UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

☒ **Annual report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**
For the fiscal year ended December 31, 2021

☐ **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.)

4546 El Camino Real, Suite B1, Los Altos, CA 94022
(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**	**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. ☐

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 of the registrant, based on the closing price of the shares of common stock on The Nasdaq Stock Market on December 31, 2021 was approximately: $37.3 million. The registrant has elected to use December 31, 2021, which was the last business day of the registrant's most recently completed fiscal year, as the calculation date because on June 30, 2021 (the last business day of the registrant's mostly recently completed second fiscal quarter), the registrant was a privately-held company.

As of March 25, 2022, the registrant had9,029,305 shares of common stock, $0.0001 par value per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

None.

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Solely for convenience, trademarks and trade names referred to in this Form 10-K may appear without the ® or ™ symbols.

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Special Note Regarding Forward-Looking Statements

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

- the sufficiency of our existing cash, cash equivalents, and investments to fund our future operating expenses and capital expenditure requirements;
- our estimates regarding expenses, future revenue, anticipated capital requirements to fund our future operating expenses, and our need for additional financing;
- our financial performance;
- our anticipated use of our existing cash, cash equivalents, and investments;
- the ability of our clinical trials to demonstrate safety and efficacy of our product candidates, and other positive results;
- the progress and focus of our current and future clinical trials, and the timing of reporting of data from those trials;
- our continued reliance on third parties to conduct clinical trials of our product candidates, and for the manufacture of our product candidates;
- the beneficial characteristics, safety, efficacy, and therapeutic effects of our product candidates;
- our ability to advance product candidates into and successfully complete clinical trials;
- our ability to further develop and expand our therapy platform, both to use different chemotherapeutic agents and to include new indications;
- expectations relating to the timing of the provision of updates on, data readouts for, and completion of our clinical trials;
- our ability to obtain and maintain regulatory approval of our product candidates and the timing or likelihood of regulatory filings and approvals, including our expectation to seek special designations, such as orphan drug designation, for our product candidates for various diseases;
- existing regulations and regulatory developments in the United States and other jurisdictions;
- our plans relating to commercializing our product candidates, if approved, including the geographic areas of focus and our potential and ability to successfully commercialize our product candidates and generate revenue;
- the implementation of our strategic plans for our business and product candidates;

- the expected potential benefits of strategic collaborations with third parties and our ability to attract collaborators with relevant and complementary expertise;
- our estimates of the number of patients in the United States who suffer from the diseases we target, and enrollment timing and projections for our clinical trials;
- our estimates of potential market opportunities and our ability to successfully realize these opportunities;
- the success of competing therapies that are or may become available;
- developments relating to our competitors and our industry, including competing product candidates and therapies;
- our plans relating to the further development and manufacturing of our product candidates, including for additional indications which we may pursue;
- our plans and ability to obtain or protect intellectual property rights, including extensions of existing patent terms where available;
- the scope of protection we are able to establish and maintain for intellectual property rights, including our therapy platform and product candidates;
- our ability to successfully negotiate and enter into agreements with distribution, strategic and corporate partners;
- our potential and ability to successfully manufacture and supply our product candidates for clinical trials and for commercial use, if approved;
- our ability to retain the continued service of our key personnel and to identify, hire, and then retain additional qualified personnel; and
- our expectations regarding the impact of the COVID-19 pandemic and geopolitical events on our business.

We have based the forward-looking statements contained in this Form 10-K primarily on our current expectations and projections about future events and trends that we believe may affect our business, financial condition, results of operations, prospects, business strategy and financial needs. The outcome of the events described in these forward-looking statements is subject to risks, uncertainties, assumptions and other factors described in the section titled "*Risk Factors*" and elsewhere in this Form 10-K. These risks are not exhaustive. Other sections of this Form 10-K include additional factors that could adversely affect our business and financial performance. Moreover, we operate in a very competitive and rapidly changing environment. New risks and uncertainties emerge from time to time and it is not possible for us to predict all risks and uncertainties that could have an impact on the forward-looking statements contained in this Form 10-K. We cannot assure you that the results, events and circumstances reflected in the forward-looking statements will be achieved or occur, and actual results, events or circumstances could differ materially from those described in the forward-looking statements. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame or at all.

In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Form 10-K, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements.

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The forward-looking statements made in this Form 10-K relate only to events as of the date on which such statements are made. We undertake no obligation to update any forward-looking statements after the date of this Form 10-K or to conform such statements to actual results or revised expectations, except as required by law. Unless the context otherwise indicates, "RenovoRx," the "Company," "we," "our," and "us" refer to RenovoRx, Inc., a Delaware corporation. All information presented herein is based on our fiscal calendar. Unless otherwise stated, references to particular years, quarters, months or periods refer to the Company's fiscal years ended in December and the associated quarters, months and periods of those fiscal years.

This Form 10-K contains market data and industry forecasts that were obtained from industry publications. These data and forecasts involve a number of assumptions and limitations, and you are cautioned not to give undue weight to such information. We have not independently verified any third-party information. While we believe the market position, market opportunity and market size information included in this Form 10-K is generally reliable, such information is inherently imprecise.

Risk Factors Summary

Investing in shares of our common stock involves a high degree of risk because our business is subject to numerous risks and uncertainties, including those outside of our control, that could cause our actual results to be harmed. The principal factors and uncertainties that make investing in shares of our common stock risky and impact our ability to execute on our business strategy include risks regarding the following, among others:

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

- We may delay or terminate the development of our product candidates at any time if we believe the perceived market or commercial opportunity does not justify further investment, which could materially harm our business.

- Our future success depends on our ability to retain our key personnel and to attract, retain, and motivate qualified personnel, especially in light of an acute workforce shortage and hyper-competitive compensation environment.

- If we are unable to protect our intellectual property effectively, we may be unable to prevent third parties from using our technologies, which would impair our competitive advantage.

- The patents issued to us may not be broad enough to provide any meaningful protection, one or more of our competitors may develop more effective technologies, designs, or methods without infringing our intellectual property rights and one or more of our competitors may design around our proprietary technologies.

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

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

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PART I

ITEM 1. BUSINESS

Overview

We are a clinical-stage biopharmaceutical company focused on developing therapies for the local treatment of solid tumors. We are currently conducting a Phase 3 registrational trial for our lead product candidate RenovoGem™. Our therapy platform, RenovoRx Trans-Arterial Micro-Perfusion, or RenovoTAMP™, utilizes approved chemotherapeutics with validated mechanisms of action and well-established safety and side effect profiles, with the goal of increasing their efficacy, improving their safety, and widening their therapeutic window by combining such chemotherapeutics with our proprietary drug delivery system. RenovoTAMP combines our patented US Food and Drug Administration, or FDA cleared delivery system, RenovoCath®, with small molecule chemotherapeutic agents that can be forced across the vessel wall using pressure, targeting these anti-cancer drugs locally to the solid tumors. While we anticipate investigating other chemotherapeutic agents for intra-arterial delivery via RenovoTAMP, our clinical work to date has focused on gemcitabine, which is a generic small molecule drug. Our first product candidate, RenovoGem, is a drug /device combination consisting of intra-arterial gemcitabine and RenovoCath. FDA has determined that RenovoGem will be regulated as, and if approved we expect will be reimbursed as, a new oncology drug product. We have secured FDA Orphan Drug Designation for RenovoGem in two rare diseases: pancreatic cancer and cholangiocarcinoma (bile duct cancer, or CCA). We have completed our RR1 Phase 1/2 and RR2 observational registry studies, with 20 and 25 patients respectively, in locally advanced pancreatic cancer, or LAPC. These studies demonstrated a median overall survival of 27.9 months in patients pre-treated with radiation followed by treatment with RenovoGem. Based on previous large randomized clinical trials, the expected survival of LAPC patients is 12 - 15 months in patients receiving only intravenous (IV) systemic chemotherapy or IV chemotherapy plus radiation (which are both considered standard of care). Unlike the randomized trials that established these standard-of-care results, our RR1 and RR2 clinical trials did not prospectively control the standard of care therapy received prior to administration of RenovoGem. Based on an FDA safety review of our Phase 1/2 study, FDA allowed us to proceed to evaluate RenovoGem within our Phase 3 registrational clinical trial. As of March 15, 2022, our Phase 3 trial had achieved approximately 50% of the target enrollment under the current statistical analysis plan (SAP). The SAP includes a planned interim analysis when a total of 65 deaths have occurred in the study. We expect to conduct the interim analysis between the fourth quarter of 2022 and the first quarter of 2023; however, given that it is predicated on the number of deaths in the study, it is difficult to predict the exact timing. We intend to evaluate RenovoGem in a second indication in a Phase 2 trial in extrahepatic (or outside the liver) cholangiocarcinoma (or eCCA), cancer that occurs in the bile ducts that lead out of the liver and join with the gallbladder. We have now completed our evaluation of the different approaches to treat this patient population and are in the process of refining our clinical protocol. We plan to meet with FDA during the second or third quarter of 2022 to discuss our trial design. If FDA does not object to our study protocol, we anticipate launching the eCCA trial in the second half of 2022. In addition, we may evaluate RenovoGem in other indications, potentially including locally advanced lung cancer, locally advanced uterine tumors, and glioblastoma (an aggressive type of cancer that can occur in the brain or spinal cord). To date, we are focused on developing drug/device candidates with gemcitabine, but in the future, we may develop other product candidates with other chemotherapeutic agents for intra-arterial delivery via our RenovoTAMP therapy platform.

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

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

- *Targeted Approach*: In a preclinical study using our therapy platform, we demonstrated up to 100 times higher local drug concentration compared to systemic chemotherapy. We believe our RenovoTAMP therapy platform allows for a targeted approach that can decrease systemic exposure and improve patient outcomes.

- *Delivery Method Independent of Tumor Vascularity*: Our therapy platform is designed to deliver small molecule chemotherapeutic agents to solid tumors resistant to systemic chemotherapy due to lack of tumor feeder blood vessels. If approved, our product candidates have the potential to treat tumors that are not directly supported by blood vessels.

- *Broad Application for Solid Tumor Indications*: Our therapy platform is not restricted to a single small molecule chemotherapeutic agent or solid tumor type. As such, it may be applied for use in additional solid tumor indications, including in solid tumors without identifiable tumor feeder blood vessels.

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Research and Development Pipeline

Our portfolio of cancer therapies is based on our RenovoTAMP therapy platform. Our current pipeline is summarized below:

RenovoGem Product Pipeline Addresses Multiple Indications

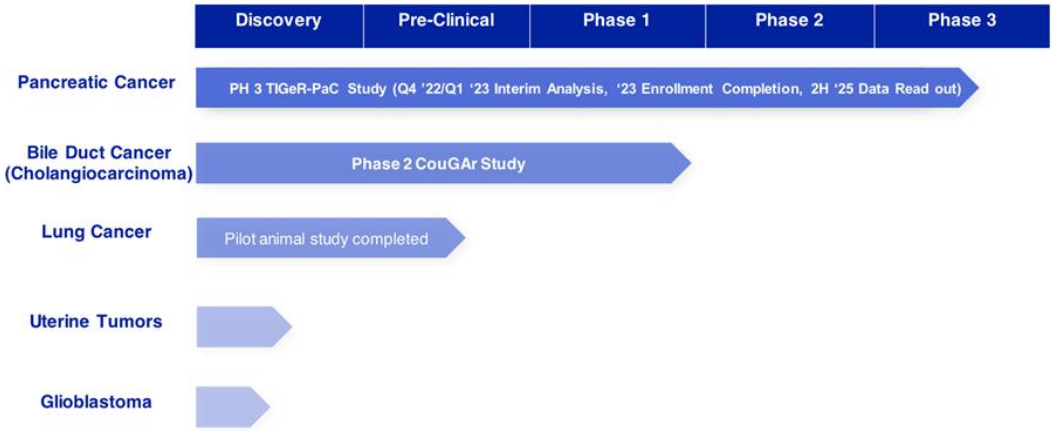

Figure 1 RenovoGem Clinical Pipeline detailing our potential portfolio of cancer therapies based on our RenovoTAMP therapy platform.

Our lead product candidate, RenovoGem, consists of gemcitabine administered through our patented delivery system, RenovoCath, and is regulated by the FDA as a new oncology drug product. Gemcitabine has been considered standard of care for several solid tumors, and the drug's anti-cancer tumor effects are well profiled. Our RenovoTAMP platform therapy utilizes pressure mediated delivery of gemcitabine across the arterial wall to bathe the pancreatic tumor tissue in 120 mL of saline with 1,000 mg/m^2 of the drug over a 20-minute delivery period (delivering 1,500-2,000 mg of drug depending upon patient body surface area). RenovoCath is a double balloon catheter designed with the capability to isolate sections of the blood vessel through the adjustment of the distance between the balloons, thereby excluding any branching blood vessel offshoots in order to create the pressure head needed to push drug across the blood vessel wall.

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

We are using gemcitabine in our initial anti-cancer product candidate, RenovoGem. However, multiple small molecule therapeutics are compatible with our RenovoTAMP platform. We intend to opportunistically develop additional anti-cancer product candidates using small molecule therapeutics in combination with our therapy platform.

While the field of oncology has seen progress in treating a handful of deadly cancers over the last few decades, there is a common objective in chemotherapy: enhanced dosing of the drug to impact the tumor while minimizing systemic toxicity. The characteristics of the blood vessels, within and surrounding the tumor, can limit or thwart the achievement of this goal. For example, LAPC and eCCA are more difficult to treat due to the lack of blood vessels that feed these tumors, making it difficult to expose tumors to chemotherapy, which is typically delivered intravenously. Trans-arterial chemoembolization (TACE) is an established first line therapy for solid tumors. A key component of this approach is to identify and isolate vessels feeding the tumor, known as tumor feeder blood vessels. However, in patients with pancreatic cancer, no tumor feeder blood vessels are visible despite attempts to image them using a variety of modalities. In the absence of visible tumor feeder blood vessels, our therapy platform has the potential to introduce drugs directly across the arterial wall into the surrounding tissue via pressurized diffusion.

RenovoGem in Locally Advanced Pancreatic Cancer (LAPC)

We are currently evaluating RenovoGem in patients with LAPC in our TIGeR-PaC Phase 3 trial in the United States. In December 2021, we elected to close our sites in Belgium, because these sites were not meeting enrollment milestones as a result of, among other factors, COVID-related recruiting challenges and differences in systemic chemotherapy standard of care compared to the US which impacted patient eligibility. We recently amended our protocol to only allow for Stereotactic Body Radiation Therapy (SBRT) radiation during the induction phase of the study, removing intensity-modulated radiation therapy (IMRT) from our study going forward. Patients receiving IMRT were required to complete 25 treatments prior to being randomized into our study. In comparison, patients receiving SBRT are only required to complete 5 treatments. IMRT is generally less tolerable than SBRT, and we had observed a higher drop out for patients on IMRT. As of March 15, 2022, our Phase 3 trial had achieved approximately 50% of the target enrollment under the current SAP. The SAP includes a planned interim analysis when a total of 65 deaths have occurred in the study. We expect to conduct the interim analysis between the fourth quarter of 2022 and the first quarter of 2023; however, given that it is predicated on the number of deaths in the study, it is difficult to predict the exact timing. We have secured Orphan Drug Designation for the treatment of pancreatic cancer, which would provide us with seven years of orphan exclusivity to market RenovoGem for our LAPC indication upon NDA approval, provided that we are the first sponsor to obtain FDA approval for intra-arterial gemcitabine for the LAPC indication.

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For our initial indication, LAPC, we have completed two studies. We launched RR1, our first-in-human, dose escalation, Phase 1/2 safety study, in May 2015 to evaluate our RenovoTAMP platform by delivering intra-arterial gemcitabine via our patented RenovoCath delivery system. In this safety study, 20 patients with a diagnosis of Stage 3 pancreatic cancer were enrolled. After completion of enrollment and demonstration of an early survival efficacy signal in this study, we launched our RR2 observational registry study in June 2016 to examine the tolerability and initial efficacy of the RenovoTAMP procedure. A combination analysis of these two studies demonstrated that survival in "all comers" (n = 31) receiving at least one cycle (two treatments over one month) was 29% at two years. In the prior-radiation therapy subset (n = 10), 24-month survival was 60% with a median overall survival (mOS) of 27.9 months. This compares favorably to IV chemotherapy, with 12% at two years, and to chemotherapy + radiation with survival of 5% at two years, and mOS of 12 - 15 months as demonstrated in historical studies.

RenovoGem in Extrahepatic Cholangiocarcinoma (eCCA)

We intend to evaluate RenovoGem in a second indication in a Phase 2 trial in eCCA, cancer that occurs in the bile ducts that lead out of the liver and join with the gallbladder. We have now completed our evaluation of the different approaches to treat this patient population and are in the process of refining our clinical protocol. We plan to meet with FDA during the second or third quarter of 2022 to discuss our trial design. If FDA does not object to our study protocol, we anticipate launching the eCCA trial in the second half of 2022. We have also secured FDA Orphan Drug Designation for RenovoGem for the treatment of cholangiocarcinoma, which would provide us with seven years of orphan exclusivity to market RenovoGem for our eCCA indication upon NDA approval, provided that we are the first sponsor to obtain FDA approval for intra-arterial gemcitabine for the eCCA indication.

Our Team

Our management team, Board of Directors, and Scientific Advisors provide us with expertise across multiple sectors to drive success through clinical development and subsequent commercialization of our novel therapy platform. Our Chief Executive Officer, Shaun Bagai, gained extensive experience running clinical trials and launching, creating, and developing new markets for novel therapies at TransVascular, Medtronic, Ardian, and HeartFlow. Dr. Ramtin Agah, our Co-Founder and Chief Medical Officer, is a practicing cardiovascular specialist who has 20 years of research experience in vascular biology and disease in both academia and industry. Our Board of Directors includes a wide range of public and private company management, board and life sciences experience, including drug/device combination and oncology experience. Clinical advisors

include experts across many specialties who treat solid tumors. Dr. Daniel Von Hoff, a medical oncologist, was instrumental as the Principal Investigator who brought to market standard of care therapies for pancreatic cancer. Dr. Michael Pishvaian, also a medical oncologist, has extensive experience running oncology studies and is an Associate Professor, and Director of the Gastrointestinal, Developmental Therapeutics, and Clinical Research Programs at the NCR Kimmel Cancer Center at Sibley Memorial Hospital Johns Hopkins University School of Medicine. Dr. Pishvaian is the Principal Investigator / Global Study Chair of our TIGeR-PaC Phase 3 study. Dr. Karyn Goodman serves as the Radiation Monitor for our TIGeR-PaC Phase 3 study and Professor and Vice Chair of Clinical Research, Department of Radiation Oncology at the Icahn School of Medicine at Mount Sinai, and Associate Director of Clinical Research at the Tisch Cancer Institute at Mount Sinai.

Strategy

RenovoGem is a combination of intra-arterial gemcitabine and our patented delivery system, RenovoCath, and is regulated by the FDA as a new oncology drug product. Our near-term goal is to develop RenovoGem to address the unmet medical needs of LAPC and eCCA patients. We intend to broaden application of our RenovoTAMP therapy platform by exploring additional cancer indications, including locally advanced lung cancer, locally advanced uterine cancer, and glioblastoma. Our long-term goal is to expand applications of our RenovoTAMP platform beyond RenovoGem by acquiring or licensing other small molecule therapies to continue to address unmet medical needs of cancer patients. To achieve our near-term and long-term goals, we intend to pursue the following strategies:

- ***Advance our lead product candidate, RenovoGem, for use in LAPC, our first indication.*** In our Phase 1/2 study, we demonstrated a median survival of approximately 28 months from diagnosis which compares favorably to 12 - 15 months in historical controls in LAPC patients. We are currently conducting our TIGeR-PaC Phase 3 clinical trial in LAPC. As of March 15, 2022, our Phase 3 trial had achieved approximately 50% of the target enrollment under the current SAP.

- ***Advance RenovoGem for use in our second indication, eCCA***. We have secured Orphan Drug Designation for RenovoGem for the treatment of extrahepatic cholangiocarcinoma and plan to meet with FDA during the second or third quarter of 2022 to discuss our trial design. If FDA does not object to our study protocol, we anticipate launching the eCCA trial in the second half of 2022.

- ***Expand RenovoGem for use in additional solid tumors indications.*** We plan to launch IND-enabling studies to explore the application of RenovoGem for the treatment of locally advanced lung cancer and other solid tumor indications, such as locally advanced uterine tumors and glioblastoma.

- ***Develop RenovoTAMP with different chemotherapeutic agents.*** Our delivery system, RenovoCath, can be used to deliver almost any small molecule therapeutic agent to solid tumors. RenovoTAMP has the potential to overcome limitations of systemic toxicity by local delivery of small molecule therapeutic agents to the tumor. We may seek regulatory approval for product candidates that use our therapy platform with drugs that are available generically, or we may enter into strategic collaborations to access other companies' proprietary drugs.

- ***Explore collaborations with biotechnology and pharmaceutical companies.*** Based on our intellectual property portfolio, we believe we have exclusive global development and commercialization rights for RenovoGem and RenovoCath, including issued patents on methods of using RenovoTAMP for all indications that we may pursue. While we may develop these products independently, we may also enter into strategic relationships with other biotechnology or pharmaceutical companies to advance our product candidates.

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Our Strengths

- ***Solid tumor targeting via local therapy.*** Our platform has the potential to efficiently target locally advanced solid tumors. Many solid tumors cannot be surgically removed and are difficult to treat. Our innovative therapy platform is designed to deliver anti-cancer drugs directly to the tumor and does not rely on the existence of extensive vasculature, also known as tumor feeder blood vessels. We believe that local delivery of approved chemotherapeutic agents directly to the tumor, utilizing RenovoTAMP, is a promising approach to improve outcomes in locally advanced solid tumors.

- ***Preliminary data indicate that our approach is feasible and well-tolerated with promising survival results***. Our Phase 1/2 data demonstrated that RenovoGem is well tolerated with multiple survival signals.

- ***Platform with broad utility to build out our pipeline.*** We believe that the flexibility of our platform combined with our exclusive global development and commercialization rights gives us the ability to grow our product pipeline by targeting a broad range of solid tumor indications and by using additional chemotherapeutic agents. Furthermore, since 2015, when we dosed the first patient with RenovoGem, dozens of clinical investigators have utilized our RenovoTAMP technique as part of our clinical program for LAPC.

Current Treatments and Limitations of Approaches

Currently, solid tumors are typically treated using one or a combination of treatment modalities: surgery, radiation, and pharmacological therapies (chemotherapy). For solid tumors, when possible, surgical resection of the tumor is the most frequently employed treatment approach. If the tumor is detected at an early stage and is localized to the affected organ, surgical removal of the entire tumor may be an effective and potentially curative treatment. In most cases, surgery is undertaken and / or completed prior to commencing additional treatment approaches. However, multiple solid tumor types, including LAPC and eCCA are diagnosed at advanced stages, which precludes surgery as a treatment approach. In many of these circumstances, the tumor has grown into adjacent anatomical structures making surgery difficult or impossible.

Intravenous (IV), or systemic chemotherapy, is considered standard of care for most solid tumors, but limitations include less than acceptable efficacy, systemic toxicities, and other side effects.

For the treatment of some localized solid tumors, TACE is an established first line therapy. Many companies have developed therapeutic products for use in this approach to treat tumors of the liver, uterus, and prostate. Many solid tumors have a dedicated blood supply: small blood vessels, called tumor feeder blood vessels, that branch off of larger native arteries and terminate in the tumors to provide nutrition to the tumors. A key aspect of TACE is to identify and isolate these tumor feeder blood vessels during x-ray angiography and then deliver the desired therapy including chemotherapy and embolic agents. In patients with LAPC, no tumor feeder blood vessels are visible during angiography due to the avascular (lack of blood vessels) nature of these tumors. This limitation has rendered TACE ineffective in the treatment of patients with LAPC, eCCA, and a subset of other solid tumors. The limitations of TACE translate to low survival rates in these tumor subtypes. The use of TACE with or without immuno-oncology treatment approaches, which harness the body's immune system to treat cancer, has not significantly improved survival rates in these subtypes. For example, due to the inability of immune cells to penetrate the tumor tissue, early studies of targeted immunotherapies in pancreatic cancer have demonstrated limited success.

Our Platform: RenovoTAMP

RenovoTAMP may work best with avascular tumors

Certain tumor types are sufficiently vascularized to enable use of systemic chemotherapy and standard of care local therapy techniques. In Figure 2 below, for example, the panel on the left depicts visualization of an actual tumor, hepatocellular carcinoma (HCC), or primary liver cancer, under x-ray angiography as dye injected through the arteries reaches the tumor itself. Further, visible tumor feeder blood vessels can be reached by simple end-hole catheters to deliver targeted therapy to these liver tumors. In contrast, the panel on the right illustrates the typical lack of tumor feeder blood vessels to a pancreatic tumor. Given the lack of tumor feeder blood vessels, the dye does not reach the tumor, rendering the tumor "invisible" under x-ray angiography.

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Tumors in Liver are Different from Hypovascular Tumors in the Pancreas

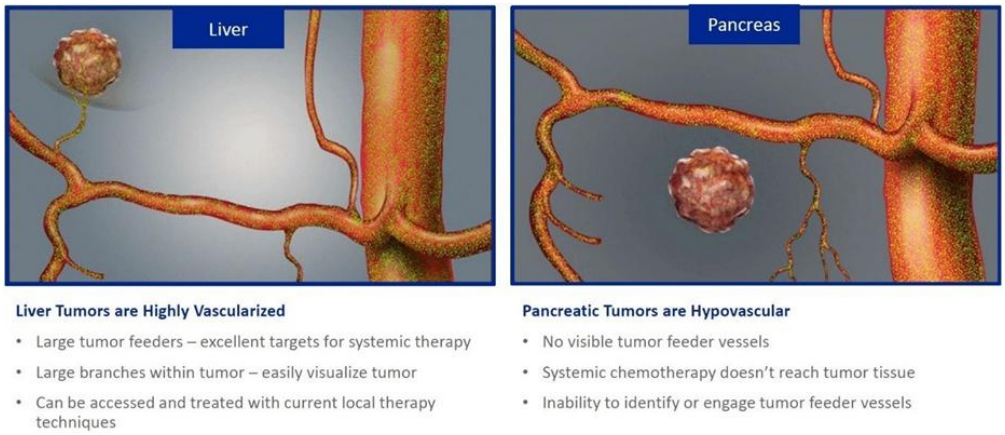

Figure 2 Showing liver tumors that are highly vascularized, and pancreatic tumors that are avascular.

RenovoTAMP has been under development for over 12 years

In 2009, our founder Dr. Ramtin Agah, an experienced interventional cardiologist with a degree in biomedical engineering, developed the concept for RenovoTAMP as a way to deliver chemotherapy locally to treat poorly vascularized tumors. He joined forces with Kamran Najmabadi, who brought significant medical device engineering experience, to found RenovoRx in 2009. Subsequently, we engaged a contract manufacturer to prototype and manufacture our RenovoCath delivery devices. We received our first FDA 510(k) clearance for RenovoCath in 2014, a second clearance to use the RenovoCath for infusion of chemotherapy agents in 2017, a further clearance to use RenovoCath with a power-injector in 2019, and a fourth clearance in 2021 to expand vessel diameter range to 3-11mm, implement certain changes in the Instructions for Use, change the recommended saline to contrast solution ratio, among other changes and improvements. RenovoCath is intended for the isolation of blood flow and delivery of fluids, including diagnostic and/or therapeutic agents, to selected sites in the peripheral vascular system. RenovoCath is also indicated for temporary vessel occlusion in applications including arteriography, preoperative occlusion, and chemotherapeutic drug infusion. RenovoCath is intended for general intravascular use in the peripheral vasculature in arteries 3 mm and larger as well as for use in arteries from 3 mm in diameter for vessel entry and to occlude vessels ranging between 3 mm to 11 mm in diameter. We are evaluating our lead product candidate RenovoGem under an IND filed in 2018. FDA has determined that RenovoGem will be regulated as, and if approved we expect will be reimbursed as, a new oncology drug product.

How it works: we developed RenovoTAMP as an attempt to solve the problems of treating avascular tumors

To overcome the limitations resulting from a lack of tumor feeder blood vessels, we explored a different approach to locally deliver anti-cancer drugs. By isolating a section of the blood vessel and then increasing the intravascular pressure in the isolated segment, we can introduce chemotherapy directly across the arterial wall into the surrounding tissue via pressurized diffusion, or Trans-Arterial Micro-Perfusion (RenovoTAMP). To isolate the vessel and create this pressure gradient, we developed RenovoCath, a patented adjustable double balloon catheter to occlude the proximal and distal part of the vessel. Using the RenovoTAMP technique in explanted (dissected out of the animal and used separately in a saline water bath) pig aorta and iliac arteries, we were able to validate our hypothesis by demonstrating >99% gemcitabine pressurized diffusion across the arterial wall in the absence of feeder vessels. This mechanism of action was further supported by exploratory acute animal studies measuring the pressure gradient within the artery during double balloon occlusion. Figure 3 demonstrates the change in intra-arterial pressure over time from catheter introduction to balloon inflation, start of infusion, and pressure plateau when chemotherapy is forced out of vessel. These changes in pressure are a result of pressure declining as the first balloon blocks blood inflow and then rising as the drug is administered and fills up the space between the balloons.

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In procedures developed for the RenovoTAMP platform, interventional radiologists utilize RenovoCath to pressurize an isolated vessel segment

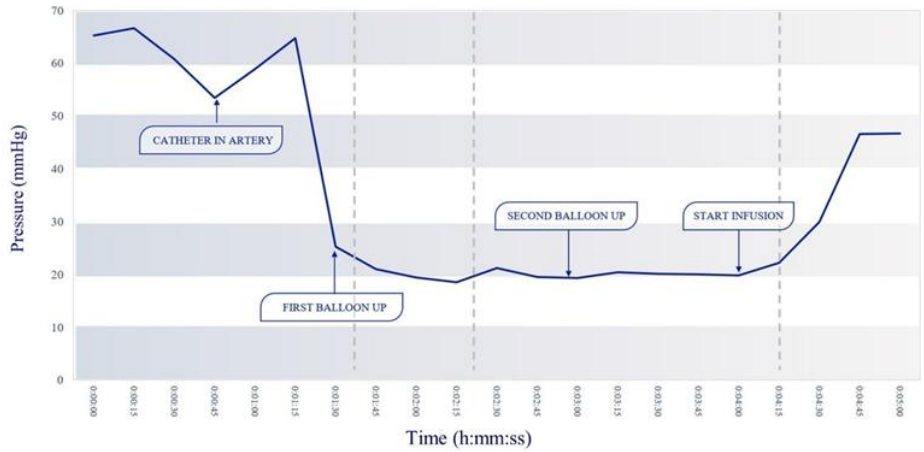

Figure 3 Occluding the vessel with RenovoCath, while adjusting the balloon-to-balloon distance to exclude all blood vessel branches, established an intravascular interstitial pressure in the isolated blood vessel segment of approximately 20 mmHg. With subsequent infusion of fluids between the balloons at 6 mls/minute, the intravascular pressure increases to above 45 mmHg, trans-arterially forcing the small molecule drug across the arterial wall via diffusion (this patented process of perfusing the vessel wall is Trans Arterial Micro Perfusion, or RenovoTAMP).

Our RenovoTAMP platform therapy utilizes pressure mediated delivery of gemcitabine across the arterial wall to bathe the pancreatic tumor tissue in 120 mL of saline with

1,000 mg/m^2 of drug over a 20-minute delivery period (delivering 1,500 - 2,000 mg of drug depending upon patient body surface area. This blanketing approach of large fluid volume delivery over time may enable the drug to approach these difficult-to-reach tumors.

Some advantages of RenovoTAMP include:

- Ideal for solid tumors where resection is not possible due to proximity/impingement of tumor on blood vessels, nerves, or other key structures
- No need for identifying tumor feeder blood vessels to deliver the drug. These generally do not exist in avascular or hypovascular tumors such as LAPC and eCCA
- In solid tumors without identifiable feeder vessels, technically easier than direct cannulation of small tumor feeder blood vessels
- High local concentration of drug into the tumor tissue
- Potential for decreased systemic exposure of drug due to local metabolism prior to systemic exposure

Developing a therapeutic platform using an adjustable two-balloon catheter and intra-arterial gemcitabine

By isolating the vessel adjacent to the tumor and creating a pressure gradient across the arterial wall between the isolated vessel segment and the surrounding tissue or tumor, we are able to force the small molecule chemotherapy across the vessel directly into surrounding tissue or tumor. To accomplish this, we needed a minimally invasive technique to isolate the blood vessel next to the tumor, exclude any branches that can cause washout of chemotherapy away from the target, and then infuse the chemotherapy into the isolated segment to achieve pressure mediated diffusion through the vessel wall and into the tumor tissue. We accomplished this with our patented RenovoCath delivery system. RenovoCath is a double balloon catheter designed with the capability to isolate the proximal and distal sections of the vessel through the adjustment of the distance between the balloons, thereby excluding any branching blood vessel offshoots. Using standard interventional techniques, an interventional radiologist inserts the RenovoCath delivery system into the body through the femoral artery and positions it in the artery closest to the tumor. Once the balloons are inflated and the position is confirmed, chemotherapy is delivered through the handle, exiting the device between the balloons. It is forced through the vessel wall into the tissue over a 20-minute period. The RenovoCath delivery system is depicted below in Figure 4.

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RenovoCath Delivers Chemotherapeutic Agent Between Two Balloons

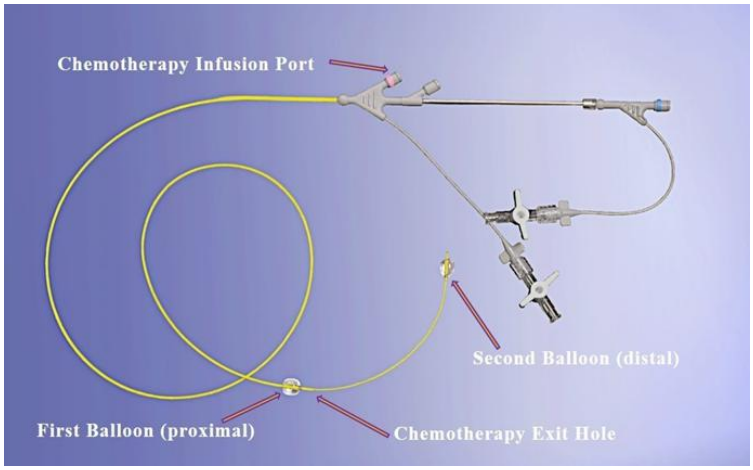

Figure 4 RenovoCath delivery system illustrating two balloon configuration to isolate the target vessel segment, and chemotherapy delivery port and exit hole.

After the procedure is complete, RenovoCath is discarded, and the patient is generally discharged the same day. On average, the entire procedure takes approximately 90 minutes. According to the TIGeR-PaC study protocol, intra-arterial treatment is administered through RenovoCath every other week for a maximum of 8 treatments for approximately 16 weeks. Interventional radiologists using the device are typically proctored for their first 2-3 cases only. In addition, platform training for our primary indication should transfer to other indications.

RenovoGem for LAPC

Disease Overview

Pancreatic cancer is one of the deadliest cancers in the US with very poor outcomes. In 2022, an estimated 62,210 new cases of pancreatic cancer will be diagnosed in the US and 49,830 people will die from the disease. For all stages combined, the 5-year relative survival rate is 11%. Pancreatic cancer is the 3rd leading cause of cancer death in the USA and is projected to become the 2nd leading cause by 2030. 54,000 new cases per year are diagnosed in the USA; worldwide, more than 300,000 new cases of pancreatic cancer are diagnosed each year.

Current Treatment Landscape and Limitations

Pancreatic cancer has limited treatment options including one or a combination of surgery, radiation, chemotherapy, and/or some targeted therapies. Only a small subset of pancreatic cancer patients is eligible for surgery (“Resectable” at the time of presentation (Stage I-II: 15%); the rest are distributed between having tumors with unresectable LAPC (Stage III: 30%) and metastatic pancreatic cancer (Stage IV: 50%).

Chemotherapy is at the forefront of systemic therapy for cancer. It can be used in the neoadjuvant (before surgery) setting to attempt to decrease tumor size in resectable or borderline resectable patients, in the adjuvant (after surgery) setting, or first line in the metastatic/advanced setting. The backbone of our first product candidate, gemcitabine, is a nucleoside metabolic inhibitor that exhibits antitumor activity by blocking the synthesis of new DNA, which results in cell death. Gemcitabine administered as an intravenous (IV) infusion has an established role in the treatment of both unresectable LAPC and metastatic pancreatic cancer. Since its introduction in the US as Gemzar® (gemcitabine for injection) in 1996 with an FDA approved indication as such, it remains in the guidelines as standard of care. It has been demonstrated to provide clinical benefit for subjects (decreased pain and improved performance status) as well as to improve the time to tumor progression and survival for subjects with metastatic pancreatic cancer and LAPC. However, major improvement in the survival curve of all pancreatic cancer subjects has been a clinical challenge, with an average median survival time for LAPC stalled at 12-15 months from time of diagnosis.

A key limitation of conventional chemotherapy in these tumors can be attributed to their avascular nature and desmoplasia (fibrosis or the growth of scar tissue) that impedes drug delivery. Pancreatic tumor cells have a thick and poorly perfused stroma, or connective tissue, and high interstitial pressure. This can potentially constrict blood vessels leading to an avascular or hypovascular environment that impedes chemotherapy from reaching tumor cells in high enough volume, rendering them relatively resistant to chemotherapy.

In patients with metastatic disease, two chemotherapy combination regimens have shown superiority to gemcitabine, albeit with increased toxicity. First, the combination of oxaliplatin, irinotecan, fluorouracil, and leucovorin (FOLFIRINOX) in a relatively young cohort of metastatic pancreatic cancer patients appears superior to gemcitabine by improving survival from 6.8 to 11.1 months. Second, in the Metastatic Pancreatic Adenocarcinoma Clinical Trial (MPACT) trial, the combination of gemcitabine plus nab-paclitaxel (Abraxane) demonstrated an OS benefit of 9 weeks versus gemcitabine alone at the cost of increased toxicity.

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A major focus of clinicians is determining the optimal method to treat patients with LAPC, patients with localized disease who are not surgical candidates, roughly 30% of all pancreatic cancer patients. IV, or systemic, administration of chemotherapy has yielded unsatisfactory results in these patients. Various localized treatments have included high dose local radiation, direct attempts at local injection of drugs, and use of adenoviral vectors to deliver toxic agents. These treatment options demonstrated limited success in the treatment of LAPC. The lack of successful treatment options represents a recognized unmet medical need for these patients.

