and leadership. We cannot be sure whether future changes to the regulatory environment will be favorable or unfavorable to our business prospects. For example, average review times at the FDA for marketing approval applications can be affected by a variety of factors, including budget and funding levels and statutory, regulatory and policy changes.

Reimbursement for any approved products may be limited or unavailable, which could make it difficult for us to sell our product candidates profitably.

In both domestic and foreign markets, sales of any of our other product candidates, if approved, will depend, in part, on the extent to which the costs of our product candidates will be covered by third-party payors, such as government health care programs, commercial insurance and managed health care organizations. These third-party payors decide which drugs will be covered and establish reimbursement levels for those drugs. The containment of health care costs has become a priority of foreign and domestic governments as well as private third-party payors. The prices of drugs have been a focus in this effort. Governments and private third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications, which could affect our ability to sell our product candidates profitably. Cost-control initiatives could cause us to decrease the price we might establish for product candidates, which could result in lower than anticipated product revenues.

Reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective relative to other alternatives, including generic products; and
- neither experimental nor investigational.

Adverse pricing limitations may hinder our ability to recoup our investment in our existing and any future product candidates, even if such product candidates obtain marketing approval.

Obtaining coverage and reimbursement approval for a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide supporting scientific, clinical and cost-effectiveness data for the use of our product candidates to the payor. Further, there is significant uncertainty related to third-party payor coverage and reimbursement of newly approved product candidates, including our product candidates if they are approved. We may not be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement. We cannot be sure that coverage or adequate reimbursement will be available for any of our product candidates. Also, we cannot be sure that reimbursement amounts will not reduce the demand for, or the price of, our product candidates. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize certain of our product candidates. In addition, in the United States, third-party payors are increasingly attempting to contain health care costs by limiting both coverage and the level of reimbursement of new product candidates. As a result, significant uncertainty exists as to whether and how much third-party payors will reimburse patients for their use of newly approved product candidates, which in turn will put pressure on pricing.

In some countries, including member states of the European Union, the pricing of prescription drugs is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after receipt of marketing approval for a product. In addition, there can be considerable pressure from governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various European Union member states and other countries and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce prices. In some countries, we may be required to conduct a clinical trial or other studies that compare the cost-effectiveness of our product candidates to other available therapies in order to obtain or maintain reimbursement or pricing approval. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If reimbursement of our product candidates is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be adversely affected.

The outbreak of the novel coronavirus disease, COVID-19, including its most recent variants, could materially adversely impact our business, results of operations and financial condition, including our clinical trials.

The COVID-19 pandemic, and government responses have created disruption in global supply chains and adversely impacting many industries. The pandemic could have a continued material adverse impact on economic and market conditions. We continue to monitor the impact of the COVID-19 pandemic, including its most recent variants, closely. The extent to which the COVID-19 pandemic will impact our operations or financial results is uncertain.

The pandemic and government measures taken in response have also had a significant impact, both direct and indirect, on businesses and commerce, as worker shortages have occurred; supply chains have been disrupted; and demand for certain goods and services, such as medical services and supplies, has spiked, while demand for other goods and services has fallen. While the extent of the impact of the COVID-19 pandemic on our business and financial results is uncertain, a continued and prolonged public health crisis such as the COVID-19 pandemic could have a material adverse effect on our business, financial condition and results of operations. As a result of the COVID-19 pandemic, including its most recent variants, we may experience disruptions that could severely impact our business and clinical trials, including:

- delays or difficulties in enrolling and retaining patients in our clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- interruption of key clinical trial activities, such as clinical trial site data monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others or interruption of clinical trial subject visits and study procedures, which may impact the integrity of subject data and clinical study endpoints;
- interruption or delays in the operations of the FDA or other regulatory authorities, which may impact review and approval timelines;

- interruption of, or delays in receiving, supplies of our product candidates from our contract manufacturing organizations due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems;
- limitations on employee and consulting resources that would otherwise be focused on the conduct of our clinical trials, including because of sickness of employees, consultants or their families or the desire of employees or consultants to avoid contact with large groups of people;
- interruption or delays to our outsourced clinical activities; or
- changes in clinical site procedures and requirements as well as regulatory requirements for conducting clinical trials during the pandemic.

