UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K/A

(Amendment No. 1)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2025

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from to

Commission File Number: 001-40738

RENOVORX, INC.

(Exact name of registrant as specified in its charter)

Delaware	**27-1448452**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

2570 West El Camino Real, Suite 640, Mountain View, CA 94040
(Address of principal executive offices, including zip code)

(650) 284-4433
(Registrant's telephone number, including area code)
Securities registered pursuant to Section 12(b) of the Act:

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

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

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

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

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

Large accelerated filer ☐	Accelerated filer ☐
Non-accelerated filer ☒	Smaller reporting company ☒
	Emerging growth company ☒

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

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates on June 30, 2024, the last business day of the registrant's most recently completed second fiscal quarter, based upon the closing price of the registrant's common stock on such date as reported by The Nasdaq Capital Market, was approximately $26.6 million. Shares of voting stock held by each officer and director have been excluded in that such persons may be deemed to be affiliates. This assumption regarding affiliate status is not necessarily a conclusive determination for other purposes.

The number of outstanding shares of the registrant's common stock, $0.0001 par value per share, as of March 23,2026, was 45,052,706.

DOCUMENTS INCORPORATED BY REFERENCE

None.

EXPLANATORY NOTE

This Amendment No. 1 on Form 10-K/A (this "Amendment") amends the Annual Report on Form 10-K of RenovoRx, Inc. ("Company") for the year ended December 31, 2025 filed with the Securities and Exchange Commission (the "Commission") on March 30, 2026 (the "Original Filing").

In response to a comment letter from the Commission staff, this Amendment is being filed solely to revise (i) Part I, Item 1A. "Risk Factors" ("Item 1A") to revise certain risk factors disclosures relating to previously identified material weaknesses in internal control over financial reporting (which were remediated as of December 31, 2025) and (ii) the Company's disclosures under Part II, Item 9A. "Controls and Procedures" ("Item 9A") by adding additional disclosure regarding management's assessments and conclusions of the Company's internal control over financial reporting as of December 31, 2025, which was not included in Item 9A in the Original Filing. Management's assessment, as reported in the Original 10-K, that such internal control over financial reporting was effective at December 31, 2025 remain unchanged.

The revised risk factors are captioned "*We have previously 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"* and *"We previously found our disclosure controls and procedures were not effective, and there is a risk that we may do so again, which could have an adverse effect on our company."*

In accordance with Rule 12b-15 of the Securities and Exchange Act of 1934, as amended, this Amendment amends and restates Item 1A and Item 9A of the Original Filing in their entirety, but solely for purposes of the above described limited revisions. In addition, as required by Rule 12b-15, new certifications by the Company's principal executive officer and principal financial officer are filed as exhibits to this Amendment.

Except as described above, no other changes have been made to the Original Filing. This Amendment continues to speak as of the date of the Original Filing, and the Company has not updated the disclosures contained therein to reflect any events that occurred subsequent to the date of the Original Filing. Accordingly, this Amendment should be read together with the Original Filing.

RENOVORX, INC.
ANNUAL REPORT ON FORM 10-K/A FOR THE YEAR ENDED DECEMBER 31, 2025
(Amendment No 1)

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PART I

Item 1A. Risk Factors

An investment in our securities is speculative and involves a high degree of risk*. You should carefully consider the risks described below, as well as the other information in this Report, including our 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

The following is a summary of principal factors and uncertainties that make investing in shares of our common stock risky and impact our ability to execute on our business strategy. This summary is not exhaustive, and readers are therefore encouraged to review this Risk Factors section in its entirety.

- We have no drug/device combination products approved for commercial sale, only limited experience as a company in the commercialization of standalone medical devices and no extended operating history as a revenue generating company. These factors make it difficult to evaluate our current business and predict our future success and viability.

- We have incurred significant net losses in each period since inception, and we expect to continue to incur net losses until we receive FDA approval for our product candidate or until our commercial strategy for RenovoCath generates sufficient revenues.

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

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

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

- Our revenues and results of operations, particularly as they relate to RenovoCath sales, are difficult to predict and may fluctuate from quarter to quarter, which could adversely affect our business and the market price of our common stock.

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

- We may consider strategic alternatives in order to maximize stockholder value, including financing, strategic alliances, and licensing arrangements. We may not be able to identify or consummate any suitable strategic alternatives and any consummated strategic alternatives may not be successful.

•The commercial viability of IAG or other product candidates remains subject to current and future preclinical studies, clinical trials (notably our Phase III TIGeR-PaC study), regulatory approvals, and the risks generally inherent in the development of a drug-device product candidate. If we are unable to successfully advance or develop IAG or any other product candidate, our business will be materially harmed.

•As our ongoing TIGeR-PaC study is our most advanced clinical trial to date, the failure of the study to achieve results conducive to progressing the study or filing and receiving NDA approval would cause our company significant harm.

•If we do not achieve our projected commercial or 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.

•We are not currently in compliance with the “minimum bid price” continued listing requirement for The Nasdaq Stock Market. If we do not regain compliance and continue to meet such requirement or any other continued listing requirements, our common stock may be delisted, which could affect the market price and liquidity for our common stock and reduce our ability to raise additional capital and otherwise properly function as a public company.

Risks Related to Our Business, Financial Condition and Capital Requirements

We have no drug/device combination products approved for commercial sale, only limited experience as a company in the commercialization of standalone medical devices and no extended operating history as a revenue generating company. These factors make it difficult to evaluate our current business and predict our future success and viability.

We are a clinical stage biopharmaceutical company who is also executing on a commercial strategy to sell our device on a standalone basis alongside our efforts to gain regulatory approval for our lead drug/device combination product. We have no drug/device combination products approved for commercial sale. While we have commenced generating revenue from RenovoCath commercial sales, our operating history as a revenue-generating company remains limited, and the commercial prospects for our novel therapy platform (either as part of an approved drug/device combination product or whether sold as a standalone product) are unproven, uncertain and involve a substantial degree of risk.

Our first drug/device product candidate consists of IA gemcitabine in combination with RenovoCath (which we call IAG). The FDA has determined that IAG 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 IAG or any other drug/device combination product candidates, manufactured a commercial scale of our lead or any other drug/device product or arranged for a third-party to do so on our behalf, or conducted sales and marketing activities necessary for successful post FDA-approval product commercialization.