Standard of care chemotherapy for the treatment of pancreatic cancer has historically shifted a couple of times with the addition of erlotinib to gemcitabine 15 years ago resulting in a 14-day survival benefit. In 2013, the addition of Abraxane to gemcitabine was approved, with immediate deep market penetration based on an 8-week survival benefit despite higher systemic drug toxicities.

Our Solution

We believe that our product candidate, RenovoGem, has the potential to address the recognized unmet medical need. Utilizing our patented RenovoTAMP therapy platform, we believe RenovoGem can enhance local drug concentration, thereby increasing efficacy and decreasing systemic exposure and toxicity to improve patient outcomes. RenovoGem is a drug/device combination product candidate consisting of intra-arterial gemcitabine and our proprietary RenovoCath delivery system which forces the anti-cancer drug into the tumor. RenovoGem is regulated by the FDA as a new oncology drug product. We do not intend to sell RenovoCath alone. Instead, we intend to sell RenovoCath only in combination with intra-arterial gemcitabine (as RenovoGem) or potentially with other therapeutic agents.

Based on primary market research and analysis of the US market sponsored by RenovoRx and conducted by third parties, we believe that over 5,000 patients per year would be excellent candidates and undergo RenovoGem treatment once it is approved in the US. The independent oncologists interviewed stated their dissatisfaction with current standard of care and the strong desire for a therapy like ours to extend potential survival while maintaining quality of life. Further, the analysis suggests, based on analogous oncology drugs with only a *modest* efficacy benefit, a novel drug can expect 50-80%+ penetration in a first line setting. The results of the Key Opinion Leader, or KOL interviews revealed that a majority of oncologists would refer 90%+ of their LAPC patients who are eligible for the procedure for RenovoTAMP if the current Phase 3 trial demonstrates at least a 4-month survival benefit over systemic chemotherapy.

RenovoTAMP Therapy Platform and First Product Candidate, RenovoGem

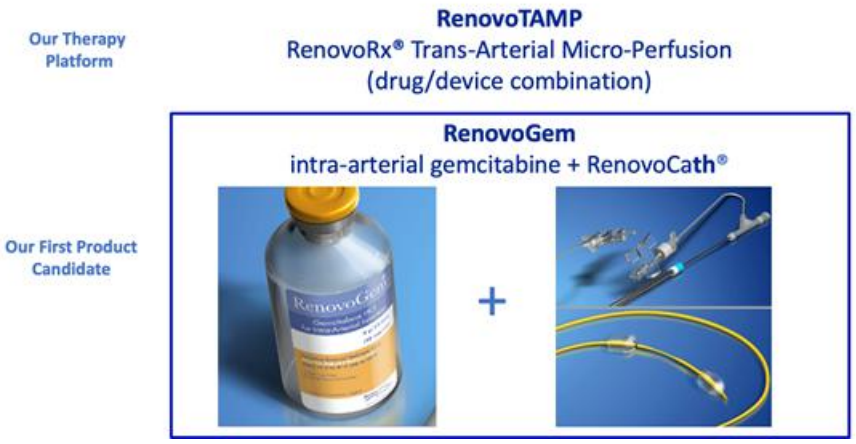

Figure 5 We invented a new therapy platform, RenovoTAMP, that uses pressure to force small molecule chemotherapeutics across the vessel wall into the surrounding tissue using our patented RenovoCath delivery system. Our first product candidate, RenovoGem, is a drug/device combination of intra-arterial gemcitabine and the RenovoCath delivery system, and is under development for LAPC and eCCA. We have secured Orphan Drug Designations for RenovoGem for the treatment of both pancreatic cancer and cholangiocarcinoma.

Clinical Development of RenovoGem in LAPC

Preclinical Studies and Data

Once RenovoCath is introduced via standard interventional technique to the arterial vessel segment next to the targeted tissue, both balloons are inflated, and the vessel segment is isolated from the rest of the circulatory system. With inflation of balloons, the pressure is observed to drop within the vessel. However, with infusion of fluids between the balloons, the intravascular pressure increases beyond 45 mmHg until plateauing, generating a gradient and trans-arterially forcing the infusate across the arterial wall via diffusion or Trans-Arterial Micro-Perfusion (TAMP). A key aspect of this approach is to adjust the distance between the balloons to exclude any side blood vessel branches in the isolated segment to allow the increase in pressure gradient, rather than drug washout via the side branches. Figure 6 shows a comparison, in an animal study, between proper balloon positioning with no side branches, allowing maximum drug to cross the arterial wall, versus improper balloon positioning to include side branches, resulting in drug washing out via the side branches.

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Infusion Pressure Achieved When Side Blood Vessel Branches Are Excluded

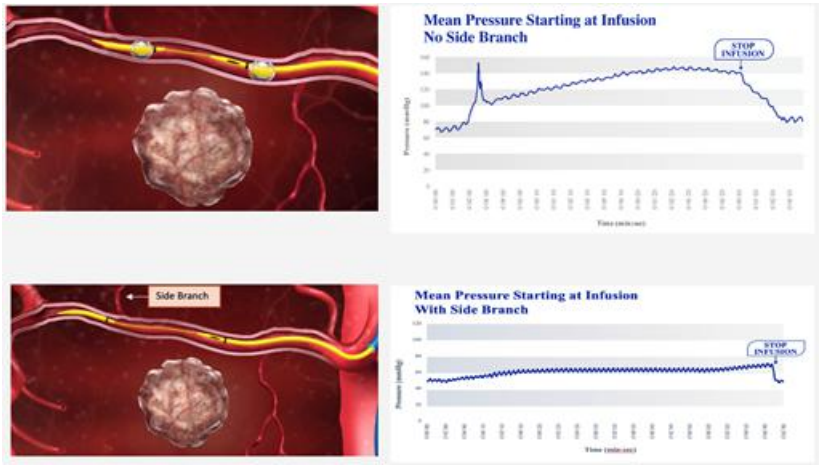

Figure 6 Top panel demonstrates proper balloon positioning with no side branch. Pressure increases with infusion and reaches plateau of approximately 75 mmHg higher than initial pressure. Bottom panel demonstrates improper balloon positioning with side branch between the balloons. Pressure increases with infusion and reaches plateau of approximately only 15mmHg higher than initial pressure.

With diffusion of fluids across the arterial wall in RenovoTAMP, we expected to be able to deliver small molecules into the surrounding tissue. We performed the following studies to validate this hypothesis:

1) In a preclinical study, 99% of the gemcitabine crossed the arterial wall via RenovoTAMP.

In explanted (dissected out of the animal and used separately in a saline water bath) pig iliac and aortic artery, with the introduction of RenovoCath and infusion of gemcitabine in the isolated vessel segment, we were able to measure (in a time dependent fashion) the amount of gemcitabine crossing the arterial wall into the surrounding fluid. We isolated the arterial vessel segment using RenovoCath and then delivered 60 mg/minute of gemcitabine into the isolated area over 20 minutes. By the end of the infusion, we measured 1,188 mg of gemcitabine in the surrounding fluid around the vessel and 9 mg in the analyzed tissue of the vessel. This demonstrated that 99% of the drug crosses the arterial wall and only 0.75% is retained in the arterial tissue (Figure 7).

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In a Preclinical Study -99% of Chemotherapy Crosses Arterial Wall with RenovoTAMP Delivery

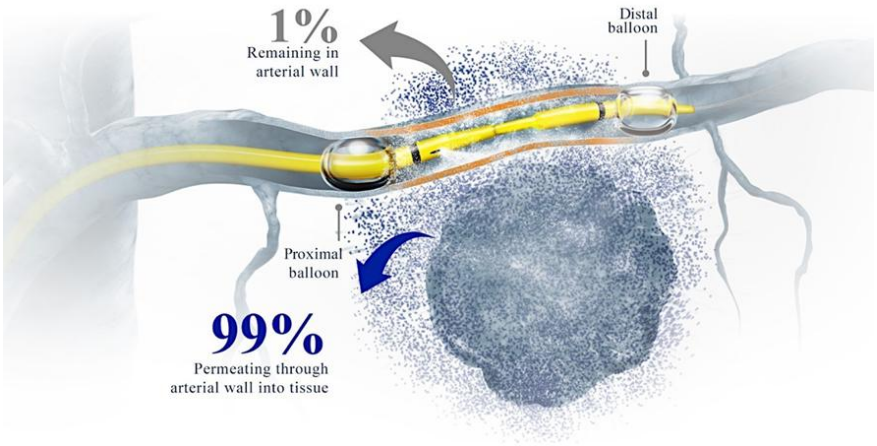

Figure 7 RenovoTAMP: delivery of chemotherapy through the RenovoCath and into the tissue to bathe the tumor in chemotherapy. In a preclinical study using gemcitabine, 99% of the drug crosses the arterial wall and less than 0.75% is retained in the vessel wall tissue.

2) Infusion of gemcitabine via RenovoTAMP has demonstrated vascular safety with acceptable toxicity in a pig model and does not cause loss of vessel integrity or inflammation.

Six pigs were treated with gemcitabine via RenovoTAMP (6 mL/min for 20 minutes). Target vessels included selection of the superficial femoral artery (SFA) and splenic arteries from each animal (either test or saline control). A total of 6 vessels (3 SFA and 3 splenic arteries) were treated with an equal number of control vessels. All animals survived the 7-day in-life period although two of the animals with gemcitabine treatment in the splenic artery experienced atypical pain during the post-operative phase and required additional pain management with eventual complete recovery.

Analysis of the vessels demonstrated preserved vessel shape with intact endothelial cells (cells on the inside of the vessels). Minimal to no inflammation was observed. The only vessel toxicity observed was a reduction of smooth muscles cells in the vessel wall, primarily close to the inside of the vessel.

3) In preclinical studies, RenovoTAMP achieved targeted local drug (dye) delivery.

I. Targeted small molecule delivery (dye) into pancreatic tissue

We further validated our approach for tissue drug delivery using acute animal experiments. Using both dye and gemcitabine infusion via the RenovoTAMP therapy, we were able to demonstrate that fully isolating a segment of a vessel (by blocking inflow and outflow in the target vessel as well as side branches with the RenovoCath double balloons) can lead to dye penetration greater than 4.0 cm from the vessel wall and drug tissue concentration (gemcitabine) up to 100-fold greater than systemic administration.

In an acute pig experiment, RenovoCath was introduced into the gastro-duodenal artery (GDA), a side branch was excluded (using small implants that block the artery, coils),

and then dye was introduced at 6mls/minute over 2 minutes. Analysis demonstrated that the blue dye diffused covered approximately 10.56 cm^2 (2.2 cm x 4.8 cm) of the pancreas.

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Dye Demonstrates RenovoTAMP Delivery of Agent into Pancreatic Tissue

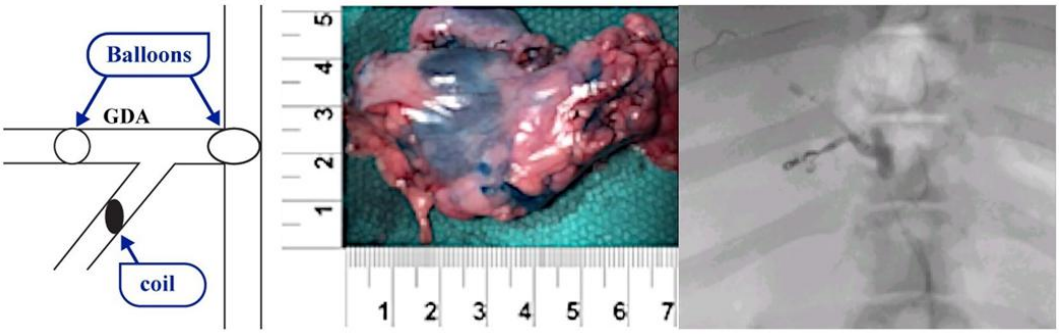

Figure 8 RenovoCath was introduced into the GDA and a side branch was excluded by coiling. This test was conducted in an acute porcine model and demonstrated a dye coverage area of approximately 10.56 cm^2 for a 2-minute dye infusion. All dimensions in above figure are in cm.

The study was repeated in 6 other vessel targets to validate the impact of vessel isolation on dye penetration into the surrounding tissue with similar results.

II. Small molecule delivery (dye and gemcitabine) locally into lung tissue

In another set of acute animal experiments, the pulmonary artery was isolated via access through the internal jugular vein. Six ml of methylene blue dye was injected over 1 min and gemcitabine was subsequently delivered locally at rate of 6 mls/minute for 20 minutes to the lung tissue using the RenovoTAMP procedure.

Dense dye staining localized to the area of the isolated vessel segment was observed. Again, analysis established penetration into surrounding tissue (4 cm). Furthermore, RenovoTAMP achieved greater than 100-fold tissue concentration of gemcitabine versus the tissue level achieved by IV (systemic) delivery of gemcitabine at the same infusion rate.

Dye Staining Demonstrates RenovoTAMP Delivery of Agent to Lung Tissue

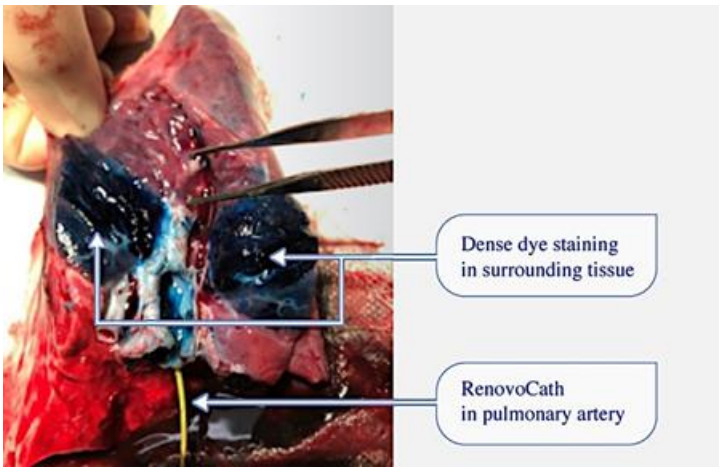

Figure 9 Dense dye staining localized to the area of the isolated pulmonary artery segment and penetrating 4 cm into surrounding tissue following 1 minute dye infusion. In addition, gemcitabine was delivered via RenovoTAMP for 20 minutes demonstrating 100-fold increase in tissue concentration of gemcitabine compared to IV delivery of gemcitabine at the same infusion rate.

We concluded that RenovoTAMP can achieve drug penetration into the surrounding tissue and can achieve high dose concentrations in local tissue. The tissue concentration with intravenous infusion and/or distant from RenovoTAMP site (likely after recirculation through systemic system) were two orders of magnitude lower than tissue levels achieved with RenovoTAMP ($p<0.02$).

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RenovoTAMP Increases Local Tissue Concentration of Gemcitabine Compared to IV Infusion

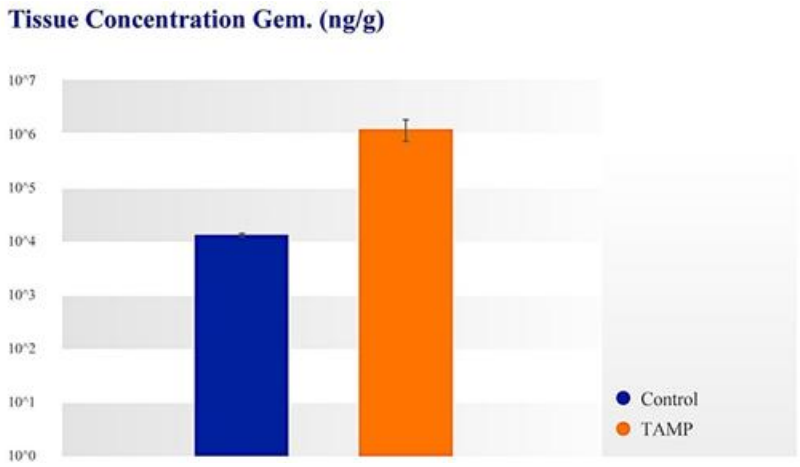

Figure 10 Local tissue concentration of gemcitabine. control (Blue): Intravenous infusion versus RenovoTAMP (Orange): RenovoTAMP: intra-arterial infusion. The tissue concentration with intravenous infusion and/or distant from RenovoTAMP site (likely after recirculation through systemic system) are 100-fold lower than tissue levels achieved with RenovoTAMP.

This animal lung study successfully validated the ability of RenovoCath to deliver small molecules locally and effectively to lung tissue.

III. Based on the results of preclinical studies, increase in local tissue delivery of gemcitabine in LAPC may enhance tumor reduction and therapeutic response

In relevant mouse models of pancreatic tumors, it has been demonstrated that targeted intra-arterial (IA) infusion of gemcitabine into the pancreas after surgical isolation of arterial blood flow has a superior therapeutic effect with greater reduction in tumor volume compared to the same concentration administered by conventional systemic (intravenous) injection. To achieve a comparable reduction in tumor growth as seen with IA treatment, gemcitabine had to be given intravenously at over 300 times the dose which was associated with increased toxicity.

RenovoTAMP and Radiation

Traditionally the goal of radiation includes debulking the tumor and/or acting as a chemo-sensitizer. In our RR1 dose escalation safety study and RR2 observational registry study, the benefit of RenovoTAMP appeared to be enhanced in patients with prior radiation. As we were observing this effect months after radiation and although several randomized studies have not demonstrated a benefit of chemotherapy + radiation versus chemotherapy alone, we hypothesized that a direct effect of radiation on the vasculature may be enhancing the effect of RenovoTAMP. One of the side effects of radiation is a decrease in the micro-vasculature in the irradiated tissue including the small blood vessels that exist in the vessel walls themselves. Therefore, we postulated that by eliminating microvasculature in and around the vessel wall, radiation may enhance drug penetration into the tissue via RenovoTAMP (Figure 11). As such, a possible enhancing effect of radiation on RenovoTAMP may involve decreasing washout of the drug as it crosses the arterial wall by preventing draining into the surrounding microvasculature.

We completed a pig study where we observed the impact of RenovoTAMP in recruiting the vasa vasorum (small blood vessels within the larger blood vessel walls) around the vessel during drug/dye infusion. It was discovered that the dye drained into the vasa vasorum and other small vessels in the adjacent tissue (Figure 11); as these vessels can directly connect to the adjacent venous system, the microvascular networks can serve as an “escape route” for drugs. Ultimately this direct washout can reduce the amount of drug concentration in the tissue. Radiation pretreatment may enhance the impact of RenovoTAMP by attenuating this escape route.

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RenovoTAMP Combined with Radiation Reduces Venous Outflow by Decreasing the Microvasculature

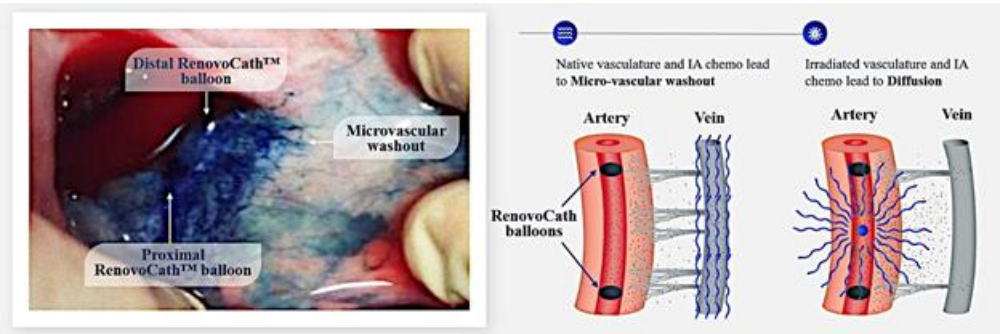

Figure 11 Mechanism of RenovoTAMP and radiation reduces venous outflow by decreasing the microvasculature networks that could act as an “escape route” for the drugs. The photo on the left illustrates this effect in a dye infusion study in the porcine animal model. The panel on the right demonstrates venous chemotherapy washout without radiation versus less venous escape routes for chemotherapy following radiation.

We further advanced this theory by conducting a pig study to directly test whether radiation can enhance tissue uptake by RenovoTAMP. In a single-animal study, we examined the use of Stereotactic Body Radiation Therapy (SBRT) pre-treatment on one leg followed by RenovoTAMP versus RenovoTAMP without prior radiation therapy on the opposite leg. The leg of the animal that was pre-treated with radiation demonstrated more pronounced tissue staining with methylene blue dye and increased gemcitabine concentration via punch biopsy. Based on these findings, we believe that the benefit of prior radiation on clinical outcomes with RenovoTAMP may be improved by the effect of radiation on microvasculature between the vessel wall and the tumor.

Dye Test Demonstrates that RenovoTAMP Plus Radiation Increases Concentration of Gemcitabine

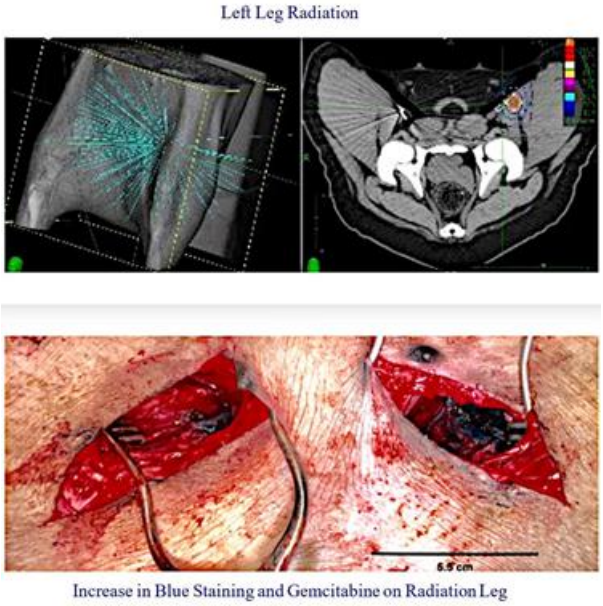

Figure 12 To demonstrate the effect of radiation pre-treatment, we delivered radiation therapy to the left leg of a pig. After waiting one month for the therapy to fully affect the vasculature, we performed RenovoTAMP on the left and right leg arteries with blue dye and gemcitabine. Dissection revealed better dye penetration into the tissue on the left (irradiated) leg, and punch biopsy demonstrated higher gemcitabine concentration in the left leg.

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We have demonstrated that the RenovoTAMP therapy allows targeted small molecule drug delivery into the tissue surrounding the vessel wall, without need to identify tumor feeder blood vessels. The mechanism of action is the exclusion of distal (downstream) and side branch vessels in the isolated segment and creating a pressure gradient by infusing the drug over time. The pressure gradient results in a diffusion-mediated delivery of drug into the surrounding tissue. With the use of gemcitabine, the procedure appears safe in terms of local toxicity in the vasculature. Using this approach, we can achieve increased drug delivery into the surrounding tissue in the range of 4 cm-tissue penetration as well as concentration orders of magnitude larger than what can be achieved with IV infusion. Lastly, RenovoTAMP appears to be enhanced by prior radiation of tissue, possibly by decreasing the microvasculature and subsequent potential chemotherapy washout.

LAPC Clinical Development

RenovoTAMP has been studied in a phase 1/2 dose-ranging study of 20 subjects with locally advanced pancreatic cancer (RR1) and in an observational study that enrolled 25 additional subjects with pancreatic cancer (RR2); two subjects from the RR1 safety study continued to receive treatment in the RR2 observational registry study. We subsequently launched a Phase 3 registration trial (TIGeR-PaC), and as of March 15, 2022, our Phase 3 trial had achieved approximately 50% of the target enrollment under the current SAP.

Phase 1/2 Dose-Ranging Study: RR1

Study Design

A phase 1/2 safety study of our RenovoTAMP therapy has been completed in subjects with LAPC (Phase 1/2 RenovoCath/Gem RR1). This multicenter, prospective, open label, interventional, nonrandomized, intra-subject dose escalation study evaluated IA gemcitabine delivered locally to the pancreas using the RenovoCath in 20 subjects with LAPC. The primary objectives of the study were (1) to establish the maximum tolerated dose (MTD) and (2) to study the safety and tolerability of intra-arterial (IA) gemcitabine administered by RenovoCath at doses ranging from 250 mg/m^2 to 1000 mg/m^2. Secondary endpoints included overall survival, CA 19-9 marker change, change in tumor size based on RECIST 1.1 (Response Evaluation Criteria in Solid Tumors) criteria, and pain scores and narcotic use. Adverse events were collected from the first IA gemcitabine infusion until 3 months following the final IA gemcitabine infusion. Subjects were followed for survival.

Treatment constituted introducing RenovoCath to target vessel (adjacent to tumor) via catheterization, occluding the targeted segments via the RenovoCath balloons, and infusing gemcitabine in the occluded segment. To minimize ischemia (damage due to cessation of blood flow) the infusion was limited to 20 minutes and an anticoagulant (heparin) was given during the procedure. Tissue markers were followed post procedure to ensure lack of local tissue damage-toxicity (AST, ALT, Lipase and Amylase).

Treatment was administered in four 28-day cycles, each of which consisted of two IA doses of gemcitabine, one on day 1 and one on day 15, with a two-week rest period between cycles. The first six subjects received a starting dose of 250 mg/m^2, and doses increased by 250 mg/m^2 in each subsequent cycle culminating with the full dose of 1,000 mg/m^2. After the initial six subjects, the starting dose increased to 500 mg/m^2 for one cycle, after which dosing increased to 750 mg/m^2 for the second cycle, and then the full 1,000 mg/m^2 dose for the remaining 2 cycles. Each subject underwent CT scanning prior to the first procedure for the selection of the optimal target vessel most proximal to the tumor.

Study Subjects and RenovoGem Exposure

The median age of subjects was 66.7 years with a gender distribution of 9 men and 11 women. Prior treatment included chemotherapy and radiation therapy in 6 (30%), chemotherapy alone in 5 (25%) and no prior therapy in 9 (45%) subjects. Collectively the 20-subject cohort received 101 IA treatments. It is important to note that 9 of the 20 subjects had a biliary stent or drain in place before the first IA procedure.

Trial Results

Safety

There was no evidence of local tissue toxicity in any patients post procedure as measured by liver and pancreatic enzymes. Out of 101 procedures, adverse events were reported in 11 subjects, including catheterization/procedure-related events with arterial dissections at treatment sites (3), pseudoaneurysm in a visceral artery (1), complications away from the treatment site and site complications (2).

Serious adverse events were reported in 9 subjects during the study. Overall survival (including deaths that occurred following disease progression) was followed in all study

subjects. The number of subjects with serious adverse events is shown in Table 1 below.

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Table 1 Summary of Serious Adverse Events for 9 subjects in RR1 Dose Ranging Study

Serious Adverse Event	N=20
Cardiac Arrest	1/20 (5%)
Dehydration	1/20 (5%)
Duodenal obstruction	1/20 (5%)
Gastritis	1/20 (5%)
Infection	1/20 (5%)
Intraoperative arterial injury-dissection	3/20 (15%)
Intraoperative arterial injury-lower extremity	1/20 (5%)
Pain-Abdominal NOS	1/20 (5%)
Respiratory failure	1/20 (5%)
Sepsis	3/20 (15%)
Neutropenia	4/20 (20%)

This table shows serious adverse events reported in 9 of the 20 subjects during the study. Several subjects had more than one serious adverse event.

Efficacy

The principal evaluation of efficacy was survival. All subjects were followed for survival after the end of IA gemcitabine treatment. All subjects have died, with the longest having an overall survival of 35.9 months.

Subjects Who Received More Intra-arterial Treatment Cycles Survived Longer

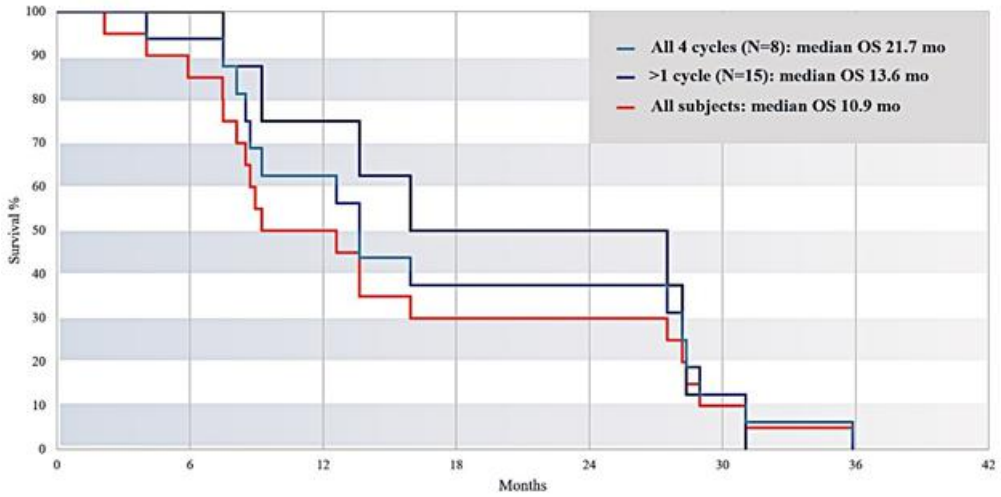

Figure 13 This chart shows survival as a function of total number of IA treatment cycles received. Subjects receiving all 4 cycles (n=8) had a median survival time of 21.7 months, compared to a median survival time of 10.9 months for all subjects (n=20).

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Subjects Who Received Greater Cumulative Exposure to RenovoGem Survived Longer

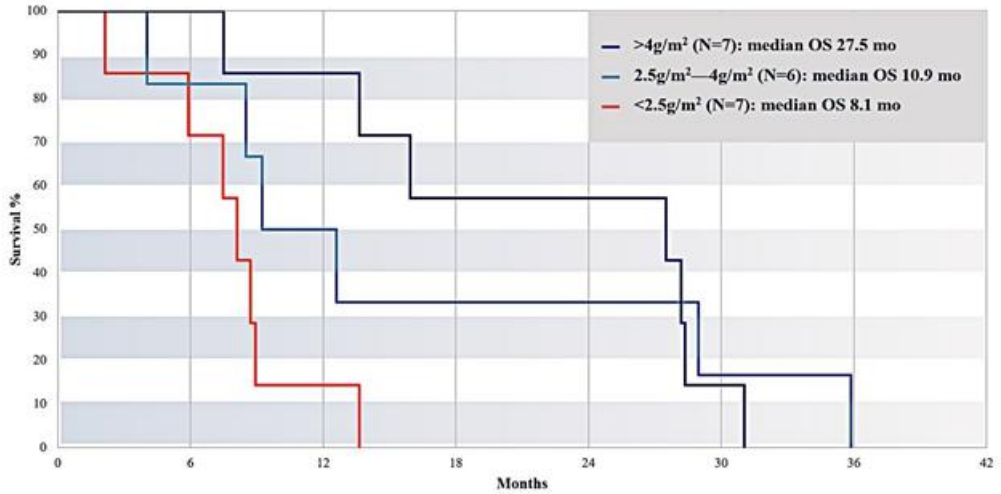

Figure 14 Splitting the entire cohort into equal tertiles based on total dose received, patients receiving the lowest total dose (<2.5g/m2; n=7) demonstrated the lowest median overall survival (8.1 months) compared to patients in the group receiving the next higher total dose (>2.5g/m2, but <4g/m2; n=6; median OS=10.9 months), and patients in the

group receiving the highest total dose (>4g/m2; n=7; median OS=27.5 months).

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Subjects Who Had Prior Radiation Exposure Survived Longer Than Those Who Did Not

As shown below in Figure 15, fifteen subjects received more than 1 cycle of intra-arterial gemcitabine treatment. The red line represents subjects without any prior treatment or received prior chemotherapy only (n=10; median OS=13.6 months). The dark green line depicts subjects who received prior chemoradiation (n=5; median OS=28.2 months). P < 0.05 for survival between the two subsets. Survival appeared to be longer in subjects who had prior chemoradiation.

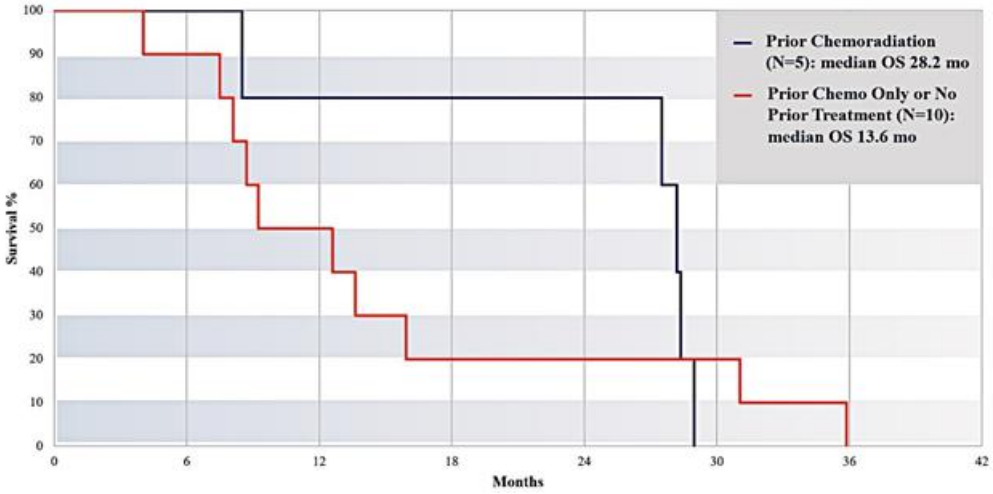

Figure 15 Survival of subjects with or without prior chemoradiation. Subjects with prior chemoradiation (n=5) had a median survival time of 28.2 months, compared with a median survival time of 13.6 months for subjects without prior chemoradiation (n=10).

Disease Progression Based on RECIST 1.1 Criteria

The RECIST 1.1 criteria was used to compare the baseline and follow up CT images submitted by sites. Follow-up CT scans obtained 5 months after initiation of IA gemcitabine therapy were submitted for 17 of the 20 subjects and were compared to the baseline images. Six of the 17 subjects (35.3%) experienced tumor progression, 1 (5.9%) had a partial response, and 10 (58.8%) demonstrated stable disease 5 months post treatment initiation. Two of the 6 subjects with tumor progression received less than 1 cycle (only 1 treatment) of IA gemcitabine. Among 15 subjects who received more than 1 cycle (2 treatments), 26.7% had disease progression, 6.7% had partial response and 66.7% had stable disease 5 months post IA therapy.

CA 19-9 Tumor Marker Change

CA19-9 is a protein that can be detected in serum and is a biomarker of pancreatic cancer; its levels can be used to assess tumor response to therapy. Twelve of 20 subjects had measurable CA 19-9 tumor markers. The final CA 19-9 tumor marker levels were lower in 7 of 12 (58%) and greater in 5 of 12 (42%) subjects. It is notable that, final tumor marker levels were lower in 4 of 5 subjects with prior chemoradiation and higher in 5 of 7 subjects without prior chemoradiation.

Observational Registry Study RR2

We launched the RR2 observational registry study in January 2016 to further explore the clinical utility of the RenovoTAMP procedure. The key inclusion criteria were patients with locally advanced or borderline resectable pancreatic adenocarcinoma confirmed by histology or cytology. This was an observational patient registry study with endpoints of safety and survival following intra-arterial gemcitabine treatment with RenovoCath. The study was conducted at 7 sites in the US and subsequently closed on August 2019 except for one US site (that did not participate in the Phase 3 study). This last site in the study was officially closed in September 2020. Over the 3 years that the trial was open, we enrolled 25 subjects with LAPC. Two of those subjects had participated in our Phase 1/2 RenovoCath/Gem RR1 trial: each received 8 IA gemcitabine infusions prior to enrollment in the RR2 study. A summary of data updated through January 2021 is presented below.

The study initially enrolled LAPC subjects without regard to prior radiation or chemotherapy. In April 2017, after the observation of longer survival of subjects with prior chemoradiation versus subjects who had not had prior radiotherapy, entry into the registry was restricted to subjects with LAPC who had received prior radiation. Of note, one subject who had prior pancreatic cancer surgery (Whipple procedure) would not normally have been enrolled in the study but was included for safety observations as her physician had previously planned IA gemcitabine therapy.

Investigators in the study reported all Serious Adverse Events from the first IA gemcitabine infusion to at least 60 days after their last procedure, but reporting of non-serious adverse events was optional. All subjects received gemcitabine 1000 mg/m^2 every two weeks, except one who received 500 mg/m^2, typically for a total of 8 doses. Subjects were followed post-treatment for survival.

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Study Subjects and RenovoGem Exposure

Twenty-five subjects were enrolled at 7 sites. The study enrolled 15 women (60%) and 10 men (40%); with a mean and median age of 73. Of the 25, 10 (40%) had no prior therapy, 8 (32%) had prior radiotherapy and chemotherapy, 6 (24%) had prior chemotherapy alone and 1 (4.5%) had surgery (Whipple procedure).

Two subjects were continuations from the previous Phase 1/2 RenovoCath/Gem RR1 study, and as a result, received more than eight treatments (total in both studies). The treatment received summary is shown in Table 2:

Table 2 Dosing Treatments for RR2 Observational Registry Study, for 25 Subjects Enrolled at 7 Sites

Number of Dosing Treatments	N=25

1	5/25 (20%)
2	3/25 (12%)
3	4/25 (16%)
4	5/25 (20%)
6	2/25 (8%)
7	2/25 (8%)
8	2/25 (8%)
>8	2/25 (8%)

Twenty-five subjects, 15 women (60%) and 10 men (40%); with a mean and median age of 73 were enrolled at 7 sites. Of 25, 10 (40%) had no prior therapy, 8 (32%) had radiotherapy and chemotherapy, 6 had chemotherapy alone and 1 (4.5%) had surgery (Whipple procedure).

In the 25 patients, 109 total IA treatments were administered through one or more of the following arteries:

- Common Hepatic Artery
- Splenic Artery
- Celiac Axis
- Superior Mesenteric Artery

Trial Results

Safety

There were number of adverse events reported. The most common were nausea (36%), vomiting (28%), abdominal pain (32%), followed by vascular access complications (16%). The less common adverse events reported (< 5%) included rash, allergic reaction, retroperitoneal hemorrhage, sepsis, ischemic bowel, arterial spasm, atrial fibrillation, chest pain, back pain, hypoglycemia, pruritis, and other GI issues. No deaths were noted in the immediate post-treatment period. No deaths were considered related to study treatment. Survival is summarized as an efficacy evaluation.

Summary of Key Safety Observations

- Neither pancreatitis nor local tissue toxicity was reported in LAPC subjects without prior surgery.
- There was no instance of arterial dissection in this study.
- The incidence of sepsis was lower in this study (1/25 subjects receiving 94 infusions) compared with the incidence in Phase 1/2 RenovoCath/Gem RR1 (3/20 subjects receiving 101 infusions). The subject with sepsis did not have a biliary stent or drain and the source of the sepsis was not identified. No sepsis events were noted after 51 infusions in 12 subjects with biliary stents, who received peri-procedure antibiotics. The incidence of sepsis in the RR2 observational registry is like that of pancreatic cancer subjects receiving myelosuppressive chemotherapeutic regiment in other studies.