Since March 2020, the FDA issued various COVID-19 related guidance documents, including guidance on conducting clinical trials during the pandemic and on good manufacturing practice considerations, among others. President Biden announced that the administration intends to end the COVID-19 national and public health emergencies on May 11, 2023. The full impact of the termination of the public health emergencies on FDA and other regulatory policies and operations are unclear.

Any legal proceedings or claims against us could be costly and time-consuming to defend and could harm our reputation regardless of the outcome.

We may in the future become subject to legal proceedings and claims that arise in the ordinary course of business, including intellectual property, product liability, employment, wage and hour, class action, derivative, whistleblower and other litigation claims, and governmental and other regulatory investigations and proceedings. Such matters can be time-consuming, divert management's attention and resources, cause us to incur significant expenses or liability, or require us to change our business practices. In addition, the expense of litigation, for which we are either not insured or only partially insured depending on the claim, and the timing of this expense from period to period will be difficult to estimate, subject to change, and could adversely affect our financial condition and results of operations. Because of the potential risks, expenses, and uncertainties of litigation, we may, from time to time, settle disputes, even where we have meritorious claims or defenses, by agreeing to settlement agreements. Any of the foregoing could adversely affect our business, financial condition, and results of operations.

Changes in tax laws or in their implementation or interpretation may adversely affect our business and financial condition.

We are or may become subject to income and non-income taxes in the United States under federal, state and local jurisdictions and in certain foreign jurisdictions in which we operate. Tax laws, regulations and administrative practices in these jurisdictions may be subject to significant change, with or without advance notice. For example, on January 1, 2022, a provision of the Tax Cuts and Jobs Act of 2017 went into effect that eliminates the option to deduct domestic research and development costs in the year incurred and instead requires taxpayers to amortize such costs over five years. The Company is currently evaluating the potential impact. Also, the Inflation Reduction Act, which introduced a 15% minimum tax on book income and a 1% excise tax on stock buybacks. Changes in tax laws (including provisions of the recently enacted federal tax legislation titled the Inflation Reduction Act), regulations, or rulings, changes in interpretations of existing laws and regulations, or changes in accounting principles could negatively and materially affect our financial position, effective tax rates, cash flows, and results of operations.

Risks Related to Intellectual Property

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.

We rely on patent protection as well as a combination of trademark, copyright and trade secret protection, and other contractual restrictions, to protect our proprietary technologies, all of which provide limited protection and may not adequately protect our rights or permit us to gain or keep any competitive advantage. We may not be successful in defending challenges made in connection with our patents and patent applications. If we fail to protect our intellectual property, we will be unable to prevent third parties from using our technologies and they will be able to compete more effectively against us.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example, others may be able to make products that are similar to our product candidates or utilize similar technology but that are not covered by the claims of the patents that we license or may own; we, or our future licensors or collaborators, might not have been the first to file patent applications covering certain of our or their inventions; and issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors or other third parties.

In addition to our patents, we rely on contractual restrictions to protect our proprietary technology. We require our employees and third parties to sign confidentiality agreements and our employees are also required to sign agreements assigning to us all intellectual property arising from their work for us. Nevertheless, we cannot guarantee that these measures will be effective in protecting our intellectual property rights. Should any of these events occur, it or they could have a material adverse effect on our business, financial condition, results of operations, and growth prospects.

If any of our patent applications do not issue as patents in any jurisdiction, we may not be able to compete effectively.

Our currently pending or future patent applications may not result in issued patents and any patents issued to us may be challenged, invalidated, or held unenforceable. Changes in either the patent laws or their interpretation in the U.S. and other countries may diminish our ability to protect our inventions, obtain, maintain, and enforce our intellectual property rights, and, more generally, could affect the value of our intellectual property or narrow the scope of our patents with respect to our product candidates. Furthermore, we cannot be certain that we were the first to make the invention claimed in our issued patents or pending patent applications in the U.S., or that we were the first to file for protection of the inventions claimed in our foreign issued patents or pending patent applications.