Alongside our Phase III clinical activities related to IAG, we commenced commercial sales of our FDA-cleared RenovoCath device on a standalone basis in late 2024 and have been generating revenue therefrom in 2025. While our commercial traction has grown, our operating experience in this business model remains limited and our commercialization efforts continue to evolve.

These factors make 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 more mature operating history.

We will encounter expenses, difficulties, complications, delays, and other known and unknown factors and risks frequently experienced by clinical stage biopharmaceutical or early commercial stage medical device companies in rapidly evolving and competitive fields. We are also transitioning 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 until we receive FDA approval for our product candidate or until our commercial strategy for RenovoCath generates sufficient revenues.

We are a clinical stage, early-revenue-stage company and have incurred significant losses since our formation. As of December 31, 2025, we have an accumulated deficit of approximately $61.4 million. For the fiscal years ended December 31, 2025 and 2024, we had net losses of approximately $11.2 million and $8.8 million, respectively. To date, we have experienced negative cash flow from the development of our drug/device product candidate, our platform technology, TAMP, and our RenovoCath delivery system. We have generated limited revenue from our RenovoCath commercial activities and we expect to incur net losses until we receive FDA approval for our product candidate or until our commercial strategy for RenovoCath generates sufficient revenues to offset our expenses. While a key goal of our company is to increase revenues from RenovoCath sales and thus reduce or losses and “cash burn”, because of the numerous risks and uncertainties associated with developing and commercializing our product candidate or our device commercial strategy, we are unable to predict with precision the extent of any future losses or when we will attain cash flow positive or profitable operations, if ever. Investors in our securities must carefully consider the substantial challenges, risks and uncertainties inherent in our business plans. We may never receive regulatory approval for IAG or any other product candidate and we may never successfully commercialize RenovoCath, and in either case, if we are unable to do so, our business could fail.

On the clinical development side of our business, any product candidates beyond IAG 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. Even with respect to our lead product candidate IAG and our TIGeR-PaC trial, we are anticipating final results of that trial in 2027, which could subsequently lead to an NDA submission and FDA review and decision. As a result, we expect that it will be at least a few years, if ever, before we receive approval to commercialize a drug/device product and generate revenue from such product. Even if we succeed in receiving marketing approval for and commercializing IAG or other drug/device product candidates, we expect that we will continue to incur substantial expenses and, if our commercial efforts do not generate sufficient revenues, operating losses. 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 or attain cash flow positive operations or profitability, we will not be able to sustain operations.

With respect to the clinical development aspect of our business, 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 may 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;
- 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 are executing on a commercial strategy for selling our RenovoCath device on a standalone basis, which is a new activity for our company and subject to significant inherent risks.

Alongside our Phase III clinical activities related to IAG, in late 2024 we commenced commercial sales of our FDA-cleared RenovoCath device on a standalone basis, and we generated nominal revenues of $43,000 for the year ended December 31, 2024 and approximately $1.1 million in revenue from such sales for the year ended December 31, 2025. While we have begun to gain commercial traction, we nonetheless have limited experience in self-commercializing medical devices. This commercial strategy, which itself is relatively new and subject to evolution and change, is subject to significant inherent risks relating to, among other matters, our manufacturing, supply chain, and sales and marketing efforts for RenovoCath, as well as our internal accounting and operational requirements for these efforts. Moreover, the past experiences of certain members of our management with commercializing medical devices may not translate to our plans for RenovoCath. Also, we may be subject to competition from alternative devices or methods of drug administration offered by larger, better funded, and more experienced companies. Therefore, we are and will continue to be faced with the risk that we may be unable to adequately execute one or more elements of our commercial plans for RenovoCath.

We may also choose to enter into a commercial collaboration with a third party who could take some or even primary responsibility for sales, marketing, and/or distribution efforts for RenovoCath. In such a case, we would be reliant, at least in part, on such third party for the success of our commercial efforts, and the failure of any such third party to execute the agreed-upon strategy could lead to suboptimal results for our company. Moreover, in any such collaboration, we would be required to share the part of the economics of RenovoCath commercialization with such third-party, which could mean less revenue generated by our company.

Regardless of which commercial strategy, or combination of strategies, we choose to employ for RenovoCath, we will be required to execute our commercialization plan effectively and efficiently. If we are unable to do so in any material respect, and if, as a result, we are unable to generate meaningful or anticipated revenues from RenovoCath sales, this could cause a material adverse effect on our results of operations, cash flow, reputation, and stock price.

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

We have based our estimates of total addressable market size, peak annual sales projections and similar matters in this Report and elsewhere in our public filings or statements based on our market research, third-party reports and publicly available information which we consider reliable. However, our commercialization efforts for RenovoCath are relatively new and evolving. Therefore, readers are cautioned that our projections regarding revenues, peak annual sales potential, total addressable market and similar metrics are merely our current, preliminary estimates and are subject to change based on many factors, including factors which are out of our control. As such, no assurances are given that any such estimates will prove to be accurate.

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

We are in the relatively early stages of our RenovoCath commercialization efforts and have not had to recognize revenue from our operations in the past. A primary goal from these efforts is to generate and recognize revenue from RenovoCath sales. However, revenue recognition under generally accepted accounting principles requires subjective judgements to be made by our management and could otherwise be complex and create uncertainties, including uncertainties arising from varying terms of sale we may offer to different customers. We may also be required to defer recognition of revenues until certain conditions are met. Risks and uncertainties relating to our accounting for revenue

recognition could have a material adverse effect on our estimates of our future revenue performance and on our actual financial results. Any statements we make in this Report or otherwise from time to time regarding our future revenue performance could prove inaccurate because of the complexities of revenue recognition, and readers should take these complexities and associated risks in accounting when assessing our statements regarding our revenues.

Our revenues and results of operations, particularly as they relate to RenovoCath sales, are difficult to predict and may fluctuate from quarter to quarter, which could adversely affect our business and the market price of our common stock.