Efficacy

Excluding the subjects with prior or post pancreatic cancer surgery, median survival (n=22) from the time of first IA gemcitabine treatment was 5.43 months, as illustrated in Figure 16 below, whereas median overall survival (from date of diagnosis) was 13.0 months (Figure 17).

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Survival of all Subjects from first IA Gemcitabine Treatment (Median 5.43 Months)

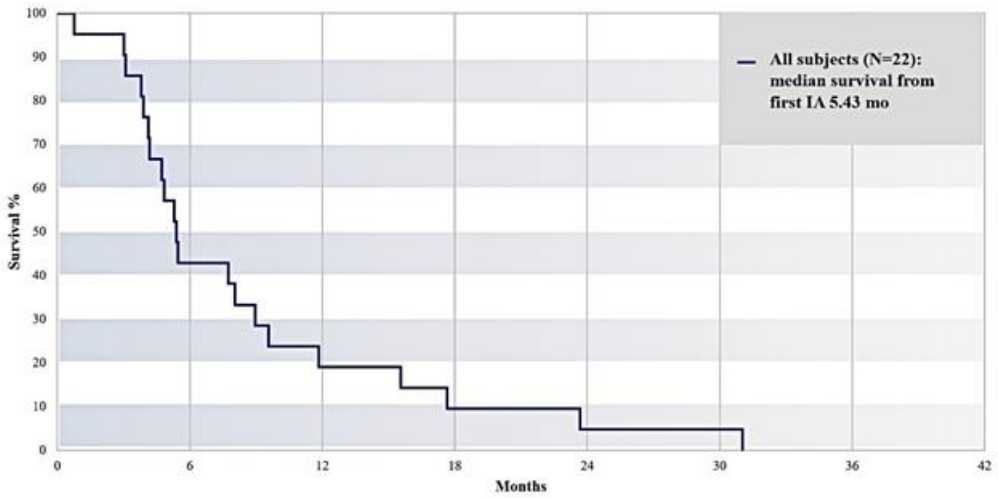

Figure 16 Overall RR2 observational registry study cohort (N=22) survival from first IA treatment until date of death.

Overall Survival of All Subjects (Median Overall Survival 13 Months)

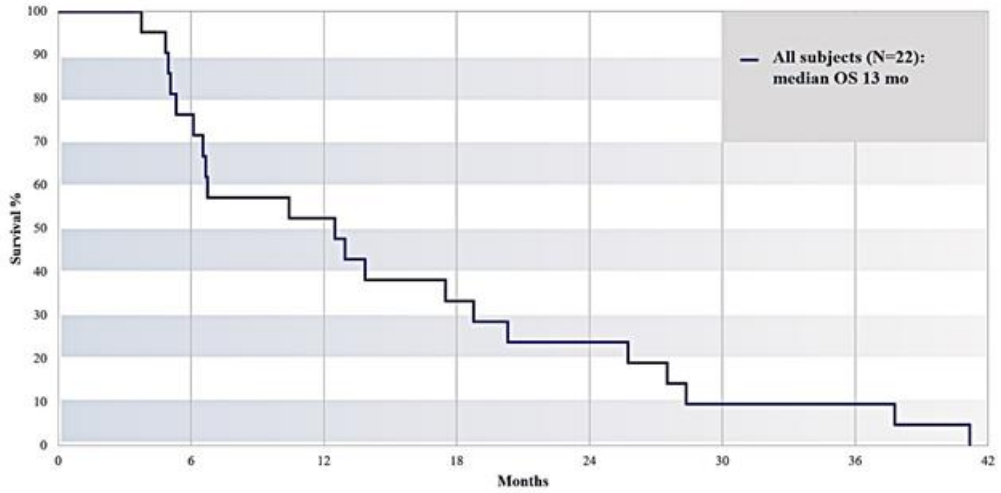

Figure 17 Overall RR2 observational registry study cohort (N=22) overall survival from date of diagnosis.

As in Phase 1/2 RenovoCath/Gem RR1, subjects with prior radiation and chemotherapy demonstrated longer survival than other subjects.

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Subjects with Prior Chemoradiation Survived Longer than Subjects with Prior Chemotherapy Only

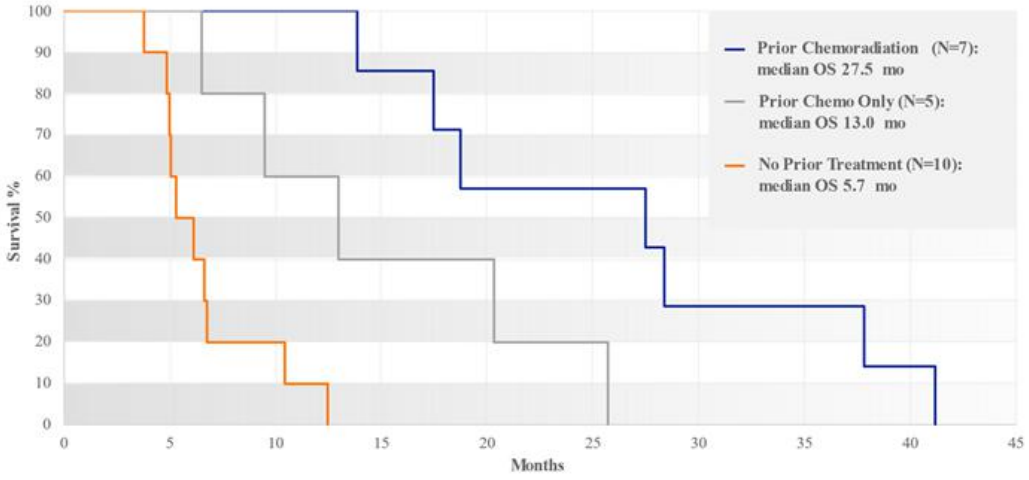

Figure 18 Survival as function of previous treatment received for RR2 registry study subjects. As in RR1 study, subjects with prior radiation and chemotherapy demonstrated longer survival than other subjects.

In summary, the results of the RR2 observational registry build on the findings of the Phase 1/2 RenovoCath/Gem RR1 study. The use of RenovoCath in this patient population can be undertaken with adequate safety, with adequate attention to procedural technique including careful use/manipulation of a guide catheter to prevent arterial dissection, and with the administration of peri-procedure antibiotics in patients with prior biliary stent/drain.

RR1 and RR2 Conclusions

Patients with LAPC treated with RenovoTAMP showed efficacy signals:

- Survival of patients with LAPC following RenovoTAMP was similar to that observed in the previous Phase 1/2 RenovoCath/Gem RR1 study.
- Patients with biliary stents or drains who received RenovoTAMP who received prophylactic peri-procedure antibiotics experienced no episodes of sepsis.
- LAPC patients who received prior radiation and chemotherapy had longer survival than those without prior radiotherapy.
- In the RR2 observational registry study, treatment via the Superior Mesenteric Artery (SMA) showed the greatest survival benefit. It is believed that this is a result of the high contact area between the SMA and the tumor tissue.
- The registry study (RR2) results combined with the Phase 1 dose escalation study (RR1) further validates prior radiation and treatment location as predictors of overall survival (in combination, RR1 and RR2 data were statistically significant for these two variables).

Based on the FDA's safety review of our phase 1/2 study and clinical outcome, the FDA allowed us to proceed to evaluate RenovoGem within our Phase 3 registrational clinical trial.

TIGeR-PaC Phase 3 Trial (RR3)

With completion of RR1 and RR2, we obtained FDA approval for Phase 3 IND study in February 2018 comparing RenovoTAMP with intra-arterial gemcitabine to standard of care. In the FDA pre-IND meeting, the FDA confirmed the study design and endpoints and indicated that this Phase 3 study should result in New Drug Application approval if successful. In April 2018, we obtained Orphan Drug Designation for the use of RenovoGem in patients with pancreatic cancer. Depending on the progress of the trial and the potential observed benefit of RenovoGem, we will evaluate submitting a request to the FDA for Breakthrough Therapy Designation.

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The primary endpoint of the study is overall survival, from time of randomization until death. Secondary endpoints include but not limited to progression free survival and quality of life questionnaire results. The study is a multi-center, open-label, randomized active-controlled study of subjects with locally advanced pancreatic adenocarcinoma which is unresectable according to NCCN guidelines. The study is currently enrolling patients in the US.

The study design is as follows: all patients receive a four-month induction phase of IV chemotherapy and radiation prior to randomizing to 4 cycles (8 treatments) of RenovoTAMP or 4 cycles of continuation of IV chemotherapy. In December 2021, we amended the protocol for our Phase 3 clinical trial to only allow for Stereotactic Body Radiation Therapy (SBRT) radiation during the induction phase of the study. We had previously permitted both SBRT and intensity-modulated radiation therapy (IMRT). Patients receiving IMRT were required to complete 25 treatments prior to being randomized into our study. In comparison, patients receiving SBRT are only required to complete 5 treatments. IMRT is generally less tolerable than SBRT, and we had observed a higher drop out for patients on IMRT. While RenovoTAMP data versus historical controls predicts a much greater survival benefit, the TIGeR-PaC study is powered to detect a 6-month survival benefit.

A study flowchart is shown below. Subjects with stable or responding disease after approximately 4 months in induction therapy and who are not surgical candidates will then be randomized 1:1.

TIGeR-PaC Study Flowchart with Chemoradiation Induction Phase

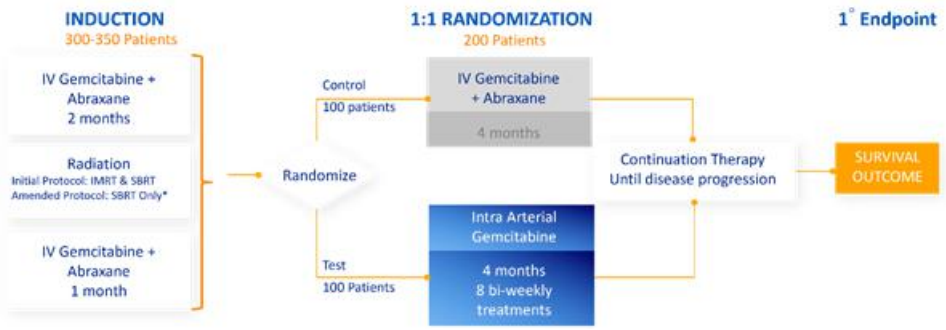

Figure 19 TIGeR-PaC Study Flowchart. All subjects undergo a 4-month induction phase that includes IV gemcitabine + Abraxane and radiation therapy. If the subjects are stable with LAPC post-induction, they are randomized 1:1 into control group (IV gemcitabine + Abraxane) versus treatment group (intra-arterial gemcitabine via RenovoTAMP therapy). Subjects are then administered continuation therapy until disease progression and followed through survival.

As of March 15, 2022, our Phase 3 trial had achieved approximately 50% of the target enrollment under the current SAP. The SAP includes a planned interim analysis when a total of 65 deaths have occurred in the study. We expect to conduct the interim analysis between the fourth quarter of 2022 and the first quarter of 2023; however, given that it is predicated on the number of deaths in the study, it is difficult to predict the exact timing. We are currently projecting completion of enrollment and randomization of the entire cohort in 2023.

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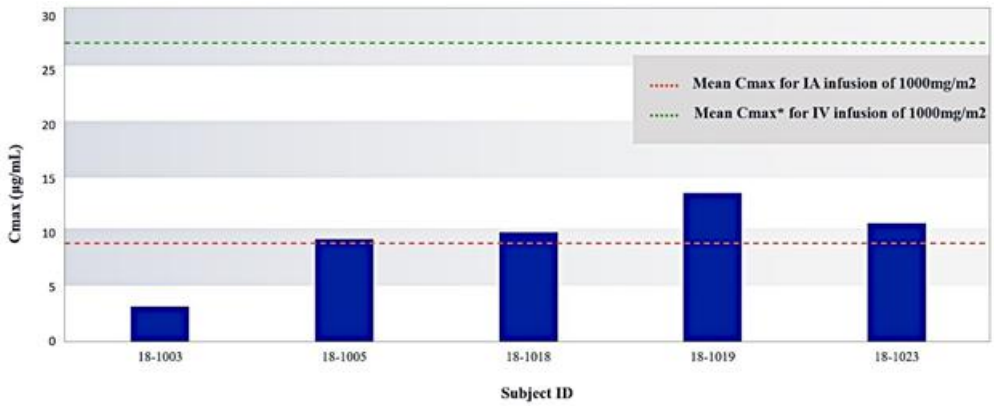
Clinical Pharmacokinetic (PK) Data in Patients with LAPC Treated with Gemcitabine via RenovoTAMP

We expect intra-arterial gemcitabine delivered via the RenovoTAMP technique to have a pharmacokinetic profile that is distinct from intravenous gemcitabine dosing. Furthermore, with local delivery of gemcitabine into the tissue via RenovoTAMP and drainage into the liver prior to systemic circulation, we anticipate lower systemic levels of gemcitabine.

We are collecting blood samples for PK analysis from 15 patients from our TIGeR-PaC Phase 3 study (Figure 20, below). Our initial data on the first 5 patients demonstrated an approximately two-thirds reduction in systemic gemcitabine when compared to systemic levels in patients traditionally receiving intravenous infusion of gemcitabine.

Systemic Levels of Gemcitabine Reduced by 2/3 with RenovoTAMP versus IV Gemcitabine



**As reported in Caffo et al., Cancer Chemother. Pharmacol., 2010; Faivre et al., Ann. Oncol., 2002; Fogli et al., Ann. Oncol., 2001*

Figure 20 Initial blood PK data demonstrated a 3-fold decrease in systemic concentration of gemcitabine (Cmax) with RenovoTAMP compared to established levels for IV gemcitabine.

Second Solid Tumor Indication

eCCA Overview

Cholangiocarcinoma is the second most common primary malignant tumor of the liver with over 7,000 new cases diagnosed annually in the US. Cholangiocarcinoma (CCA) develops after malignant transformation of the biliary tract mucosa. The global market of CCA was estimated to be $385 million in 2018 and the US accounted for the largest market size of CCA. Furthermore, the market size for global CCA therapeutics is estimated to grow by $83 million during 2019-2023 with a compound annual growth rate of 6%. Advanced age, male gender, primary sclerosing cholangitis (PSC), inflammatory bowel disease, pancreatitis, and cirrhosis are some predisposing factors for development of CCA.

Based on the tumor location CCA is defined as intra-hepatic, or within the liver, or extrahepatic, or outside the liver. The eCCA subset of CCA patients are about 3,000 cases per year. eCCA is a disease with an exceptionally poor prognosis.

eCCA Current Treatment Landscape and Limitations

Most patients with eCCA have localized disease with possible extension of the tumor around the bile duct. Based on local extension of the disease, treatment options include surgery, chemotherapy, and radiation therapy. Surgical resection offers the only chance for curative therapy for patients with eCCA; however, the surgery is associated with high mortality and morbidity and most patients are not candidates. Systemic chemotherapy is a primary mode of treatment in these patients as a form of palliation, which is associated with morbidity and limited improvement in survival.

Current standard chemotherapy treatment in these patients is based on the ABC-2 Trial: a randomized trial of 410 patients with unresectable CCA (the study included intrahepatic, within the liver, and extrahepatic cholangiocarcinoma patients). Patients were treated with gemcitabine plus cisplatin, consisting of a three-week cycle, with treatments on Days 1 and 8 and dosing of gemcitabine at 1000 mg/m^2 and cisplatin at 25 mg/m^2. Reported median overall survival for patients on such a regimen (11.7 months) was greater than for patients receiving gemcitabine alone (8.1 months). With this standard of care treatment, commonly observed Grade 3-4 toxicities include anemia, leukopenia, neutropenia, thrombocytopenia, lethargy, nausea/vomiting, and anorexia. In the ABC-02 trial the efficacy of gemcitabine/cisplatin combination was not significantly different from that of gemcitabine alone in patients with extrahepatic cholangiocarcinoma. For this reason, a standard of care practice has not been established for extrahepatic cholangiocarcinoma.

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RenovoGem for the Treatment of eCCA

Similar to RenovoGem for LAPC, we believe that RenovoGem may overcome the current treatment limitations of eCCA. In this setting, patients with eCCA have several tumor characteristics that create the potential for RenovoGem to be more effective than systemic chemotherapy. These characteristics include:

- Local disease with possible extension of disease to local vasculature;
- Avascular nature of the tumor lends itself to our RenovoTAMP approach, overcoming the limitations in drug delivery by targeting the periductal proper hepatic artery or left or right hepatic artery;
- Gemcitabine, used as a target molecule for this tumor type, has already been demonstrated to be safe in terms of local toxicity targeted via our approach to this vasculature and organ; and
- The bile duct around the hilum is usually within 1-14 mm (mean of 3.8 mm) of the hepatic artery: a reasonable target for RenovoTAMP therapy given the potential 4 cm tissue penetration of drug.

Clinical Development of RenovoGem in eCCA

Rationale

In May 2020, the FDA granted us Orphan Drug Designation in May 2020 for RenovoGem for the treatment of CCA. We have now completed our evaluation of the different approaches to treat this patient population and are in the process of refining our clinical protocol. We plan to meet with FDA during the second or third quarter of 2022 to discuss our trial design. If FDA does not object to our study protocol, we anticipate launching the eCCA trial in the second half of 2022.

Market Opportunity

We are currently developing RenovoGem for LAPC. We also intend to develop it for eCCA, and potentially for locally advanced lung cancer, locally advanced uterine cancer and glioblastoma. We estimate that the total annualized addressable market opportunity for RenovoGem for our first market, LAPC, in the United States is approximately $0.5 billion and globally could exceed $1 billion based on a third-party market research analysis. The total cost of care for a patient on the standard of care treatment of gemcitabine + Abraxane is estimated at $67,216, which if applied to 60,000 pancreatic cancer cases per year would total $4 billion per year for the total US pancreatic cancer market.

Beyond our initially targeted subset of LAPC patients, we see potential to evaluate RenovoGem in additional settings where it may help to get more patients to surgery, prolong life, enhance systemic therapy or provide local therapy with fewer side effects than alternative treatments. These may include patients with stage 1 or stage 2 pancreatic cancer receiving neoadjuvant as well as in subpopulations of patients with metastases who also have locally advanced disease. Based on third-party market research, several physicians mentioned a role for local therapy as an adjunct for systemic chemotherapy as well as for patients who decline systemic chemotherapy. Among the locally advanced (stage 3) patients diagnosed with the cancers shown in Figure 22, we estimate that ~125,000 could be potentially addressable via RenovoGem.

Below is published epidemiology data showing the 2021 estimated annual incidence of the following tumor types in the United States to be greater than 350,000 patients in the aggregate.

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Market Opportunity for RenovoTAMP

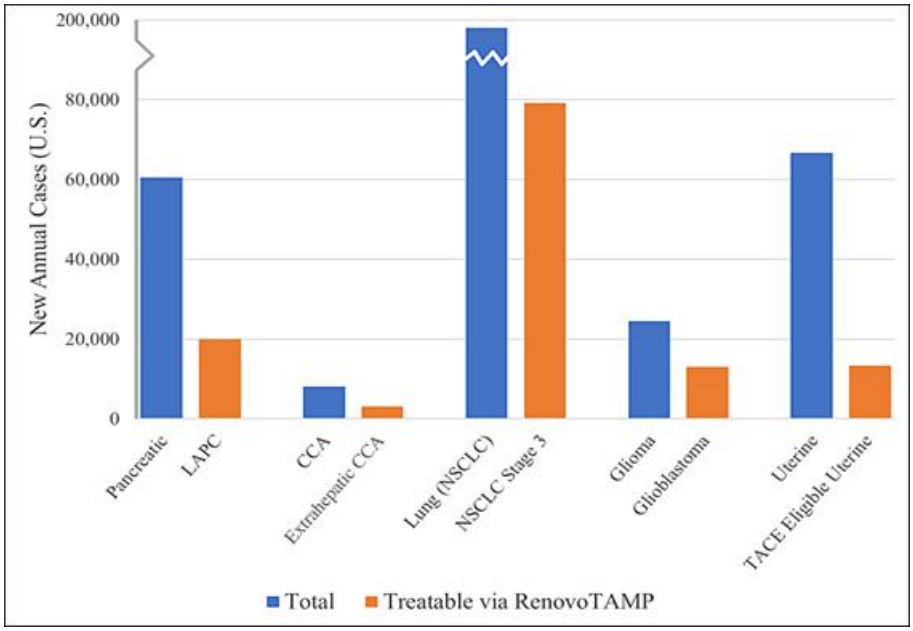

Figure 21 ***US Annual Incidence of Initial RenovoTAMP Target Tumor Types,****showing overall incidence in blue, and those treatable via RenovoTAMP in orange.*

- *All Pancreatic Cancers compared to Locally Advanced Pancreatic Cancers (LAPC)*
- *All Cholangiocarcinoma (CCA) compared to Extrahepatic CCA*
- *All Non-Small Cell Lung Cancers (NSCLC) compared to Stage 3 NSCLC*
- *All Glioma compared to Glioblastoma*
- *All Uterine cancers versus Transcatheter arterial chemoembolization (TACE) eligible uterine cancers*

We believe RenovoTAMP is broadly applicable to locally advanced tumors: our platform may be used with multiple small molecule chemotherapeutic agents in multiple solid tumor indications.

Intellectual Property

Our success depends in part on our ability to obtain patents and trademarks, maintain trade secret and know-how protection, enforce our proprietary rights against infringers, and operate without infringing on the proprietary rights of third parties. Because of the length of time and expense associated with developing new products and bringing them through the regulatory approval process, the health care industry places considerable emphasis on obtaining patent protection and maintaining trade secret protection for new technologies, products, processes, know-how, and methods.

Our intellectual property protection stems from several issued device and method patents on our RenovoCath delivery system that optimizes delivery of the anti-cancer drug and the RenovoTAMP therapy platform. Our issued patents also provide exclusivity as it relates to utilizing RenovoCath with anti-cancer drugs.

We have 7 US patents issued, 1 European patent issued, and 1 patent pending in each of China, Japan, Europe, and India. In addition, we have three pending US patents. We continue to explore additional opportunities to further bolster our IP position. Table 3 below describes our issued patents, all of which have been assigned to us.

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Table 3 RenovoRx has Significant Patent Protection with 8 Issued Patents

Family	App. No. Filing Date	Type of Patent Protection	Patent Focus	Patent #	Estimated Expiration**
Dual Balloon Methods and Apparatuses	12/958711 Filed: 12/2/2010	US Utility patent	Methods: isolating splenic artery with 2 balloons (sliding inner catheter)	US8,821,476	January 25, 2033
Dual Balloon Methods and Apparatuses	14/870833 Filed: 9/30/2015	US Utility patent	Apparatus: 2 balloons, seal to isolate lumen, and infusion aperture	US9,463,304	December 2, 2030
Dual Balloon Methods and Apparatuses	14/293603 Filed: 6/2/2014	US Utility patent	Apparatus: 2 balloons (sliding inner catheter), 2 ports for fluid handling	US9,457,171	April 16, 2031
Dual Balloon Methods and Apparatuses	15/351922 Filed: 11/15/2016	US Utility patent	Kits for chemotherapy including catheter with 2 balloons, an infusion aperture and 2 ports	US10,512,761	April 16, 2031
Dual Balloon Methods and Apparatuses	108351107 Filed: 12/2/2010	E.U. Utility patent, nationalized in BE, CH, DE, ES, FR, GB, IE, IT and NL	A two occlusion element, adjustable delivery apparatus having inner and outer catheter, seal to isolate lumen	EU 2506913	December 2, 2030
Side Branch Isolation Device and Methods	14/958428 Filed: 12/3/2015	US Utility patent	Apparatuses and Methods: 3 balloon catheters for isolating side branches	US10,099,040	December 3, 2035
Trans-Arterial Micro-Perfusion (TAMP)	15/807011 Filed: 11/8/2017	US Utility patent	Methods delivering radiation to devascularize then TAMP	U.S., 10,695,543	August 28, 2038
Dual Balloon Methods and Apparatuses	16/685950 Filed: 11/15/2019	US Utility patent (Pending application)	Methods of treating bile duct	PENDING	April 16, 2031*
Trans-Arterial Micro-Perfusion (TAMP)	16/685974 Filed: 11/15/2019	US Utility patent (Pending application)	Devascularization in conjunction with TAMP	US11,052,224	November 8, 2037
Dual Balloon Methods and Apparatuses	IN 1632MUMNP2012 Filed: 12/2/2010	IN Utility patent (Pending application)	A two occlusion element, adjustable delivery apparatus having inner and outer catheter, seal to isolate lumen	PENDING	December 2, 2030
Trans-Arterial Micro-Perfusion (TAMP)	CN 2018800033529 Filed: 5/18/2018	CN Utility patent (Pending application)	Devascularization in conjunction with TAMP	PENDING	November 8, 2037*
Trans-Arterial Micro-Perfusion (TAMP)	EP 187315908 Filed: 5/18/2018	EP Utility patent (Pending application)	Devascularization in conjunction with TAMP	PENDING	November 8, 2037*

Trans-Arterial Micro-Perfusion (TAMP)	JP 2020514151 Filed: 5/18/2018	JP Utility patent (Pending application)	Devascularization in conjunction with TAMP	PENDING	November 8, 2037*
Trans-Arterial Micro-Perfusion (TAMP)	17/315220 Filed: 5/7/2021	US Utility patent (Pending application)	Devascularization in conjunction with TAMP	PENDING	November 8, 2037*
Trans-Arterial Micro-Perfusion (TAMP)	17/367046 Filed: 7/2/21	US Utility patent (Pending application)	Devascularization in conjunction with TAMP	PENDING	November 8, 2037*
Dual Balloon Methods and Apparatuses	17/558577 Filed: 12/21/2021	US Utility patent (Pending application)	Methods of treating bile duct	PENDING	April 16, 2031*

* Predicted earliest expiration date. The actual expiration date will depend on factors related to patent prosecution and issuance.
** Estimated expiration dates assume all maintenance fees are paid.

Orphan drug designation provides seven years post-approval market exclusivity protection. Gemcitabine is generic; however, we have exclusivity for the intra-arterial route of administration. RenovoGem is regulated by the FDA as a new oncology drug product. We intend to make intra-arterial gemcitabine and RenovoCath available as a combined product and not to make either component available separately. Once approved, we will have exclusivity over the use of intra-arterial gemcitabine as it will be approved by the FDA in combination with RenovoCath.

When appropriate, we actively pursue protection of our proprietary products, technologies, processes, and methods by filing United States and international patent and trademark applications. We seek to pursue additional patent protection for technology invented through research and development, manufacturing, and clinical use of our technology that will enable us to expand our patent portfolio around advances to our current systems, technology, and methods for our current applications as well as others.

There can be no assurance that the pending patent applications will result in the issuance of patents, that patents issued to or licensed by us will not be challenged or circumvented by competitors, or that these patents will be found to be valid or sufficiently broad to protect our technology or provide us with a competitive advantage.

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To maintain our proprietary position, we also rely on trade secrets and proprietary technological experience to protect proprietary manufacturing processes, technology, and know-how relating to our business. We rely, in part, on confidentiality agreements with our marketing partners, employees, advisors, vendors and consultants to protect our trade secrets and proprietary technological expertise. In addition, we also seek to maintain our trade secrets through maintenance of the physical security of the premises where our trade secrets are located. There can be no assurance that these agreements will not be breached, that we will have adequate remedies for any breach, that others will not independently develop equivalent proprietary information or that third parties will not otherwise gain access to our trade secrets and proprietary knowledge.

In certain circumstances, United States patent law allows for the extension of a patent's duration for a period of up to five years after FDA approval. We intend to seek extension for one of our patents after FDA approval if it has not expired prior to the date of approval. In addition to our proprietary protections, the FDA has granted us two orphan drug designations that provide us a seven-year period of exclusive marketing beginning on the date that our NDA is approved by the FDA for the designated orphan drug. While the exclusivity only applies to the indication for which the drug has been approved, we believe that this exclusivity will provide us with added protection once commercialization of an orphan drug designated product begins.

There has been and continues to be substantial litigation regarding patent and other intellectual property rights in the pharmaceutical and medical device areas. If a third party asserts a claim against us, we may be forced to expend significant time and money defending such actions and an adverse determination in any patent litigation could subject us to significant liabilities to third parties, require us to redesign our product, require us to seek licenses from third parties, and, if licenses are not available, prevent us from manufacturing, selling or using our system. Additionally, we plan to enforce our intellectual property rights vigorously and may find it necessary to initiate litigation to enforce our patent rights or to protect our trade secrets or know-how. Patent litigation can be costly and time consuming and there can be no assurance that the outcome will be favorable to us.

Manufacturing and Supply

For the catheter component (RenovoCath) of the drug/device combination, we currently rely on a single-source contract manufacturer, Medical Murray, North Barrington, IL. However, we are in early discussions with an additional manufacturer. We are subject to regulatory requirements of the FDA's Quality System Regulation (QSR), for medical devices sold in the United States, and the European Medical Device Directive 93/42/EEC, which was replaced by the EU Medical Device Regulation (MDR) in May 2021, following a four-year transition period for medical devices marketed in the European Union. We have an agreement in place with Medical Murray to produce the RenovoCath through October 2024 with automatic annual renewal until termination by either party with 12 months' notice. While we believe Medical Murray has the capabilities to scale RenovoCath production to peak forecasted commercial volumes, manufacturing can be transferred to additional vendors if needed.

The FDA monitors compliance with QSR through periodic inspections of both our facility and the facility of our contact manufacturer. Our European Union Notified Body, British Standards Institute (BSI), monitors compliance with the MDR requirements through both annual scheduled audits and periodic unannounced audits of our facilities as well as our contract manufacturer's facilities.

Our failure or the failure of our contract manufacturer to maintain acceptable quality requirements could result in the shutdown of our manufacturing operations or the recall of products which could be detrimental to our company. If our contract manufacturer fails to maintain acceptable quality requirements, we may have to qualify a new contract manufacturer and could experience a material adverse effect to manufacturing and manufacturing delays as a result.

We do not own or operate and do not intend to establish our own gemcitabine manufacturing facilities.

Within our TIGeR-PaC Phase 3 trial, hospitals are sourcing generic gemcitabine labeled for IV use from their respective pharmacies to use in conjunction with the RenovoCath for the RenovoTAMP procedures. In the commercial setting, we expect to rely on contract manufacturing organizations for gemcitabine production, relabeling and co-packaging with the RenovoCath. The formulation of gemcitabine used in the TIGeR-PaC Phase 3 trial and in the commercial setting will be identical, however, the labeling of gemcitabine will be intra-arterial gemcitabine to be used exclusively in conjunction with RenovoCath.

Government Regulation

Our products are subject to extensive and rigorous government regulation by foreign regulatory agencies and the FDA. Foreign regulatory agencies, the FDA and comparable regulatory agencies in state and local jurisdictions impose extensive requirements upon the clinical development, pre-market clearance and approval, manufacturing, labeling, marketing, advertising and promotion, pricing, storage and distribution of pharmaceutical and medical device products. Failure to comply with applicable foreign regulatory agency or FDA requirements may result in Warning Letters, fines, civil or criminal penalties, suspension or delays in clinical development, recall or seizure of products, partial or total suspension of production or withdrawal of a product from the market.

United States Regulatory Environment

In the US, the FDA regulates drug and device products, including combination, under the FDCA, and its implementing regulations. RenovoGem is subject to regulation as a combination product, which means it is composed of both a drug component and device component. Each component of a combination product is subject to the requirements established by the FDA for that type of component and if marketed individually, each component would be subject to different regulatory pathways and reviewed by different centers within the FDA. A combination product, however, is assigned to a center that will have primary jurisdiction over its pre-market review and regulation based on a determination of its primary mode of action, which is the single mode of action that provides the most important therapeutic action. The center that regulates the portion of the

product that has the primary mode of action becomes the lead evaluator. When evaluating an application, a lead center may consult other centers but still retain complete reviewing authority, or it may collaborate with another center, by which the center assigns review of a specific section of the application to another center, delegating its review authority for that section. Typically, an applicant submits a single marketing application to the center selected to be the lead evaluator, although separate applications for each constituent part may be submitted to the applicable centers. Combination products where the drug provides the primary mechanism of action are often referred to as "drug-led combination" products.

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In a drug/device combination product, containing two or more separate products packaged together in a single package or as a unit and comprised of drug and device products, where the primary mode of action is typically a drug mode of action with the Center for Drug Evaluation and Research, or CDER, as the lead Center, CDER would review the NDA in consultation with the Center for Devices and Radiological Health on device-specific issues. For co-packaged or single-entity combination products there are two ways to comply with current good manufacturing practice, or cGMP, requirements. Manufacturers can either (i) demonstrate compliance with all cGMP regulations applicable to each of the constituent parts in the combination product or (ii) in the case of drug/device combination products, demonstrate compliance with either the drug cGMP regulations or the device Quality System Regulation, or QSR, and also demonstrate compliance with additional provisions from the other of these two sets of cGMP requirements, as specified in the combination products regulations. Failure to comply with applicable regulatory requirements can result in enforcement action by the FDA, which may include any of the following sanctions: warning or untitled letters, fines, injunctions, civil or criminal penalties, recall or seizure of current or future products, operating restrictions, partial suspension or total shutdown of production, refusal or denial of submissions for new products, or withdrawal of clearance, authorization, or approval.

In the case of RenovoGem, the primary mode of action is attributable to the drug component of the product, which means that the Center for Drug Evaluation and Research, has primary jurisdiction over its pre-market development and review. The underlying RenovoCath drug delivery device system used in RenovoGem has been separately cleared by the FDA as a Class II medical device (without any prepackaged drug product) for the isolation of blood flow and delivery of fluids, including diagnostic and/or therapeutic agents, to selected sites in the peripheral vascular system. The RenovoCath is also indicated for temporary vessel occlusion in applications including arteriography, preoperative occlusion, and chemotherapeutic drug infusion. The RenovoCath is intended for general intravascular use in the peripheral vasculature in arteries 3mm and larger. The RenovoCath is intended for use in arteries from 3mm in diameter for vessel entry and to occlude vessels ranging between 3mm to 11mm in diameter.

The process required by the FDA before drug product candidates, including drug-led combination products, may be marketed in the United States generally involves the following:

- submission to the FDA of an IND, which must become effective before human clinical trials may begin and must be updated periodically, but at least annually;
- completion of extensive preclinical laboratory tests and preclinical animal studies, all performed in accordance with the FDA's Good Laboratory Practice, or GLP, regulations;
- performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the product candidate for each proposed indication;
- submission to the FDA of an NDA after completion of all pivotal clinical trials;
- a determination by the FDA within 60 days of its receipt of an NDA to file the NDA for review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facilities at which the product is produced and tested to assess compliance with cGMP regulations; and
- FDA review and approval of an NDA prior to any commercial marketing or sale of the drug in the United States.

The development and approval process requires substantial time, effort and financial resources, and we cannot be certain that any approvals for our product will be granted on a timely basis, if at all.

The results of preclinical tests (which include laboratory evaluation as well as GLP studies to evaluate toxicity in animals) for a particular product candidate, together with related manufacturing information and analytical data, are submitted as part of an IND to the FDA. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises concerns or questions about the conduct of the proposed clinical trial, including concerns that human research subjects will be exposed to unreasonable health risks. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. IND submissions may not result in FDA authorization to commence a clinical trial. A separate submission to an existing IND must also be made for each successive clinical trial conducted during product development. Further, an independent institutional review board, or IRB, for each medical center proposing to conduct the clinical trial must review and approve the plan for any clinical trial before it commences at that center and it must monitor the study until completed. The FDA, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk. Clinical testing also must satisfy extensive good clinical practice, or GCP, regulations and regulations for informed consent and privacy of individually identifiable information. Similar requirements to the United States IND are required in the EU and other jurisdictions in which we may conduct clinical trials.

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Clinical Trials

For purposes of NDA submission and approval, clinical trials are typically conducted in the following sequential phases, which may overlap:

- Phase 1 Clinical Trials. Studies are initially conducted in a limited population to test the product candidate for safety, dose tolerance, absorption, distribution, metabolism and excretion, typically in healthy humans, but in some cases in patients.
- Phase 2 Clinical Trials. Studies are generally conducted in a limited patient population to identify possible adverse effects and safety risks, explore the initial efficacy of the product for specific targeted indications and to determine dose range or pharmacodynamics. Multiple Phase 2 clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.
- Phase 3 Clinical Trials. These are commonly referred to as pivotal studies. When Phase 2 evaluations demonstrate that a dose range of the product is effective and has an acceptable safety profile, Phase 3 clinical trials are undertaken in large patient populations to further evaluate dosage, provide substantial evidence of clinical efficacy and further test for safety in an expanded and diverse patient population at multiple, geographically dispersed clinical trial centers.
- Phase 4 Clinical Trials. The FDA may approve an NDA for a product candidate, but require that the sponsor conduct additional clinical trials to further assess the drug after NDA approval under a post-approval commitment. In addition, a sponsor may decide to conduct additional clinical trials after the FDA has approved an NDA. Post-approval trials are typically referred to as Phase 4 clinical trials.

Sponsors of clinical trials may submit proposals for the design, execution, and analysis for their pivotal trials under a Special Protocol Assessment, or SPA. A SPA is an evaluation by the FDA of a protocol with the goal of reaching an agreement that the Phase 3 trial protocol design, clinical endpoints, and statistical analyses are acceptable to

support regulatory approval of the drug product candidate with respect to effectiveness for the indication studied. Under a SPA, the FDA agrees to not later alter its position with respect to adequacy of the design, execution or analyses of the clinical trial intended to form the primary basis of an effectiveness claim in an NDA, without the sponsor's agreement, unless the FDA identifies a substantial scientific issue essential to determining the safety or efficacy of the drug after testing begins.

As a result of the COVID-19 public health emergency, we may be required to develop and implement additional clinical trial policies and procedures designed to help protect subjects from the COVID-19 virus. For example, in March 2020, the FDA issued a guidance, which the FDA subsequently updated, on conducting clinical trials during the pandemic. Additional COVID-19 related guidance documents released by the FDA, including updates to previously published guidance and new guidance, address resuming normal drug and biologics manufacturing operations; manufacturing, supply chain, and inspections; and statistical considerations for clinical trials during the COVID-19 public health emergency, among others. In view of the spread of the COVID-19 variants, FDA may issue additional guidance and policies that may materially impact our business and clinical development timelines. The ultimate impact of the COVID-19 pandemic on our business operations and clinical development plans is highly uncertain and subject to change and will depend on future developments, including new regulatory requirements and changes to existing regulations. If new guidance and policies are promulgated by the FDA that require changes in our clinical protocol or clinical development plans, our anticipated timelines and regulatory approval may be delayed or materially impacted.