There are numerous recent changes to the patent laws and proposed changes to the rules of the United States Patent and Trademark Office (“USPTO”), which may have a significant impact on our ability to protect our technology and enforce our intellectual property rights. For example, in September 2011, the U.S. enacted sweeping changes to the U.S. patent system under the Leahy-Smith America Invents Act, including changes that transitioned the U.S. from a “first-to-invent” system to a “first-to-file” system and alter the processes for challenging issued patents. These changes could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. In addition, we may become subject to interference proceedings conducted in the patent and trademark offices of various countries to determine our entitlement to patents, and these proceedings may conclude that other patents or patent applications have priority over our patents or patent applications.

It is also possible that a competitor may successfully challenge our patents through various proceedings and those challenges may result in the elimination or narrowing of our patents, and therefore reduce our patent protection. The patent prosecution process is expensive, time-consuming, and complex, and we may not be able to file, prosecute, maintain, enforce, or license all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output in time to obtain patent protection. We may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the rights to patents licensed to third parties. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. Any parties who enter into nondisclosure or confidentiality agreements with us that have access to confidential or patentable aspects of our research and development output may breach such agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. In addition, rights under any of our issued patents, patent applications or future patents may not provide us with commercially meaningful protection for our products or afford us a commercial advantage against our competitors or their competitive products or processes.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our unregistered trademarks or trade names may be challenged, infringed, circumvented, or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential collaborators or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our unregistered trademarks or trade names. Over the long term, if we are unable to successfully register our trademarks and trade names and establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively, and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely impact our financial condition or results of operations.

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.

If we are not able to protect our proprietary technology, trade secrets and know-how, our competitors may use our inventions to develop competing products. Our patents may not protect us against our competitors, and patent litigation is very expensive. We may not have sufficient cash available to pursue any patent litigation to its conclusion because we currently do not generate revenues other than licensing, milestone and royalty income.

We cannot rely solely on our current patents to be successful. The standards that the USPTO and foreign patent office's use to grant patents, and the standards that U.S. and foreign courts use to interpret patents, are not the same, are not always applied predictably or uniformly and can change, particularly as new technologies develop. As such, the degree of patent protection obtained in the U.S. may differ substantially from that obtained in various foreign countries.

We cannot be certain of the level of protection, if any, that will be provided by our patents if they are challenged in court, where our competitors may raise defenses such as invalidity, unenforceability, or possession of a valid license. In addition, the type and extent of any patent claims that may be issued to us in the future are uncertain. Any patents that are issued may not contain claims that will permit us to stop competitors from using similar technology.

We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights.

Third parties may challenge the validity, inventorship or ownership of our patents and other intellectual property rights, resulting in costly litigation or other time-consuming and expensive proceedings, which could deprive us of valuable rights. If we become involved in any intellectual property litigation, interference or other judicial or administrative proceedings, we will incur substantial expenses and the attention of our technical and management personnel will be diverted. An adverse determination may subject us to significant liabilities or require us to seek licenses that may not be available from third parties on commercially favorable terms, if at all. Further, if such claims are proven valid, through litigation or otherwise, we may be required under applicable law to pay substantial monetary damages, which can be tripled if the infringement is deemed willful, or be required to discontinue or significantly delay development, marketing, selling and licensing of the affected products and intellectual property rights.