Our commercial sales activities for our RenovoCath device are still relatively new. While our goal is to grow our revenues over time, at present our revenues and results of operations are difficult to predict and may fluctuate substantially from quarter to quarter, with fluctuations potentially being the result of just a small number of RenovoCath procedures undertaken by our customers. These fluctuations can adversely affect our business and the market price of our common stock. Revenues in any quarter depend substantially upon our total contracting activity with our customers, and our ability to recognize revenues in that quarter in accordance with our revenue recognition policies. Our contracting activity is difficult to forecast for a variety of reasons, including the following:

- our sales cycle per customer and in general may vary as a result of factors such as a customer's familiarity with RenovoCath;
- the size of sales orders can vary significantly and may not be predicable on a customer-by-customer basis or generally;
- economic downturns are often characterized by decreased product demand, price erosion, technological shifts, work slowdowns and layoffs, which can substantially reduce contracting activity;
- customers may unexpectedly postpone or cancel orders due to changes in their strategic priorities, budgetary constraints or the existence of competitive technology;
- customer evaluations and purchasing processes vary significantly from company to company, and a customer's internal approval and expenditure authorization process can be difficult and time consuming;
- changes in our pricing policies and discount plans may affect customer purchasing patterns;
- the number, timing and significance of our and our competitors' product enhancements may affect purchasing decisions; and
- certain expenses, including those over which we exercise little or no control, such as health costs, compliance with new legislation, and property and liability insurance, may be difficult to manage; and

Due to all of the foregoing factors, in some future quarters our operating results may fall below the expectations of securities analysts and investors. In such event, the market price of our common stock would likely decrease.

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

As of March 23, 2026 (taking into account the net proceeds from our March 2026 private placement), we had cash and cash equivalents of approximately $13.0 million. Due to our recurring operating losses and the expectation that we will continue to incur net losses in the future, we face the risk that we may be required to raise additional capital over the longer term to both (i) complete the testing, development and (assuming FDA approval) commercialization of IAG or other product candidates and (ii) separately engage in sales and marketing activities for RenovoCath as a standalone device. We have historically financed our operations primarily through public and private sales of our equity or equity-linked securities as well as debt financing. 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 $50.0 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. 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 (which is significantly above our current stock price). 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 our development and/or commercialization plans, 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. Based on our operating plans, we expect that our current cash and cash equivalents as the date of this Report will be sufficient to fund our operating, investing and financing cash flow needs for at least the next twelve months, assuming our programs advance as currently contemplated. Based upon our review and our current financial condition, we have concluded that we will be able to continue operating as a going concern.

Our financial statements as of December 31, 2025 have been prepared on a going concern basis and do not include any adjustments that may result from the outcome of this uncertainty. 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. If we seek additional financing to fund our business activities in the future, 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 common stock.

We may consider strategic alternatives in order to maximize stockholder value, including financing, strategic alliances, and licensing arrangements. We may not be able to identify or consummate any suitable strategic alternatives and any consummated strategic alternatives may not be successful.

We may consider all strategic alternatives that may be available to us to maximize stockholder value, including financing, strategic alliances, and licensing arrangements, including a commercial sales partner as of our evolving RenovoCath commercial strategy. Our exploration of various strategic alternatives may not result in any specific action or transaction. To the extent that this engagement results in a transaction, our business objectives may change depending upon the nature of the transaction. There can be no assurance that we will enter into any transaction as a result of the engagement. Furthermore, if we determine to engage in a strategic transaction, we cannot predict the impact that such strategic transaction might have on our operations or stock price. We also cannot predict the impact on our stock price if we fail to enter into a transaction.

In addition, we face significant competition in seeking appropriate strategic partners, and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our business activities because they may be deemed to be at too early of a stage of development for collaborative effort. Any delays in entering into new strategic partnership agreements harm our business prospects, financial condition and results of operations.

If we license or acquire products or businesses, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture. We cannot be certain that, following a strategic transaction, license, or acquisition, we will achieve the results, revenue or specific net income that justifies such transaction.

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

The commercial viability of IAG or other product candidates remains subject to current and future preclinical studies, clinical trials (notably our Phase III TIGeR-PaC study), regulatory approvals, and the risks generally inherent in the development of a drug-device product candidate. If we are unable to successfully advance or develop IAG or any other 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 drug or drug-device combination product candidate. The success of our business depends in part upon our ability to successfully advance the development of IAG and future product candidates through preclinical studies and clinical trials (notably our Phase III TIGeR-PaC study with respect to IAG), have such 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 (notably our Phase III TIGeR-PaC study) 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 chemistry, manufacturing and controls 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 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 our lead drug/device combination product candidate or any other product candidate, 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 (notably our Phase III TIGeR-PaC study or IAG) 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. 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.

As our ongoing TIGeR-PaC study is our most advanced clinical trial to date, the failure of the study to achieve results conducive to progressing the study or filing and receiving NDA approval would cause our company significant harm.

With respect to our ongoing Phase III TIGeR-PaC study of IAG in LAPC specifically, this study is our most advanced clinical trial to date and is therefore very important to us. While we have previously announced positive interim data from such study, and while the second interim analysis was completed in 2025 and the Data Monitoring Committee recommended continuation of the study, there can be no assurance that the final data will be positive or support an NDA submission or approval. We expect to complete enrollment in the TIGeR-PaC study by mid-2026 and anticipate final data readout in 2027, though there is a risk that enrollment or data completion could be delayed. In addition, for clinical or commercial reasons, we may be unable to, or may elect not to, even file an NDA for IAG. The failure of our TIGeR-PaC study to achieve results conducive to filing and receiving NDA approval would cause our company, and likely our stock price, significant harm. Some harm could occur if we are required to postpone, or elect not to, file an NDA for IAG in LAPC for any reason.

If we do not achieve our projected commercial or 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 commercial, scientific, clinical, regulatory and product development goals, which we sometimes refer to as milestones. These milestones may include projected results (including revenue generation) from our RenovoCath commercialization activities as well as 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 or results of some of these milestones. All of these milestones are and will be based on numerous assumptions and are subject to inherent known and unknown risks. For example, the revenues we generate from RenovoCath sales may be less than we anticipate or are projected by securities analysts who follow our company. Also, important milestones such as the actual timing for full enrollment in, or data readout from, our TIGeR-PaC study, or any related NDA submission, could change due to a variety of factors, some of which are beyond our control. Therefore, you are advised that the actual timing and results of these milestones can vary dramatically compared to our estimates or the estimates of securities analysts. If we do not meet these milestones as publicly announced, our stock price may decline and it may become more difficult to operate and finance our company.