New Drug Applications (NDAs)

The results of drug development, preclinical studies and clinical trials are submitted to the FDA as part of an NDA. NDAs also must contain extensive chemistry, manufacturing and control information. An NDA must be accompanied by a significant user fee, which may be waived in certain circumstances. Once the submission has been accepted for filing, the FDA's goal is to review applications within ten months of submission or, if the application relates to an unmet medical need in a serious or life-threatening indication, six months from submission. The review process is often significantly extended by FDA requests for additional information or clarification. The FDA may refer the application to an advisory committee for review, evaluation and recommendation as to whether the application should be approved. For new oncology products, the FDA will often solicit an opinion from an Oncologic Drugs Advisory Committee, or ODAC, a panel of expert authorities knowledgeable in the fields of general oncology, pediatric oncology, hematologic oncology, immunologic oncology, biostatistics, and other related professions. The ODAC panel reviews and evaluates data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of cancer, and makes appropriate recommendations to the Commissioner of Food and Drugs. The FDA is not bound by the recommendation of an advisory committee.

Before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. Additionally, the FDA will generally inspect the facility or the facilities at which the drug is manufactured. The FDA will not approve the product unless compliance with cGMPs is satisfactory, and the NDA contains data that provide substantial evidence that the drug is safe and effective in the indication studied. After the FDA evaluates the NDA and the manufacturing facilities, it issues either an approval letter or a complete response letter, or CRL. A CRL generally outlines the deficiencies in the submission and may require substantial additional testing, or information, in order for the FDA to reconsider the application. If, or when, those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. A CRL may require additional clinical data and/or an additional pivotal Phase 3 clinical trial(s), and/or other significant, expensive and time-consuming requirements related to clinical trials, preclinical studies or manufacturing. Data from clinical trials are not always conclusive and the FDA may interpret data differently than we or our collaborators interpret data. Approval may be contingent on a Risk Evaluation and Mitigation Strategy, or REMS, that limits the labeling, distribution or promotion of a drug product. Once issued, the FDA may withdraw product approval if ongoing regulatory requirements are not met or if safety problems occur after the product reaches the market. In addition, the FDA may require testing, including Phase IV clinical trials, and surveillance programs to monitor the safety effects of approved products which have been commercialized, and the FDA has the power to prevent or limit further marketing of a product based on the results of these post-marketing programs or other information.

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There are three primary regulatory pathways for an NDA under Section 505 of the FDCA: Section 505 (b)(1), Section 505 (b)(2) and Section 505(j). A Section 505 (b)(1) application is used for approval of a new drug (for clinical use) whose active ingredients have not been previously approved. A Section 505 (b)(2) application is used for a new drug that relies on data not developed by the applicant. Section 505(b)(2) of the FDCA was enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act. This statutory provision permits the approval of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The Hatch-Waxman Act permits the applicant to rely in part upon the FDA's findings of safety and effectiveness for previously approved products. Section 505(j) application, also known as an abbreviated NDA, is used for a generic version of a drug that has already been approved.

An approval letter authorizes commercial marketing of the drug product with specific prescribing information for specific indications. As a condition of NDA approval, the FDA may require a REMS to help ensure that the benefits of the drug outweigh the potential risks. REMS can include medication guides, communication plans for healthcare professionals, and elements to assure safe use. The requirement for a REMS can materially affect the potential market and profitability of the drug. Moreover, product approval may require substantial post-approval testing and surveillance to monitor the drug's safety or efficacy. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing.

Changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of a new NDA or NDA supplement before the change can be implemented. An NDA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing NDA supplements as it does in reviewing NDAs.

The NDA review process for drug-led combination includes a review of the device constituent. In this case, the device constituent for RenovoGem is RenovoCath, which is cleared by the FDA.

Orphan Drug Exclusivity

Some jurisdictions, including the United States, may designate drugs for relatively small patient populations as orphan drugs. Pursuant to the Orphan Drug Act, the FDA grants orphan drug designation to drugs intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States. The orphan designation is granted for a combination of a drug entity and an indication and therefore it can be granted for an existing drug with a new (orphan) indication. Applications are made to the Office of Orphan Products Development at the FDA and a decision or request for more information is rendered in 60 days. NDAs for designated orphan drugs are exempt from user fees, obtain additional clinical protocol assistance, are eligible for tax credits up to 50% of research and development costs, and are granted a seven-year period of exclusivity upon approval. The FDA cannot approve the same drug for the same condition during this period of exclusivity, except in certain circumstances where a new product demonstrates superiority to the original treatment. Exclusivity begins on the date that the marketing application is approved by the FDA for the designated orphan drug, and an orphan designation does not limit the use of that drug in other applications outside the approved designation in either a commercial or investigational setting.

We have received orphan drug designations for RenovoGem for pancreatic cancer and cholangiocarcinoma.

The granting of orphan drug designations does not mean that the FDA has approved a new drug. Companies must still pursue the rigorous development and approval process that requires substantial time, effort and financial resources, and we cannot be certain that any approvals for our product will be granted at all, or on a timely basis.

FDA Medical Device Regulation

Unless an exemption applies, each new or significantly modified drug delivery medical device that we develop based on the current 510(k)-cleared RenovoCath and which we seek to commercially distribute in the United States will require a premarket notification to the FDA requesting permission for commercial distribution under Section 510(k) of the FDCA, also referred to as a 510(k) clearance, unless addressed as part of a new drug application for a drug/device combination product. New medical devices without an applicable predicate device as well as higher-risk medical devices are subject to premarket approval by the FDA under a PMA or a de novo classification from the FDA. The

510(k) clearance, PMA approval, and de novo classification processes can be resource intensive, expensive, and lengthy, and require payment of significant user fees, unless an exemption is available.

Under the FDCA, medical devices are classified into one of three classes – Class I, Class II or Class III – depending on the degree of risk associated with each medical device and the extent of manufacturer and regulatory control needed to ensure its safety and effectiveness.

Class I includes devices with the lowest risk to the patient and are those for which safety and effectiveness can be reasonably assured by adherence to a set of FDA regulations, referred to as the general controls for medical devices, which require compliance with the applicable portions of cGMP regulations known as the Quality System Regulation, or QSR, facility registration and product listing, reporting of adverse events and malfunctions, and appropriate, truthful, and non-misleading labeling and promotional materials. Some Class I devices, also called Class I reserved devices, also require premarket clearance by the FDA through the 510(k) premarket notification process described below. Most Class I products are exempt from the premarket notification requirements.

Class II devices are those that are subject to the general controls and special controls, as deemed necessary by the FDA to ensure the safety and effectiveness of the device. These special controls can include performance standards, patient registries, FDA guidance documents, and post-market surveillance. Most Class II devices are subject to premarket review and clearance by the FDA. Premarket review and clearance by the FDA for Class II devices is accomplished through the 510(k) premarket notification process.

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Class III devices include devices deemed by the FDA to pose the greatest risk such as life-supporting or life-sustaining devices, or implantable devices, or devices that have a new intended use or use advanced technology that are not substantially equivalent to that of a legally marketed predicate device. The safety and effectiveness of Class III devices cannot be reasonably assured solely by the general controls and special controls described above. All clinical investigations of devices to determine safety and effectiveness must be conducted in accordance with the FDA's investigational device exemption (IDE), regulations which govern investigational device labeling, prohibit promotion of the investigational device, and specify an array of recordkeeping, reporting and monitoring responsibilities of study sponsors and study investigators. If the device presents a "significant risk" to human health, as defined by the FDA, the FDA requires the device sponsor to submit an IDE application to the FDA, which must become effective prior to commencing human clinical trials. If the device under evaluation does not present a significant risk to human health, then the device sponsor is not required to submit an IDE application to the FDA before initiating human clinical trials, but must still comply with abbreviated IDE requirements when conducting such trials. Therefore, these devices are subject to the PMA process, which is generally more costly and time consuming than the 510(k) process.

The 510(k) clearance process

Under the 510(k) process, the manufacturer must submit to the FDA a premarket notification, demonstrating that the device is "substantially equivalent," as defined in the statute, to a legally marketed predicate device. A predicate device is a legally marketed device that is not subject to premarket approval, i.e., a device that was legally marketed prior to May 28, 1976 (pre-amendments device) and for which a PMA is not required, a device that has been reclassified from Class III to Class II or I, or a device that was previously found substantially equivalent through the 510(k) process. The FDA's 510(k) clearance process usually takes from three to 12 months, but may take longer. The FDA may require additional information, including clinical data, to make a determination regarding substantial equivalence. In addition, FDA collects user fees for certain medical device submissions and annual fees and for medical device establishments.

If the FDA agrees that the device is substantially equivalent to a predicate device currently on the market, it will grant 510(k) clearance to commercially market the device. If the FDA determines that the device is not "substantially equivalent" to a predicate device, the device is automatically classified into Class III. The device sponsor must then fulfill the much more rigorous premarketing requirements of the PMA approval process, or seek risk-based reclassification of the device through the de novo process, which is a route to market for novel medical devices that are low to moderate risk and are not substantially equivalent to a predicate device. A manufacturer can also submit a petition for direct de novo review if the manufacturer is unable to identify an appropriate predicate device and the new device or new use of the device presents a moderate or low risk.

After a device receives 510(k) clearance or de novo classification, any modification that could significantly affect its safety or effectiveness, or that would constitute a new or major change in its intended use, will require a new 510(k) clearance or, depending on the modification, could require a PMA or de novo classification. The FDA requires each manufacturer to determine whether the proposed change requires submission of a 510(k) or a PMA in the first instance, but the FDA can review any such decision and disagree with a manufacturer's determination. Many minor modifications are accomplished by a letter-to-file in which the manufacture documents the change in an internal letter-to-file. The letter-to-file is in lieu of submitting a new 510(k) to obtain clearance for such change. The FDA can always review these letters to file in an inspection. If the FDA disagrees with a manufacturer's determination regarding whether a new premarket submission is required for the modification of an existing device, the FDA can require the manufacturer to cease marketing and/or recall the modified device until marketing authorization is obtained. Also, in these circumstances, the manufacturer may be subject to significant regulatory fines or penalties.

Other FDA Regulatory Requirements

Products manufactured or distributed pursuant to FDA approvals are subject to continuing regulation by the FDA, including recordkeeping, annual product quality review and reporting requirements. Adverse event experiences with the product, including both drug-related and device-related adverse events (including device malfunctions and medical device reporting), must be reported to the FDA in a timely fashion and pharmacovigilance programs to proactively look for these adverse events are mandated by the FDA. Drug and device manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with ongoing regulatory requirements, including cGMP and QSR, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Following such inspections, the FDA may issue notices on Form 483, Untitled Letters or Warning Letters that could cause us or our third-party manufacturers to modify certain activities. A Form 483 Notice, if issued at the conclusion of an FDA inspection, list conditions the FDA investigators believe may have violated cGMP, QSR or other FDA regulations or guidelines. In addition to Form 483 Notices and Untitled Letters or Warning Letters, failure to comply with the statutory and regulatory requirements can subject a manufacturer to possible legal or regulatory action, such as suspension of manufacturing, seizure of product, injunctive action or possible civil penalties. We cannot be certain that we or our present or future third-party manufacturers or suppliers will be able to comply with the cGMP regulations, QSR and other ongoing FDA regulatory requirements. If we or our present or future third-party manufacturers or suppliers are not able to comply with these requirements, the FDA may require us to recall our products from distribution or withdraw any potential approvals of an NDA for that product.

The FDA closely regulates the post-approval marketing and promotion of drugs and devices, including standards and regulations for direct-to-consumer advertising, dissemination of off-label information, industry-sponsored scientific and educational activities and promotional activities involving the Internet. Drugs and devices may be marketed only for the approved indications and in accordance with the provisions of the approved label. Further, if there are any modifications to the drug or device, including changes in indications, labeling, or manufacturing processes or facilities, we may be required to submit and obtain FDA approval of a new or supplemental NDA or clearance or approval of the modified device, respectively, which may require us to develop additional data or conduct additional preclinical studies and clinical trials. Failure to comply with these requirements can result in adverse publicity, Warning Letters, corrective advertising and potential civil and criminal penalties.

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Physicians may prescribe legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties, in particular in oncology. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, impose stringent restrictions on manufacturers' communications regarding off-label use.

In addition, the distribution of prescription pharmaceutical products is subject to the Prescription Drug Marketing Act, or PDMA, which regulates the distribution of drugs and drug samples at the federal level and sets minimum standards for the registration and regulation of drug distributors by the states. Both the PDMA and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution.

Foreign Regulatory Environment

If we seek to market RenovoGem in foreign jurisdictions, we could become subject to a variety of foreign regulations regarding development, approval, commercial sales, and distribution of our products in addition to regulations in the United States. Whether or not we obtain FDA approval for a product, we must obtain the necessary approvals by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country and can involve additional product testing and additional review periods. The review process may take longer or shorter than that required to obtain FDA approval. The requirements governing, among other things, the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others. If we fail to comply with applicable foreign regulatory requirements, we may be subject to fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions, and/or criminal prosecution.

Other United States Healthcare Laws

In addition to FDA restrictions on marketing of pharmaceutical and medical device products, including drug/device combination products, pharmaceutical companies are subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which they conduct their business and may constrain the financial arrangements and relationships through which we research, as well as sell, market and distribute any products for which we obtain marketing authorization. Such laws include, without limitation, state and federal anti-kickback, fraud and abuse, false claims, data privacy and security, and transparency laws and regulations related to drug pricing and payments and other transfers of value made to physicians and other healthcare providers. If manufacturers' operations, including activities engaged by their contractors or agents, are found to be in violation of any of such laws or any other governmental regulations that apply, they may be subject to penalties, including, without limitation, administrative, civil and criminal penalties, damages, fines, disgorgement, the curtailment or restructuring of operations, integrity oversight and reporting obligations, exclusion from participation in federal and state healthcare programs and imprisonment.

The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce, or in return for, purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid, or other federally financed healthcare programs. The Affordable Care Act, or ACA, amended the intent element of the federal statute so that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to commit a violation. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers, among others, on the other. Although there are a number of statutory exceptions and regulatory safe harbors protecting certain business activities from prosecution or other regulatory sanctions, the exceptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor.

Federal civil and criminal false claims laws, including the federal civil False Claims Act, prohibit any person or entity from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to have a false claim paid. This includes claims made to programs where the federal government reimburses, such as Medicare and Medicaid, as well as programs where the federal government is a direct purchaser, such as when it purchases off the Federal Supply Schedule. Pharmaceutical and other healthcare companies have been prosecuted under these laws for, among other things, allegedly inflating drug prices they report to pricing services, which in turn were used by the government to set Medicare and Medicaid reimbursement rates, and for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. In addition, certain marketing practices, including off-label promotion, may also violate false claims laws. Additionally, the ACA amended the federal Anti-Kickback Statute such that a violation of that statute can serve as a basis for liability under the federal False Claims Act. Most states also have statutes or regulations similar to the federal Anti-Kickback Statute and civil False Claims Act, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

Other federal statutes pertaining to healthcare fraud and abuse include the civil monetary penalties statute, which prohibits, among other things, the offer or payment of remuneration to a Medicaid or Medicare beneficiary that the offeror or payor knows or should know is likely to influence the beneficiary to order a receive a reimbursable item or service from a particular supplier, and the additional federal criminal statutes created by the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which prohibits, among other things, knowingly and willfully executing or attempting to execute a scheme to defraud any healthcare benefit program or obtain by means of false or fraudulent pretenses, representations or promises any money or property owned by or under the control of any healthcare benefit program in connection with the delivery of or payment for healthcare benefits, items or services.

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In addition, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their respective implementing regulations, impose obligations on certain healthcare providers, health plans, and healthcare clearinghouses, known as covered entities, as well as their business associates that perform certain services involving the storage, use or disclosure of individually identifiable health information, including mandatory contractual terms, with respect to safeguarding the privacy, security, and transmission of individually identifiable health information, and require notification to affected individuals and regulatory authorities of certain breaches of security of individually identifiable health information. HITECH increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions. In addition, many state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, and often are not preempted by HIPAA.

Further, pursuant to the ACA, the CMS has issued a final rule that requires applicable manufacturers of covered products, including prescription drugs and certain medical devices, to collect and annually report information on certain payments or transfers of value made in the previous year to physicians (defined to include doctors of medicine and osteopathy, dentists, podiatrists, optometrists and licensed chiropractors), certain non-physician healthcare professionals (such as physician assistants and nurse practitioners, among others) and teaching hospitals, as well information regarding investment interests held by physicians and their immediate family members. The reported data is made available in searchable form on a public website on an annual basis. Failure to submit required information may result in civil monetary penalties. In addition, several states now require prescription drug companies to report certain expenses relating to the marketing and promotion of drug products and to report gifts and payments to individual healthcare practitioners in these states. Other states prohibit various marketing-related activities and/or require the posting of information relating to clinical studies and their outcomes. Some states require the reporting of certain pricing information, including information pertaining to and justifying price increases, or prohibit prescription drug price gouging. In addition, certain states require pharmaceutical companies to implement a healthcare compliance program or code of conduct. Certain states and local jurisdictions also require the registration of pharmaceutical sales representatives. Compliance with these federal and state laws is difficult and time consuming, and companies that do not comply with these state laws are exposed to liabilities and civil penalties.

Efforts to ensure that business arrangements with third parties comply with applicable healthcare laws and regulations involve substantial costs. If a drug company's operations are found to be in violation of any such requirements, it may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, the curtailment or restructuring of its operations, loss of eligibility to obtain approvals from the FDA, exclusion from participation in government contracting, healthcare reimbursement or other federal or state government healthcare programs, including Medicare and Medicaid, integrity oversight and reporting obligations, imprisonment, and reputational harm. Although effective compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, these risks cannot be entirely eliminated. Any action for an alleged or suspected violation can cause a drug company to incur significant legal expenses and divert management's attention from the operation of the business, even if such action is successfully defended.

Healthcare Reform

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, each as amended, collectively known as the ACA, was enacted, which substantially changed the way healthcare is financed by both governmental and private insurers, and significantly affected the pharmaceutical industry. The ACA contained a number of provisions, including those governing enrollment in federal healthcare programs, reimbursement adjustments and changes to fraud and abuse laws. Additionally, the ACA:

- increased the minimum level of Medicaid rebates payable by manufacturers of brand name drugs from 15.1% to 23.1% of the average manufacturer price;
- required collection of rebates for drugs paid by Medicaid managed care organizations;
- required manufacturers to participate in a coverage gap discount program, under which they must agree to offer 70 percent 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
- imposed a non-deductible annual fee on pharmaceutical manufacturers or importers who sell "branded prescription drugs" to specified federal government programs.

Since its enactment, there have been judicial, executive and Congressional challenges to certain aspects of the ACA. For example, in June 2021 the U.S. Supreme Court held that Texas and other challengers had no legal standing to challenge the ACA, dismissing the case on procedural grounds without specifically ruling on the constitutionality of the ACA. Thus, the ACA will remain in effect in its current form. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how any such challenges and healthcare measures promulgated by the Biden administration will impact the ACA, our business, financial condition and results of operations.

Other legislative changes have been proposed and adopted since the ACA was enacted, including aggregate reductions of Medicare payments to providers of 2% per fiscal year, which went into effect in April 2013 and will remain in effect through 2031, with the exception of a temporary suspension implemented under various COVID-19 relief legislation from May 1, 2020 through March 31, 2022, unless additional action is taken by Congress. Under current legislation, the actual reduction in Medicare payments will vary from 1% in 2022 to up to 4% in the final fiscal year of this sequester.

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Moreover, there has recently been heightened governmental scrutiny over the manner in which 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 addition, Congress is considering legislation that, if passed, could have significant impact on prices of prescription drugs covered by Medicare, including limitations on drug price increases and allowing Medicare to negotiate pricing for certain covered drug products. The impact of these regulations and any future healthcare measures and agency rules implemented by the Biden administration on us and the pharmaceutical industry as a whole is currently unknown.

At the state level, legislatures have increasingly passed legislation and implemented 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, in some cases, designed to encourage importation from other countries and bulk purchasing. For example, 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 after obtaining regulatory approval for any of our products.

Coverage and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any product candidate for which we may seek regulatory approval. Sales in the U.S. will depend, in part, on the availability of sufficient coverage and adequate reimbursement from third-party payors, which include government health programs such as Medicare, Medicaid, TRICARE and the Veterans Administration, as well as managed care organizations and private health insurers. Prices at which we or our customers seek reimbursement for our product candidates can be subject to challenge, reduction or denial by third-party payors.

The process for determining whether a third-party payor will provide coverage for a product is typically separate from the process for setting the reimbursement rate that the payor will pay for the product. A third-party payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be available. Additionally, in the U.S. there is no uniform policy among payors for coverage or reimbursement. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies, but also have their own methods and approval processes. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. If coverage and adequate reimbursement are not available, or are available only at limited levels, successful commercialization of, and obtaining a satisfactory financial return on, any product we develop may not be possible.

Third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. In order to obtain coverage and reimbursement for any product that might be approved for marketing, we may need to conduct expensive studies in order to demonstrate the medical necessity and cost-effectiveness of any products, which would be in addition to the costs expended to obtain regulatory approvals. Third-party payors may not consider our product candidates to be medically necessary or cost-effective compared to other available therapies, or the rebate percentages required to secure favorable coverage may not yield an adequate margin over cost or may not enable us to maintain price levels sufficient to realize an appropriate return on our investment in drug development.

We are developing a new drug product, RenovoGem, which is intra-arterial gemcitabine delivered via the proprietary RenovoCath delivery system. If the drug is approved, it is expected to be sold together with the catheter used to administer the drug in the National Drug Code (NDC) created when the drug receives FDA approval. The reimbursement pathway involves separate payments for the drug product and for the occlusion procedure to administer it. As to the latter, it is anticipated that the procedure is accurately described by an existing code with existing payment levels. Given the expectation that the drug will be a novel, non-generic drug, a unique code and payment based on pricing information for the product should be established.

For the reasons discussed above, we believe there is a clear path to reimbursement for RenovoGem and its related procedure in both the hospital outpatient and physician office settings (which may include freestanding entities such as catheterization laboratories). As is typical for a product still in clinical development, it is difficult to predict whether there would be any Medicare coverage obstacles, which there usually are not for FDA approved drugs being used for on-label use. We believe the most important step we can take to enhance reimbursement for our products is the development of published, peer-reviewed clinical literature supporting their clinical benefit.

Competition

The oncology biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies and strong competition. While we believe that our knowledge, leadership, experience, scientific resources, intellectual property, regulatory barriers, and the advanced stage of our clinical development provide us with competitive advantages, we may face competition from major pharmaceutical companies, specialty pharmaceutical companies, and biotechnology companies, worldwide. Many potential competitors have substantially greater scientific, research, financial, technical, and/or human resources than we do.

Many companies are active in the oncology market both in terms of commercially marketed products and products in development that could potentially compete with our products and product candidates for the treatment of solid tumors. Any product candidates that we successfully develop and commercialize may compete directly with approved and/or new therapies that may be approved in the future. Our competitors may also obtain FDA or foreign regulatory approval for their products more rapidly than we may obtain approval for our product candidates which could result in our competitors establishing a strong market position prior to us entering the market. Key competitive factors affecting the success of our product candidates, if approved, are likely to be their safety, efficacy, convenience, price, and the availability of reimbursement from government and other third-party payors. Many companies are developing new therapeutics and we cannot predict what the standard of care will be as our product candidate progresses through clinical development.

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Currently, there are a handful of companies in Phase 3 clinical trials for the treatment of LAPC including Angiodynamics, Bausch Health, Fibrogen, NovoCure, and SynCore Biotechnology. We are aware of a number of companies in Phase 1 and Phase 2 clinical trials for the treatment of LAPC including one interventional company, TriSalus Lifesciences.

Many of our competitors have substantially greater financial, technological, research and development, marketing and personnel resources. Inaddition, some of our competitors have considerable experience in conducting clinical trials, regulatory, manufacturing and commercialization capabilities. Our competitors may develop alternative treatment methods, or achieve earlier product development, in which case the likelihood of us achieving meaningful revenues or profitability will be substantially reduced.

Employees and Human Capital Resources

As of the date of this Annual Report, we had 6 full-time employees. None of our employees are represented by a labor union or covered by a collective bargaining agreement. We focus on employee engagement and believe our relationship with our employees is good. We have 10 key consultants in the areas of quality, regulatory, finance, legal, IT, clinical, and marketing.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, and incentivizing our existing employees. The principal purposes of our equity and cash incentive plans are to attract, retain and reward personnel through the granting of stock-based and cash-based compensation awards, in order to increase stockholder value and the success of our company by motivating such individuals to perform to the best of their abilities and achieve our objectives.

Facilities

Our administrative headquarters is located at 4546 El Camino Real, Ste. B1, Los Altos, CA 94019. The office space is approximately 1,480 square feet, and the rent is $5,920 per month and expires on May 31, 2022. We believe that our facility is adequate for our current operations and purposes, and that suitable additional or alternative space will be available in the future on commercially reasonable terms, if required.

Legal Proceedings

From time to time, we are engaged in various legal actions, claims and proceedings arising in the ordinary course of business, none of which are expected to be material.

ITEM 1A. RISK FACTORS

An investment in our securities involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this Annual Report on Form 10-K, 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.

Risks Related to Our Business, Financial Condition and Capital Requirements

We are a clinical stage biopharmaceutical company, have a limited operating history and have no drug/device combination products approved for commercial sale, which makes it difficult to evaluate our current business and predict our future success and viability.

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

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

We have incurred significant net losses in each period since inception, and we expect to continue to incur net losses for the foreseeable future.

We are a clinical stage company and have incurred significant losses since our formation. As of December 31, 2021, we have an accumulated total deficit of approximately $21.3 million. For the fiscal years ended December 31, 2021 and 2020, we had net losses of approximately $6.3 million and $3.8 million, respectively. To date, we have experienced negative cash flow from development of our product candidate, RenovoGem, our platform technology, RenovoTAMP, and our RenovoCath delivery system. We have not generated any revenue from operations, and we expect to incur substantial net losses for the foreseeable future as we seek to further develop and commercialize RenovoGem and expand our pipeline of product candidates. Because of the numerous risks and uncertainties associated with developing and commercializing RenovoGem, we are unable to predict the extent of any future losses or when we will attain profitability, if ever. Investors in our common stock must carefully consider the substantial challenges, risks and uncertainties inherent in the attempted development and commercialization of RenovoGem. We may never successfully commercialize RenovoGem, and our business may not be successful.

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

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

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

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

We will need to raise substantial additional capital to develop and commercialize RenovoGem, and our failure to obtain funding when needed may force us to delay, reduce or eliminate our product development programs or collaboration efforts.

As of December 31, 2021, our cash and cash equivalents and working capital were approximately $15.2 million. Due to our recurring operating losses and the expectation that we will continue to incur net losses in the future, we will be required to raise additional capital to complete the development and commercialization of our product candidates. We have historically financed our operations primarily through private sales of our equity, debt financings and the sale of common stock and warrants in our initial public offering, or IPO. To raise additional capital, we may seek to sell additional equity and/or debt securities, obtain a credit facility or other loan or enter into collaborations, licenses or other similar arrangements, which we may not be able to do on favorable terms, or at all. Our ability to obtain additional financing will be subject to a number of factors, including market conditions, fluctuations in interest rates, our operating performance and investor sentiment. If we are unable to raise additional capital when required or on acceptable terms, we may have to significantly delay, scale back or discontinue the development and/or commercialization of our product candidates, restrict or cease our operations or obtain funds by entering into agreements on unfavorable terms. Failure to obtain additional capital on acceptable terms, or at all, would result in a material and adverse impact on our operations.

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

Our product candidates' commercial viability remains subject to current and future preclinical studies, clinical trials, regulatory approvals, and the risks generally inherent in the development of a pharmaceutical product candidate. If we are unable to successfully advance or develop our product candidate, our business will be materially harmed.

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

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

- may not deem our product candidate to be safe and effective;

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

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

We cannot assure you that the results of late-stage clinical trials will be favorable enough to support the continued development of our product candidates. A number of companies in the pharmaceutical and biopharmaceutical industries have experienced significant delays, setbacks and failures in all stages of development, including late-stage clinical trials, even after achieving promising results in preclinical testing or early-stage clinical trials. Accordingly, results from completed preclinical studies and early-stage clinical trials of our product candidates may not be predictive of the results we may obtain in later-stage trials. Furthermore, even if the data collected from preclinical studies and clinical trials involving our product candidates demonstrate a favorable safety and efficacy profile, such results may not be sufficient to support the submission of a New Drug Application 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.

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

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

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

Our product candidates may exhibit undesirable side effects when used alone or in combination with other approved pharmaceutical products or investigational new drugs, which may delay or preclude further development or regulatory approval or limit their use if approved.

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

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

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

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

- communications with the FDA, or similar regulatory authorities in different countries, regarding the scope or design of a trial or trials;

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

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

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

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

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

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

We have limited resources dedicated to designing, conducting, and managing preclinical studies and clinical trials. We intend to rely on third parties, including clinical research organizations, consultants, and principal investigators, to assist us in designing, managing, monitoring and conducting our preclinical studies and clinical trials. We intend to rely on these vendors and individuals to perform many facets of the drug development process, including certain preclinical studies, the recruitment of sites and patients for participation in our clinical trials, maintenance of good relations with the clinical sites, and ensuring that these sites are conducting our trials in compliance with the trial protocol, including safety monitoring and applicable regulations. If these third parties fail to perform satisfactorily, or do not adequately fulfill their obligations under the terms of our agreements with them, 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. Additionally, certain third parties with whom we engage or may engage for preclinical studies or clinical studies may have to adjust their operations or limit their capacity in light of the effects of the COVID-19 pandemic, including the effects of recent variants.

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

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

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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 4 clinical trials. In addition, we or our collaborators may encounter delays in, or fail to gain, regulatory approval for any of our product candidates based upon additional governmental regulation resulting from future legislative, administrative action or changes in FDA's or other similar foreign regulatory authorities' policy or interpretation during the period of product development. Delays or failures in obtaining regulatory approval to advance any of our product candidates through clinical development, and ultimately to commercialize them, may:

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

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

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

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

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

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

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

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

We may experience delays in clinical testing of our product candidates. We do not know whether planned clinical trials will begin on time, will need to be redesigned or will be completed on schedule, if at all, especially in light of the effects of the COVID-19 pandemic, including the effects of recent variants. From time to time, based on our experience with a clinical trial, we may amend the clinical trial protocol to address any issues that we observe as the trial is progressing, including in response to COVID-19 related factors or other factors impacting safety and the data collected, or we may be required to make certain changes in response to issues raised by the FDA, IRB, other regulatory authorities, investigators or clinical sites. Protocol amendments are subject to IRB and regulatory approval before we implement material changes, can result in additional costs, require additional data or participants, and may negatively impact the timelines for the trial. For example, in December 2021, we amended the protocol for our Phase 3 clinical trial to only allow for Stereotactic Body Radiation Therapy (SBRT) radiation during the induction phase of the study. We had previously permitted both SBRT and intensity-modulated radiation therapy (IMRT). Patients receiving IMRT were required to complete 25 treatments prior to being randomized into our study. In comparison, patients receiving SBRT are only required to complete 5 treatments. IMRT is generally less tolerable than SBRT, and we had observed a higher drop out for patients on IMRT. This change may limit the clinical trial sites that can participate in our study, impact enrollment, and delay the completion of the study, any of which can increase the cost of our operations 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. FDA and other regulatory authorities may also impose other restrictions in our proposed labeling, which could have a material adverse effect on the prospects of our product candidates, if approved, and our business.

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

ability to generate revenue.

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

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

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

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

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

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

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

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

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

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

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

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

Our business operations and activities may be directly or indirectly subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act. If we obtain FDA approval for any of our product candidates and begin commercializing those product candidates in the United States, our potential 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.

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As a developer of pharmaceuticals and drug/device combination products, 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. The laws include:

- the federal healthcare program anti-kickback law, which prohibits, among other things, persons from soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs;

- federal false claims laws which prohibit, among other things, individuals, or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent, and which may apply to entities like us which provide coding and billing information to customers;

- the federal Health Insurance Portability and Accountability Act of 1996, which prohibits executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters and which also imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information;

- the federal Open Payments program under the Physician Payments Sunshine Act, created under Section 6002 of the ACA and its implementing regulations, which requires certain manufacturers of covered drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) and applicable group purchasing organizations to report annually to CMS information related to payments or other transfers of value made in the previous year to covered recipients, including physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician healthcare professionals (such as physician assistants and nurse practitioners, among others), and teaching hospitals, and information regarding ownership and investment interests held by physicians (as defined above) and their immediate family members;

- the federal Food, Drug, and Cosmetic Act, which among other things, strictly regulates drug manufacturing and product marketing, prohibits manufacturers from marketing drug products for off-label use and regulates the distribution of drug samples;

- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;

- federal government drug price reporting laws, changed by the ACA to, among other things, increase the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program and offer such rebates to additional populations, that require us to calculate and report complex pricing metrics to government programs, where such reported prices may be used in the calculation of reimbursement or discounts on our marketed drugs (participation in these programs and compliance with the applicable requirements may subject us to potentially significant discounts on our product candidates, increased infrastructure costs, and potentially limit our ability to offer certain marketplace discounts);

- the Foreign Corrupt Practices Act, a United States law which regulates certain financial relationships with foreign government officials (which could include, for example, certain medical professionals);

- analogous state and foreign laws and regulations, including: state anti-kickback and false claims laws which may apply to our business practices, including, but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by state governmental and non-governmental third-party payors, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government; state laws that require drug manufacturers to track gifts and other remuneration and items of value provided to healthcare professionals and entities; state and local laws that require the registration of pharmaceutical sales representatives; and state laws that require drug manufacturers to report information relating to pricing and marketing information; and

- state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by federal laws, thus complicating compliance efforts.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws may involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws. If our operations are found to be in violation of any of the laws described above or any governmental regulations that apply to us, we may be subject to 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.

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

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

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

all of the clinical indications for which we are seeking approval or may contain significant limitations on the conditions of use.

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

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

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

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

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

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

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

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 3 clinical trials for the treatment of LAPC including Angiodynamics, Bausch Health, FibroGen, Novocure, and SynCore Biotechnology. In addition, we are aware of a number of companies in Phase 1 and Phase 2 clinical trials for the treatment of LAPC including one interventional company, TriSalus Lifesciences. Our commercial opportunity will be reduced or eliminated if our competitors develop and commercialize any products that are safer, more effective, have fewer side effects or are less expensive than our product candidates. These potential competitors compete with us in recruiting and retaining key and qualified scientific and management personnel, establishing clinical trial sites, and patient enrollment for clinical trials, as well as in acquiring technologies and technology licenses complementary to our programs or advantageous to our business.

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

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

- successfully identify and develop key points of product differentiation from currently available therapies;
- successfully and timely complete clinical trials and submit for and obtain all requisite regulatory approvals in a cost-effective manner;
- maintain a proprietary position for our products and manufacturing processes and other related product technology;

- attract and retain key and qualified personnel;
- develop relationships with physicians prescribing these products; and
- build an adequate sales and marketing infrastructure for our products, if approved.

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

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

Because we have limited financial and managerial resources, we intend to focus on developing product candidates for specific indications that we identify as most likely to succeed, in terms of their potential both to gain regulatory approval and to achieve commercialization. As a result, we may forego or delay 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 manufacture our clinical supplies. Any curtailment in the availability of gemcitabine, or RenovoCath, the drug delivery device, however, could result in production or other delays with consequent adverse effects on us. In addition, because regulatory authorities must generally approve raw material sources for pharmaceutical products, changes in raw material suppliers may result in production delays or higher raw material costs.

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

The manufacture of pharmaceutical products, including drug/device combination products, requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of pharmaceutical products may encounter difficulties in production, particularly in scaling up production. 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. In addition, any delay or interruption in the supply of clinical trial supplies, due to the effects of the COVID-19 pandemic or otherwise, could delay the completion of our clinical trials, increase the costs associated with conducting our clinical trials and, depending upon the period of delay, require us to commence new clinical trials at significant additional expense or to terminate a clinical trial.

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

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

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

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

- an outbreak of disease or similar public health threat, such as the existing threat of COVID-19, 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. 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.

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

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

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

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

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

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

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

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

our product revenue may be limited, and it may be more difficult for us to achieve or maintain profitability.

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If third-party contract manufacturers upon whom we rely to formulate and manufacture our product candidates do not perform, fail to manufacture according to our specifications or fail to comply with strict regulations, our preclinical studies or clinical trials could be adversely affected and the development of our product candidate could be delayed or terminated or we could incur significant additional expenses.

We do not own or operate any manufacturing facilities. We intend to rely on cGMP manufacturers, FDA inspected third-party contractors, at least for the foreseeable future to formulate and manufacture these preclinical and clinical materials. Our reliance on third-party contract manufacturers exposes us to a number of risks, any of which could delay or prevent the completion of our preclinical studies or clinical trials, or the regulatory approval or commercialization of any of our product candidates, result in higher costs, or deprive us of potential product revenues.

Some of these risks include:

- our third-party contractors failing to develop an acceptable formulation to support later-stage clinical trials for, or the commercialization of, our product candidates;
- our contract manufacturers failing to manufacture our product candidates according to their own standards, our specifications or cGMP, QSR or otherwise manufacturing material that we or the FDA may deem to be unsuitable in our clinical trials;
- our contract manufacturers being unable to increase the scale of, increase the capacity for, or reformulate the form of any of our product candidates. We may experience a shortage in supply, or the cost to manufacture our products may increase to the point where it adversely affects the cost of our product candidates. We cannot assure you that our contract manufacturers will be able to manufacture our product candidates at a suitable scale, or we will be able to find alternative manufacturers acceptable to us that can do so;
- our contract manufacturers placing a priority on the manufacture of their own products, or other customers' products;
- our contract manufacturers failing to perform as agreed or not remaining in the contract manufacturing business;
- our contract manufacturers experiencing the effects of any strikes or other work stoppages; or
- our contract manufacturers' plants being closed as a result of regulatory sanctions or a natural disaster.

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

Due to regulatory restrictions inherent in an IND or NDA, or for economic reasons, various steps in the manufacture of any of our product candidates may need to be sole-sourced. We currently obtain our RenovoCath delivery system, subject to requirements under the QSR, from a single supplier. In accordance with cGMP regulations and QSR, changing manufacturers may require the re-validation of manufacturing processes and procedures, and may require further preclinical studies or clinical trials to show comparability between the materials produced by different manufacturers, and further regulatory review and approval. Changing our current or future contract manufacturers may be difficult for us and could be costly, which could result in our inability to manufacture our product candidate for an extended period of time and therefore a delay in the development of any of our product candidates. 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 then 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 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.