Our competitors may have filed, and may in the future file, patent applications covering technology similar to ours. Any such patent application may have priority over our patent applications and could further require us to obtain rights to issued patents covering such technologies. There may be third-party patents, patent applications and other intellectual property relevant to our potential products that may block or compete with our potential products or processes. If another party has filed a U.S. patent application on inventions similar to ours, we may have to participate in an interference proceeding declared by the USPTO to determine priority of invention in the U.S. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful, resulting in a loss of our U.S. patent position with respect to such inventions. In addition, we cannot assure you that we would prevail in any of these suits or that the damages or other remedies that we are ordered to pay, if any, would not be substantial. Claims of intellectual property infringement, misappropriation or other violations against us may require us to enter into royalty or license agreements with third parties that may not be available on acceptable terms, if at all. We may also be subject to injunctions against the further development and use of our technology, which could materially adversely affect our business, prospects and financial condition.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could materially adversely affect our ability to raise the funds necessary to continue our operations.

Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. In the United States, patents have a limited lifespan, and if all maintenance fees are timely paid, the natural expiration of a patent is generally 20-years from its earliest U.S. non-provisional filing date. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent application process and following the issuance of a patent. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In certain circumstances, even inadvertent noncompliance events may permanently and irrevocably jeopardize patent rights. In such an event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

If we are unable to obtain licenses from third parties on commercially reasonable terms or fail to comply with our obligations under such agreements, our business could be harmed.

It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our products, in which case we would be required to obtain a license from these third parties. If we are unable to license such technology, or if we are forced to license such technology, on unfavorable terms, our business could be materially harmed. If we are unable to obtain a necessary license, we may be unable to develop or commercialize the affected product candidates, which could materially harm our business, and the third parties owning such intellectual property rights could seek either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties and/or other forms of compensation. Even if we are able to obtain a license, agreements we may enter into in the future, if any, may not provide exclusive rights to use certain intellectual property and technology retained by the collaborator in all relevant fields of use and in all territories in which we may wish to develop or commercialize our technology and products in the future. As a result, we may not be able to prevent competitors or other third parties from developing and commercializing competitive products that utilize technology retained by such collaborators to the extent such products are not also covered by our intellectual property. In such an event, our business, financial condition, results of operations, and growth prospects could be materially harmed.

We rely on confidentiality agreements to protect our trade secrets. If these agreements are breached by our employees or other parties, our trade secrets may become known to our competitors. We may also be subject to claims that our employees, consultants, or advisors have wrongfully used or disclosed alleged trade secrets or claims asserting ownership of what we regard as our own intellectual property.

We rely on trade secrets that we seek to protect through confidentiality agreements with our employees and other parties. If these agreements are breached, our competitors may obtain and use our trade secrets to gain a competitive advantage over us. We may not have any remedies against our competitors and any remedies that may be available to us may not be adequate to protect our business or compensate us for the damaging disclosure. In addition, we may have to expend resources to protect our interests from possible infringement by others.

In addition, although we try to ensure that our employees, consultants, and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these individuals have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer. Litigation may be necessary to defend against these claims.

Risks Related to Our Common Stock

An active trading market for our common stock may not be sustained.

Prior to the closing of our IPO in August 2021, there was no public trading market for our common stock. Although our common stock is listed on the Nasdaq Capital Market, the market for our shares has demonstrated varying levels of trading activity. Our ability to raise capital to continue to fund operations by selling shares of our common stock and our ability to acquire other companies or technologies by using shares of our common stock as consideration may be impaired if an active trading market for our common stock is not sustained.

The market price of our common stock may be volatile and fluctuate substantially, which could result in substantial losses for investors.

The market price of our common stock is likely to be highly volatile and may be subject to wide fluctuations in response to a variety of factors, some of which are beyond our control. These factors include the following:

- any delay in the commencement, enrollment and ultimate completion of our clinical trials;
- any delay in submitting an NDA and any adverse development or perceived adverse development with respect to the FDA's review of that NDA;
- failure to successfully develop and commercialize RenovoGem;
- inability to obtain additional funding;
- regulatory or legal developments in the United States and other countries applicable to RenovoGem or any other product candidate;
- adverse regulatory decisions;
- changes in the structure of healthcare payment systems;
- inability to obtain adequate product supply for RenovoGem, RenovoCath or any other product candidate, or the inability to do so at acceptable prices;
- introduction of new products, services or technologies by our competitors;
- failure to meet or exceed financial projections we provide to the public;
- failure to meet or exceed the estimates and projections of the investment community;
- changes in the market valuations of companies similar to ours;
- market conditions in the pharmaceutical and biotechnology sectors, and the issuance of new or changed securities analysts' reports or recommendations;
- announcements of significant acquisitions, strategic collaborations, joint ventures or capital commitments by us or our competitors;
- significant lawsuits, including patent or stockholder litigation, and disputes or other developments relating to our proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- additions or departures of key scientific or management personnel;
- sales of our common stock or other securities by us, our insiders or our other stockholders;
- expiration of market standoff or lock-up agreements;
- trading volume of our common stock;

- fluctuations in interest rates and inflation rates;
- general economic, industry and market conditions;
- health epidemics and outbreaks, including the COVID-19 pandemic, or other natural or manmade disasters which could significantly disrupt our preclinical studies and clinical trials, and therefore our receipt of necessary regulatory approvals could be delayed or prevented; and
- the other factors described in this “Risk Factors” section.

In addition, the stock markets have experienced extreme price and volume fluctuations that have affected and continue to affect the market prices of equity securities of many companies. These fluctuations have often been unrelated or disproportionate to the operating performance of those companies. Broad market and industry factors, as well as general economic, political, regulatory and market conditions, may negatively affect the market price of our common stock, regardless of our actual operating performance. In particular, stock markets have experienced extreme volatility due to the ongoing COVID-19 pandemic, including the emergence of new variants; recent inflationary concerns; and investor concerns and uncertainty related to the impact of the pandemic on the economies of countries worldwide.

Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our product candidates on unfavorable terms to us.

We may seek additional capital through a variety of means, including through public or private equity, debt financings or other sources, including up-front payments and milestone payments from strategic collaborations. For example, we have filed an omnibus shelf registration statement on Form S-3 that provides for aggregate offerings of up to \$50 million of the Company’s securities subject to various limitations, including limited sales in any twelve-month period while we are subject to the “baby-shelf” rules. On April 3, 2023, we completed the Registered Direct Offering under our shelf registration statement on Form S-3 for the purchase and sale of 1,557,632 shares of the Company’s common stock (or pre-funded common stock warrants) at a purchase price of \$3.21 per share of common stock (or pre-funded common stock warrants) to a certain institutional investor. Additionally, in a concurrent private placement, we issued to the investor unregistered warrants to purchase up to 1,947,040 shares of its common stock. The aggregate gross proceeds from the March 2023 Offering were approximately \$5 million before deducting placement fees and other offering expenses. We also have filed a registration statement on Form S-1 to register the cash exercise of our outstanding warrants, with such cash exercise only expected to occur when the trading price of our common stock is in excess of the \$10.80 per share exercise price of our outstanding warrants. To the extent that we raise additional capital through the sale of equity or convertible debt or equity securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder. Such financing may result in dilution to stockholders, imposition of debt covenants, increased fixed payment obligations or other restrictions that may affect our business. If we raise additional funds through up-front payments or milestone payments pursuant to strategic collaborations with third parties, we may have to relinquish valuable rights to our product candidates or grant licenses on terms that are not favorable to us. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans.

The Nasdaq Stock Market may delist our securities from its exchange, which could limit investors’ ability to make transactions in our securities and subject us to additional trading restrictions.

Our common stock is listed on the Nasdaq Capital Market. We cannot assure you that, in the future, our securities will meet the continued listing requirements to be listed on the Nasdaq Capital Market. If the Nasdaq Stock Market delists our common stock, we could face significant material adverse consequences, including:

- a limited availability of market quotations for our securities;
- a determination that our common stock is a “penny stock” which will require brokers trading in our common stock to adhere to more stringent rules and possibly resulting in a reduced level of trading activity in the secondary trading market for our common stock;
- a limited amount of news and analyst coverage for our Company; and
- a decreased ability to issue additional securities or obtain additional financing in the future.

We could be subject to securities class action litigation.