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, including the effects of recent variants; and

•the supply or quality of drug material or the supply of our RenovoCath delivery service necessary to conduct our preclinical studies or clinical trials being insufficient, inadequate or unavailable.

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 (but are not required to) 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. We have previously announced initial interim data for our ongoing Phase III TIGeR-PaC study. 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 (if any) 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, or 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 make elect 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.

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 the 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 and formulating the results of such test could result in increased costs to us and delay our ability to obtained necessary regulatory approves and 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. 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 various 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 the FDA. We submitted a protocol amendment to the 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. In August 2023, we received comments from the FDA on the Modified SAP, which we responded to in September 2023. Based on the FDA's feedback, we plan to submit the revised SAP and a protocol amendment to reflect the changes in the statistical analysis for the study. Such amendment and Modified SAP are subject to IRB and regulatory review that may result in additional costs and may negatively impact the timelines for the trial. We cannot provide assurance that the FDA will not raise any objections or disagree with our Modified SAP or the protocol amendments, including our proposed SAP or how we interpret the data. 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, and further, based on guidance we may receive from our clinical trial Data Monitoring Committee, we may elect to not disclose the details of interim data beyond the recommendation of our Data Monitoring Committee relating to whether or not to continue the study. The changes in our study protocol may limit the clinical trial sites that can participate in our study, impact enrollment, and delay regulatory approval. 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. 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.

See Item 1. Business—Government Regulation for more information.

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.

Particularly as it relates to our commercial efforts for RenovoCath as a standalone device, which efforts are still in their relatively early stages, we are in the process of developing and utilizing policies and practices aimed at ensuring full compliance in all material respects with these types of laws, rules and regulations. Moreover, 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.

See Item 1. Business—Government Regulation for more information.

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 IAG or any other 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 IAG or any of our other 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. Even with respect to IAG, we cannot predict with certainty 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 will remain 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 revenues. 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 our lead drug/device combination product 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 our lead drug/device combination product 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. Our lead product candidate utilizes RenovoCath with the existing chemotherapy gemcitabine and received Orphan Drug Designation for pancreatic cancer and bile duct cancer, which provides 7 years of market exclusivity upon approval by the FDA. 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 AB Science SA, AngioDynamics, Bausch Health, FibroGen, Inc., Novocure, SynCore Biotechnology, Bristol Myers Squibb, and ViewRay Systems, Inc. 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 Life Sciences. 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, our lead drug/device combination product 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 our product.

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. We have expanded our relationship with Medical Murray, our U.S.-based third-party RenovoCath manufacturer, and received our first commercial orders for RenovoCath devices in December 2024. 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 IA 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 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 are responsible for ensuring that our 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 are 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 oversee compliance of our contract manufacturers, ultimately, we have no 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 our lead drug/device combination product 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 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 IAG or any of our future 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 IAG, our lead drug/device combination product, and our other product candidates may not be as large as we expect.

Our estimates of the potential market opportunity for IAG, our lead drug/device combination product, and any of our other future 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 or FDA-approved products 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 17 employees as of December 31, 2025. 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 headquarters, employees and a majority of our 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, public health emergencies, 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 headquarters, that damaged critical infrastructure, such as the manufacturing facilities of our third-party contract manufacturers, or the infrastructure where are clinical trials are being conducted, or that otherwise disrupted our operations or the operations of our RenovoCath customers, it may be difficult or, in certain cases, impossible for us to continue our business to a material degree 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.

Moreover, ongoing armed conflicts between Russia and Ukraine and in the Middle East (including the U.S. and Israel's military actions against Iran commencing in March 2026) have resulted in sustained global geopolitical unrest, including significant instability in the financial and commodities markets and the continued imposition of extensive international sanctions. The geopolitical landscape remains highly volatile following the 2024 U.S. elections and the subsequent transition in U.S. administration and policy priorities in 2025 and 2026 (including the imposition of tariffs by the U.S. administration). It is not possible to predict the near or long-term consequences of these shifts, which may include new or expanded sanctions, trade embargoes, increased tariffs, changes in international trade agreements, and heightened regional instability. These factors, alongside potential fluctuations in inflation, currency exchange rates, and macroeconomic conditions, may create prolonged uncertainty in the global markets and could have a material adverse effect on our business, financial condition, and results of operations.

Security threats to our and our commercial partners' 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 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 advent of remote working, 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 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.

We may seek to expand our sales and marketing activities internationally. 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, 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 2023 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 macroeconomic factors such as tariffs and rate of inflation.

Particularly given that we have entered the revenue generation phase of our company, our business and operations are subject to the effects of macroeconomic factors that are beyond our control. For example, recent policy decisions have raised tariffs on non-U.S. goods, which could impact the cost of materials used in our products or product candidates. Price increases for these materials could effect our pricing and the demand for our products and product candidates. Economic uncertainty generally as a result of tariffs could impact our customers' purchasing choices to our detriment. In addition, current or future tariffs could also result in increased research and development expenses, including with respect to increased costs associated with raw materials, laboratory equipment and research materials and components. Trade restrictions affecting the import of materials necessary for clinical trials could result in delays to our development timelines.

Moreover, the United States has experienced high levels of inflation in recent years. While inflation rates have moderated more recently, if the inflation rate increases, for example due to increases in the costs of labor and supplies, it could 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 our operating costs.

As such, any of these or similar factors 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 2032, with the exception of a temporary suspension implemented under various COVID-19 relief legislation.

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. Various industry stakeholders, including certain pharmaceutical companies and industry interest groups, have initiated lawsuits against the federal government asserting that the price negotiation provisions of the Inflation Reduction Act are unconstitutional. The impact of these judicial challenges and future legislative, executive, and administrative actions and any 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.

See Item 1. Business—Government Regulation and Item 1. Business—Healthcare Reform for more information.

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 RenovoCath or (if approved) IAG or any of our other drug product candidates, 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.

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. We are 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.

Our ability to use our net operating losses to offset future taxable income may be subject to certain limitations.