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We may delay or terminate the development of our product candidates at any time if we believe the perceived market or commercial opportunity does not justify further investment, which could materially harm our business.

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

Risks Related to Our Operations

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

We are highly dependent on the development, regulatory, commercialization, and business development expertise of Shaun Bagai, our Chief Executive Officer, as well as the other principal members of our management, scientific and clinical teams. Although we have employment agreements, offer letters or consulting agreements with our executive

officers, these agreements do not prevent them from terminating their services at any time.

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

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

We are a small company with less than 10 employees. 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.

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

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

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

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

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

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

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

negatively affect our reputation, damage our network infrastructure and our ability to deploy our products and services, harm our relationship with customers and partners that are affected, and expose us to financial liability, including the possibility of consequential damages resulting from cyber-attacks and other security threats.

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

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

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

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

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

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

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

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

- multiple, conflicting and changing laws and regulations, such as privacy regulations, tax laws, export and import restrictions, employment laws, regulatory requirements and other governmental approvals, permits and licenses;
- failure by us to obtain and maintain regulatory approvals for the use of our products in various countries;
- additional potentially relevant third-party patent rights;
- complexities and difficulties in obtaining protection and enforcing our intellectual property;
- difficulties in staffing and managing foreign operations;
- complexities associated with managing multiple payor reimbursement regimes, government payors or patient self-pay systems;
- limits in our ability to penetrate international markets;
- financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises on demand and payment for our products and exposure to foreign currency exchange rate fluctuations;
- 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, the availability and cost of credit and government stimulus programs in the U.S. and other countries, including those related to the COVID-19 pandemic, have contributed to increased volatility. If the economic climate deteriorates or is poor, our business, as well as the financial condition of our suppliers and our third-party payors, could be negatively impacted, which could materially adversely affect our business, prospects and financial condition.

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

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

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

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

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

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

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

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

Moreover, there has recently been heightened governmental scrutiny over the manner in which drug manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. For example, under the American Rescue Plan Act of 2021, effective January 1, 2024, the statutory cap on Medicaid Drug Rebate Program rebates that manufacturers pay to state Medicaid programs will be eliminated. Elimination of this cap may require pharmaceutical manufacturers to pay more in rebates than it receives on the sale of products, which could have a material impact on our business. Further, based on a recent executive order, the Biden administration expressed its intent to pursue certain policy initiatives to reduce drug prices. The HHS has released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and potential legislative policies that Congress could pursue to advance these principles. While no legislation or administrative actions have been finalized to implement these principles, Congress is considering legislation that, if passed, could have significant impact on prices of prescription drugs covered by Medicare, including limitations on drug price increases and allowing Medicare to negotiate pricing for certain covered drug products. The impact of these legislative, executive, and administrative actions and any future healthcare measures and agency rules implemented by the Biden administration 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 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 revenues. 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.

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

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

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

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

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

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

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

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

In January 2020, the World Health Organization declared the outbreak of COVID-19 as a "Public Health Emergency of International Concern," which continues to spread throughout the world and has adversely impacted global commercial activity and contributed to significant volatility in financial markets. The COVID-19 outbreak and government responses are creating disruption in global supply chains and adversely impacting many industries. The outbreak could have a continued material adverse impact on economic and market conditions. We continue to monitor the impact of the COVID-19 outbreak, including its most recent variants, closely. The extent to which the COVID-19 outbreak will impact our operations or financial results is uncertain.

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

- delays or difficulties in enrolling and retaining patients in our clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;

- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- interruption of key clinical trial activities, such as clinical trial site data monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others or interruption of clinical trial subject visits and study procedures (such as endoscopies that are deemed non-essential), which may impact the integrity of subject data and clinical study endpoints;
- interruption or delays in the operations of the FDA or other regulatory authorities, which may impact review and approval timelines;
- interruption of, or delays in receiving, supplies of our product candidates from our contract manufacturing organizations due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems;
- limitations on employee and consulting resources that would otherwise be focused on the conduct of our clinical trials, including because of sickness of employees, consultants or their families or the desire of employees or consultants to avoid contact with large groups of people;
- interruption or delays to our outsourced clinical activities; or
- changes in clinical site procedures and requirements as well as regulatory requirements for conducting clinical trials during the pandemic.

We may be required to develop and implement additional clinical trial policies and procedures designed to help protect subjects from the COVID-19 virus. For example, in March 2020, the FDA issued guidance, which FDA subsequently updated, on conducting clinical trials during the pandemic, which describes a number of considerations for sponsors of clinical trials impacted by the pandemic, including the requirement to include in the clinical trial report contingency measures implemented to manage the trial, and any disruption of the trial as a result of the COVID-19 pandemic; a list of all subjects affected by the COVID-19 pandemic related study disruption by unique subject identifier and by investigational site and a description of how the individual's participation was altered; and analyses and corresponding discussions that address the impact of implemented contingency measures (e.g., participant discontinuation from investigational product and/or study, alternative procedures used to collect critical safety and/or efficacy data) on the safety and efficacy results reported for the trial.

The COVID-19 pandemic continues to evolve rapidly, including the emergence of new variants, with the status of operations and government restrictions evolving frequently. The extent to which the outbreak impacts our business and clinical trials will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the duration of the pandemic, the continued effectiveness of the vaccines, vaccination and infection rates, new travel restrictions or social distancing in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease.

The ultimate impact of the COVID-19 pandemic on our business operations is highly uncertain and subject to change and will depend on future developments, which cannot be accurately predicted, including the duration of the pandemic, the ultimate geographic spread of the disease, additional or modified government actions, new information that will emerge concerning the severity and impact of COVID-19, including the emergence of new variants, and the actions taken to contain COVID-19, including vaccination efforts, or address its impact in the short and long term, among others. We do not yet know the full extent of potential delays or impacts on our business, our clinical trials, our research programs, healthcare systems or the global economy. We will continue to monitor the situation closely.

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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.

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 offices use to grant patents, and the standards that U.S. and foreign courts use to interpret patents, are not the same, are not always applied predictably or uniformly and can change, particularly as new technologies develop. As such, the degree of patent protection obtained in the U.S. may differ substantially from that obtained in various foreign countries.

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Our Common Stock

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

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

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

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

- any delay in the commencement, enrollment and ultimate completion of our clinical trials;
- any delay in submitting an NDA and any adverse development or perceived adverse development with respect to the FDA's review of that NDA;
- failure to successfully develop and commercialize RenovoGem;
- inability to obtain additional funding;
- regulatory or legal developments in the United States and other countries applicable to RenovoGem or any other product candidate;
- adverse regulatory decisions;
- changes in the structure of healthcare payment systems;

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- inability to obtain adequate product supply for RenovoGem, RenovoCath or any other product candidate, or the inability to do so at acceptable prices;
- introduction of new products, services or technologies by our competitors;
- failure to meet or exceed financial projections we provide to the public;
- failure to meet or exceed the estimates and projections of the investment community;
- changes in the market valuations of companies similar to ours;
- market conditions in the pharmaceutical and biotechnology sectors, and the issuance of new or changed securities analysts' reports or recommendations;
- announcements of significant acquisitions, strategic collaborations, joint ventures or capital commitments by us or our competitors;
- significant lawsuits, including patent or stockholder litigation, and disputes or other developments relating to our proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- additions or departures of key scientific or management personnel;
- sales of our common stock by us, our insiders or our other stockholders;
- expiration of market standoff or lock-up agreements;
- trading volume of our common stock;
- fluctuations in interest rates and inflation rates;

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

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

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

We may seek additional capital through a variety of means, including through public or private equity, debt financings or other sources, including up-front payments and milestone payments from strategic collaborations. 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.

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

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

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

We could be subject to securities class action litigation.

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

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

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

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

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

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

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

Pursuant to Section 404 of SOX ("Section 404"), we will be required to furnish a report by our senior management on our internal control over financial reporting beginning

with our second filing of an Annual Report on Form 10-K with the SEC.

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

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

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

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

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

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

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

As a public company, we are subject to the periodic reporting requirements of the Exchange Act. We designed our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

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.

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

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

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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.

In addition, on December 7, 2021, following a competitive selection process, the Audit Committee of our board of directors approved the engagement of Baker Tilly US, LLP as the Company's independent registered public accounting firm for the December 31, 2021 audit. The dismissal of Frank, Rimerman + Co. LLP was approved by such Audit

Committee, and Frank, Rimerman + Co. LLP was notified on December 7, 2021 of its dismissal. We may have to revert to Frank, Rimerman + Co. LLP for certain auditor consents.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

Our administrative headquarters is located at 4546 El Camino Real, Ste. B1, Los Altos, CA 94019. The office space is approximately 1,480 square feet, and the rent is $5,920 per month and expires on May 31, 2022. We believe that our facility is adequate for our current operations and purposes, and that suitable additional or alternative space will be available in the future on commercially reasonable terms, if required.

ITEM 3. LEGAL PROCEEDINGS

From time to time, we may be involved in various legal actions, including claims and proceedings arising in the ordinary course of business. We are currently not a party to any legal proceedings, the adverse outcome of which, in management's opinion, individually or in the aggregate, would have a material adverse effect on our results of operations or financial position, and, to the best of management's knowledge, no such litigation is currently pending or threatened. Regardless of outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources, negative publicity, reputational harm and other factors.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

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PART II

ITEM 5. MARKET FOR THE REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information for Common Stock

Our common stock is publicly traded on the Nasdaq Capital Market under the symbol "RNXT."

Holders of Record of Common Stock

As of March 25, 2022, there were approximately 120 holders of record of our common stock. The actual number of stockholders is greater than this number of record holders and includes stockholders who are beneficial owners but whose shares are held in street name by brokers and other nominees. As of such date, there were 9,029,305 shares of our common stock issued and outstanding.

Dividend Policy

We have not declared or paid any cash dividends on our common stock since our inception. We currently intend to retain all available funds and any future earnings to support our operations and finance the growth and development of our business, and do not anticipate paying any cash dividends in the foreseeable future. Any future determination related to our dividend policy will be made at the discretion of our Board of Directors and will depend upon, among other factors, our results of operations, financial condition, capital requirements, contractual restrictions, business prospects and other factors our Board of Directors may deem relevant.

Securities Authorized for Issuance Under Equity Compensation Plans

Reference is made to the information contained in the Equity Compensation Plan table contained in Item 12 of this Annual Report on Form 10-K.

Use of Proceeds from Public Offering of Common Stock

On August 25, 2021, our registration statement on Form S-1 (File No. 333-258071) relating to the initial public offering ("IPO") of our securities was declared effective by the SEC. In connection with the IPO, we issued and sold an aggregate of 1,850,000 units at a price of $9.00 per unit. Each unit consisted of (i) one share of common stock and (ii) one warrant to purchase one share of common stock at an exercise price equal to $10.80 per share, which is exercisable for a period of five years after the issuance date. Our shares of common stock began trading on the Nasdaq Capital Market on August 26, 2021, and the transaction formally closed on August 30, 2021. We received aggregate gross proceeds of $16.7 million from the IPO, paid underwriting discounts and commissions of $1.3 million and incurred other expenses of $0.8 million. The net offering proceeds, after deducting underwriting discounts and commissions and other expenses, were $14.6 million. Roth Capital Partners served as the sole book-running manager for the IPO. Maxim Group LLC acted as lead manager for the offering. No payments were made by us to directors, officers or persons owning ten percent or more of our common stock or to their associates, or to our affiliates, other than payments in the ordinary course of business to officers for salaries and to non-employee directors pursuant to our Outside Director Compensation Policy, as amended.

There has been no material change in the planned use of proceeds from our IPO as described in our final prospectus filed with the SEC on August 27, 2021, pursuant to Rule 424(b)(4). We placed the funds received into a money market account.

Recent Sales of Unregistered Securities

In March 2020, the Company entered into a note purchase agreement for the issuance of up to $4.0 million of convertible promissory notes, which, if not converted, had an initial maturity date of March 31, 2021. The Company entered into a series of convertible note payable agreements (the "2020 Convertible Notes") for aggregate borrowings of $3.0 million. The 2020 Convertible Notes bore interest at the rate of 5% per annum and could not be prepaid prior to the maturity date unless approved in writing by the Company and requisite holders, see Note 5, *Convertible Notes*.

The terms of the 2020 Convertible Notes provided for automatic conversion into equity shares in the next equity financing round with total proceeds of not less than $10.0 million (a "Qualified Financing"), at a conversion price per share equal to 80% of the price per share paid by investors purchasing such equity securities in a Qualified Financing. For purposes of the 2020 Convertible Notes, equity securities meant the Company's common stock, preferred stock or any securities providing for rights to purchase the Company's common stock, preferred stock or securities convertible into or exchangeable for the Company's common stock or preferred stock issued in the Qualified Financing. If the Company consummated a Change of Control prior to a Qualified Financing, the Company would repay each holder in cash an amount equal to the greater of (a) two times (2x) the entire outstanding principal balance of the 2020 Convertible Notes or (b) the amount the holder would receive if the 2020 Convertible Notes had been converted into shares of the Company's Series B convertible preferred stock immediately prior to the consummation of the Change in Control, at a conversion price equal to the Series B convertible preferred stock original issue price.

On March 1, 2021, the Company entered into an amendment to the 2020 Convertible Notes which extended the maturity date of the 2020 Convertible Notes from March 31, 2021 to October 30, 2021 and provided for the conversion of the 2020 Convertible Notes into shares of the Company's common stock upon a Qualified Financing that is an IPO. No other terms of the 2020 Convertible Notes were amended. This amendment was accounted for as a troubled debt restructuring pursuant to FASB ASC Topic 470-60, "*Troubled Debt Restructurings by Debtors*." As the future undiscounted cash flows of the 2020 Convertible Notes were greater than their carrying amount, the carrying amount was not adjusted and no gain was recognized as a result of the modification of terms.

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The Company determined that the redemption features contained rights and obligations for conversion were contingent upon a potential future financing event or a change in control. Thus, the embedded redemption features were bifurcated from the face value of the notes and accounted for as a derivative liability to be remeasured at the end of each

reporting period. The fair value of the derivative liability at December 31, 2021 and December 31, 2020 was $0 and $856,000, respectively. Debt issuance costs were $22,000 at December 31, 2020. There were no debt issuance costs as of December 31, 2021. The derivative liability was subject to fair value remeasurement at the end of each reporting period. The debt discount and debt issuance costs were being amortized to interest expense using the effective interest method over the expected term of the 2020 Convertible Notes. For the years ended December 31, 2021 and December 31, 2020, the Company recognized $379,000 and $477,000 for amortization of the debt discount and debt issuance costs, respectively. This amortization expense is recognized as interest expense in the statements of operations. The effective interest rate of the 2020 Convertible Notes was 0% at December, 2021 and 30.8% at December 31, 2020, compared to the stated rate of 5% per annum. The effective interest rate immediately prior to the conversion of the Convertible Notes resulting from the Company's IPO was 8.6% per annum. As a result, the Company's reported interest expense was significantly higher than the contractual cash interest payments. During the years ended December 31, 2021 and December 31, 2020, the Company recognized interest expense in the statements of operations of $101,000 in each year, related to the 2020 Convertible Notes.

In April 2021, the Company entered into a note purchase agreement and a series of convertible note payable agreements (the "2021 Convertible Notes," together with the 2020 Convertible Notes, the "2020 and 2021 Convertible Notes") for aggregate borrowings of $2.0 million. Outstanding borrowings under the 2021 Convertible Notes and accrued interest were due in April 2022, if not previously converted. The 2021 Notes bore interest at the rate of 5% per annum. Pursuant to the 2021 Convertible Notes, the outstanding principal and accrued interest are automatically convertible into equity shares in a Qualified Financing at a conversion price per share equal to 87.5% of the price per share paid by investors purchasing such equity securities in a Qualified Financing, see Note 5, *Convertible Notes*.

The Company determined that these redemption features in the 2021 Convertible Notes contained rights and obligations for conversion that were contingent upon a potential future financing event or a change in control. Thus, the embedded redemption features were bifurcated from the face value of the note and accounted for as a derivative liability to be remeasured at the end of each reporting period. Upon issuance of the notes, the Company recorded the fair value of the derivative liability of $363,000 and debt issuance costs of $23,000, with the offsetting amount being recorded as a debt discount. The discount and debt issuance costs were amortized to interest expense using the effective interest method over the expected term of the 2021 Convertible Notes. For the year ended December 31, 2021, the Company recognized $386,000 for the amortization of the debt discount and debt issuance costs as interest expense in the statements of operations. The effective interest rate immediately prior to the conversion of the 2021 Convertible Notes resulting from the Company's IPO was 46.5% per annum compared to the stated rate of 5% per annum. During the year ended December 31, 2021, the Company recognized interest expense in the statements of operations of $38,000 relating to the 2021 Convertible Notes.

The Company completed an IPO on August 30, 2021, which triggered the automatic conversion of the outstanding Convertible Notes plus accrued interest into an aggregate of 708,820 units (the "Exchange"). The 2020 Convertible Notes converted at a 20% discount to the IPO price and the 2021 Convertible Notes converted at a 12.5% discount to the IPO price. Each unit consisted of (a) one share of common stock and (b) one five-year warrant to purchase one share of common stock at an exercise price equal to $10.80 per share. Upon conversion of the 2020 and 2021 Convertible Notes, the outstanding principal, including debt discount and debt issuance costs for those Convertible Notes of $5.3 million, was derecognized into stockholders' equity. The unamortized debt discount totaling $78,000 was recognized as a loss on extinguishment of debt and is included in loss (gain) on loan extinguishment in the Company's statements of operations.

The Exchange was made pursuant to an exemption from registration provided by Section 3(a)(9) of the Securities Act. The following facts were relied upon: (1) no payment was made in connection with the Exchange, (2) the Convertible Notes, the common stock, and the warrants were issued by the same issuer, (3) the Convertible Note holders were not required to contribute cash or any other property, and (4) the Exchange was made only to existing note holders.

Issuer Purchases of Equity Securities

None.

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ITEM 6. [RESERVED]

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with the financial statements and related notes thereto included in Part II, Item 8, "Financial Statements and Supplementary Data," of this Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this Form 10-K, including information with respect to our plans and strategy for our business, includes forward-looking statements that involves risks and uncertainties. See "Special Note Regarding Forward-Looking Statements" and "Risk Factors" for a discussion of forward-looking statements and important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements. All information presented herein is based on our fiscal calendar. Unless otherwise stated, references to particular years, quarters, months or periods refer to our fiscal years ended December 31 and the associated quarters, months and periods of those fiscal years.

Overview

We are a clinical-stage biopharmaceutical company focused on developing therapies for the local treatment of solid tumors. We are currently conducting a Phase 3 registrational trial for our lead product candidate RenovoGem™. Our therapy platform, RenovoRx Trans-Arterial Micro-Perfusion, or RenovoTAMP™, utilizes approved chemotherapeutics with validated mechanisms of action and well-established safety and side effect profiles, with the goal of increasing their efficacy, improving their safety, and widening their therapeutic window by combining such chemotherapeutics with our proprietary drug delivery system. RenovoTAMP combines our patented FDA cleared delivery system, RenovoCath®, with small molecule chemotherapeutic agents that can be forced across the vessel wall using pressure, targeting these anti-cancer drugs locally to the solid tumors. While we anticipate investigating other chemotherapeutic agents for intra-arterial delivery via RenovoTAMP, our clinical work to date has focused on gemcitabine, which is a generic small molecule drug. Our first product candidate, RenovoGem, is a drug /device combination consisting of intra-arterial gemcitabine and RenovoCath. FDA has determined that RenovoGem will be regulated as, and if approved we expect will be reimbursed as, a new oncology drug product. We have secured FDA Orphan Drug Designation for RenovoGem in two indications: pancreatic cancer and cholangiocarcinoma (bile duct cancer, or CCA). We have completed our RR1 Phase 1/2 and RR2 observational registry studies, with 20 and 25 patients respectively, in locally advanced pancreatic cancer, or LAPC. These studies demonstrated a median overall survival of 27.9 months in patients pre-treated with radiation followed by treatment with RenovoGem. Based on previous large randomized clinical trials, the expected survival of LAPC patients is 12 - 15 months in patients receiving only intravenous (IV) systemic chemotherapy or IV chemotherapy plus radiation (which are both considered standard of care). Unlike the randomized trials that established these standard-of-care results, our RR1 and RR2 clinical trials did not prospectively control the standard of care therapy received prior to administration of RenovoGem. Based on an FDA safety review of our Phase 1/2 study, FDA allowed us to proceed to evaluate RenovoGem within our Phase 3 registrational clinical trial. As of March 15, 2022, our Phase 3 trial had achieved approximately 50% of the target enrollment under the current SAP. The SAP includes a planned interim analysis when a total of 65 deaths have occurred in the study. We expect to conduct the interim analysis between the fourth quarter of 2022 and the first quarter of 2023; however, given that it is predicated on the number of deaths in the study, it is difficult to predict the exact timing. We intend to evaluate RenovoGem in a second indication in a Phase 2 trial in extrahepatic (or outside the liver) cholangiocarcinoma (or eCCA), cancer that occurs in the bile ducts that lead out of the liver and join with the gallbladder. We have now completed our evaluation of the different approaches to treat this patient population and are in the process of refining our clinical protocol. We plan to meet with FDA during the second or third quarter of 2022 to discuss our trial design. If FDA does not object to our study protocol, we anticipate launching the eCCA trial in the second half of 2022. In addition, we may evaluate RenovoGem in other indications, potentially including locally advanced lung cancer, locally advanced uterine tumors, and glioblastoma (an aggressive type of cancer that can occur in the brain or spinal cord). To date, we are focused on developing drug/device candidates with gemcitabine, but in the future, we may develop other product candidates with other chemotherapeutic agents for intra-arterial delivery via our RenovoTAMP therapy platform.

Since our inception, we have devoted substantially all of our efforts to developing our cancer therapy platform and product candidates, raising capital and organizing and staffing our company. Through December 31, 2021, we have received an aggregate of $35.0 million to finance our operations comprising of the following:

- $12.5 million net proceeds through the issuance of convertible preferred stock, including beneficial conversion features and warrants;
- $5.0 million in gross proceeds through the issuance of convertible notes;
- $0.1 million loan pursuant to the Paycheck Protection Program ("PPP") under the Coronavirus Aid, Relief and Economic Security Act, which was forgiven in February 2021;
- $14.6 million in net offering proceeds upon completion of our IPO in August 2021, after deducting underwriting discounts and commissions and offering expenses. We received $16.7 million in gross proceeds and paid underwriting discounts and commissions of $1.3 million and incurred additional offering expenses of $0.8 million;
- $2.7 million from the exercise of common stock units in connection with our IPO; and
- $0.1 million from the exercise of common stock options.

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We have incurred significant operating losses and generated negative cash flows from operations since our inception. As of December 31, 2021, we had cash and cash equivalents of $15.2 million. We had net losses of $6.3 million and $3.8 million for the years ended December 31, 2021 and December 31, 2020, respectively. As of December 31, 2021, we had an accumulated deficit of $21.3 million. We expect to continue to incur significant expenses, increasing operating losses and negative cash flows for the foreseeable future. We do not expect to generate revenues from product sales unless and until we successfully complete development and obtain regulatory approval for one or more product candidates. We expect that our expenses will increase substantially in connection with our ongoing research and development activities, particularly as we:

- Advance clinical development of RenovoGem and our platform technology by continuing to enroll patients in our ongoing TIGeR-PaC Phase 3 clinical trial, expanding the number of clinical trials including our planned clinical trial in HCCA, and advancing RenovoGem through preclinical and clinical development in additional indications;
- Hire additional research, development, and engineering personnel;
- Maintain, expand, enforce, defend, and protect our intellectual property portfolio; and
- Expand our operational, financial and management systems and increase personnel, including personnel to support our clinical development, manufacturing and commercialization efforts and our operations as a public company.

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

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

Impact of COVID-19

In December 2019, a novel strain of coronavirus, which causes the disease known as COVID-19, was reported to have surfaced in Wuhan, China. Since then, COVID-19, including recent variants, has spread globally. In March 2020, the World Health Organization declared the COVID-19 outbreak a pandemic. The ongoing COVID-19 global and national health emergency has caused significant disruption in the international and U.S. economies and financial markets. The spread of COVID-19, and its variants, has caused illness, quarantines, cancellation of events and travel, business and school shutdowns, reduction in business activity and financial transactions, labor shortages, supply chain interruptions and overall economic and financial market instability.

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

We are not able to estimate the duration of the pandemic and the potential impact on our business. As the COVID-19 global pandemic continues to evolve, it could result in significant long-term disruption of global financial markets, reducing our ability to raise additional capital when needed and on acceptable terms, if at all, which could negatively affect our liquidity. The extent to which the COVID-19 pandemic impacts our clinical development and regulatory efforts will depend on future developments that are highly uncertain and cannot be predicted with confidence, such as the duration of the continued outbreak, travel restrictions, quarantines and social distancing requirements in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the virus. We will continue to monitor the COVID-19 situation closely.

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Components of Our Results of Operations

Revenue

We have not generated any revenue from product sales and do not expect to generate any revenue from the sale of products for several years, if at all. If our development efforts for our current or future product candidates are successful and result in marketing approval or collaboration or license agreements with third parties, we may generate revenue in the future from a combination of product sales or payments from collaboration or license agreements that we may enter into with third parties.

Operating Expenses

Research and Development

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

Our research and development expenses include:

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

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

Due to the impact of the COVID-19 pandemic and work-from-home policies and other operational limitations mandated by federal, state, and local governments as a result of the pandemic, certain of our research and development activities have been delayed and may be further delayed until such operational limitations are lifted.

General and Administrative

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

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Other Income (Expenses), Net

Interest Income (Expenses) Net

Interest expense consists of charges relating to the amortization of the debt discount and debt issuance costs as well as interest on amounts outstanding on our convertible notes. In March 2020, we completed the offering of $3.0 million of convertible notes, the 2020 Convertible Notes, that provided for the automatic conversion into shares of our common stock and warrants at the closing of our IPO at a 20% discount to the public offering price of the units. In April 2021, we completed the offering of $2.0 million of convertible notes, the 2021 Convertible Notes, that provided for the automatic conversion into shares of our common stock and warrants at the closing of our IPO at a 12.5% discount to the public offering price of the units.

Interest income is earned from cash deposited in our money market account.

Other Income (Expenses), Net

Other income, net primarily represents the mark-to-market adjustment on the derivative liability resulting from the 2020 and 2021 Convertible Notes. Upon the completion of our IPO in August 2021, the 2020 and 2021 Convertible Notes were converted into units consisting of (a) one share of common stock and (b) one five-year warrant to purchase one share of common stock at an exercise price equal to $10.80 per share.

Gain on Loan Extinguishment

The gain (loss) on loan extinguishment represents the loss from the conversion and settlement of our 2020 and 2021 Convertible Notes of $0.1 million as well as the gain on loan extinguishment from the forgiveness and cancellation of our PPP loan of $0.1 million.

Income Tax Expense

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

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

recognize interest and/or penalties related to income tax matters in income tax expense.

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

Results of Operations

Comparison of the Years Ended December 31, 2021 and 2020

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

	Year Ended December 31,		Increase / (Decrease)	
	2021	2020	$	%
	(in thousands, except percentages)			
Operating expenses:				
Research and development	$ 3,039	$ 2,386	$ 653	27%
General and administrative	2,632	818	1,814	222%
Total operating expenses	5,671	3,204	2,467	77%
Loss from operations	(5,671)	(3,204)	2,467	77%
Other income (expense), net				
Interest (expense) income, net	(834)	(587)	(247)	42%
Other income (expense), net	119	(7)	126	-1800%
Gain on loan extinguishment	62	-	62	
Total other income (expense), net	(653)	(594)	(59)	10%
Net loss	$ (6,324)	$ (3,798)	$ (2,526)	67%

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Research and Development

The following table summarizes our research and development expenses (in thousands):

	Year Ended December 31,		Increase / (Decrease)
	2021	2020	$
Clinical development	$ 1,528	$ 1,277	$ 251
Clinical site payments for RenovoCath devices	(233)	(241)	8
Preclinical research and development	861	479	382
Regulatory	300	339	(39)
Personnel	583	532	51
Total research and development	$ 3,039	$ 2,386	$ 653

Research and development expenses were $3.0 million for the year ended December 31, 2021, an increase of $0.7 million, compared to $2.4 million for the year ended December 31, 2020. This increase was primarily due to clinical development expenses incurred for the ongoing Phase 3 trial of $0.2 million and clinical consulting to support the trial of $0.2 million, partially offset by software enhancement costs of $0.1 million. Payments for use of RenovoCath delivery devices remained relatively unchanged and represent the cash payment made by clinical trial sites for the devices used in the Phase 3 clinical trial. To date, payments received from clinical trial sites for the devices have been adequate to cover our direct costs of manufacturing the RenovoCath delivery devices and offset research and development expense. Preclinical research and development expenses increased by $0.4 million for the year ended December 31, 2021, compared to the preceding year, and represent costs associated with establishing a secondary manufacturer for RenovoCath devices of $0.2 million, an increase of $0.3 million in allocated general and administrative support costs for personnel, facility and office supply costs, offset by $0.1 million in the costs of supplies and manufacturing costs of RenovoCath devices. Regulatory and employee and related benefits expenses remained relatively unchanged from the prior year. We expect research and development costs to increase during the next year.

General and Administrative Expenses

The following table summarizes our general and administrative expenses (in thousands):

	Year Ended December 31,		Increase / (Decrease)
	2021	2020	$
Personnel	$ 998	$ 576	$ 422
Legal fees	270	170	100
Professional services and other	1,364	72	1,292
Total general and administrative	$ 2,632	$ 818	$ 1,814

General and administrative expenses were $2.6 million for the year ended December 31, 2021, an increase of $1.8 million, compared to $0.8 million for the year ended December 31, 2020. This increase was primarily due to higher employee and related benefits costs of $0.4 million, related to salaries and benefit expenses. Legal fees increased $0.1 million during fiscal year 2021, primarily due to our transition to being a publicly traded company. Professional services expenses increased during the year, primarily in connection with preparing for our IPO in August 2021 including continuing post-IPO support of $1.1 million, Directors and Officers Liability Insurance expense of $0.5 million, partially offset by an increase of $0.3 million in the allocation of general and administrative expenses to research and development. We expect general and administrative expenses to increase in the next fiscal year.

Interest (Expense) Income, Net (in thousands)

	Year Ended December 31,		Increase / (Decrease)
	2021	2020	$
Interest (expense) income, net	$ (834)	$ (587)	$ (247)

Interest (expense) income, net was $0.8 million for the year ended December 31, 2021, an increase of $0.2 million, compared to $0.6 million for the year ended December 31, 2020. The increase in interest (expense) income, net was primarily due to the issuance of the 2021 Convertible Notes. Interest expense includes both the stated interest on the

2020 and 2021 Convertible Notes of 5% per annum, or $0.1 million, and the amortization of the discount and debt issuance costs associated with the 2020 and 2021 Convertible Notes of $0.7 million in fiscal year 2021 compared to the stated interest on the 2020 Convertible Notes of 5% per annum, or $0.1 million, as well as the amortization of the debt discount and debt issuance costs of $0.5 million in fiscal year 2020. We do not expect to incur additional interest expense in the next fiscal year due to the conversion of the 2020 and 2021 Convertible Notes in fiscal year 2021.

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Other Income (Expense), Net (in thousands)

	Year Ended December 31,		Increase / (Decrease)
	2021	2020	$
Other income (expense), net	$ 119	$ (7)	$ 126

Other income, net was $0.1 million for the year ended December 31, 2021, and represents the mark-to-market adjustment on the derivative liabilities resulting from the 2020 and 2021 Convertible Notes. There was no other income, net for December 31, 2020.

On March 1, 2021, the Company entered into an amendment to the 2020 Convertible Notes which extended the maturity date of the 2020 Convertible Notes from March 31, 2021 to October 30, 2021 and provided for the conversion of the 2020 Convertible Notes into shares of the Company's common stock upon a Qualified Financing that is an IPO. No other terms to the 2020 Convertible Notes were amended. This amendment was accounted for as a troubled debt restructuring pursuant to FASB ASC Topic 470-60, "Troubled Debt Restructurings by Debtors." As the future undiscounted cash flows of the 2020 Convertible Notes were greater than their carrying amount, the carrying amount was not adjusted and no gain was recognized as a result of the modification of terms. We do not expect to incur additional income or expense in the next fiscal year due to the conversion of the 2020 and 2021 Convertible Notes in fiscal year 2021.

Gain on Loan Extinguishment (in thousands)

	Year Ended December 31,		Increase / (Decrease)
	2021	2020	$
Gain on loan extinguishment	$ 62	$ -	$ 62

The gain on loan extinguishment of $0.1 million for the year ended December 31, 2021 represents a loss of $0.1 million on the automatic conversion of the 2020 and 2021 Convertible Notes upon completion of our IPO, offset by the forgiveness and cancellation of our PPP loan of $0.1 million.

Liquidity and Capital Resources

For the years ended December 31, 2021 and December 31, 2020, our net losses were $6.3 million and $3.8 million, respectively. As of December 31, 2021, we had an accumulated deficit of $21.3 million. We expect to incur additional losses and increased operating expenses in future periods. Since our inception, our primary sources of liquidity have been the issuance of convertible preferred stock, convertible notes and common stock, including in our IPO, and from the exercise of warrants.

As of December 31, 2021, we had $15.2 million in cash and cash equivalents. During the year ended December 31, 2021, we used $5.9 million of cash in operations. Our primary requirements for liquidity have been to fund our clinical trial activity and general corporate and working capital needs. In August 2021, we completed our IPO for aggregate gross proceeds of $16.7 million. We paid underwriting discounts and commissions of $1.3 million, and incurred expenses of $0.8 million in connection with the offering. As a result, the net offering proceeds to us, after deducting underwriting discounts and commissions and offering expenses, were $14.6 million. In February 2021, we received notification and confirmation from Silicon Valley Bank that our PPP loan of $0.1 million, had been forgiven in its entirety and automatically cancelled by the U.S. Small Business Administration.

Based on our operating plans, we expect that our current cash and cash equivalents as of December 31, 2021, will be sufficient to fund our operating, investing and financing cash flow needs for at least the next twelve months and into 2023, assuming our programs advance as currently contemplated. Management regularly reviews our available liquidity relative to our operating budget and forecast to monitor the sufficiency of our working capital and anticipates drawing upon available sources of new capital when appropriate, including equity and debt instruments, to support our product development activities. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our clinical trials or other operations. If any of these events occur, our ability to achieve our operational goals would be adversely affected. Our future capital requirements and the adequacy of available funds will depend on many factors, including those described in "Risk Factors." Depending on the severity and direct impact of these factors on us, we may be unable to secure additional financing to meet our operating requirements on commercially acceptable terms favorable to us, or at all.

Sources of Liquidity

We believe that our existing cash, cash equivalents, and investments as of December 31, 2021 will be sufficient to fund our current operating plan through at least the next twelve months.

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

We have financed our operations primarily through the issuance and sale of convertible preferred stock and convertible debt. Through the date of this report, we have raised an aggregate of $35.0 million from private placements of our convertible preferred stock, convertible debt securities, the issuance of securities in our August 2021 IPO, and the exercise of warrants and common stock options. This amount also includes a loan under the PPP, which was forgiven in February 2021.

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Cash Flows

Our primary uses of cash are to fund our operations including research and development and general and administrative expenses. We will continue to incur operating losses in the future and expect that our research and development and general and administrative expenses will continue to increase as we continue our research and development efforts with respect to clinical development of our product candidates and further develop our platform. We expect that we will use a substantial portion of the net proceeds of the IPO, in combination with our existing cash and cash equivalents, for these purposes and for the increased expenses associated with being a public company. Cash used to fund operating expenses is impacted by the timing of when we pay expenses, as reflected in the change in our outstanding accounts payable and accrued expenses.

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

	Year Ended December 31,	
	2021	2020
Net cash (used in) provided by:		
Operating activities	$ (5,916)	$ (3,528)
Investing activities	(15)	-
Financing activities	19,328	3,199
Increase (decrease) in cash and cash equivalents	$ 13,397	$ (329)

Cash Used in Operating Activities

Cash used in operating activities for the year ended December 31, 2021 reflected a net loss of $6.3 million and a net change in our operating assets and liabilities of $0.4 million, offset by non-cash charges of $0.7 million consisting primarily of amortization of a debt discount, gain/loss on loan/convertible debt extinguishments and stock-based compensation expense. Net cash used in operating activities for year ended December 31, 2020 reflected a net loss of $3.8 million and non-cash charges of $0.5 million representing amortization of debt discount and stock-based compensation expense.

Cash Used in Investing Activities

Net cash used in investing activities for the year ended December 31, 2021 consisted of capital expenditures made for leasehold improvements to our new office space. There were no investment activities for the year ended December 31, 2020.

Cash Provided by Financing Activities

Net cash provided by financing in the year ended December 31, 2021 was $19.3 million, consisting of net proceeds of $14.6 million from the issuance of common stock in our IPO, $2.0 million from the issuance of convertible notes and $2.8 million from the exercise of warrants and stock options. Net cash provided by financing activities for the year ended December 31, 2020 was $3.2 million, consisting of $3.0 million in proceeds from the issuance of convertible notes and $0.2 million in proceeds from the PPP loan and the exercise of the Series A-1 warrants and stock options.

Contractual Obligations and Other Commitments

As of the date of this report, we have no contractual obligations or other commitments. In August 2021, the 2020 and 2021 Convertible Notes, including accrued interest, of $5.3 million were converted to common shares upon the completion of our IPO. In February 2021, the Company received notification and confirmation from Silicon Valley Bank that its PPP loan of $0.1 million, had been forgiven in its entirety and automatically cancelled by the U.S. Small Business Administration. There have been no other significant changes in our contractual obligations or other commitments as of December 31, 2021.

Critical Accounting Policies and Significant Judgments and Estimates

The accompanying management's discussion and analysis of our financial condition and results of operations are based upon our financial statements and the related disclosures, which have been prepared in accordance with accounting principles generally accepted in the United States, or GAAP. The preparation of these audited financial statements requires us to make estimates, assumptions and judgments that affect the reported amounts in our audited financial statements and accompanying notes. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. To the extent that there are material differences between these estimates and actual results, our future financial statement presentation, financial condition, results of operations and cash flows will be affected. While our significant accounting policies are described in the notes to our financial statements included elsewhere in this report, we believe that the following critical accounting policies are most important to understanding and evaluating our reported financial results because they require us to make estimates, assumptions and judgments about matters that are inherently uncertain.