In the past, securities class action and derivative litigation has often been brought against companies following a decline in the market price of their securities or upon the occurrence of other corporate events. This risk is especially relevant for us because biotechnology companies have experienced significant share price volatility in recent years. If we face such litigation, it could result in substantial costs, for which we are not insured, and a diversion of management’s attention and resources, which could harm our business.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, the market price for the shares and trading volume could decline.

The trading market for our common stock depends in part on the research and reports that securities or industry analysts publish about us or our business. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. If one or more of the analysts who cover us downgrades our common stock or publishes inaccurate or unfavorable research about our business, the market price for our common stock would likely decline. If one or more of these analysts cease coverage of our Company or fail to publish reports on us regularly, we could lose visibility in the financial markets, which, in turn, could cause the market price or trading volume for our common stock to decline.

We do not expect to pay dividends in the foreseeable future, and you must rely on price appreciation of your shares for return on your investment.

We have paid no cash dividends on any class of our stock to date, and we do not anticipate paying cash dividends in the near term. For the foreseeable future, we intend to retain any earnings to finance the development and expansion of our business, and we do not anticipate paying any cash dividends on our stock. Accordingly, investors must be prepared to rely on sales of their shares of common stock after price appreciation to earn an investment return, which may never occur. Investors seeking cash dividends should not purchase our shares of common stock. Any determination to pay dividends in the future will be made at the discretion of our board of directors and will depend on our results of operations, financial condition, contractual restrictions, restrictions imposed by applicable law and other factors our board deems relevant.

We have incurred and will continue to incur increased costs as a result of operating as a public company, and our management has devoted and will continue to devote substantial time to new compliance initiatives and corporate governance practices.

As a public company, we have incurred and particularly after we no longer qualify as an emerging growth company, we will continue to incur significant legal, accounting and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act of 2002 (“SOX”), the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of Nasdaq, and other applicable securities rules and regulations impose various requirements on U.S. reporting public companies, including the establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel will need to continue to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations have increased our legal and financial compliance costs and have made some activities more time-consuming and costly. For example, we expect that these rules and regulations may make it more expensive for us to obtain director and officer liability insurance, which in turn could make it more difficult for us to attract and retain qualified senior management personnel or members for our board of directors. In addition, these rules and regulations are often subject to varying interpretations, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

Pursuant to Section 404 of SOX (“Section 404”), we will be required to furnish a report by our senior management on our internal control over financial reporting beginning with our second filing of an Annual Report on Form 10-K with the SEC.

However, while we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To prepare for eventual compliance with Section 404, once we no longer qualify as an emerging growth company, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by Section 404.

We have identified material weaknesses in our internal control over financial reporting. Failure to maintain effective internal controls could cause our investors to lose confidence in us and adversely affect the market price of our common stock. If our internal controls are not effective, we may not be able to accurately report our financial results or prevent fraud.

Effective internal control over financial reporting is necessary for us to provide reliable financial reports in a timely manner. In connection with the audit of our financial statements as of and for the years ended December 31, 2022, 2021, 2020 and 2019, we identified material weaknesses in our internal control over financial reporting. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis. Specifically, we determined that we lacked a sufficient number of qualified accounting and financial reporting personnel with an appropriate level of knowledge, training and experience to address complex accounting issues, sufficient written policies and procedures for accounting and financial reporting in accordance with U.S. Generally Accepted Accounting Principles (“GAAP”), and adequate management review controls. In addition, we 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.

The above material weaknesses could result in a misstatement of our account balances or disclosures that would result in a material misstatement of our annual or interim financial statements that would not be prevented or detected. To address the material weaknesses, we have implemented, and are continuing to implement, measures designed to improve internal control over financial reporting, including expanding our accounting and finance team to add additional qualified accounting and finance resources, which may include third party consultants, and new financial processes. We intend to continue to take steps to remediate the material weaknesses through the hiring or engagement of additional experienced accounting and financial reporting personnel, formalizing documentation of policies and procedures and further evolving the accounting processes, including implementing appropriate segregation of duties. We expect to incur additional costs to remediate these weaknesses, including personnel, consulting and other costs.