As of December 31, 2025, we had net operating loss ("NOL") carryforwards for federal and state income tax purposes which may be available to offset taxable income in future years. A lack of future taxable income would adversely affect our ability to utilize these NOLs before they expire. The utilization of our NOLs could be subject to annual limitations under Section 382 and 383 of the Internal Revenue Code ("IRC" or the "Code") of 1986, and similar state tax provisions due to ownership change limitations that may have occurred previously or that could occur in the future. In general, under Section 382, a corporation that undergoes an "ownership change" (as defined under Section 382 of the Code and applicable Treasury Regulations) is subject to limitations on its ability to utilize its pre-change NOLs to offset its future taxable income. As of December 31, 2025, we have not conducted an analysis of an ownership change under Section 382. To the extent that a study is completed, and an ownership change is deemed to occur, in the past or future, our NOLs and any NOLs of companies that we have acquired could be limited to offset any future taxable income.

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

We are not currently in compliance with the "minimum bid price" continued listing requirement for The Nasdaq Stock Market. If we do not regain compliance and continue to meet the such requirement or any other continued listing requirements, our common stock may be delisted, which could affect the market price and liquidity for our

common stock and reduce our ability to raise additional capital and otherwise properly function as a public company.

On December 31, 2025, we received a letter from the Listing Qualifications Staff of the Nasdaq Stock Market, LLC ("Nasdaq") indicating that we are not in compliance with the requirement to maintain a minimum bid price of $1.00 per share required for continued listing on Nasdaq, as set forth in Nasdaq Listing Rule 5550(a)(2) (the "Minimum Bid Price Requirement") for 32 consecutive trading days.

Pursuant to Nasdaq Listing Rule 5810(c)(3)(A), we have 180 calendar days from receipt of a notice from Nasdaq (the "Compliance Period"), to regain compliance with the Minimum Bid Price Requirement. If at any time during the Compliance Period, the bid price of our common stock closes at or above $1.00 per share for a minimum of ten consecutive business days, Nasdaq will provide us with written confirmation of compliance with the Minimum Bid Price Requirement and the matter will be closed. In the event we do not regain compliance with the Minimum Bid Price Requirement by the end of the Compliance Period, we may be eligible for an additional 180-calendar day grace period. Pursuant to Nasdaq Listing Rule 5810(3)(A)(iii), if during any compliance period specified in Nasdaq Listing Rule 5810(c)(3)(A), a company's security has a closing bid price of $0.10 or less for ten consecutive trading days, the Listing Qualifications Department of Nasdaq will issue a Staff Delisting Determination under Nasdaq Listing Rule 5810 with respect to that security (the "Low Priced Stocks Rule"). If a company receives such delisting notice, the company can request a hearing before a Nasdaq hearings panel (the "Panel"). If our common stock closes at or below $0.10 for ten consecutive days during the Compliance Period or any additional compliance period, we could receive a Staff Delisting Determination during the Compliance Period or any additional compliance period or, if we receive such Staff Delisting Determination, Nasdaq may not grant our request for a hearing, or if Nasdaq grants our request for a hearing, the Panel may not grant our request for continued listing of our common stock on The Nasdaq Capital Market pending our compliance with all applicable listing criteria, including the Minimum Bid Price Requirement, or we may be unable to timely satisfy the terms of any extension that may be granted by the Panel.

We will continue to monitor the closing bid price of our common stock and seek to regain compliance with all applicable Nasdaq requirements within the allotted compliance periods and may, if appropriate, consider available options, including implementation of a reverse stock split, to regain compliance with the Minimum Bid Price Requirement or the Low Priced Stocks Rule, as applicable. A reverse stock split, if implemented, could have a material adverse effect on our stock price and valuation.

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

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 has been and may continue 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:

- our progress with our strategy to sell RenovoCath as a standalone device, including the level our initial and any subsequent revenues generated from such activity;
- 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, gain marketing approval for and commercialize our lead drug/device combination product;

•inability to obtain additional funding;

•Regulatory or legal developments in the United States and other countries applicable to our RenovoCath device, our lead drug/device combination product or any other product candidate;

•adverse regulatory decisions;

•changes in the structure of healthcare payment systems;

•inability to obtain adequate product supply for our RenovoCath device, our lead drug/device combination product 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, including pursuant to the existing primary and secondary shelf registration statements that we have filed with the SEC;

•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 or other natural or man-made 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. This is particularly true for biotechnology companies like ours. 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.

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 have and will likely continue to 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 our securities subject to various limitations, including limited sales in any twelve-month period while we are subject to the "baby-shelf" rules. 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.

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

Our common stock is listed on the Nasdaq Capital Market. In order to maintain our listing, we must meet minimum financial and other requirements, including a minimum amount in stockholders' equity. As noted above, we are currently not in compliance with Nasdaq's $1.00 minimum bid price requirement.

Previously, on August 21, 2023, we received a notice from Nasdaq notifying us that, as of August 18, 2023, we were not in compliance with the minimum stockholders' equity requirement for continued listing on The Nasdaq Capital Market, under Listing Rule 5550(b)(1), because our stockholders' equity of $1,188,000 as reported in the Company's Quarterly Report on Form 10-Q for the period ended June 30, 2023 was below the required minimum of $2.5 million (the "Equity Requirement"), and because, as of June 30, 2023, we did not meet the alternative compliance standards, relating to the market value of listed securities of $35 million or net income from continuing operations of $500,000 in the most recently completed fiscal year. We were ultimately able to maintain our listing and raise capital to cure this listing deficiency.

On December 31, 2025, we received a letter from the Listing Qualifications Staff of the Nasdaq Stock Market, LLC ("Nasdaq") indicating that we are not in compliance with the requirement to maintain a minimum bid price of $1.00 per share required for continued listing on Nasdaq. We have until the end of June 2026 to regain compliance with this requirement, which may be extended for 180 days. If we do not regain compliance and continue to not meet such requirement or any other continued listing requirements of Nasdaq, our common stock may be delisted, which could affect the market price and liquidity for our common stock and reduce our ability to raise additional capital and otherwise properly function as a public company.

In addition to our current non-compliance with the Nasdaq Minimum Bid Price requirement, we may also face difficulties in meeting other Nasdaq requirements, including with respect to our market capitalization. Failure to comply with these or any other Nasdaq continued listing standards could result in delisting, which would significantly impact our ability to raise capital and maintain investor confidence and could lead to additional regulatory scrutiny and potential penalties.

Sales of a significant number of shares of our common stock in the public markets, or the perception that such sales could occur, including shares of common stock issued in our January 2024 private placement, April 2024 at market private placement, February 2025 public offering and March 2026 at market private placement could depress the market price of our common stock.