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A critical accounting policy is defined as one that is both material to the presentation of our financial statements and requires management to make difficult, subjective, or complex judgments that could have a material effect on our financial condition and results of operations. Specifically, critical accounting estimates have the following attributes: (i) we are required to make assumptions about matters that are highly uncertain at the time of the estimate; and (ii) different estimates we could reasonably have used, or changes in the estimate that are reasonably likely to occur, would have a material effect on our financial condition or results of operations.

Clinical Trial Expenses

We make payments in connection with our Phase 3 clinical trial under contracts with clinical trial sites and contract research organizations that support conducting and managing clinical trials. The financial terms of these agreements are subject to negotiation and vary from contract to contract and may result in uneven payment flows. Generally, these agreements set forth the scope of work to be performed at a fixed fee, unit price or on a time and materials basis. A portion of the obligation to make payments under these contracts depends on factors such as the successful enrollment or treatment of patients or the completion of other clinical trial milestones.

Expenses related to clinical trials are accrued based on estimates and/or representations from service providers regarding work performed, including actual level of patient enrollment, completion of patient studies and progress of the clinical trials. Other incidental costs related to patient enrollment or treatment are accrued when reasonably certain. If the amounts we are obligated to pay under clinical trial agreements are modified (for instance, as a result of changes in the clinical trial protocol or scope of work to be performed), the accruals are adjusted accordingly. Revisions to contractual payment obligations are charged to expense in the period in which the facts that give rise to the revision become reasonably certain.

Stock-Based Compensation

We estimate the fair value of stock options using the Black-Scholes option pricing model, which incorporates various assumptions including those related to the fair value of our common stock, volatility, expected term, and risk-free interest rate. Compensation related to service-based awards is recognized starting on the grant date on a straight-line basis over the vesting period, which is generally four years, see Note 9, *Equity Inventive Plan – Stock-Based Compensation and Common Stock Warrants.*

Determining the grant date fair value of options using the Black-Scholes option pricing model requires management to make assumptions and judgments. If any of the assumptions used in the Black-Scholes model change significantly, stock-based compensation for future awards may differ materially compared with the awards granted previously. The assumptions and estimates are as follows:

Fair Value of Common Stock—Given the absence of a public trading market, pre-IPO, our Board considered numerous objective and subjective factors to determine the fair value of our common stock at each grant date. These factors included but were not limited to: (i) contemporaneous third-party valuations of common stock; (ii) the prices for preferred stock sold to outside investors; (iii) the rights and preferences of preferred stock relative to common stock; (iv) the lack of marketability of our common stock; (v) developments in the business; and (vi) the likelihood of achieving a liquidity event, such as an IPO or sale of the business, given prevailing market conditions. The methodology to determine the fair value of our common stock included estimating the fair value of the enterprise using the "backsolve" method, which is a market approach that assigns an implied enterprise value by accounting for all share class rights and preferences based on the latest round of financing. The total equity value implied was then applied in the

context of an option pricing model to determine the value of each class of our shares.

For grants issued post-IPO, we rely on the closing price of our common stock as reported on the date of grant to determine the fair value of our common stock, as shares of our common stock are traded in the public market.

Expected Term—The expected term represents the period that the stock-based awards are expected to be outstanding. We determine the expected term using the simplified method for pre-IPO awards. The simplified method deems the term to be the average of the time-to-vesting and the contractual life of the options. For stock-based awards granted post-IPO, the expected term equals the average for industry peers, consisting of several public companies in the Company's industry that are either similar in size, stage, or financial leverage.

Expected Volatility—Given the absence of a public trading market, the expected volatility was estimated by taking the average historic price volatility for industry peers, consisting of several public companies in our industry that are either similar in size, stage, or financial leverage, over a period equivalent to the expected term of the awards.

Risk-Free Interest Rate—The risk-free interest rate is calculated using the average of the published interest rates of U.S. Treasury zero-coupon issues with maturities that are commensurate with the expected term.

Dividend Rate—The dividend yield assumption is zero as we have no plans to make dividend payments.

Convertible Instruments and Embedded Derivatives

We evaluate all of our agreements to determine whether such instruments have derivatives or contain features that qualify as embedded derivatives. We account for certain redemption features that are associated with the terms of convertible notes as liabilities at fair value and adjusts the instruments to their fair value at the end of each reporting period. For derivative financial instruments that are accounted for as liabilities, the derivative instrument is initially recorded at its fair value and is then re-valued at each reporting date, with changes in the fair value reported in other income (expenses), net in the statements of operations. Derivative instrument liabilities are classified in the balance sheets as current or non-current based on whether or not net-cash settlement of the derivative instrument could be required within 12 months of the balance sheet date. As of December 31, 2020, our derivative financial instruments were related to the 2020 and 2021 Convertible Notes, which contained certain redemptive features. On August 30, 2021, we completed our IPO which triggered the automatic conversion of all outstanding Convertible Notes and accrued interest into shares of common stock.

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Emerging Growth Company and Smaller Reporting Company Status

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

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

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

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

Recently Issued and Adopted Accounting Pronouncements

See Note 2, *Summary of Significant Accounting Policies*, to our audited financial statements included elsewhere in this Annual Report on Form 10-K for more information.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Our financial statements and the reports of our independent registered public accounting firm, as listed under Part IV, Item 15. "Exhibits and Financial Statement Schedules," are included as a separate section of this report beginning on page F-1 and are incorporated herein by reference.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

On December 7, 2021, our Board dismissed Frank, Rimerman + Co. LLP as the Company's independent registered public accounting firm. The report of Frank, Rimerman + Co. LLP on the Company's financial statements for each of the fiscal years ended December 31, 2020, and December 31, 2019, did not contain an adverse or disclaimer of opinion, nor were they qualified or modified as to uncertainty, audit scope, or accounting principles, with the exception that the report dated May 12, 2021, contained an explanatory paragraph relating to the Company's ability to continue as a going concern.

During the fiscal years ended December 31, 2020 and December 31, 2019, and the subsequent interim period through December 7, 2021, there were no "disagreements," as that term is defined in Item 304(a)(1)(iv) of Regulation S-K, between the Company and Frank, Rimerman + Co. LLP on any matter of accounting principles or practices, financial statement disclosures or auditing scope or procedures, which disagreements, if not resolved to the satisfaction of Frank, Rimerman + Co. LLP, would have caused Frank, Rimerman + Co. LLP to make reference to the subject matter of the disagreement in its reports on the financial statements for such years.

There were no "reportable events," as that term is defined in Item 304(a)(1)(v) of Regulation S-K, during the fiscal years ended December 31, 2020, and December 31, 2019, and the subsequent interim period through December 7, 2021, except for the existence of material weaknesses identified during Frank, Rimerman + Co. LLP's audit of our financial statements for the fiscal years ended December 31, 2020 and December 31, 2019 related to (i) the Company's control environment, in particular that there was an insufficient number of qualified accounting and financial reporting personnel with an appropriate level of knowledge, training and experience to address complex accounting issues and a lack of appropriate segregation of duties due to the small size of the accounting and financing department, and (ii) management review controls, specifically that the Company did not properly design or maintain effective controls over journal entry review and account reconciliation. These material weaknesses have not yet been remediated.

On December 7, 2021, the Company engaged Baker Tilly US, LLP ("Baker Tilly") to serve as the Company's independent registered public accounting firm.

During the Company's fiscal years ended December 31, 2020 and 2019, and the subsequent interim period through December 7, 2021, neither the Company nor anyone acting on its behalf has consulted with Baker Tilly regarding (i) the application of accounting principles to a specified transaction, either completed or proposed, or the type of audit opinion that might be rendered on the Company's financial statements, and neither a written report nor oral advice was provided to the Company that Baker Tilly concluded was an important factor considered by the Company in reaching a decision as to any accounting, auditing, or financial reporting issue, (ii) any matter that was the subject of a disagreement within the meaning of Item 304(a)(1)(iv) of Regulation S-K, or (iii) any reportable event within the meaning of Item 304(a)(1)(v) of Regulation S-K.

ITEM 9A. CONTROLS AND PROCEDURES

(a) Evaluation of Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial and Accounting Officer, we conducted an evaluation of the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of the end of the year ended December 31, 2021. Based on this evaluation, our Chief Executive Officer and Chief Financial and Accounting Officer have concluded that, during the period covered by this Annual Report on Form 10-K, our disclosure controls and procedures were not effective due to our previously identified material weaknesses in internal control over financial reporting. As a result, we have performed additional analysis as deemed necessary to ensure that our financial statements were prepared in accordance with U.S. GAAP. Accordingly, notwithstanding the identified material weaknesses, management, including our Chief Executive Officer and Chief Financial and Accounting Officer, believes the financial statements included in this Annual Report on Form 10-K are fairly presented, in all material respects, in accordance with U.S. GAAP.

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

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

In preparation for our IPO, we identified a material weakness in our internal control over financial reporting related to our control environment. Specifically, we have determined that we have not maintained adequate formal accounting policies, processes and controls related to complex transactions as a result of a lack of finance and accounting staff with the appropriate GAAP technical expertise needed to identify, evaluate and account for complex and non-routine transactions. We also determined that we have not maintained sufficient staffing or written policies and procedures for accounting and financial reporting, which contributed to the lack of a formalized process or controls for management's timely review and approval of financial information. More specifically, we have determined that our financial statement close process includes significant control gaps mainly driven by the small size of our accounting and finance staff and, as a result, a significant lack of appropriate segregation of duties. A material weakness is a deficiency, or combination of significant deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected and corrected on a timely basis.

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

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

We intend to complete the implementation of our remediation plan during 2022. Although we believe that our remediation plan will improve our internal control over financial reporting, additional time may be required to fully implement it and to make conclusions regarding the effectiveness of our internal control over financial reporting. Our management will closely monitor and modify, as appropriate, the remediation plan to eliminate the identified material weakness.

This Annual Report on Form 10-K does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of the Company's registered public accounting firm due to a transition period established by SEC rules for newly public companies. For as long as we remain an emerging growth company under the JOBS Act, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal control over financial reporting. When we lose our status as an emerging growth company and reach an accelerated filer threshold, our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting.

(c) Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the last fiscal quarter ended December 31, 2021 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

On March 24, 2022, the Company's Board of Directors approved an amendment to the Amended and Restated Bylaws codifying certain technical changes to the advance notice

provisions. Our Amended and Restated Bylaws now provide that stockholders seeking to bring business before our annual meeting of stockholders, or to nominate candidates for election as directors at our annual meeting of stockholders, must provide timely notice of their intent in writing. To be timely, a stockholder's notice must be delivered to the secretary at our principal executive offices not later than 5 p.m., local time, on the 90th day nor earlier than 5 p.m., local time, on the 120th day prior to the first anniversary of the preceding year's annual meeting; provided, however, that in the event the date of the annual meeting is more than 30 days before or more than 60 days after such anniversary date, or if no annual meeting was held in the preceding year, notice by the stockholder to be timely must be so delivered not earlier than 5 p.m., local time, on the 120th day prior to such annual meeting and not later than 5 p.m., local time, on the later of the 90th day prior to such annual meeting or the 10th day following the day on which a public announcement of the date of such meeting is first made by us.

Also on March 24, 2022, the Company's Compensation Committee approved an increase in Mr. Bagai's annual base salary to $495,000 from $363,000, retroactively effective to January 1, 2022, to align Mr. Bagai's compensation more closely to the 50th percentile of the peer group of companies that the Company benchmarks its compensation against. Mr. Bagai's annual bonus target was not changed.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

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PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The following table sets forth the name and position of each of our executive officers and directors, and each such person's age as of March 30, 2022. All directors serve one-year terms or until each of their successors are duly qualified and elected. Our executive officers will serve in such capacities until their respective successors have been duly elected and qualified, or until their earlier death, resignation, disqualification or removal from office.

Name	Age	Position
Shaun R. Bagai	45	Chief Executive Officer and Director
Christopher J. Lehman	61	Chief Financial Officer
Ramtin Agah, M.D.	56	Chief Medical Officer, Founder and Chairman of the Board of Directors
David Diamond(1)	72	Director
Kirsten Angela Macfarlane(2)	57	Director
Laurence J. Marton, M.D.(3)	78	Director
Una S. Ryan, O.B.E., Ph.D., D.Sc.(4)	80	Director

(1) Chairperson of the Audit Committee and member of the Compensation Committee
(2) Chairperson of the Compensation Committee and member of the Nominating and Corporate Governance Committee
(3) Member of the Audit Committee and the Nominating and Corporate Governance Committee
(4) Chairperson of the Nominating and Corporate Governance Committee and member of the Audit Committee

The Board believes that the combination of the business and professional experience of our directors and the diversity of their areas of expertise has been a contributing factor to its effectiveness and provides a valuable resource to management. The following also includes, as to each of our directors, how long such person has been a director of our company; a description of the specific experience, qualifications, attributes and skills of each director; other public company directorships; and other factors considered in the determination that such person possesses the requisite qualifications and skills to serve as a member of our Board. Additionally, the Company is currently in compliance with the board diversity requirements of Sections 301.3 and 301.4 of the California Corporations Code.

Business Experience

Shaun R. Bagai. Mr. Bagai has served as our Chief Executive Officer and director since June 2014. Prior to joining us, Mr. Bagai led Global Market Development for HeartFlow, Inc. from 2011 to 2014, which included directing Japanese market research, regulatory/payer collaboration, and Key Opinion Leader development to create value resulting in a company investment to form HeartFlow-Japan. During his tenure at HeartFlow, he successfully orchestrated their largest clinical trial to date and contracted HeartFlow's first global customers. In addition, Mr. Bagai has launched innovative technologies into regional and global marketplaces in both large corporations and growth-phase novel technology companies. He was instrumental in developing the European market for renal denervation for the treatment of hypertension leading to the acquisition of the first renal denervation company — Ardian, Inc. by Medtronic in 2011. Mr. Bagai is a graduate from the University of California, Santa Barbara with a BSc. in Biology/Pre-Med.

Mr. Bagai brings over eight years of experience leading RenovoRx. During his tenure, the Company received several FDA clearances and CE Mark for the device component of the drug/device combination, was issued several US and European patents, began to scale production of its catheter delivery system, conducted and reported on its Phase 1/2 and observational registry clinical studies, launched its ongoing Phase 3 study, and completed multiple financings, including its initial public offering. Mr. Bagai not only has a deep understanding of, and experience with our therapy platform, but also has an extensive background in operations, clinical development and medical device market development and commercial launch, making him well-positioned to lead our management team and provide essential insight to the Board.

Christopher J. Lehman. Since December 2020, Mr. Lehman has been affiliated with LS Associates, Inc. which provides on-demand C-level executives. Pursuant to our contract with LS Associates, Inc., Mr. Lehman became our Chief Financial Officer upon consummation of our IPO. From December 2019 to August 2020, Mr. Lehman was Chief Financial Officer of Avellino Lab USA, Inc., a precision medicine company. From October 2017 to February 2019, he was affiliated with Eureka Therapeutics, Inc., an immuno-oncology company, as Vice President, Finance from 2017 to 2018 and Chief Financial Officer from 2018 to 2019. From October 2013 to June 2017, Mr. Lehman was Vice President, Financial Strategy of Coherus Biosciences, Inc., a global biosimilars and immuno-oncology company. For over 25 years, Mr. Lehman has worked with venture-backed private and public industry leaders in areas of therapeutics, biosimilars, diagnostics, contract research and industrial biotechnology. He has experience in leveraging his broad industry network with investment banks, venture capital, and strategic pharmaceutical partners to raise dilutive and non-dilutive capital and has experience with investors and strategic partners in the United States, Europe, and Asia.

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Ramtin Agah, M.D. Dr. Agah has served as our Chief Medical Officer and Co-Founder since December 2009, and as Chairman of the Board since May 2018. Dr. Agah is currently an Interventional Cardiologist at El Camino Hospital, Mountain View, a role he began in September 2005. He also has acted as a physician consultant for Abbott Vascular since July 2012. Previously, Dr. Agah was an Assistant Professor of Internal Medicine with the Division of Cardiology, University of Utah. Dr. Agah completed a Fellowship in Interventional Cardiology with Cleveland Clinic Foundation, a Residency in Internal Medicine with Baylor College of Medicine and a Fellowship in Cardiology with University of California, San Francisco. He received his M.D. from the University of Texas Southwestern Medical School.

As one of our co-founders, Dr. Agah has a deep understanding of our therapy platform, our history and culture. His initial education in biomedical engineering and vascular

biology established the foundation for our therapy. His experience as a practicing vascular specialist and as the proctor for many of our procedures, has given him a deep understanding of the procedural aspects of our therapy. This background, taken together with his deep understanding of the cancers we are seeking to treat and his clinical trial experience enables him to bring a unique perspective and provide strong leadership to our Board.

David Diamond. Mr. Diamond was appointed to the Board on May 9, 2021. Mr. Diamond currently provides strategic guidance and operational oversight to CEOs and boards of directors in the Life Sciences industry. Mr. Diamond has extensive experience assisting management teams and boards of directors with capital financing and strategic business planning nationally and internationally and has built strong relationships with prominent investment bankers. He currently serves on the Board of Advisors for Scynce LED as well as the National Life Sciences and Technology Practice Lead at Mayer Hoffman McCann P.C., a national CPA firm since 2015 and has over 30 years of experience in both public accounting and industry. Mr. Diamond previously served as Audit Committee Chair and Board Member of Oncotelic Therapeutics, Inc. as well as Board member for Kreston International Limited ($2 billion CPA network), a member of the board of San Diego Venture Group and was a Founding Member of UCSD Connect. He is a Certified Director in Corporate Governance from UCLA Anderson Graduate School of Management and an active CPA, licensed in the United States, Israel and South Africa.

Mr. Diamond brings to the Board extensive business, financial and operational expertise, particularly in the life sciences industry. Mr. Diamond's service, both on other boards and as an advisor to board and management teams, his management experience and public accounting background make him well-positioned to serve as the chair of the Audit Committee and as a member of the Compensation Committee.

Kirsten Angela Macfarlane. Ms. Macfarlane has served as our director since September 2018. She currently serves as CEO of Perceive Biotherapeutics, Inc., a biotech company dedicated to solving the major unsolved causes of vision loss. Ms. Macfarlane founded and serves as a Managing Partner of ForSight Labs, LLC an ophthalmic incubator formed in 2005 to focus on innovation in ophthalmology which has started eight companies in both therapeutics and medical devices. Ms. Macfarlane served as both the founding CEO of ForSight VISION4, Inc. through the acquisition (acquired by ROCHE - FDA approved SUSVIMO®), and the founding CEO of ForSight VISION5, Inc. and then at acquisition (acquired by Allergan plc). Previously, Ms. Macfarlane served as Chief Technology Counsel to The Foundry, LLC, a medical technology incubator, and Technology Counsel for Thomas J. Fogarty, M.D., a renowned physician/entrepreneur where she participated in formation development of nine companies from 1999 to 2004. She previously served on the senior management teams and counsel at TransVascular, Inc. (acquired by Medtronic), AneuRx, Inc. (acquired by Medtronic), and VidaMed Inc. (through IPO). Ms. Macfarlane is an inventor on 25 U.S. issued patents. She received her BA in Business Administration from San Francisco State University, and her J.D. from Golden Gate University School of Law. She currently serves on the board of Perceive Biotherapeutics, Inc., ForSight VISION6, Inc., Recognify Life Sciences, Inc., Spiral Therapeutics, Inc., the non-profit Fogarty Innovation and is a mentor in the Ferolyn Powell Leadership Program.

Ms. Macfarlane brings extensive operational, business development and management expertise to our Board. She has extensive experience in drug/device combination therapies with successful exits to large biotech/pharma companies. Her experience leading and growing companies is invaluable to us as we continue to develop our pipeline and identify new indications and small molecules to be used with our therapy platform. Ms. Macfarlane's background and experience positions her well to serve as the Chairperson of the Compensation Committee and as a member of the Nominating and Corporate Governance Committee.

Laurence J. Marton, M.D. Dr. Marton has served as our director since December 2012. In addition, in the nonprofit sector, Dr. Marton serves on the Board of Trustees of the American Association for Cancer Research Foundation and on the Board of Directors of Cancer Commons. In the for-profit sector, he serves on the boards of Cellsonics Inc., Matternet Inc., Microsonic Systems Inc., Nanotics LLC, Omniox Inc., and xCures Inc., and is an advisor to Assurance Health Data, Enable Medicine Inc., Immunai Inc., PharmaJet, Inc., and the Precision Medicine World Conference. Previously, Dr. Marton was Dean of the University of Wisconsin Medical School and Chaired the Department of Laboratory Medicine at UCSF, where he was a Professor in the Departments of Laboratory Medicine and Neurological Surgery. Dr. Marton received his M.D. from the Albert Einstein College of Medicine.

Dr. Marton brings deep experience in cancer research and treatment, operational expertise and years of working in the life sciences industry to our Board. His strategic advisory experience and membership on boards of various organizations make him a valuable member of our Audit and Nominating and Corporate Governance Committees.

Una S. Ryan, O.B.E., Ph.D., D.Sc. Dr. Ryan has served as our director since 2013. Dr. Ryan has extensive experience leading public, private and non-profit companies. She serves on the boards of Cortexyme, Inc. (CRTX), Elemental Machines, Inc. (chair), Cambridge in America, and Bristol University US Foundation (chair). Dr. Ryan is a limited partner at Breakout Ventures, L.P. and Lionheart Ventures Fund, L.P. She focuses on women-led ventures as Managing Director of Golden Seeds, and partner in Astia Angels. She has a large portfolio of early-stage companies in San Francisco and Boston. She was a serial CEO of Diagnostics for All, Inc., Waltham Technologies, Inc., and AVANT Immunotherapeutics, Inc. (now Celldex Therapeutics, Inc.). Continuing a career translating science to successful businesses, Dr. Ryan is now translating science to art and founded ULUX (www.uluxart.com) bringing science perspectives to the art world. Dr. Ryan holds a Ph.D. from Cambridge University, B.Sc. degrees and honorary D.Sc. from Bristol University. Her academic career included Professorships of Medicine at Miami, Washington and Boston Universities. She held the titles Howard Hughes Investigator, American Heart Association Established Investigator, and NIH MERIT Awardee. She has received numerous awards including the Albert Einstein Award (2007) for outstanding achievement in the life sciences, the Cartier Award (2009) and World Economic Forum Tech Pioneer (2011). In 2002, Her Majesty Queen Elizabeth II awarded Dr. Ryan the Order of the British Empire (OBE).

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Dr. Ryan brings both extensive operations, investment and life sciences industry experience to our Board. Her public company operational, financial and corporate governance experience is a valuable resource to our Board and makes her well-positioned to serve as the Chair of the Nominating and Governance Committee and member of the Audit Committee.

Family Relationships

There are no family relationships between any of the Company's directors or executive officers.

Involvement in Certain Legal Proceedings

During the past ten years, none of our directors or executive officers are involved in any legal proceedings described in Item 401(f) of Regulation S-K.

Corporate Governance

Code of Ethics

The Board has adopted a Code of Business Conduct and Ethics applicable to all members of the Board, executive officers and employees of the Company, which constitutes our "code of ethics" within the meaning of Section 406 of the Sarbanes-Oxley Act of 2002. A copy of the Code of Business Conduct and Ethics is available on our website at www.renovorx.com. We intend to satisfy the disclosure requirement under Item 5.05 of Form 8-K regarding an amendment to, or waiver from, a provision of our Code of Business Conduct and Ethics by posting such information on our website within four business days following the date of the amendment or waiver.

Audit Committee

The Board has established a standing Audit Committee consisting of Mr. Diamond (Chair), Drs. Ryan, and Marton.

Each member of our Audit Committee is considered an "independent director," as defined in the Nasdaq Stock Market, Inc. Marketplace Rule (the "Nasdaq Marketplace Rule") 5605(a)(2) and meets the criteria for independence set forth in Rule 10A-3(b)(1) of the Exchange Act, as determined by our Board. All members of our Audit Committee meet the financial literacy requirements under applicable rules and regulations of the SEC and Nasdaq Marketplace Rules. Our Board has determined that each of Mr. Diamond and

Dr. Ryan qualify as an "audit committee financial expert" as such term is defined in Item 407(d)(5)(ii) of Regulation S-K. In making this determination, our Board considered each of Mr. Diamond's and Dr. Ryan's prior experience, business acumen and independence, as discussed in the section titled "*Business Experience.*"

ITEM 11. EXECUTIVE COMPENSATION

Our Compensation Committee is responsible for the executive compensation programs for our executive officers and reports to our Board on its discussions, decisions and other actions. This section presents information concerning compensation arrangements for our named executive officers (NEOs) for the years ended December 31, 2021 and 2020. After the information on our NEOs, we also provide information relating to the compensation of our directors (other than Mr. Bagai and Dr. Agah).

Summary Compensation Table

The following table sets forth information concerning the compensation of our NEOs for the years ended December 31, 2021 and 2020.

Name and Position	Year	Salary ($)	Bonus ($)	Option Awards[1] ($)	Total ($)
Shaun R. Bagai	2021	322,813	160,000[2]	504,938	987,751
Chief Executive Officer	2020	253,000			253,000
Christopher J. Lehman	2021	129,700[3]			129,700
Chief Financial Officer	2020				
Ramtin Agah, M.D.	2021	166,668	50,000[4]	223,638	440,306
Chief Medical Officer	2020	120,180			120,180
Paul Manners[5]	2021	160,650			
Former Vice President, Finance and Principal Financial Officer	2020	43,421		7,030	50,451

(1) The amounts in this column represent the aggregate grant date fair value of the stock option awards computed in accordance with FASB guidance on stock-based compensation. The relevant assumptions made in the valuations for the 2021 and 2020 stock option awards may be found in Note 9 of the Notes to the Financial Statements in our 2021 Annual Report on Form 10-K. The grant date fair value of stock options is determined based on the number of options awarded and the fair value of the stock option on the grant date, which is the Black Scholes value of closing sales price per share of our common stock.

(2) Represents (i) a $70,000 bonus paid to Mr. Bagai in connection with the completion of our IPO and (ii) a discretionary bonus payment of $90,000 paid to Mr. Bagai in recognition of Company and individual performance during the year ended December 31, 2021.

(3) Amount represents fees paid to LS Associates, a division of LifeSci Advisors, LLC, relating to the consulting arrangement under which Lehman, a representative of LifeSci Advisors, was engaged initially as a consultant and then in August 2021 as our Chief Financial Officer. Pursuant to such consulting arrangement the Company paid LifeSci Advisors an hourly rate of $400.00 per hour for Mr. Lehman's services.

(4) Represents a discretionary bonus payment of $50,000 paid to Dr. Agah in recognition of Company and individual performance during the year ended December 31, 2021.

(5) Mr. Manners' Consulting Agreement terminated in December 2021.

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Outstanding Equity Awards as of December 31, 2021

The following table sets forth information with respect to outstanding equity awards for each of our NEOs as of December 31, 2021.

	Option Awards				
Name	Grant Date	Number of Shares of Stock Underlying Unexercised Options Exercisable	Number of Shares of Stock Underlying Unexercised Options Unexercisable	Option Exercise Price	Option Expiration Date
Shaun R. Bagai	03/19/2017	60,000	—	$ 0.50	05/18/2027
	07/11/2018	110,000	10,000[1]	$ 0.65	07/11/2028
	09/30/2021	9,822	108,044[2]	$ 6.04	09/30/2031
Ramtin Agah, M.D.	05/19/2017	60,000	—	$ 0.50	05/18/2027
	07/11/2018	36,667	3,333[1]	$ 0.65	07/11/2028
	06/04/2021	5,833	14,167[3]	$ 2.45	06/03/2031
	09/30/2021	4,350	47,853[2]	$ 6.04	09/30/2031
Paul Manners	02/05/2020	4,667	—	$ 0.70	02/04/2030

(1) Stock option vests over four years, with 25% vesting on April 19, 2019, the first anniversary of the vesting commencement date, and the remainder vesting monthly thereafter, subject to continued service with us through the applicable vesting date.

(2) Stock option vests monthly over four years commencing on September 26, 2021, subject to continued service with us through the applicable vesting date.

(3) Stock option vests monthly over two years commencing on June 14, 2021, subject to continued service with us through the applicable vesting date.

Narrative Disclosure to Summary Compensation Table

The primary elements of compensation for our NEOs are base salary, annual performance bonuses and equity awards. The NEOs also participate in employee benefit plans and programs that we offer to our other employees, as described below.

Annual Base Salary

We pay our NEOs a base salary, base consulting fee or hourly consulting fee to compensate them for the satisfactory performance of services rendered to us. The base compensation payable to each NEO is intended to provide a fixed component of compensation reflecting the executive's skill set, experience, role and responsibilities.

Our Compensation Committee will periodically review the base salaries of our NEOs and will make adjustments as necessary to maintain base compensation at competitive levels.

In August 2021, Mr. Bagai's base salary was increased from $300,000 to $363,000. In March 2022, Mr. Bagai's annual base salary was increased to $495,000, retroactively effective to January 1, 2022, to align Mr. Bagai's compensation more closely to the 50th percentile of the peer group of companies that the Company benchmarks its compensation against. In November 2021, we entered into a third amendment to the Consulting Agreement with Dr. Agah whichprovides for a monthly consulting fee of $21,667.67, based on Dr. Agah spending no less than 24 hours per week on Company matters. Dr. Agah's monthly consulting fee was increased to $24,083.33 effective January 1, 2022. The Company may, in its discretion, proportionally adjust the monthly consulting fee if Dr. Agah's time commitment decreases.

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Bonus Compensation

For 2020 and 2021, annual bonuses were based on such factors as the Board deemed appropriate, including the achievement of certain corporate performance goals. In connection with our IPO, Mr. Bagai received a $70,000 bonus. In December 2021, Mr. Bagai and Dr. Agah received an annual bonus based on the achievement of certain clinical and company milestones of $90,000 and $50,000, respectively.

Mr. Bagai and Dr. Agah have an established annual bonus target of 50% and 35% of annual base salary, respectively.

In November 2021, the Board adopted a Key Service Provider Incentive Compensation Plan, which is described below in more detail, pursuant to which future bonus compensation goals and payments for Mr. Bagai and Dr. Agah will be established, evaluated, and paid.

Equity-Based Incentive Awards

Our equity-based incentive awards are designed to align our interests and the interests of our stockholders with those of our employees and consultants, including our NEOs. In general, the Board or its Compensation Committee is responsible for approving equity grants. Following our IPO, we generally grant equity awards to our employees, including our NEOs, as long-term incentive components of our compensation program. We typically grant equity awards to new hires upon their commencing employment with us. Additionally, we may grant equity awards at such times as the Board determines appropriate. Generally, our equity awards vest over four years, subject to the employee's continued employment with us on each vesting date.

In September 2021, we granted Mr. Bagai an option to purchase 117,866 shares of our common stock under our 2021 Omnibus Equity Incentive Plan (the "2021 Plan"). The options vest monthly over a 48-month period and have an exercise price of $6.04, which was the fair market value of our common stock on the grant date. In March 2022, we granted Mr. Bagai options to purchase an additional 48,313 shares of our common stock under the 2021 Plan. The options vest monthly over a 48-month period and have an exercise price of $3.17, which was the fair market value of our common stock on the grant date.

In June 2021, we granted Dr. Agah an option to purchase 20,000 shares of our common stock under our 2013 Equity Incentive Plan. The options vest monthly over a 24-month period and have an exercise price of $2.45 per share, which was the fair market value of our common stock on the grant date as determined by our Board. In September 2021, we granted Dr. Agah an option to purchase 52,203 shares of our common stock under our 2021 Omnibus Equity Incentive Plan. The options vest monthly over a 48-month period and have an exercise price of $6.04 per share, which was the fair market value of our common stock on the grant date. In March 2022, we granted Dr. Agah options to purchase an additional 21,398 shares of our common stock under the 2021 Plan. The options vest monthly over a 48-month period and have an exercise price of $3.17, which was the fair market value of our common stock on the grant date.

Other Elements of Compensation

Perquisites, Health, Welfare and Retirement Benefits

Our NEOs are eligible to participate in our employee benefit plans, including our medical, dental and vision plans, in each case on the same basis as all of our other employees.

We generally do not provide perquisites or personal benefits to our NEOs, except in limited circumstances.

401(k) Plan

Effective January 2022, we established a defined contribution employee retirement plan, or 401(k) plan, for our employees. Our NEOs are eligible to participate in the 401(k) plan on the same basis as our other employees. The 401(k) plan is intended to qualify as a tax-qualified plan under Section 401(k) of the U.S. Internal Revenue Code of 1986, as amended (the Code). The 401(k) plan provides that each participant may make pre-tax deferrals from his or her compensation up to the statutory limit, which is $20,500 for calendar year 2021, and other testing limits. Participants that are 50 years or older can also make "catch-up" contributions, which in calendar year 2021 may be up to an additional $6,500 above the statutory limit. Commencing in 2022, we will make matching contributions of 100% of employee contributions up to 4% of their eligible compensation. Participant contributions are held and invested, pursuant to the participant's instructions, by the plan's trustee.

Employment Agreements with our Named Executive Officers

Shaun R. Bagai

Mr. Bagai has been our Chief Executive Officer since 2014, initially as a consultant. In December 2015, we entered into an offer letter with Mr. Bagai that set forth the terms and conditions of his employment. The letter became effective on January 1, 2016, and was amended in June 2017 and December 2020. The most recent amended offer letter provided for (i) an annual base salary of $300,000; (ii) a $2,500 monthly stipend for Mr. Bagai's health insurance expenses, which continued until we begin offering health insurance as a benefit to all employees; (iii) a $70,000 bonus to be paid in connection with the IPO; and (iv) an additional performance bonus upon achievement of certain clinical and company milestones established by the Board in 2021. Upon consummation of our IPO, Mr. Bagai's annual base salary was increased to $363,000.

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In November 2021, we entered into a Confirmatory Employment Letter with Mr. Bagai. The Confirmatory Employment Letter has no specific term and provides that Mr. Bagai is an at-will employee. The Confirmatory Employment Letter supersedes all existing agreements and understandings that Mr. Bagai may have entered into concerning his employment relationship with us. In March 2022, Mr. Bagai's annual base salary was increased from to $495,000 from $363,000, retroactively effective to January 1, 2022. Mr. Bagai is eligible for an annual target cash incentive bonus equal to 50% of his annual base salary and will also be entitled to receive other employee benefits generally available to all employees of the Company. In November 2021, we entered into a Change in Control and Severance Agreement with Mr. Bagai, the terms of which are described below under the heading "Change in Control and Severance Agreement."

Ramtin Agah, M.D.

In January 2018, we entered into a consulting agreement with Dr. Agah, pursuant to which Dr. Agah provides consulting services as our Chief Medical Officer by overseeing Company-sponsored clinical trials. The Agreement continues in force for as long as Dr. Agah is providing consulting services and may be terminated by either party on thirty (30) days' notice. Initially, the sole compensation payable to Dr. Agah was the continued vesting of his options to purchase shares of common stockIn December 2018, Dr. Agah's agreement was amended to provide that he would receive cash compensation of $4,000 per month for certain proctoring services, and in September 2019, his

compensation was increased to $10,000 per month to compensate for additional services he was providing. In November 2021, we entered into a third amendment to the Consulting Agreement with Dr. Agah which provides for a monthly consulting fee of $21,667.67, based on Dr. Agah spending no less than 24 hours per week on Company matters. Dr. Agah's monthly consulting fee was increased to $24,083.33 effective January 1, 2022. The Company may, in its discretion, proportionally adjust the monthly consulting fee if Dr. Agah's time commitment decreases. Dr. Agah's agreement also provides for his eligibility for an annual target cash incentive bonus equal to 35% of his annualized base consulting fee. In November 2021, we entered into a Change in Control and Severance Agreement with Dr. Agah, the terms of which are described below under the heading "Change in Control and Severance Agreement."

Christopher J. Lehman

Christopher J. Lehman became our Chief Financial Officer in August 2021. In July 2021, we entered into an agreement with LS Associates, Inc., or LS, pursuant to which Mr. Lehman serves as our Chief Financial Officer. The term of the agreement is for two years, and we will be billed monthly by LS at a rate of $400 per hour.

Paul Manners

Mr. Manners served as a consultant from July 2019 to December 2021. Mr. Manners served as our Chief Financial Officer through July 2021 and then served as our Vice President of Finance and Principal Financial Officer. In August 2021, Mr. Manner's stepped down from his role as Principal Financial Officer. Under his original consulting agreement, Mr. Manners received a consulting fee of $50 per hour, which was increased to $150 per hour in December 2020.

Change In Control and Severance Agreements

In November 2021, we entered into a Change in Control and Severance Agreement, or theSeverance Agreement, with each of Mr. Bagai and Dr. Agah (each an "Executive" and collectively, the "Executives"). Capitalized terms used herein and not otherwise defined shall have the meaning assigned to such term in the Severance Agreement. Each Severance Agreement will continue indefinitely until terminated by written consent of the parties to the Severance Agreement.

Termination Outside of Change in Control Period

Under the Severance Agreement, if Mr. Bagai or Dr. Agah are terminated outside a period beginning on the date of a Change in Control and ending on (and inclusive of) the date that is the one-year anniversary of a Change in Control (the "Change in Control Period"), either by us without Cause (other than due to death or Disability) or by the Executive for Good Reason, they will receive:

- Annual Base Compensation Severance: A single, lump sum payment equal to the specified percent of the Executive Officer's Annual Base Compensation (which is base salary or, for Dr. Agah, annual base consulting fee, if applicable), which was in effect immediately before such termination (or, if the termination is due to a resignation for Good Reason based on a material reduction in the Executive Officer's annual base salary (or, for Dr. Agah, annual base consulting fee, if applicable), then Executive's annual base salary (or, for Dr. Agah, annual base consulting fee, if applicable) in effect immediately prior to the reduction), or if greater, the base salary (or, for Dr. Agah, annual base consulting fee, if applicable), in effect immediately prior to the Change in Control):

  (i) Mr. Bagai: 100% of Annual Base Compensation
  (ii) Dr. Agah: 50% of Annual Base Compensation; and

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- Bonus Severance: A single, lump sum payment of the pro rata portion (based on period of employment) of the Executive Officer's target bonus in effect immediately before such termination or if greater, the target bonus in effect immediately prior to the Change in Control; and

- COBRA Severance: payment or reimbursement of COBRA continuation coverage premiums for group health, dental and vision coverage for the Executive Officer and his eligible dependents, for:

  (i) Mr. Bagai: up to 12 months
  (ii) Dr. Agah (if he was an employee immediately prior to the termination): up to 6 months

Or, if providing such payment would violate applicable law, a taxable payment for an equivalent amount in lieu thereof.