We may not be successful in implementing these changes or in developing other internal controls, which may undermine our ability to provide accurate, timely and reliable reports on our financial and operating results. Further, we will not be able to fully assess whether the steps we are taking will remediate the material weakness in our internal control over financial reporting until we have completed our implementation efforts and sufficient time passes in order to evaluate their effectiveness. In addition, until we remediate these weaknesses, or if we identify additional material weaknesses in our internal control over financial reporting, we may not detect errors on a timely basis and our financial statements may be materially misstated. Moreover, in the future we may engage in business transactions, such as acquisitions, reorganizations or implementation of new information systems that could negatively affect our internal control over financial reporting and result in material weaknesses.

If we identify new material weaknesses in our internal control over financial reporting, if we are unable to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, or if we are unable to assert that our internal control over financial reporting is effective, we may be late with the filing of our periodic reports, investors may lose confidence in the accuracy and completeness of our financial reports, and the market price of our common stock could be negatively affected. As a result of such failures, we could also become subject to investigations by the stock exchange on which our securities are listed, the SEC, or other regulatory authorities, and become subject to litigation from investors and stockholders, which could harm our reputation, financial condition or divert financial and management resources from our core business.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

As a public company, 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 Chief Financial Officer or persons performing similar functions, as appropriate, to allow timely decisions regarding required disclosure. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that 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. These inherent limitations include the fact that judgments in decision-making can be faulty and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial and Accounting Officer, we conducted an evaluation of the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of the end of the year ended December 31, 2022. Based on this evaluation, our Chief Executive Officer and Chief Financial and Accounting Officer have concluded that, during the period covered by this Annual Report on Form 10-K, 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 U.S. GAAP. Accordingly, notwithstanding the identified material weaknesses, management, including our Chief Executive Officer and Chief Financial and Accounting Officer, believes the financial statements included in this Annual Report on Form 10-K are fairly presented, in all material respects, in accordance with U.S. GAAP.

We are an "emerging growth company," and the reduced reporting requirements applicable to emerging growth companies may make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including exemption from compliance with the auditor attestation requirements of Section 404; the ability to delay the implementation of new or revised financial accounting standards; reduced disclosure obligations regarding executive compensation; and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. As a result, the information we provide stockholders will be different than the information that is available with respect to other public companies. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the closing of our IPO, (b) in which we have total annual gross revenue of at least \$1.07 billion or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock held by non-affiliates exceeds \$700 million as of the end of our prior second fiscal quarter, or (2) the date on which we have issued more than \$1.0 billion in non-convertible debt during the prior three-year period.

In addition, under the JOBS Act, emerging growth companies may delay adopting new or revised accounting standards until such time as those standards apply to private companies. We may elect not to avail ourselves of this exemption from new or revised accounting standards and, therefore, may be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result of these exemptions, there may be a less active trading market for our common stock and our share price may be more volatile.

Anti-takeover provisions contained in our certificate of incorporation and bylaws, as well as provisions of Delaware law, could impair a takeover attempt.

Our certificate of incorporation, bylaws and Delaware law contain provisions that could have the effect of rendering more difficult, delaying or preventing an acquisition deemed undesirable by our board of directors. Our corporate governance documents include provisions:

- authorizing “blank check” preferred stock, which could be issued by our board of directors without stockholder approval and may contain voting, liquidation, dividend, and other rights superior to our common stock;
- limiting the liability of, and providing indemnification to, our directors and officers;
- limiting the ability of our stockholders to call and bring business before special meetings;
- requiring advance notice of stockholder proposals for business to be conducted at meetings of our stockholders and for nominations of candidates for election to our board of directors;
- controlling the procedures for the conduct and scheduling of board of directors and stockholder meetings; and
- providing our board of directors with the express power to postpone previously scheduled annual meetings and to cancel previously scheduled special meetings.

These provisions, alone or together, could delay or prevent hostile takeovers and changes in control or changes in our management.