Sales of a significant number of shares of our common stock in the public markets, or the perception that such sales could occur as a result of our utilization of a universal shelf registration statement or otherwise could depress the market price of our common stock and impair our ability to raise capital through the sale of additional equity securities. Notably, we have registered for public resale in the very near term all of the shares of common stock and common stock underlying warrants issued in our January 2024 private placement, April 2024 at market private placement,

February 2025 public offering and March 2026 at market private placement, which collectively will represent a very large number of shares relative to our current shares of common stock outstanding. Following the effectiveness of such registration, a large number of shares of our common stock could be sold in the public market, depressing our stock price. Moreover, we cannot in general predict the effect that future sales of our common stock or the market perception that we are permitted to sell a significant number of our securities would have on the market price of our common stock.

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 (as of January 1, 2027), 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 are 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 previously 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 year ended December 31, 2024, 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, these material weaknesses related to (i) inadequate formal accounting policies for complex and non-routine transactions; (ii) insufficient personnel with appropriate U.S. Generally Accepted Accounting Principles ("GAAP") technical expertise; (iii) deficiencies in the financial statement close process, including the absence of formalized and timely review and approval procedures and inadequate segregation of duties due to the small size of our finance and accounting team; and (iv) ineffective information technology general controls over user access. We continued to note material weaknesses during 2025, even though we worked to remediate them. At December 31, 2025 our management's assessment of our internal financial and reporting controls was that previously identified weaknesses were remediated and such controls were effective. See Item 9A of this report for further information.

However, if in the future 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.

We previously found our disclosure controls and procedures were not effective, and there is a risk that we may do so again, which could have an adverse effect on our company.

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. In prior periods, including as of December 31, 2024 and subsequently during 2025, our management found that our disclosure controls and procedures were not effective. However, at December 31, 2025, our management's assessment of our disclosure controls and procedures were that previously identified weaknesses had been remediated and that such controls and procedures were effective (see Item 9A of this Report).

Readers are cautioned, however, 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, and no assurances can be given that such controls and procedures will prevent or detect all errors or acts of fraud.

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.

Moreover, there is a risk that we could face challenges and negative ramifications for our company in the future regarding our disclosure controls and procedures, which could have a material adverse effect on our ability to prepare proper financial statements and other disclosures, could adversely impact our reputation and stock price, and could otherwise make it more challenging to operate our company.

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 Jumpstart Our Business Startups Act ("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 initial public offering (i.e., December 31, 2026), (b) in which we have total annual gross revenue of at least $1.235 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. Moreover, once we no longer qualify as an emerging growth company (beginning January 1, 2027), we may incur additional costs and be required to take further time and attention to comply with applicable securities laws.

Anti-takeover and other provisions contained in our certificate of incorporation and bylaws, as well as provisions of Delaware law, could impair a takeover attempt and have other impacts on our corporate governance.

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 or otherwise impact our corporate governance. 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;
- providing our board of directors with the express power to postpone previously scheduled annual meetings and to cancel previously scheduled special meetings; and
- providing for a quorum comprised of stockholders representing one-third of the voting power of our outstanding shares of common stock to hold valid annual or special meetings of our stockholders.

These provisions, alone or together, could delay or prevent hostile takeovers and changes in control or changes in our management. Our reduced quorum requirement could also lead to corporate governance changes resulting from stockholder required votes in which a minority of one-third of our outstanding stockholders could take actions at annual or special meetings of our stockholders that impact our company as compared to other companies in which a majority of stockholders are required for a quorum.

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. These provisions and the impact of the reduced quorum requirement 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 our company or our stockholders, creditors, or other stakeholders;
- 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 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.

PART II

ITEM 9A. CONTROLS AND PROCEDURES

(a) Management's Evaluation of Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial 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 December 31, 2025.

Based on our management's evaluation (with the participation of our Chief Executive Officer and Chief Financial Officer, who are our principal executive officer and our principal financial officer, respectively) of our disclosure controls and procedures as required by Rule 13a-15 under the Exchange Act, and taking into account the remediation of previously identified material weaknesses discussed below, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were effective as of December 31, 2025.

(b) Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Our internal control framework and processes were designed to provide reasonable assurance to management and the Board of Directors that our financial reporting is reliable and that our financial statements for external purposes have been prepared in accordance with accounting principles generally accepted in the United States ("U.S. GAAP").

Our management recognizes its responsibility for fostering a strong ethical climate so that our affairs are conducted according to the highest standards of personal and corporate conduct.

Our internal control over financial reporting includes policies and procedures that: (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect our business transactions; (ii) provide reasonable assurance that transactions are recorded as necessary to permit the preparation of financial statements in accordance with U.S. GAAP, and that receipts and expenditures of the issuer are being made only in accordance with authorizations of management and directors of the issuer; and (iii) provide reasonable assurance that the unauthorized acquisition, use, or disposition of our assets will be prevented or detected in a timely manner.

Management assessed the effectiveness of our internal control over financial reporting as of December 31, 2025. In making these assessments, Management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control - Integrated Framework (2013). Based on our assessments and those criteria, management determined that we maintained effective internal control over financial reporting as of December 31, 2025.

Remediation of Previously Identified Material Weakness

As reported in our Annual Report on Form 10-K for the year ended December 31, 2024 and Quarterly Reports on Form 10-Q for the quarterly periods ended March 31, 2025, June 30, 2025 and September 30, 2025, we previously identified material weakness in our internal control financial reporting related to (i) inadequate formal accounting policies for complex and non-routine transactions; (ii) inexperienced finance and accounting personnel with appropriate U.S. GAAP technical expertise; (iii) deficiencies in the financial statement close process around the absence of a formalized and timely review and approval, inadequate segregation of duties driven by the small size of the finance and accounting team; and (iv) ineffective information technology general controls ("ITGCs") over user access.

To remediate these material weaknesses, management engaged a national consulting firm and implemented the following measures to strengthen the control environment, enhance the financial statement close process, and improve the overall design and operating effectiveness of internal controls:

- Implemented formal, written accounting policies and procedures for complex and non-routine transactions and established standardized review and approval workflows for such transactions.

•Increased finance and accounting staffing with personnel processing relevant U.S. GAAP and SEC reporting experience to enhance technical accounting capabilities.