Termination During Change in Control Period

Under the Severance Agreement, if Mr. Bagai or Dr. Agah are terminated during the Change in Control Period, either by us without Cause (other than due to death or Disability), or by the Executive for Good Reason, they will receive:

- Base Compensation Severance: A single, lump sum payment equal to the specified percent of the Executive Officer's Annual Base Compensation:

  (i) Mr. Bagai: 150% of Annual Base Compensation
  (ii) Dr. Agah: 100% of Annual Base Compensation; and

- COBRA Severance: payment or reimbursement of COBRA continuation coverage premiums for group health, dental and vision coverage for the executive officer and his eligible dependents, for:

  (i) Mr. Bagai: up to 18 months
  (ii) Dr. Agah (if he was an employee immediately prior to the termination): up to 12 months

Or, if providing such payment would violate applicable law, a taxable payment for an equivalent amount in lieu thereof; and

- Vesting Acceleration of Service-based Equity Awards: Full vesting of the outstanding and unvested equity awards (other than equity award subject to performance-based vesting criteria).

The Severance Agreement provides that if any payments or benefits received by Mr. Bagai or Dr. Agah under the Severance Agreement or otherwise would constitute "parachute payments" within the meaning of Section 280G of the Internal Revenue Code (the "Code") and be subject to excise taxes imposed by Section 4999 of the Code, such amount will either be delivered in full or reduced so as not to be subject to excise taxation, whichever amount is higher. The Severance Agreement does not require us to provide any tax gross-ups.

To receive the severance described above, the Executive Officers must sign and not revoke our standard separation agreement and release of claims within the timeframe that is set forth in the Severance Agreement.

Key Service Provider Incentive Compensation Plan

In November 2021, our Board adopted a Key Service Provider Incentive Compensation Plan, or Bonus Plan, and determined that our Compensation Committee will be the administrator of the Bonus Plan. The Bonus Plan allows the Compensation Committee (i) determine which employees or other service providers may receive incentive awards under the Bonus Plan, and (ii) provide incentive awards to selected employees, including our NEOs and other service providers, which may be based upon performance goals established by our Compensation Committee. Our Compensation Committee, in its sole discretion, may establish a target award for each participant under the Bonus Plan, which may be expressed as a percentage of the participant's average annual base salary for the applicable performance period or a fixed dollar amount or such other amount or based on such other formula or factors as the Compensation Committee determines.

Under the Bonus Plan, our Compensation Committee will determine the performance goals, if any, applicable to awards and such performance goals may differ from participant to participant and from award to award. Performance goals may be based on any factors our Compensation Committee determines relevant, including, without limitation, on an individual, divisional, portfolio, project, business unit, segment, or Company-wide basis, and may include criteria related to research and development, regulatory, business development, financial and operational performance or other subjective or objective criteria. Any criteria used may be measured on such basis as our Compensation Committee determines. As determined by our Compensation Committee, the performance goals may be based on GAAP or non-GAAP results and any actual results may be adjusted by our Compensation Committee for one-time items or unbudgeted or unexpected items and/or payment of actual awards when determining whether the performance goals have been met.

Our Compensation Committee, at any time prior to payment of an actual award, may increase, reduce or eliminate a participant's actual award, and/or increase, reduce or eliminate the amount allocated to the bonus pool. The actual award may be below, at or above a participant's target award, in our Compensation Committee's discretion. Our Compensation Committee may determine the amount of any increase, reduction or elimination of an actual award based on such factors as it deems relevant, and it will not be required to establish any allocation or weighting with respect to the factors it considers.

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Actual awards generally will be paid in cash (or its equivalent) in a single lump sum. The Compensation Committee reserves the right to settle an actual award with a grant of an equity award with such terms and conditions, including any vesting requirements, as determined by the Compensation Committee. Unless otherwise determined by our Compensation Committee, to earn an actual award, a participant must be employed by us (or an affiliate of us, as applicable) on the date the bonus is paid. Payment of bonuses occurs as soon as practicable after the end of the applicable performance period, but no later than the dates set forth in the Bonus Plan.

All awards under the Bonus Plan will be subject to reduction, cancellation, forfeiture, or recoupment in accordance with any clawback policy that we are required to adopt pursuant to any rule, regulation, or law. Our Compensation Committee may also impose such other clawback, recovery or recoupment provisions with respect to an award under the Bonus Plan as it may determine is necessary or appropriate.

If we are required to prepare an accounting restatement due to our material noncompliance, as a result of misconduct, with any financial reporting requirement under the securities laws, then any participant who knowingly or through gross negligence engaged in, or failed to prevent, the misconduct, will reimburse us for the amount of any payment with respect to an award earned or accrued under the Bonus Plan during the twelve month period following the first to occur of the public issuance or filing with the SEC, of the financial document embodying such financial reporting requirement.

Our Board or its Compensation Committee will have the authority to amend or terminate the Bonus Plan provided such action does not alter or impair the existing rights of any participant with respect to any earned bonus without the participant's consent. The Bonus Plan will remain in effect until terminated in accordance with the terms of the Bonus Plan.

Director Compensation

Prior to our IPO, we did not have a formal policy with respect to compensation payable to our non-employee directors for their service as directors. From time to time, we have granted equity awards to attract them to join our Board and for their continued service on our Board. We also have reimbursed our directors for expenses associated with attending meetings of our Board and its committees.

In 2021, our Compensation Committee retained Compensia, a third-party compensation consultant, to provide our Board and the Compensation Committee with an analysis of publicly available market data and assistance in determining compensation to be provided to our non-employee directors following our IPO. Based on the discussions with and assistance from Compensia, the Board developed an equity compensation framework for our non-employee directors for 2021 service and in November 2021, the Board adopted an Outside Director Compensation Policy. For 2021, the Board determined to grant Mr. Diamond, who joined our Board in May 2021, an initial option grant with a grant date fair value of $120,000, which would vest and become exercisable monthly over three years. The Board determined to grant all non-employee directors options with a grant date fair value of $65,000, which would vest and become exercisable monthly over 12 months.

The following table provides information regarding compensation of our non-employee directors, other than Dr. Agah who is also a NEO, for service as directors for the year ended December 31, 2021. Dr. Agah does not receive any additional compensation as a director. For information on Dr. Agah's compensation, see – "Summary Compensation Table."

Name	Fees Earned or Paid in Cash ($)	Options Awards[1][2] ($)	Total Compensation ($)
David Diamond	18,667	140,168[3]	158,835
Kirsten Angela Macfarlane	17,000	46,724[4]	63,724
Laurence J. Marton, M.D.	15,333	46,724[4]	62,057
Una S. Ryan, O.B.E., Ph.D., D.Sc.	17,000	46,724[4]	63,724
Former Director			
Mahkam Zanganeh, DDS[5]	-	-	-

(1) The number of unexercised stock options held by the directors named in the above table as of December 31, 2021, was as follows: Mr. Diamond (35,462), Ms. Macfarlane (43,154), Dr. Marton (89,072), and Dr. Ryan (27,154).

(2) The amounts in this column represent the aggregate grant date fair value of the stock option awards computed in accordance with FASB guidance on stock-based compensation. The relevant assumptions made in the valuations for the 2021 and 2020 stock option awards may be found in Note 9 of the Notes to the Financial Statements in our 2021 Annual Report on Form 10-K. The grant date fair value of stock options is determined based on the number of options awarded and the fair value of the stock option on the grant date, which is the Black Scholes value of closing sales price per share of our common stock.

(3) Mr. Diamond joined our Board in May 2021. In May 2021, he was granted a stock option to purchase 2,000 shares of common stock, which vests and become exercisable over 12 months, with $1/12^{th}$ vesting on the 14^{th} day of each month commencing on June 14, 2021. In September 2021, he was granted a stock option to purchase 22,308 shares of common stock, which vests and become exercisable over three years, with $1/36^{th}$ vesting on the 26^{th} day of each month commencing on October 26, 2022.

(4) On October 1, 2021, each non-employee director was granted a stock option to purchase 11,154 shares of common stock, which vests and become exercisable over 12 months, with $1/12^{th}$ vesting monthly on the first day of each month commencing on November 1, 2021.

(5) Dr. Zanganeh resigned from the Board in August 2021.

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Outside Director Compensation Policy

Under our Outside Director Compensation Policy, each non-employee director, other than Dr. Agah, receives the cash and equity compensation for his or her services as a member of our Board, as described below. We also will continue to reimburse our non-employee directors for reasonable, customary, and documented travel expenses to meetings of our Board or its committees.

The Outside Director Compensation Policy includes a maximum annual limit of $250,000 of cash compensation and equity awards that may be paid, issued, or granted to a non-employee director in any fiscal year (increased to $300,000 in the fiscal year in which the non-employee director joins the Board). For purposes of these limitations, the value of an equity award is based on its grant date fair value. Any cash compensation paid or equity awards granted to a person for his or her services as an employee, or for his or her services as a consultant (other than as a non-employee director), will not count for purposes of the limitation. The maximum limit does not reflect the intended size of any potential compensation or equity awards to our non-employee directors.

Cash Compensation

Non-employee directors are paid an annual cash retainer of $36,000. In addition, each non-employee director who serves as the chair or a member of a committee of the Board will be eligible to earn additional annual cash fees as follows:

- $15,000 per year for service as Chair of the Audit Committee;
- $10,000 per year for service as Chair of the Compensation Committee;
- $10,000 per year for service as Chair of the Nominating and Corporate Governance Committee; and
- $5,000 per year for service as a member of each of the Audit, Compensation, and Nominating and Corporate Governance committees.

Equity Compensation

Initial Options

Each individual who first becomes a non-employee director will be granted options at a grant date fair value of $120,000 in the aggregate (an "Initial Award"), on the date on which such individual first becomes a non-employee director, whether through election by the stockholders of the Company or appointment by the Board to fill a vacancy. Each Initial Award will vest and become exercisable over three years, with $1/36^{th}$ of the Initial Award vesting each month on the same day of the month as the commencement of the applicable individual's service as non-employee director.

Annual Options

On October 1 of each year, commencing October 1, 2022, each non-employee director will be automatically granted options at a grant date fair value of $70,000 in the aggregate (an "Annual Award"). Each Annual Award will vest and become exercisable over 12 months, with $1/12^{th}$ of the Annual Award vesting monthly after October 1 on the first day of each subsequent month. On October 1, 2021, each non-employee director was granted options at a fair market value of $65,000. These options vest and become exercisable over 12 months, with $1/12^{th}$ of the Annual Award vesting monthly after October 1 on the first day of each subsequent month.

Change in Control

In the event of our "change in control" (as defined in the Outside Director Compensation Policy), each non-employee director will fully vest in his or her outstanding company equity awards provided that the non-employee director continues to be a non-employee director through the date of our change in control.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The following table shows information regarding the beneficial ownership of our common stock as of March 15, 2022 for the following:

- Each stockholder known by us to beneficially own more than 5% of our common stock;
- Each of our directors;
- Each named executive officer named in the "Named Executive Officers"; and
- All directors and executive officers as a group.

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The table is based on information supplied to us by directors, executive officers and principal stockholders and filings under the Exchange Act. We have based our calculation of the percentage of beneficial ownership on 9,017,589 shares of our common stock issued and outstanding as of March 15, 2022, unless otherwise noted. The beneficial ownership reported in the following table is determined in accordance with the applicable rules of the SEC and does not necessarily indicate beneficial ownership for any other purpose. For purposes of the following tables, an entity or individual is considered the beneficial owner of shares of common stock if he or she has the right to acquire within 60 days of March 15, 2022, such common stock and directly or indirectly has or shares voting power or investment power, as defined in the rules of the SEC, with respect to such shares.

Except as indicated in the footnotes below, the address of the persons or groups named below is c/o RenovoRx, Inc., 4546 El Camino Real, Suite B1 Los Altos, California 94022.

	Beneficial Ownership	
Name of Beneficial Owner	**Shares**	**Percentage**
5% or Greater Stockholders:		
Kamran Najmabadi[(1)]	1,045,000	11.51%
Boston Scientific Corporation[(2)]	543,971	6.03%

Named Executive Officers and Directors:		
Shaun R. Bagai[3]	453,753	4.92%
Christopher J. Lehman	-	-
Ramtin Agah, M.D.[4]	1,099,856	12.03%
Laurence J. Marton, M.D.[5]	87,096	*
Una S. Ryan, O.B.E., Ph.D., D.Sc. [5]	23,844	*
Kirsten Angela Macfarlane[5]	38,511	*
David Diamond[5]	18,171	*
All executive officers and directors as a group (7 persons)	1,721,233	18.80%

* Less than 1% of outstanding shares.

(1) Based solely on the Schedule 13G filed with the SEC on February 14, 2022. Consists of (i) 10,000 shares of common stock over which Mr. Najmabadi has sole voting and dispositive power, (ii) 60,000 shares of common stock underlying stock options that are currently exercisable, (iii) 731,250 shares of common stock held by The Najmabadi Family Trust dated April 22, 2021, for which Mr. Najmabadi serves as trustee, (iv) 121,875 shares of common stock held by The Navid Najmabadi Irrevocable Trust dated April 22, 2021, for which Mr. Najmabadi serves as trustee, and (v) 121,875 shares of common stock held by The Leili Najmabadi Irrevocable Trust dated April 22, 2021, for which Mr. Najmabadi serves as trustee.

(2) Based solely on the Schedule 13G filed with the SEC on February 10, 2022. Consists of 543,971 shares of common stock over which Boston Scientific Corporation has sole voting and dispositive power. The address of Boston Scientific Corporation is 300 Boston Scientific Way, Marlborough, MA 01752.

(3) Includes 246,057 shares of common stock and 207,696 shares of common stock underlying stock options that are exercisable within 60 days of March 15, 2022.

(4) Includes 976,295 shares of common stock, 1,295 shares of common stock issuable upon the exercise of warrants, and 122,266 shares of common stock underlying stock options that are exercisable within 60 days of March 15, 2022.

(5) Consists of shares of common stock underlying stock options that are exercisable within 60 days of March 15, 2022.

Equity Compensation Plan Information

All of our equity compensation plans have been approved by our stockholders. The following table provides information as of December 31, 2021, with respect to the shares of our common stock that may be issued under our existing equity compensation plans.

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights (a)	Weighted Average Exercise Price of Outstanding Options, Warrants and Rights (b)	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a))[1] (c)
2013 Equity Incentive Plan	684,327	$ 0.65	-
2021 Omnibus Equity Incentive Plan	244,052	$ 6.08	1,941,780
Total	926,379		

(1) The 2021 Plan provides an annual increase on the first day of each calendar year beginning with January 1, 2022 and ending with the last January 1 during the initial ten-year term of the 2021 Plan, equal to the lesser of (a) three percent (3%) of the shares outstanding on the final day of the immediately preceding calendar year; (b) 343,734 shares; and (c) such lesser number of shares as determined by the Board.

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ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The following includes a summary of transactions since January 1, 2020 to which we have been a party in which the amount involved exceeded or will exceed the lesser of $120,000 or 1% of the average of our total assets as of December 31, 2021 and 2020, and in which any of our directors, executive officers or, to our knowledge, beneficial owners of more than 5% of our capital stock or any member of the immediate family of any of the foregoing persons had or will have a direct or indirect material interest, other than equity and other compensation, termination, change in control and other arrangements, which are described under Item 11. “Executive and Director Compensation” of this Annual Report on Form 10-K, see also Note 13, *Related Party Transactions*.

Mr. Kamran Najmabadi, one of our co-founders, has served as our consulting technical engineering advisor on manufacturing and intellectual property matters since January 2020. Previously Mr. Najmabadi was our CEO from December 2009 until January 2013; Chief Technical and Operations Officer from January 2013 until January 2019; and Chief Technology Officer from January 2019 to January 2020. Mr. Najmabadi currently receives cash compensation quarterly of $3,000. He received option grants in 2016 and 2018, which are now fully vested.

Policies and Procedures for Related Person Transactions

Our Board has adopted a written related person transaction policy, setting forth the policies and procedures for the review and approval or ratification of related person transactions. This policy covers, with certain exceptions set forth in Item 404 of Regulation S-K under the Securities Act, any transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships, in which we were or are to be a participant, where the amount involved exceeds the lesser of $120,000 or 1% of the average of our total assets at year-end for the last two completed fiscal years and a related person had, has or will have a direct or indirect material interest, including without limitation, purchases of goods or services by or from the related person or entities in which the related person has a material interest, indebtedness, guarantees of indebtedness and employment by us of a related person. In reviewing and approving any such transactions, our Audit Committee is tasked to consider all relevant facts and circumstances, including, but not limited to, whether the transaction is on terms comparable to those that could be obtained in an arm’s length transaction and the extent of the related person’s interest in the transaction. All of the transactions described in this section occurred prior to the adoption of this policy.

Director Independence

It is our policy that a majority of the members of the Board be independent of our management. For a director to be deemed independent, the Board must affirmatively determine that the director has no direct or indirect material relationship with our company other than in his or her capacity as a board member. To assist the Board in determining which of our directors qualify as independent for purposes of Nasdaq rules, as well as applicable rules and regulations adopted by the SEC, the Nominating and

Corporate Governance Committee of the Board follows Nasdaq's corporate governance rules on the criteria for director independence.

The Board has determined that each of David Diamond, Kirsten Angela MacFarlane, Laurence Marton, and Una Ryan qualifies as an independent director of our Company.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

On December 7, 2021, following a competitive selection process, the Audit Committee of our board of directors approved the engagement of Baker Tilly US, LLP as the Company's independent registered public accounting firm for the December 31, 2021 audit. Frank, Rimerman + Co. LLP served as our independent registered public accounting firm for the year ended December 31, 2020.

The following table represents aggregate fees incurred for professional audit services rendered by Frank Rimerman + Co. LLP during the years ended December 31, 2021 and 2020.

	December 31,	
	2021	2020
Audit Fees [1]	$ 47,250	$ 181,000
Audit Related Fees	-	-
Tax Fees[2]	-	-
All Other Fees	-	-
Total	$ 47,250	$ 181,000

(1) Audit fees represent fees for professional services rendered for the audit of our financial statements, review of interim financial statements and services normally provided by the independent registered public accounting firm in connection with regulatory filings, including registration statements.

(2) Represents fees for tax services, including tax compliance, tax advice, filing of tax returns and tax planning provided during the ordinary course of operations.

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The following table sets forth the fees accrued or paid to Baker Tilly US, LLP, in connection with our December 31, 2021 audit.

	December 31,
	2021
Audit Fees [1]	$ 105,000
Audit Related Fees	-
Tax Fees	-
All Other Fees	-
Total	$ 105,000

(1) Audit fees represent fees for professional services rendered for the audit of our financial statements, review of interim financial statements and services normally provided by the independent registered public accounting firm in connection with regulatory filings, including registration statements.

Pre-Approval of Audit and Non-Audit Services

In accordance with its Charter, the Audit Committee pre-approves all audit and permitted non-audit and tax services provided by our independent registered public accounting firm.

Prior to the annual engagement of our independent registered public accounting firm, the Audit Committee pre-approves all services to be provided. During the year, circumstances may arise when it may become necessary to engage the independent registered public accounting firm for additional services. In such circumstances, our management seeks approval of the non-audit services that it recommends the Audit Committee engage the independent registered public accounting firm to provide for the fiscal year. A budget, estimating the specific non-audit service spending for the fiscal year, is provided to the Audit Committee along with the request. The Audit Committee will be regularly informed of the non-audit services actually provided by the independent auditor pursuant to this pre-approval process. All fees paid to Frank Rimerman + Co. LLP for the fiscal years ended December 31, 2021 and 2020 and all fees accrued or paid to Baker Tilly US, LLP, in connection with our December 31, 2021 audit were pre-approved by either our Board or our Audit Committee.

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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

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 Form 10-K.

3. Exhibits

See "Exhibit Index" immediately preceding the signature page of this Form 10-K, which is incorporated herein by reference.

ITEM 16. FORM 10-K SUMMARY

None.

RENOVORX, INC.
EXHIBIT INDEX

		Incorporated by Reference			
Exhibit No.	**Exhibit Description**	**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.	Filed herewith			
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	Description of Securities	Filed herewith			
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	Filed herewith			
10.3†	Amended and Restated Outside Director Compensation Policy	Filed herewith			
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	Filed herewith			
10.8†	Change in Control and Severance Agreement, by and between RenovoRx, Inc. and Shaun Bagai, effective as of November 11, 2021	10-Q	001-40738	10.7	November 15, 2021
10.9†	Change in Control and Severance Agreement, by and between RenovoRx, Inc. and Ramtin Agah, M.D., effective as of November 11, 2021	10-Q	001-40738	10.8	November 15, 2021

10.10†	Key Service Provider Incentive Compensation Plan	10-Q	001-40738	10.9	November 15, 2021

10.11†	Consulting Agreement with Paul Manners	S-1	333-258071	10.4	August 25, 2021
10.12†	Amended Consulting Agreement with Paul Manners	S-1	333-258071	10.5	August 25, 2021
10.13†	Form of Indemnification Agreement	S-1	333-258071	10.7	August 25, 2021
10.14+	Master Supply Agreement, dated October 28, 2019, by and between Medical Murray, Inc. and RenovoRx, Inc.	S-1	333-258071	10.11	August 25, 2021
10.15†	Client Agreement between RenovoRx, Inc. and LS Associates, Inc.	S-1	333-258071	10.12	August 25, 2021
16.1	Letter from Frank, Rimerman + Co. LLP to the Securities and Exchange Commission dated December 9, 2021.	8-K	001-40738	16.1	December 10, 2021
23.1	Consent of Baker Tilly US, LLP	Filed herewith			
23.2	Consent of Frank, Rimerman + Co., LLP	Filed herewith			
24.1	Power of Attorney (included on signature page of this Form 10-K)	Filed herewith			
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			
101.INS	Inline XBRL Taxonomy Extension Instance Document (the instance document does not appear on the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document).	Filed herewith			
101.SCH	Inline XBRL Taxonomy Extension Schema Document	Filed herewith			
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document	Filed herewith			
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document	Filed herewith			
101.LAB	Inline XBRL Taxonomy Extension Labels Linkbase Document	Filed herewith			
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document	Filed herewith			
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in the Interactive Data Files submitted as Exhibit 101).	Filed herewith			

† Indicates management contract or compensatory plan 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.

* 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 report to be signed on its behalf by the undersigned, thereunto duly authorized.

RENOVORX, INC.

Date: March 29, 2022

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

Date: March 29, 2022

/s/ Christopher J. Lehman
Christopher J. Lehman
Chief Financial Officer, Principal Financial and Accounting Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Shaun R. Bagai and Christopher J. Lehman as his or her true and lawful attorneys-in-fact and agents, each with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K and to file the same, with all exhibits thereto and all documents in connection therewith, with the U.S. Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that such attorneys-in-fact and agents or any of them, or his or her or their substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

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)	March 29, 2022
/s/ Christopher J. Lehman Christopher J. Lehman	Chief Financial Officer (Principal Financial and Accounting Officer)	March 29, 2022
/s/ Ramtin Agah Ramtin Agah, M.D.	Chairman of the Board of Directors	March 29, 2022
/s/ Laurence J. Marton Laurence J. Marton, M.D.	Director	March 29, 2022
/s/ Una S. Ryan Una S. Ryan, O.B.E., Ph.D., D.Sc.	Director	March 29, 2022
/s/ Kirsten Angela Macfarlane Kirsten Angela Macfarlane	Director	March 29, 2022
/s/ David Diamond David Diamond	Director	March 29, 2022

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and the Board of Directors of RenovoRx, Inc.

Opinion on the Financial Statements

We have audited the accompanying balance sheet of RenovoRx, Inc. (the "Company") as of December 31, 2021, the related statements of operations, convertible preferred stock and stockholders' equity, and cash flows for the year then ended, and the related notes to the financial statements (collectively the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2021, and the results of its operations and its cash flows for the year then ended, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audit included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audit provides a reasonable basis for our opinion.

/s/ Baker Tilly US, LLP
Campbell, California
We have served as the Company's auditors since 2021.
March 29, 2022

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and the Board of Directors of
RenovoRx, Inc.
Los Altos, CA

Opinion on the Financial Statements

We have audited the accompanying balance sheet of RenovoRx, Inc. (the "Company") as of December 31, 2020 and the related statements of operations, convertible preferred stock and stockholders' deficit, and cash flows for each of the year ended December 31, 2020, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2020, and the results of its operations and its cash flows for year ended December 31, 2020, in conformity with accounting principles generally accepted in the United States of America.

Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has incurred recurring losses from operations, has negative cash flows from operating activities and has an accumulated deficit that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (the "PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the U.S. Securities and Exchange Commission (the "SEC") and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit, we are required to obtain an understanding of internal control over financial reporting, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audit included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audit provides a reasonable basis for our opinion.

/s/ Frank, Rimerman +Co. LLP
San Francisco, California

May 12, 2021 (August 19, 2021 as to the effects of the reverse stock split described in Note 1 and the effects of the amendment to the 2013 Plan in addition to the adoption of the RenovoRx, Inc. 2021 Omnibus Equity Incentive Plan described in Note 9)

We served as the Company's auditor from 2019 to 2021.

RenovoRx, Inc.

Balance Sheets
(in thousands, except share and per share data)

	As of December 31,	
	2021	**2020**
Assets		
Current assets:		
Cash and cash equivalents	$ 15,192	$ 1,795
Prepaid expenses and other current assets	1,089	115
Total current assets	16,281	1,910
Leasehold improvements, net	6	-
Deposits	-	4
Total assets	$ 16,287	$ 1,914
Liabilities, Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 525	$ 162
Accrued expenses	413	311
Promissory note, current	-	117
Convertible note	-	2,650
Derivative liability	-	856
Total current liabilities	938	4,096
Promissory note, net of current portion	-	23
Total liabilities	938	4,119
Commitments and contingencies (Note 12)		
Convertible preferred stock, $0.0001 par value; 15,000,000 and 22,360,455 shares authorized; 0 and 3,535,469 shares issued and outstanding at December 31, 2021 and 2020, respectively (aggregate liquidation preference of $0 and $12,782 at December 31, 2021 and 2020, respectively)	-	12,451

Stockholders' equity (deficit):		
Common stock, $0.0001 par value; 250,000,000 and 42,000,000 shares authorized; 8,933,989 and 2,233,139 shares issued and outstanding as of December 31, 2021 and 2020, respectively	1	1
Additional paid-in capital	36,632	303
Accumulated deficit	(21,284)	(14,960)
Total stockholders' equity (deficit)	15,349	(14,656)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 16,287	$ 1,914

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

RenovoRx, Inc.

Statements of Operations
(in thousands, except per share data)

	Year Ended December 31,	
	2021	**2020**
Operating expenses:		
Research and development	$ 3,039	$ 2,386
General and administrative	2,632	818
Total operating expenses	5,671	3,204
Loss from operations	(5,671)	(3,204)
Other income (expense), net:		
Interest income (expense), net	(834)	(587)
Other income (expense), net	119	(7)
Gain on loan extinguishment	62	-
Total other income (expense), net	(653)	(594)
Net loss	$ (6,324)	$ (3,798)
Net loss per share - basic and diluted	$ (1.21)	$ (1.72)
Weighted average shares of common stock - basic and diluted	5,217	2,214

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

RenovoRx, Inc.

Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)
(in thousands, except share amounts)

	Convertible Preferred Stock		Common Stock		Additional Paid-In	Accumulated	Total Stockholders' Equity
	Shares	**Amount**	**Shares**	**Amount**	**Capital**	**Deficit**	**(Deficit)**
Balances at January 1, 2020	3,508,631	$ 12,391	2,177,187	$ 1	$ 235	$ (11,162)	$ (10,926)
Issuance of restricted stock award to nonemployee for service	-	-	24,478	-	17	-	17
Issuance of Series A-1 convertible preferred stock upon exercise of warrant	26,838	25	-	-	-	-	-
Issuance of common stock upon exercise of stock options	-	-	31,474	-	18	-	18
Warrant liability transferred to mezzanine equity	-	35	-	-	-	-	-
Stock-based compensation expense	-	-	-	-	33	-	33
Net loss	-	-	-	-	-	(3,798)	(3,798)
Balances at December 31, 2020	3,535,469	12,451	2,233,139	1	303	(14,960)	(14,656)
Conversion of convertible preferred stock to common stock upon initial public offering	(3,535,469)	(12,451)	3,535,469	-	12,451	-	12,451
Conversion of convertible notes and accrued interest to common stock upon initial public offering	-	-	708,820	-	5,279	-	5,279
Reclassification of derivative liability upon conversion of convertible notes	-	-			1,101	-	1,101
Proceeds from initial public offering, net of underwriters' commissions, discounts and issuance costs of $2,089	-	-	1,850,000	-	14,563	-	14,563
Issuance of common stock upon exercise of warrants issued upon initial public offering	-	-	248,200	-	2,681	-	2,681
Issuance of common stock upon exercise of stock options	-	-	358,332	-	107	-	107
Reverse stock split adjustment	-	-	29	-	-	-	-
Stock-based compensation expense	-	-	-	-	147	-	147
Net loss	-	-	-	-	-	(6,324)	(6,324)
Balances at December 31, 2021	-	$ -	8,933,989	$ 1	$ 36,632	$ (21,284)	$ 15,349

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

RenovoRx, Inc.

Statements of Cash Flows
(in thousands)

	Year Ended December 31,	
	2021	**2020**
Cash flows from operating activities:		
Net loss	$ (6,324)	$ (3,798)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	147	33
Amortization on leasehold improvements	9	-
Issuance of restricted stock awards to nonemployee	-	17
Gain on change in fair value of derivative liability	(118)	-
Gain on loan extinguishment from PPP loan	(140)	-
Loss on loan extinguishment	78	-
Amortization of debt discount	687	477
Amortization of debt issuance cost	10	12
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(974)	27
Other Assets	4	-
Accounts payable	363	(376)
Accrued expenses	342	(21)
Interest accrued on convertible notes	-	101
Net cash used in operating activities	(5,916)	(3,528)
Cash flows from investing activities:		
Expenditures for leasehold improvements	(15)	-
Net cash used in investing activities	(15)	-
Cash flows from financing activities:		
Net proceeds from issuance of common stock upon initial public offering	14,563	-
Proceeds from exercise of warrants	2,681	-
Proceeds from convertible notes	1,977	3,038
Payment of debt issuance costs	-	(22)
Proceeds from promissory note	-	140
Proceeds from exercise of Series A-1 warrant	-	25
Proceeds from exercise of stock options	107	18
Net cash provided by financing activities	19,328	3,199
Increase (Decrease) in cash and cash equivalents	13,397	(329)
Cash and cash equivalents, beginning of year	1,795	2,124
Cash and cash equivalents, end of year	$ 15,192	$ 1,795
Supplemental disclosure of non-cash investing and financing activities:		
Derivative liability	$ 738	$ 743
Conversion of convertible preferred stock upon initial public offering	$ 12,451	$ -
Conversion of convertible notes upon initial public offering	$ 5,279	$ -

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

RenovoRx, Inc.
Notes to Financial Statements

1. Organization

Description of the Business

RenovoRx, Inc. (the "Company") was incorporated in the state of Delaware in December 2012 and operates from its headquarters in Los Altos, California. The Company is a clinical-stage biopharmaceutical company focused on developing therapies for the local treatment of solid tumors and conducting a phase 3 pancreatic cancer clinical trial for its lead product candidate RenovoGem™. The Company's therapy platform, RenovoRx Trans-Arterial Micro-Perfusion, or RenovoTAMP™ utilizes approved chemotherapeutics with validated mechanisms of action and well-established safety and side effect profiles, with the goal of increasing their efficacy, improving their safety, and widening their therapeutic window.

Initial Public Offering

On August 25, 2021, the Company's Registration Statement on Form S-1 (File No. 333-258071) relating to its initial public offering ("IPO") of units of securities, or units, was declared effective by the U.S. Securities and Exchange Commission, (or "SEC"), and its shares of common stock began trading on the Nasdaq Capital Market on August 26, 2021. The transaction formally closed on August 30, 2021. In connection with the IPO, the Company issued and sold an aggregate of 1,850,000 units at a price of $9.00 per unit. Each unit consisted of (a) one share of common stock and (b) one warrant to purchase one share of common stock at an exercise price equal to $10.80 per share, which is exercisable for a period of five years after the issuance date. The Company also granted the underwriters an over-allotment option, exercisable for 45 days after August 25, 2021, to purchase any combination of up to 277,500 shares of its common stock and/or common stock warrants to purchase277,500 shares of common stock with an exercise price of $10.80 per share. The underwriters exercised their over-allotment option to purchase277,500 common stock warrants on August 30, 2021. In connection with the IPO, the underwriters were issued a five-year warrant, exercisable on or after February 25, 2022, to purchase up to198,875 shares of the Company's common stock at an exercise price of $10.80.

The Company received aggregate gross proceeds of $16.7 million from the IPO, paid underwriting discounts and commissions of $1.3 million and incurred other expenses of $0.8 million. As a result, the net offering proceeds to the Company, after deducting underwriting discounts and commissions and other offering expenses, were $14.6 million. Immediately prior to the closing of the IPO, all shares of convertible preferred stock then outstanding were converted into 3,535,469 shares of common stock after giving effect to the reverse stock split. In addition, all of the outstanding Convertible Notes, representing principal and accrued but unpaid interest of $5.3 million, converted into an aggregate of 708,820 units. Each unit consisted of (a) one share of common stock and (b) one warrant to purchase one share of common stock at an exercise price equal to $10.80 per share, which is exercisable for a period of five years after the issuance date.The 2020 Convertible Notes converted at a 20% discount to the IPO price and the 2021 Convertible Notes converted at a 12.5% discount to the IPO price, see Note 5, *Convertible Notes* .

Reverse Stock Split

The Company filed a certificate of amendment to its Fifth Amended and Restated Certificate of Incorporation to effect a 1-for-5 reverse stock split of its issued and outstanding preferred stock and common stock, which became effective on August 5, 2021. The number of authorized shares and the par values of the common stock and convertible preferred stock were not adjusted as a result of the reverse stock split. Adjustments corresponding to the reverse stock split were made to the ratio at which the Company's convertible preferred stock converted into the Company's common stock. Accordingly, all share and per share amounts related to the common stock, stock options, warrants and restricted stock awards for all periods presented in the accompanying financial statements and notes thereto have been retroactively adjusted, where applicable, to reflect the effect of the reverse stock split.

Liquidity and Capital Resources

The Company raised $14.6 million in net proceeds from its IPO in August 2021 and from the Company's inception through December 31, 2021, it has raised an aggregate of $35.0 million from private placements of the Company's convertible preferred stock, convertible debt securities, the issuance of securities in its August 2021 IPO, and the exercise of warrants and common stock options. The Company had cash and cash equivalents of $15.2 million as of December 31, 2021.

The Company has incurred significant losses and negative cash flows from operations since its inception. For the year ended December 31, 2021, the Company reported a net loss of $6.3 million and an accumulated deficit of $21.3 million and does not expect to generate positive cash flows from operations in the foreseeable future. The Company expects to incur significant and increasing losses until regulatory approval is granted for its first product candidate, RenovoGem™. Regulatory approval is not guaranteed and may never be obtained. The Company may seek to raise additional capital through debt financings, private or public equity financings, license agreements, collaborative agreements or other arrangements with other companies, or other sources of financing. There can be no assurance that such financing will be available or will be at terms acceptable to the Company. The inability to raise capital as and when needed would have a negative impact on the Company's financial condition and its ability to pursue its business strategy. The Company will need to generate significant revenue to achieve profitability, and it may never do so.

The Company has reviewed the relevant conditions and events surrounding its ability to continue as a going concern including among others: historical losses, projected future results, including the effects of the novel coronavirus ("COVID-19") pandemic, cash requirements for the upcoming year, funding capacity, net working capital, total stockholders' equity and future access to capital. Based upon the Company's current operating plan, management believes that its existing cash and cash equivalents as of December 31, 2021, will be sufficient to allow the Company to fund operating, investing and financing cash flow needs for at least twelve months from the date of issuance of these financial statements. The accompanying financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. The accompanying financial statements do not reflect any adjustments relating to the recoverability and reclassifications of assets and liabilities that might be necessary if the Company is unable to continue as a going concern.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying financial statements are presented in U.S. dollars and have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP") and applicable rules and regulations of the SEC for annual reporting. Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as found in the Accounting Standards Codification ("ASC") and as amended by Accounting Standards Update ("ASU") of the Financial Accounting Standards Board ("FASB").

Risks and Uncertainties

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

In March 2020, the World Health Organization declared COVID-19 a pandemic. The COVID-19 pandemic has negatively impacted the global economy, disrupted global supply chains and created significant volatility and disruption of financial markets. The full extent to which the COVID-19 pandemic will directly or indirectly impact the Company's business, results of operations and financial condition, including expenses, clinical trials and research and development costs, will depend on future developments that are highly uncertain, including as a result of new information that may emerge concerning COVID-19 and the actions taken to contain or treat COVID-19, as well as the economic impact on local, regional, national and international markets.

Use of Estimates

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

Concentration of Credit Risk and Significant Suppliers

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash and cash equivalents. The Company maintains bank deposits in federally insured financial institutions and these deposits may exceed federally insured limits of $250,000. The Company is exposed to credit risk in the event of default by the financial institutions holding its cash and cash equivalents to the extent recorded in the balance sheets. The Company has not experienced any losses on its deposits of cash and cash equivalents.

The Company relied, and expects to rely, on a small number of third-party manufacturers to manufacture and supply its RenovoCath devices and its product candidates for clinical trials. These activities could be adversely affected by a significant interruption in supply of these items. If the Company does not successfully commercialize or partner any of its product candidates, it will be unable to generate product revenue or achieve profitability.

Operating Segment

The Company operates and manages its business as one reportable and operating segment, which is the development of a therapy platform to deliver de-risked small molecules for localized treatment of solid cancer tumors. The Company's chief executive officer, who is the chief operating decision maker, reviews financial information on an aggregate basis for allocating resources and evaluating financial performance.

Deferred Offering Costs

The Company capitalizes certain legal, professional, accounting and other third-party fees that are directly associated with in-process financings as deferred offering costs until such financings are consummated. After consummation of the financing, these costs are recorded as a reduction of the proceeds received from the financing. The Company incurred offering costs consisting of legal, accounting and other fees directly attributable to the Company's IPO. For the twelve months ended December 31, 2021, the Company charged $0.8 million of deferred offering costs to additional paid-in capital upon completion of the IPO in August 2021. There wereno deferred offering costs at December 31, 2021 and 2020.