As a Delaware corporation, we are also subject to provisions of Delaware law, including Section 203 of the Delaware General Corporation law, which prevents some stockholders holding more than 15% of our outstanding common stock from engaging in certain business combinations without approval of the holders of substantially all of our outstanding common stock.

Any provision of our certificate of incorporation, bylaws or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock, and could also affect the price that some investors are willing to pay for our common stock.

Our certificate of incorporation, as amended, designates the Court of Chancery of the State of Delaware as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders’ ability to obtain a favorable judicial forum for disputes with us or our directors, officers or other employees.

Our certificate of incorporation requires that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will, to the fullest extent permitted by law, be the sole and exclusive forum for each of the following:

- any derivative action or proceeding brought on our behalf;
- any action asserting a claim for breach of any fiduciary duty owed by any director, officer or other employee of ours to the Company or our stockholders, creditors or other constituents;
- any action asserting a claim against us or any director or officer of ours arising pursuant to, or a claim against us or any of our directors or officers, with respect to the interpretation or application of any provision of, the DGCL, our certificate of incorporation or bylaws; or
- any action asserting a claim governed by the internal affairs doctrine;

provided, that, if and only if the Court of Chancery of the State of Delaware dismisses any of the foregoing actions for lack of subject matter jurisdiction, any such action or actions may be brought in another state court sitting in the State of Delaware.

The exclusive forum provision is limited to the extent permitted by law, and it will not apply to claims arising under the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or for any other federal securities laws which provide for exclusive federal jurisdiction.

Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our second amended and restated certificate of incorporation provides that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring such a claim arising under the Securities Act against us, our directors, officers, or other employees in a venue other than in the federal district courts of the United States of America. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our second amended and restated certificate of incorporation.

Although we believe this provision benefits us by providing increased consistency in the application of Delaware law in the types of lawsuits to which it applies, this provision may limit or discourage a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. Alternatively, if a court were to find the choice of forum provision contained in our certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business and financial condition.

We note that there is uncertainty as to whether a court would enforce the provision and that investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder. Although we believe this provision benefits us by providing increased consistency in the application of Delaware law in the types of lawsuits to which it applies, the provision may have the effect of discouraging lawsuits against our directors and officers.

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

Unregistered Sales of Equity Securities

On March 31, 2023, the Company issued 30,000 shares of restricted stock to an entity as consideration for a commercial contract. The shares were issued in a private placement in reliance on the exemption from registration available under Section 4(a)(2) of the Securities Act.

Use of Proceeds from Public Offering of Common Stock

There has been no material change in the planned use of proceeds from our IPO as described in our final prospectus filed with the SEC on August 27, 2021, pursuant to Rule 424(b)(4). We placed the funds received into an interest bearing money market account. No payments were made by us to directors, officers or persons owning ten percent or more of our common stock or to their associates, or to our affiliates, other than payments in the ordinary course of business to officers for salaries and to non-employee directors pursuant to our Outside Director Compensation Policy, as amended.

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.	10-K	001-40738	3.2	March 30, 2022
10.1*	Amended and Restated Outside Director Compensation Policy	10-K	001-40738	10.3	March 31, 2023
10.2	Form of Placement Agency Agreement by and between RenovoRx, Inc. and Roth Capital Partners, LLC, dated March 30, 2023	8-K	001-40738	10.1	April 3, 2023
10.3	Form of Securities Purchase Agreement, by and between RenovoRx, Inc. and other party thereto, dated March 30, 2023	8-K	001-40738	10.2	April 3, 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	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 12, 2023

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

Date: May 12, 2023

By: _____
/s/ James M. Ahlers
James M. Ahlers
Chief Financial 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 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 12, 2023

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, James M. Ahlers, 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 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 12, 2023

By: /s/ James M. Ahlers
Chief Financial 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, 2023 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 12, 2023

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, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, James M. Ahlers, 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 12, 2023

By: /s/ James M. Ahlers
Chief Financial Officer