•Implemented a structured financial close calendar with defined responsibilities and deadlines, along with documented review procedures and sign-off over key financial reporting areas.

•Reorganized finance roles and workflows to improve segregation of duties, supplemented by secondary reviews and higher-level management oversight, and began deploying automation tools and templates (FloQast) to support reconciliations and close activities.

•Established role-based access within financial systems, formalized review and approval requirements for non-standard and manual journal entries, and instituted periodic reviews of user access and system rights.

•Centralized IT user access management processes, implemented periodic independent user access reviews, and documented access changes and related review procedures to provide an audit trail over ITGC user access controls.

Management has completed the implementation of these remedial measures and, based on testing of the design and operating effectiveness of the remediated controls, concluded that the previously identified material weaknesses were remediated as of December 31, 2025.

We maintain a dynamic system of internal controls and processes--including internal control over financial reporting--designed to ensure reliable financial recordkeeping, transparent financial reporting and protection of physical and intellectual property.

However, all internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation.

This Report does not include an attestation report of the Company’s registered public accounting firm. For as long as we remain (i) an emerging growth company under the JOBS Act or (ii) a smaller reporting company and a non-accelerated filer, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal control over financial reporting. When we lose our status as an emerging growth company, a smaller reporting company and reach the thresholds for becoming an "accelerated filer" (as defined in the Exchange Act), our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting.

(c) Changes in Internal Control over Financial Reporting

Other than the changes as noted above, there were no other changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the last fiscal quarter ended December 31, 2025 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) The following documents are filed as part of this Annual Report on Form 10-K

1. Financial Statements

The financial statements required to be filed in the Form 10-K/A are listed in Part IV, Item 15 of the Original Filing.

2. Financial Statement Schedules

All financial statement schedules have been omitted because the required information is not applicable or is not present in amounts sufficient to require submission of the schedules, or because the information required is included in the financial statements and accompanying notes included in this Report.

3. Exhibits

See “Exhibit Index” immediately preceding the signature page of this Report, which is incorporated herein by reference.

RENOVORX, INC.
EXHIBIT INDEX

Exhibit No.	Exhibit Description	Incorporated by Reference			
		Form	File No.	Exhibit	Filing Date
3.1	Sixth Amended and Restated Certificate of Incorporation of RenovoRx, Inc.	8-K	001-40738	3.1	August 31, 2021
3.2	Amended and Restated Bylaws of RenovoRx, Inc.	8-K	001-40738	3.1	September 11, 2023
4.1	Form of Private Common Stock Warrant (related to the 2020 Convertible Notes and 2021 Convertible Notes)	10-Q	001-40738	4.1	November 15, 2021
4.2	Form of Underwriter's Warrant	S-1	333-258071	4.1	August 25, 2021
4.3	Form of Warrant Agent Agreement (including the terms of the Warrants)	S-1	333-258071	4.2	August 25, 2021
4.4	Specimen Stock Certificate evidencing the Shares of Common Stock	S-1	333-258071	4.4	August 25, 2021
4.5	Form of Warrant Certificate	S-1	333-258071	4.5	August 25, 2021
4.6	Form of Pre-Funded Common Stock Purchase Warrant	8-K	001-40738	4.1	April 3, 2023
4.7	Form of Common Stock Purchase Warrant	8-K	001-40738	4.2	April 3, 2023
4.8	Form of Warrant to Purchase Common Stock Issued in January 2024 Private Placement	8-K	001-40738	10.3	January 29, 2024
4.9	Form of Placement Agent Warrant Issued in January 2024 Private Placement	8-K	001-40738	10.5	January 29, 2024
4.10	Form of Pre-Funded Common Stock Purchase Warrant issued in April 2024 Private Placement	8-K	001-40738	10.2	April 15, 2024
4.11	Form of Series A Warrant to Purchase Common Stock issued in April 2024 Private Placement	8-K	001-40738	10.3	April 15, 2024
4.12	Form of Series B Warrant to Purchase Common Stock issued in April 2024 Private Placement	8-K	001-40738	10.4	April 15, 2024
4.13	Form of Placement Agent Warrant to Purchase Common Stock issued in April 2024 Private Placement	8-K	001-40738	10.5	April 15, 2024
4.14	Common Stock Purchase Warrant Issued to Medical Murray, Inc., dated September 25, 2024	10-Q	001-40738	4.14	November 13, 2024
4.15	Form of Underwriter Warrant issued in February 2025 Public Offering	8-K	001-40738	4.1	February 10, 2025

4.16	Description of Securities	10-K	001-40738	4.6	March 30, 2022
4.17	Form of Pre-Funded Warrant Issued to Investors in the March 2026 Private Placement	8-K	001-40738	4.1	March 23, 2026
4.18	Form of Milestone Warrant Issued to Investors in the March 2026 Private Placement.	8-K	001-40738	4.2	March 23, 2026
10.1	Amended and Restated Investor Rights Agreement, dated as of April 18, 2018	10-Q	001-40738	10.1	November 15, 2021
10.2†	Amended and Restated 2021 Omnibus Equity Incentive Plan and Forms of Stock Option Grant Notice and Option Agreement	10-Q	001-40738	10.1	August 14, 2025
10.3†	Amended and Restated Outside Director Compensation Policy	10-K	001-40738	10.3	April 1, 2024
10.4†	Confirmatory Offer Letter, by and between RenovoRx, Inc. and Shaun Bagai, dated November 11, 2021	10-Q	001-40738	10.4	November 15, 2021
10.5†	Consulting Agreement, by and between RenovoRx, Inc. and Ramtin Agah, M.D., dated January 1, 2018	10-Q	001-40738	10.5	November 15, 2021
10.6†	Amendment to Consulting Agreement, by and between RenovoRx, Inc. and Ramtin Agah, M.D., dated November 11, 2021	10-Q	001-40738	10.6	November 15, 2021
10.7†	Amendment to Consulting Agreement, by and between RenovoRx, Inc. and Ramtin Agah, M.D., dated January 25, 2022	10-K	001-40738	10.7	March 30, 2022
10.8†	Amended and Restated Change in Control and Severance Agreement, by and between RenovoRx, Inc. and Shaun Bagai, dated November 10, 2025	10-Q	001-40738	10.1	November 13, 2025
10.9†	Amended and Restated Change in Control and Severance Agreement, by and between RenovoRx, Inc. and Ramtin Agah, dated November 10, 2025	10-Q	001-40738	10.2	November 13, 2025
10.10†	Key Service Provider Incentive Compensation Plan	10-Q	001-40738	10.9	November 15, 2021
10.11†	Form of Indemnification Agreement	S-1	333-258071	10.7	August 25, 2021
10.12+	Supply Agreement, dated June 5, 2025, between RenovoRx, Inc. and Medical Murray, Inc.	10-Q	001-40738	10.2	August 14, 2025
10.13†	Amended and Restated Change in Control and Severance Agreement, by and between RenovoRx, Inc. and Ronald Kocak, dated November 10, 2025	10-Q	001-40738	10.3	November 13, 2025

10.14†	Amended and Restated Change in Control and Severance Agreement, by and between RenovoRx, Inc. and Leesa Gentry, dated November 10, 2025	10-Q	001-40738	10.4	November 13, 2025
10.15†#	Consulting Agreement, dated February 4, 2026, by and between RenovoRx, Inc. and Mark Voll	8-K	001-40738	10.1	February 6, 2026
10.16†	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
10.17†	Form of Securities Purchase Agreement	8-K	001-40738	10.2	April 3, 2023
10.18	Subscription Agreement, by and between RenovoRx, Inc. and the investors thereto	8-K	001-40738	10.1	January 29, 2024
10.19	Offering Extension, dated January 12, 2024	8-K	001-40738	10.2	January 29, 2024
10.20	Placement Agent Agreement, by and between RenovoRx, Inc. and Paulson Investment Company, LLC, dated November 14, 2023	8-K	001-40738	10.4	January 29, 2024
10.21	Amended and Restated Offer Letter, by and between RenovoRx, Inc. and Ronald B. Kocak	8-K	001-40738	10.1	February 9, 2024
10.22	Amended and Restated Offer Letter, by and between RenovoRx, Inc. and Leesa Gentry	8-K	001-40738	10.1	March 14, 2024
10.23	Form of Subscription Agreement (April 2024 Private Placement)	8-K	001-40738	10.1	April 15, 2024
10.24†	Form of Securities Purchase Agreement in the March 2026 Private Placement	8-K	001-40738	10.1	March 23, 2026
10.25†	Agah Offer Letter, dated March 24, 2026 and effective February 27, 2026, by and between RenovoRx, Inc. and Ramtin Agah	8-K	001-40738	10.1	March 27, 2026
19.1	Insider Trading Policy	10-K	001-40738	19.1	April 1, 2024
23.1	Consent of Frank, Rimerman + Co. LLP	10-K	001-40738	23.1	March, 30, 2026
31.1	Certification of Principal Executive Officer Pursuant to Rule 13a-14(a)/15d-14(a).	Filed herewith			
31.2	Certification of Principal Financial Officer Pursuant to Rule 13a-14(a)/15d-14(a).	Filed herewith			
32.1*	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350.	Furnished herewith			
32.2*	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350.	Furnished herewith			

97.1	Policy Related to Recovery of Erroneously Awarded Compensation, adopted September 7, 2023	10-K	001-40738	97.1	April 1, 2024	
101.INS	Inline XBRL Instance Document-the instance document does not appear in the Interactive Data File as its XBRL tags are embedded within the Inline XBRL document	Filed herewith				
101.SCH	Inline XBRL Taxonomy Extension Schema with Embedded Linkbase Documents	Filed herewith				
104	Cover Page formatted as Inline XBRL and contained in Exhibit 101	Filed herewith				

† Indicates management contract or compensatory plan or arrangement

+ Confidential portions of this Exhibit were redacted pursuant to Item 601(b)(2) of Regulation S-K and RenovoRx, Inc. agrees to furnish supplementally to the Securities and Exchange Commission a copy of any redacted information or omitted schedule and/or exhibit upon request.

Certain information has been omitted from this exhibit pursuant to Item 601(a)(6) or Item 601(b)(10)(iv) of Regulation S-K.

* The certifications attached as Exhibits 32.1 and 32.2 that accompany this Annual Report on Form 10-K 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 Annual Report, irrespective of any general incorporation language contained in such filing.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this Amendment No. 1 to its report to be signed on its behalf by the undersigned, thereunto duly authorized.

RENOVORX, INC.

Date: May 15, 2026

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

Date: May 15, 2026

/s/ Mark Voll
Mark Voll
Chief Financial Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Shaun R. Bagai Shaun R. Bagai	Chief Executive Officer, Director (Principal Executive Officer)	May 15, 2026
/s/ Mark Voll Mark Voll	Chief Financial Officer (Principal Financial and Accounting Officer)	May 15, 2026
/s/ Ramtin Agah Ramtin Agah, M.D.	Executive Chairman and Chief Medical Officer	May 15, 2026
/s/ Laurence J. Marton Laurence J. Marton, M.D.	Director	May 15, 2026
/s/ Una S. Ryan Una S. Ryan, O.B.E., Ph.D., D.Sc.	Director	May 15, 2026
/s/ Kirsten Angela Macfarlane Kirsten Angela Macfarlane	Director	May 15, 2026
/s/ Robert J. Spiegel Robert J. Spiegel, M.D., FACP	Director	May 15, 2026

Exhibit 31.1

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

I, Shaun R. Bagai, certify that:

1.I have reviewed this Annual Report on Form 10-K/A 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.The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a)Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b)Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c)Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d)Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

4.The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a)All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b)Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 15, 2026

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

Exhibit 31.2

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

I, Mark Voll, certify that:

1.I have reviewed this Annual Report on Form 10-K/A 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.The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a)Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b)Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c)Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d)Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

4.The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a)All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b)Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 15, 2026

By: */s/ Mark Voll*
Mark Voll
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

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

In connection with the Annual Report of RenovoRx, Inc. (the "Company") on Form 10-K/A for the year ended December 31, 2025 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1)The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2)The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 15, 2026

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

Exhibit 32.2

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

In connection with the Annual Report of RenovoRx, Inc. (the "Company") on Form 10-K/A for the year ended December 31, 2025 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1)The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2)The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 15, 2026

By: */s/ Mark Voll*
Mark Voll
Chief Financial Officer
(Principal Financial Officer)