Net Loss per Share

Basic net loss per common share is calculated by dividing net loss by the weighted-average number of shares of common stock outstanding during the period, without consideration of common stock equivalents. Diluted net loss per share is computed by dividing net loss by the weighted-average number of shares of common stock and common stock equivalents of potentially dilutive securities outstanding for the period determined using the treasury stock and if-converted methods. Potentially dilutive common stock equivalents are comprised of convertible preferred stock, convertible notes, and warrants including options and restricted stock awards outstanding under the Company's Equity Incentive Plan. For the years ended December 31, 2021 and 2020, there was no difference in the number of shares used to calculate basic and diluted shares outstanding as the inclusion of the potentially dilutive securities would be anti-dilutive.

Fair Value of Financial Instruments

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability, or an exit price, in the principal or most advantageous market for that asset or liability in an orderly transaction between market participants on the measurement date. Fair value measurement establishes a fair value hierarchy that requires an entity to maximize the use of observable inputs, where available, and minimize the use of unobservable inputs when measuring fair value.

The Company determined the fair value of financial assets and liabilities using the fair value hierarchy that describes three levels of inputs that may be used to measure fair value, as follows:

Level 1 – Valuations based on quoted prices for identical assets and liabilities in active markets.

Level 2 – Valuations based on observable inputs other than quoted prices included in Level 1, such as quoted prices for similar assets and liabilities in active markets, quoted prices for identical or similar assets and liabilities in markets that are not active, or other inputs that are observable or can be corroborated by observable market data.

Level 3 – Valuations based on unobservable inputs reflecting the Company's assumptions, consistent with reasonably available assumptions made by other market participants. These valuations require significant judgment.

The estimated fair value of financial instruments disclosed in the financial statements has been determined by using available market information and appropriate valuation methodologies. In certain cases where there is limited activity or less transparency around inputs to valuation, securities are classified as Level 3.

The carrying amount of current assets, accounts payable and accrued expenses are generally considered to be representative of their respective fair values because of their short-term nature.

Cash and Cash Equivalents

The Company considers all highly liquid investments purchased with original maturities of 90 days or less from the purchase date to be cash equivalents. Cash and cash equivalents are held in accounts at financial institutions. Cash equivalents consist of amounts held in a money market account. Such deposits have and will continue to exceed federally insured limits in the foreseeable future. The Company held no funds in restricted cash at December 31, 2021 and 2020.

Leasehold Improvements, Net

Leasehold improvements are presented at cost, net of accumulated amortization. Amortization expense is recorded using the straight-line method over the shorter of the remaining lease term or the estimated useful life.

Convertible Instruments and Embedded Derivatives

The Company accounts for certain redemption features that are associated with convertible notes as liabilities at fair value and adjusts the instruments to their fair value at the end of each reporting period. For derivative financial instruments that are accounted for as liabilities, the derivative instrument is initially recorded at its fair value and is then re-valued at each reporting date, with changes in the fair value reported in other income (expense), net in the statements of operations. Derivative instrument liabilities are

classified in the balance sheets as current or non-current based on whether or not net-cash settlement of the derivative instrument could be required within 12 months of the balance sheet date. As of December 31, 2020, the Company's only derivative financial instrument was related to the 2020 Convertible Notes, which contained certain redemptive features. The Company completed its IPO on August 30, 2021, which triggered the automatic conversion of all outstanding Convertible Notes, plus accrued interest, into units, consisting of (a) one share of common stock and (b) one five-year warrant to purchase one share of common stock at an exercise price equal to $10.80 per share. Upon the conversion of the Convertible Notes, the outstanding Convertible Notes, plus accrued interest thereon totaling $5.3 million, net of unamortized debt discounts, were derecognized into stockholders' equity, see Note 5, *Convertible Notes*.

Research and Development Costs

Research and development expenses are charged to expense as incurred. Research and development expenses includes personnel costs including salaries, benefits and stock-based compensation. In addition, it includes expenses for consultants that support clinical trial studies, materials costs, external clinical drug product manufacturing costs, outside services costs, regulatory activities including filing fees, fees for maintaining licenses and other amounts due to third-party agreements, laboratory materials, clinical trial, as noted above, and supplies to support our research activities, including allocated facility and general and administrative indirect overhead related costs. The Company also receives payments from clinical trial sites for RenovoCath devices used in the Phase 3 clinical trial. These payments received from clinical sites cover the direct costs of manufacturing the RenovoCath delivery devices and offset research and development expenses.

Clinical Trial Expenses

The Company makes payments in connection with its ongoing Phase 3 clinical trial under contracts with clinical trial sites and contract research organizations that support conducting and managing clinical trials. The financial terms of these agreements are subject to negotiation and vary from contract to contract and may result in uneven payment flows. Generally, these agreements set forth the scope of work to be performed at a fixed fee, unit price or on a time and materials basis. A portion of the obligation to make payments under these contracts depends on factors such as the successful enrollment or treatment of patients or the completion of other clinical trial milestones.

Expenses related to clinical trials are accrued based on estimates and/or representations from service providers regarding work performed, including actual level of patient enrollment, completion of patient studies and progress of the clinical trials. Other incidental costs related to patient enrollment or treatment are accrued when reasonably certain. If amounts and obligations to pay under clinical trial agreements are modified (for instance, as a result of changes in the clinical trial protocol or scope of work to be performed), the accruals are adjusted accordingly. Revisions to contractual payment obligations are charged to expense in the period in which the facts that give rise to the revision become reasonably certain.

General and Administrative

General and administrative expenses consist of salaries, benefits, and stock-based compensation for personnel in executive, finance and administrative functions, professional services and associated costs related to accounting, tax, audit, legal, intellectual property, consulting costs, conferences and travel, including allocated facility and general and administrative indirect overhead related costs to research and development expenses. General and administrative expenses are expensed in the period incurred.

Convertible Preferred Stock

The Company records preferred stock at fair value on the date of issuance, net of issuance costs. Preferred stock was previously recorded outside of stockholders' equity (deficit) because the shares contained liquidation features that were not solely within the Company's control and was classified as mezzanine equity (temporary equity). The Company elected not to adjust the carrying value of the preferred stock to the liquidation preferences of such shares because it was uncertain whether or when an event would occur that would obligate the Company to pay the liquidation preferences to holders of shares of the preferred stock. Subsequent adjustments to the carrying values to the liquidation preferences were made only when it was probable that such a liquidation event occurred. The Company completed its IPO on August 30, 2021, which triggered the automatic conversion of all outstanding convertible preferred stock to common stock.

Stock-Based Compensation

The Company estimates the fair value of stock options using the Black-Scholes option pricing model, which incorporates various assumptions including volatility, expected term and risk-free interest rate. Compensation related to service-based awards is recognized starting on the grant date on a straight-line basis over the vesting period, which is generally four years.

The determination of the fair value of each stock award using this option-pricing model is affected by the Company's assumptions regarding a number of complex and subjective variables. These variables include, but are not limited to, the fair value of the common stock at the date of grant, the expected term of the awards, the expected stock price volatility over the term of the awards, the risk-free interest rate, and the dividend rate as follows:

Fair Value of Common Stock—Prior to the IPO, given the absence of a public trading market, the Company's Board of Directors considered numerous objective and subjective factors to determine the fair value of the Company's common stock at each grant date. These factors included, but were not limited to: (i) contemporaneous third-party valuations of common stock; (ii) the prices for preferred stock sold to outside investors; (iii) the rights and preferences of preferred stock relative to common stock; (iv) the lack of marketability of the Company's common stock; (v) developments in the business; and (vi) the likelihood of achieving a liquidity event, such as an IPO or sale of the business, given prevailing market conditions. The methodology to determine the fair value of the Company's common stock included estimating the fair value of the enterprise using the "backsolve" method, which is a market approach that assigns an implied enterprise value by accounting for all share class rights and preferences based on the latest round of financing. The total equity value implied was then applied in the context of an option pricing model to determine the value of each class of the Company's shares.

For grants issued post-IPO the closing price of the Company's common stock as reported on the date of grant will determine the fair value of the Company's common stock, as shares of the Company's common stock are traded in the public market.

Expected Term—The expected term represents the period that the stock-based awards are expected to be outstanding. The Company determines the expected term using the simplified method for pre-IPO awards. The simplified method deems the term to be the average of the time-to-vesting and the contractual life of the options. For stock options granted post-IPO, the expected term equals the average for industry peers, consisting of several public companies in the Company's industry that are either similar in size, stage, or financial leverage.

Expected Volatility—Given the absence of a public trading market, the expected volatility is estimated by taking the average historic price volatility for industry peers, consisting of several public companies in the Company's industry that are either similar in size, stage, or financial leverage, over a period equivalent to the expected term of the awards.

Risk-Free Interest Rate—The risk-free interest rate is calculated using the average of the published interest rates of U.S. Treasury zero-coupon issues with maturities that are commensurate with the expected term.

Dividend Rate—The dividend yield assumption is zero as the Company has no plans to make dividend payments.

The Company generally granted stock options, pre-IPO, to its employees and consultants for a fixed number of shares with an exercise price equal to the fair value of the underlying shares at date of grant. For all post-IPO grants issued, the fair value will be the closing price of the Company's common stock on the date of the grant. The Company accounts for all stock option grants using the fair value method and stock-based compensation is recognized as the underlying options vest.

Income Taxes

Deferred tax assets and liabilities are measured based on differences between the financial reporting and tax basis of assets and liabilities using enacted rates and laws that are expected to be in effect when the differences are expected to reverse. The Company records a valuation allowance for the full amount of deferred assets, which would otherwise be recorded for tax benefits relating to operating loss and tax credit carryforwards, as realization of such deferred tax assets cannot be determined to be more likely than not.

Emerging Growth Company Status

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

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

Recent Accounting Pronouncements

Recently Adopted Accounting Pronouncements

In June 2018, the FASB issued Accounting Standards Updates ("ASU") No. 2018-07,*Improvements to Nonemployee Share-Based Payment Accounting* (ASU 2018-07). The standard simplifies the accounting for share-based payments granted to nonemployees for goods and services and aligns most of the guidance on such payments to the nonemployees with the requirements for share-based payments granted to employees. ASU 2018-07 is effective for the Company for annual reporting periods beginning after December 15, 2019, and interim periods within fiscal years beginning after December 15, 2020, with early adoption permitted. The guidance should be applied to new awards granted after the date of adoption. The Company adopted this new standard on January 1, 2020, and the adoption of this standard did not have an impact on its financial statements.

In August 2018, the FASB issued ASU 2018-13,*Fair Value Measurement (Topic 820), Disclosure Framework — Changes to the Disclosure Requirements for Fair Value Measurement* (ASU 2018-13). The standard eliminates, adds and modifies certain disclosure requirements for fair value measurements. Entities will no longer be required to disclose the amount of and reasons for transfers between Level 1 and Level 2 of the fair value hierarchy, but public companies will be required to disclose the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements. The standard is effective for annual reporting periods beginning after December 15, 2019, and for interim periods within those periods. The Company adopted this new standard on January 1, 2020, with no material impact on its financial statements.

In November 2016, the FASB ASU 2016-18,*Statement of Cash Flows (Topic 230): Restricted Cash* (ASU 2016-18), which requires that a statement of cash flows explain the change during the period in the total of cash, cash equivalents and restricted cash. Therefore, amounts described as restricted cash should be included with cash and cash equivalents when reconciling the beginning of period and end of period amounts shown on the statement of cash flows. The Company adopted this guidance on January 1, 2019, and it did not have an impact on its financial results, but it did result in a change in the presentation of restricted cash and cash equivalents within the statements of cash flows.

Recent Accounting Pronouncements Not Yet Adopted

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

In June 2016, the FASB issued ASU No. 2016-13,*Financial Instruments – Credit Losses* (ASU 2016-13), which requires the measurement of expected credit losses for financial instruments carried at amortized cost, such as accounts receivable, held at the reporting date based on historical experience, current conditions and reasonable forecasts. The main objective of this standard is to provide financial statement users with more decision-useful information about the expected credit losses on financial instruments and other commitments to extend credit held by a reporting entity at each reporting date. In November 2018, the FASB issued ASU No. 2018-19, *Codification Improvements to Topic 326, Financing Instruments – Credit Losses* (ASU 2018-19), which included an amendment of the effective date. The standard is effective for the Company for annual reporting periods beginning after December 15, 2021, and for interim periods within those periods. Early adoption is permitted. The Company plans to adopt this new standard on January 1, 2022 and does not believe that adoption will have a significant impact on its financial statements.

In December 2019, the FASB issued ASU No. 2019-12,*Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*(ASU 2019-12), which simplifies the accounting for income taxes, and is effective on a prospective basis for annual reporting periods beginning after December 15, 2021, and for interim periods within fiscal years beginning after December 15, 2022, with early adoption permitted. The Company plans to adopt this new standard on January 1, 2022 and does not believe that adoption will have a significant impact on its financial statements.

In August 2020, the FASB issued ASU No. 2020-06,*Debt – Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging – Contracts in Entity's Own Equity (Subtopic 815-40)* (ASU 2020-06): *Accounting for Convertible Instruments and Contracts in an Entity*, which simplifies the accounting for certain financial instruments with characteristics of liabilities and equity, including convertible instruments and contracts on an entity's own equity. The updated guidance is effective on a prospective basis for annual reporting periods beginning after December 15, 2023 and for interim periods within those periods. Early adoption is permitted. The Company has not yet determined the impact that this new standard will have on its financial position and results of operations.

3. Accrued Expenses

The components of accrued expenses as of December 31, 2021 and 2020 are as follows (in thousands):

	December 31, 2021	December 31, 2020
Clinical trial	$ 358	$ 171
Interest	-	101
Employee benefits	33	39
Other	22	-
Total accrued expenses	$ 413	$ 311

4. Fair Value Measurements

The following table sets forth by level, within the fair value hierarchy, the financial assets and liabilities that are measured at fair value on a recurring basis at December 31, 2021 and 2020 (in thousands):

	Fair Value Measurements at December 31, 2021 using:			
Assets:	Level 1	Level 2	Level 3	Total
Money market funds	$ 14,997	$ -	$ -	$ 14,997
	$ 14,997	$ -	$ -	$ 14,997

	Fair Value Measurements at December 31, 2020 using:			
Assets:	Level 1	Level 2	Level 3	Total
Money market funds	$ 1,703	$ -	$ -	$ 1,703
	$ 1,703	$ -	$ -	$ 1,703
Liabilities:				
Derivative liability – 2020 Convertible Notes	$ -	$ -	$ 856	$ 856
	$ -	$ -	$ 856	$ 856

- The change in the fair value of the Series A-1 preferred stock warrant liability is summarized below (in thousands):

Fair value, beginning of period	$ 35
Change in fair value upon warrant exercise in January 2020 recorded in other income (expense), net	-
Fair value as of January 2020	$ 35
Reclassification of warrant liability to mezzanine equity upon exercise of warrant	(35)
Fair value, end of period	$ -

The Series A-1 preferred stock warrant liability consisted of the fair value of the warrant to purchase Series A-1 convertible preferred stock and was based on significant inputs not observable in the market, which represents a Level 3 measurement within the fair value hierarchy. The fair value of the Series A-1 preferred stock warrant liability was determined using the "backsolve" method to estimate the enterprise value of the Company and the Option Pricing Model to allocate the enterprise value of the Company. The enterprise value was allocated among the various share classes and warrant using the Option Pricing Model. Generally, increases or decreases in the fair value of the underlying convertible preferred stock would result in a directionally similar impact in the fair value measurement of the warrant liability.

The change in the fair value of the derivative liability is summarized below (in thousands):

	Year Ended December 31, 2021	Year Ended December 31, 2020
Fair value, beginning of period	$ 856	$ -
Initial fair value of instruments issued	363	856
Change in fair value of instruments	(118)	-
Conversion upon IPO	(1,101)	-
Fair value, end of period	$ -	$ 856

The derivative liability in the table above relates to the 2020 and 2021 Convertible Notes and represents the fair value of the redemption-like contingent conversion feature. The Company calculated the fair value of the derivative liability using a probability weighted discounted cash flow analysis. The inputs used to determine the estimated fair value of the derivative were based primarily on the probability of an underlying event occurring that would trigger the embedded derivative and the timing of such event. The Company's derivative liability was measured at fair value on a recurring basis and was classified as a Level 3 liability. The Company recorded subsequent adjustments to reflect the increase or decrease in estimated fair value at each reporting date in other income (expense), net in the statements of operations, see Note 5, *Convertible Notes.*

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

5. Convertible Notes

In March 2020, the Company entered into a note purchase agreement for the issuance of up to $4.0 million of convertible promissory notes, which, if not converted, had an initial maturity date of March 31, 2021. The Company entered into a series of convertible note payable agreements (the "2020 Convertible Notes") for aggregate borrowings of $3.0 million. The 2020 Notes bore interest at the rate of 5% per annum and could not be prepaid prior to the maturity date unless approved in writing by the Company and requisite holders.

The terms of the 2020 Convertible Notes provided for automatic conversion into equity shares in the next equity financing round with total proceeds of not less than $10.0 million (a "Qualified Financing'), at a conversion price per share equal to 80% of the price per share paid by investors purchasing such equity securities in a Qualified Financing. For purposes of the 2020 Convertible Notes, equity securities meant the Company's common stock, preferred stock or any securities providing for rights to purchase the Company's common stock, preferred stock or securities convertible into or exchangeable for the Company's common stock or preferred stock issued in the Qualified Financing. If the Company consummated a Change of Control prior to a Qualified Financing, the Company would repay each holder in cash an amount equal to the greater of (a) two times (2x) the entire outstanding principal balance of the 2020 Convertible Notes or (b) the amount the holder would receive if the 2020 Convertible Notes had been converted into shares of the Company's Series B convertible preferred stock immediately prior to the consummation of the Change in Control, at a conversion price equal to the Series B convertible preferred stock Original Issue Price.

On March 1, 2021, the Company entered into an amendment to the 2020 Convertible Notes which extended the maturity date of the 2020 Convertible Notes from March 31, 2021 to October 30, 2021 and provided for the conversion of the 2020 Convertible Notes into shares of the Company's common stock upon a Qualified Financing that is an IPO. No other terms of the 2020 Convertible Notes were amended. This amendment was accounted for as a troubled debt restructuring pursuant to FASB ASC Topic 470-60, "*Troubled Debt Restructurings by Debtors*." As the future undiscounted cash flows of the 2020 Convertible Notes were greater than their carrying amount, the carrying amount was not adjusted and no gain was recognized as a result of the modification of terms.

The Company determined that the redemption features contained rights and obligations for conversion were contingent upon a potential future financing event or a change in control. Thus, the embedded redemption features were bifurcated from the face value of the notes and accounted for as a derivative liability to be remeasured at the end of each reporting period. The fair value of the derivative liability at December 31, 2021 and 2020 was $0 and $856,000, respectively. Debt issuance costs were $22,000 at December 31, 2020. There were no debt issuance costs as of December 31, 2021. The derivative liability was subject to fair value remeasurement at the end of each reporting period. The debt discount and debt issuance costs were being amortized to interest expense using the effective interest method over the expected term of the 2020 Convertible Notes. For the year ended December 31, 2021, the Company recognized $379,000 for amortization of the debt discount and debt issuance costs, of which $369,000 pertains to the debt discount and $10,000 pertained to debt issuance costs. For the year ended December 31, 2020, the Company recognized $477,000 of amortization of debt discount and $12,000 of amortization of debt issuance costs as interest expense in the statement of operation for the year ended December 31, 2020. The effective interest rate of the 2020 Convertible Notes was 0% and 30.8% at December 31, 2021 and 2020, respectively, compared to the stated rate of 5% per annum. The effective interest rate immediately prior to the conversion of the Convertible Notes resulting from the Company's IPO was 8.6% per annum. As a result, the Company's reported interest expense was significantly higher than the contractual cash interest payments. The Company recognized interest expense in the statements of operations of $101,000, in each of the years ended December 31, 2021 and 2020, related to the 2020 Convertible Notes.

In April 2021, the Company entered into a note purchase agreement and a series of convertible note payable agreements (the "2021 Convertible Notes," together with the 2020 Convertible Notes, the "2020 and 2021 Convertible Notes") for aggregate borrowings of $2.0 million. Outstanding borrowings under the 2021 Convertible Notes and accrued interest were due in April 2022, if not previously converted. The 2021 Notes bore interest at the rate of 5% per annum. Pursuant to the 2021 Convertible Notes, the outstanding principal and accrued interest are automatically convertible into equity shares in a Qualified Financing at a conversion price per share equal to 87.5% of the price per share paid by investors purchasing such equity securities in a Qualified Financing.

The Company determined that these redemption features in the 2021 Convertible Notes contained rights and obligations for conversion contingent upon a potential future financing event or a change in control. Thus, the embedded redemption features were bifurcated from the face value of the note and accounted for as a derivative liability to be remeasured at the end of each reporting period. Upon issuance of the notes, the Company recorded the fair value of the derivative liability of $363,000 and debt issuance costs of $23,000, with the offsetting amount being recorded as a debt discount. The derivative liability was subject to fair value remeasurement at the end of each reporting period. The discount and debt issuance costs were being amortized to interest expense using the effective interest method over the expected term of the 2021 Convertible Notes. For the year ended December 31, 2021, the Company recognized $386,000 for the amortization of the debt discount and debt issuance costs, of which $363,000 pertains to the debt discount and $23,000 pertained to debt issuance costs. This amortization expense was recognized as interest expense in the statements of operations. The effective interest rate of the 2021 Convertible Notes was 0% at December 31, 2021 compared to the stated rate of 5%. As a result, the Company's reported interest expense was significantly higher than the contractual cash interest payments. During the year ended December 31, 2021, the Company recognized interest expense in the statements of operations of $38,000 related to the 2021 Convertible Notes.

The Company completed an IPO on August 30, 2021, which triggered the automatic conversion of the outstanding Convertible Notes plus accrued interest into an aggregate of 708,820 units. Each unit consisted of (a) one share of common stock and (b) one five-year warrant to purchase one share of common stock at an exercise price equal to $10.80 per share (Note 7, *Warrant Liability*). Upon conversion of the 2020 and 2021 Convertible Notes, the outstanding principal, including debt discount and debt issuance costs for those Convertible Notes of $5.3 million, was derecognized into stockholders' equity (deficit). The unamortized debt discount totaling $78,000 was recognized as a loss on extinguishment of debt and is included in loss (gain) on loan extinguishment in the Company's statements of operations.

6. Promissory Note

On April 22, 2020, the Company entered into a promissory note with Silicon Valley Bank that provided for the receipt by the Company of loan proceeds of $140,000 (the "PPP Loan"), with an interest rate of 1.0% per annum, pursuant to the Paycheck Protection Program under the Coronavirus Aid, Relief and Economic Security Act (the "CARES Act"). Under certain conditions, the loan and accrued interest were forgivable, including if the loan proceeds were used for eligible purposes, including payroll, benefits, rent and utilities, and maintaining payroll levels. In October 2020, the Paycheck Protection Program Flexibility Act of 2020 extended the deferral period for borrower payments of principal, interest, and fees on all PPP loans from 6 months to 10 months. If not forgiven earlier, the PPP Loan was to mature on April 22, 2022. The PPP Loan contained events of default and other provisions customary for a loan of this type. The Company recorded the PPP Loan as a promissory note in the December 31, 2020 balance sheet as both a current and non-current liability.

On February 6, 2021, the Company received notification and confirmation from Silicon Valley Bank that its PPP loan and related accrued interest were forgiven in their entirety by the U.S. Small Business Administration and automatically cancelled. During the year ended December 31, 2021, the $140,000 was recorded to loss (gain) on loan extinguishment in the statements of operations.

7. Warrant Liability

In conjunction with the January 2013 Series A-1 convertible preferred stock financing, the Company issued a warrant to purchase 26,838 shares of the Company's Series A-1

convertible preferred stock at $0.9315 per share. The warrant was to expire on the earlier of (a) the date that was seven (7) years after the date of the original issuance of the warrant, (b) the date of consummation of an acquisition or (c) the effective date of an IPO. The Company accounts for stock warrants in accordance with FASB ASC Topic 480, *Distinguishing Liabilities from Equity*, either as derivative liabilities or as equity instruments depending on the specific terms of the warrant agreement. As described in Note 8, all of the Company's issued and outstanding convertible preferred stock is classified in mezzanine equity. The Company determined that the warrant should be classified as a liability, because it was exercisable for shares of Series A-1 preferred stock that are puttable upon a deemed liquidation event. The warrant was exercised on January 23, 2020 for proceeds of $25,000. Upon exercise, the warrant liability associated with this warrant was adjusted to its fair value of $35,000. The fair value of $35,000 was subsequently transferred to mezzanine equity as of the date of exercise. The Company also recognized a non-cash loss on settlement of the warrant of $8,000 which was recorded in other income (expenses), net in the statements of operations as of December 31, 2020.

8. Capital Stock

Common Stock

On August 25, 2021, the Company's Registration Statement on Amendment No. 4 to the Form S-1 relating to its IPO was declared effective by the SEC. In connection with the IPO, the Company issued and sold an aggregate of 1,850,000 units at a price of $9.00 per unit. Each unit consisted of (a) one share of common stock and (b) one warrant to purchase one share of common stock at an exercise price equal to $10.80 per share, which is exercisable for a period of five years after the issuance date. The Company received net proceeds of $14.6 million from the IPO, after deducting underwriting discounts and commissions of $1.3 million and other costs incurred with the offering of $0.8 million. Upon the closing of the IPO, all of the 3,535,469 outstanding shares of the Company's convertible preferred stock automatically converted into3,535,469 shares of common stock and the outstanding 2020 and 2021 Convertible Notes, including accrued but unpaid interest, representing $5.3 million, converted to 708,820 units, which consisted of (a) one share of common stock and (b) one five-year warrant to purchase one share of common stock at an exercise price equal to $10.80 per share. Upon completion of the offering on August 30, 2021, the Company was authorized to issue 250,000,000 shares of common stock, par value of $0.0001 per share and 15,000,000 shares of preferred stock, par value of $0.0001 per share.

Convertible Preferred Stock

All classes of convertible preferred stock have a par value of $0.0001 per share and are not redeemable at the option of the holder. Any shares of convertible preferred stock that are redeemed, purchased, converted or exchanged by the Company will be cancelled and retired and will not be reissued or transferred. Upon the closing of the IPO, all of the 3,535,469 outstanding shares of the Company's convertible preferred stock automatically converted into3,535,469 shares of common stock.

Voting

The holders of shares of the convertible preferred stock are entitled to vote, together with the holders of the common stock and not as a separate class, on all matters submitted to stockholders to vote. Each holder of convertible preferred stock is entitled to one vote for each share of common stock into which their shares would convert.

As long as any shares of Series A-2 and Series A-1 remained outstanding, the holders of Series A-2 and Series A-1, voting together as a separate class, are entitled to elect one member of the Company's Board of Directors. The holders of common stock, voting as a separate class, are entitled to elect two members of the Company's Board of Directors. The holders of common stock and convertible preferred stock, voting together on an as-if-converted basis, are entitled to elect three members of the Company's Board of Directors.

Protective Provisions

The holders of convertible preferred stock have certain protective provisions. As long as any shares of preferred stock remain outstanding, the Company cannot, without the approval of a majority of the voting power of preferred stock then outstanding, voting together as a single class on an as-converted basis, take any actions to, among other things: (i) amend the Company's Certificate of Incorporation or Bylaws; (ii) increase or decrease the total number of authorized shares of common stock or convertible preferred stock; (iii) authorize or designate any new series of stock or any other securities convertible into equity securities; (iv) redeem or repurchase shares of convertible preferred stock or common stock or pay or declare dividends; (v) result in any agreement for merger, consolidation or sale of control (including any liquidation event, asset transfer or acquisition); (vi) create or authorize the issuance of any debt security; or (vii) increase the number of shares available for issuance under the Company's equity incentive plan.

Conversion Rights

Any shares of the convertible preferred stock may, at the option of the holder, be converted at any time after the date of issuance into fully paid and nonassessable shares of common stock. The number of shares of common stock to which the holder of the convertible preferred stock is entitled upon conversion will be determined by multiplying the conversion rate by the number of shares of Series A-1, A-2, A-3 and B being converted.

Each share of convertible preferred stock automatically converts into the number of shares of common stock determined in accordance with the then-effective and applicable convertible preferred stock conversion price, (i) at any time upon the affirmative vote or written consent or agreement of the holders of at least a two-thirds of the outstanding shares of Series A-1, A-2, A-3 and B, or (ii) immediately upon the closing of the sale of shares of common stock to the public in a firm-commitment underwritten public offering of common stock resulting in at least $50.0 million of gross cash proceeds to the Company.

The conversion rate is determined by dividing the original issue price for each series of convertible preferred stock of such shares of each series by the original conversion price of the series. The conversion price is equal to the original issue price for the respective series of convertible preferred stock, as adjusted for any stock splits, dividends, reclassifications, and the like. The conversion price for each share of convertible preferred stock is equal to the Original Issue Price.

Dividends

The holders of preferred stock are entitled to receive non-cumulative dividends prior to and in preference to any declaration or payment of dividends on common stock, when and if declared by the Board of Directors. Dividends would be payable at the non-cumulative rates of 6% of the original issue price per share with original issue price per share is defined as follows: $0.9315 for Series A-1, $1.6215 for Series A-2, $4.1850 for Series A-3, and $5.5150 for Series B, as adjusted for any recapitalizations and the like. After payment of the above dividends to holders of convertible preferred stock, any additional dividends will be distributed pro rata amongst the holders of common stock. No dividends have been declared or paid as of December 31, 2021.

Liquidation Rights

In the event of any liquidation, dissolution or winding up of the Company, either voluntary or involuntary, the holders of convertible preferred stock then outstanding are entitled to be paid, out of the available funds and assets, and prior and in preference to any payment or distribution of any such funds on any shares of common stock, an amount per share equal to the Original Issue Price for the convertible preferred stock, plus all accrued and declared but unpaid dividends. The holders of convertible preferred stock have liquidation preferences over the common stockholders in the following amounts: $0.9315, $1.6215, $4.1850 and $5.5150 for Series A-1, Series A-2, Series A-3, and

Series B, respectively. The liquidation preferences totaled approximately $12.8 million as of December 31, 2020. If, upon the occurrence of a liquidation, dissolution or winding up of the Company, the assets and funds to be distributed among the holders of convertible preferred stock are insufficient to permit the payment to such holders, then the entire assets and funds of the Company legally available for distribution will be distributed ratably among the holders of convertible preferred stock in proportion to the preferential amount each such holder is otherwise entitled to receive. After the liquidation preferences of the holders of convertible preferred stock have been satisfied, the remaining assets of the Company will be distributed ratably among the holders of outstanding shares of common stock and convertible preferred stock on an as-if-converted basis.

If at any time after the Series B convertible preferred stock issue date, the Company sells or issues additional shares of common stock for no consideration or at a price below the then-effective convertible preferred stock conversion price, then the existing convertible preferred stock conversion price on the sale or issue date will be reduced.

The Company classified its convertible preferred stock as mezzanine equity on the balance sheet at December 31, 2020 as the shares were contingently redeemable upon deemed liquidation events, such as a change of control. In August 2021, immediately prior to the completion of the IPO and after giving effect to the 1-for-5 reverse stock split, all outstanding shares of the Company's convertible preferred stock were automatically converted into 3,535,469 shares of common stock. There were no shares of preferred stock outstanding as of December 31, 2021.

9. Equity Inventive Plan – Stock-Based Compensation and Common Stock Warrants

2021 Omnibus Equity Incentive Plan

On July 19, 2021, the Company's Board of Directors adopted the RenovoRx, Inc. 2021 Omnibus Equity Incentive Plan (the "2021 Plan"). The 2021 Plan, which became effective immediately prior to the closing of the IPO, provides for the grant of incentive stock options ("ISO"), non-statutory stock options ("NSO"), restricted stock, restricted stock units, stock appreciation rights, and other stock-based awards to selected employees, directors, and consultants. The Company initially reserved 2,175,000 shares of common stock, including the addition of 10,832 common shares available pursuant to the Amended and Restated 2013 Equity Incentive Plan (the "2013 Plan"). The Company's 2013 Plan was terminated immediately prior to the closing of the IPO; however, shares subject to awards granted under the 2013 Plan will continue to be governed by the 2013 Plan. Shares subject to awards granted under the 2013 Plan that are repurchased by, or forfeited to, the Company will also be reserved for issuance under the 2021 Plan. The 2021 Plan provides an annual increase on the first day of each calendar year beginning with the first January 1, 2022 and ending with the last January 1 during the initial ten-year term of the 2021 Plan, equal to the lesser of (A) three percent (3%) of the shares outstanding on the final day of the immediately preceding calendar year; (B) 343,734 shares; and (C) such lesser number of shares as determined by the Board; provided, that, shares of common stock issued under the 2021 Plan with respect to an "Exempt Award" shall not count against such share limit. The term "Exempt Award" means (i) an award granted in assumption of, or in substitution for, outstanding awards previously granted by another business entity acquired by the Company or any of its subsidiaries or with which the Company or any of its subsidiaries merge, or (ii) an award that a participant purchases at fair value. Upon adoption of the 2021 Plan, no further awards shall be issued under the 2013 Plan, but all awards under the 2013 Plan which are outstanding, including any Grandfathered Arrangement, shall continue to be governed by the terms, conditions and procedures set forth in the Prior Plan and any applicable Award Agreement.

Options under the 2021 Plan may be granted for periods of up to 10 years and at exercise prices no less than 100% of the estimated fair value of the underlying shares of common stock on the date of grant as determined by the Board of Directors provided that the exercise price of an ISO and NSO granted to a 10% stockholder shall not be less than 110% of the estimated fair value of the shares on the date of grant. The 2021 Plan requires that options be exercised no later than 10 years after the grant. Options granted to employees generally vest ratably on a monthly basis over four years, subject to cliff vesting restrictions. Since the date of adoption of the 2013 and 2021 Plans and through September 30, 2021, the Company has issued stock-based awards to its employees, directors, and consultants. In most instances, the options vest over a four-year period, subject to continuing service.

A summary of the stock option activity for the year ended December 31, 2021 is as follows:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2020	998,166	$ 0.42	5.84	$ 276
Granted	312,252	5.23		
Exercised	(358,332)	0.30		
Forfeited	(25,625)	0.68		
Expired	(82)	0.70		
Outstanding at December 31, 2021	926,379	$ 2.08	6.47	2,856
Vested and exercisable at December 31, 2021	620,260	$ 0.72	5.41	$ 2,584
Vested and expected to vest at December 31, 2021	926,379	$ 2.08	6.47	$ 2,890

The aggregate intrinsic value of options outstanding, vested and exercisable, and vested and expected to vest were calculated as the difference between the exercise price of the option and the stock price of the Company's common stock as of December 31, 2021.

The following table summarizes the outstanding and exercisable options as of December 31, 2021:

Exercise Price Per Share	Options Outstanding at End of the Year	Weighted Average Remaining Contractual Life (Years)	Options Exercisable at End of the Year	Weighted Average Remaining Contractual Life (Years)
$ 0.00 - $1.00	624,927	5.54	587,774	5.52

$	2.01 - $3.00	57,400	9.42	8,400	9.40
$	5.01 - $6.00	66,924	9.75	9,914	9.75
$	6.01 - $7.00	170,069	9.75	14,172	9.75
$	8.01 - $9.00	7,059	9.86	-	-
		926,379		620,260	

The Company uses the Black-Scholes option pricing model to estimate the fair value of each option grant on the date of grant or any other measurement date. The following sets forth the weighted average assumptions used to determine the fair value of stock options for the years ended December 31, 2021 and 2020:

	December 31,	
	2021	2020
Expected term (years)	5.00 – 6.33	5.24
Risk-free interest rate	0.62% - 1.36%	1.29%
Volatility factor	41.66% - 82.12%	38%
Dividend yield	-	-

- Volatility—The Company estimates the expected volatility of its common stock at the date of grant based on the historical volatility of comparable public companies over the expected term.
- Expected term—The expected term for pre-IPO grants is estimated as the midpoint between the requisite service period and the contractual term of the award. For grants issued post-IPO, the expected term is based on an average of comparable public companies.
- Risk-free interest rate—The risk-free rate for periods within the estimated term of the stock award is based on the U.S. Treasury yield curve in effect at the date of grant.
- Dividend rate—The assumed dividend yield is based upon the Company's expectation of not paying dividends in the foreseeable future.

As of December 31, 2021, the total unrecognized stock-based compensation expense related to non-vested stock options was $0.9 million, which the Company expects to recognize over a weighted-average period of approximately 2.75 years.

During the years ended December 31, 2021, and 2020, the Company recognized $147,000 and $33,000, respectively, in stock-based compensation expense from stock option grants and restricted stock awards. The compensation expense is allocated on a departmental basis, based on the classification of the option holder. No income tax benefits have been recognized in the statements of operations for stock-based compensation arrangements.

The following table summarizes the components of stock-based compensation expense recognized in the Company's statements of operations during the years ended December 31, 2021, and 2020 (in thousands):

	December 31,	
	2021	2020
Research and development	$ 26	$ 8
General and administrative	121	25
Total stock-based compensation expense	$ 147	$ 33

In February 2020, the Company granted 24,478 shares of restricted common stock under the 2013 Plan to a consultant as partial consideration for services rendered, with a deemed fair value of $0.70 per share or $17,000. The fair value of this restricted stock award was expensed as stock-based compensation on the date of grant as they were fully vested on that date.

Common Stock Warrants

In connection with the IPO, the Company issued warrants to purchase 3,035,195 shares of the Company's common stock, of which, warrants to purchase 198,875 shares of the Company's common stock expire on August 25, 2026, and warrants to purchase 2,836,320 shares of the Company's common stock expire on August 31, 2026. See Note 1, *Initial Public Offering*.

The following is a summary of the common stock warrant activity during the year ended December 31, 2021:

	Shares Issuable Upon Exercise of Outstanding Warrants	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding as of December 31, 2020	-	-	-	-
Issued	3,035,195	$ 10.80	-	-
Exercised	(248,200)	$ 10.80	-	-
Expired	-	-	-	-
Outstanding as of December 31, 2021	2,786,995	$ 10.80	4.67	$ 30,100

10. Income Tax

For the years ended December 31, 2021 and 2020, the Company's income tax provision is zero due to a full valuation allowance against the deferred tax assets.

The differences between the statutory tax expense (benefit) rate and the effective tax expense (benefit) rate, were as follows (in thousands):

	December 31,	
	2021	2020

Statutory federal income tax rate	$ (1,321)	$ (799)
Increase (decrease) resulting from:		
Change in valuation allowance	1,624	844
Permanent Items	134	107
Prior year true ups	70	-
Tax credits	(176)	(125)
State	(331)	(28)
Other	-	1
Income tax provision/(benefit)	$ -	$ -

The components of our deferred tax assets and liabilities consist of (in thousands):

	December 31,	
	2021	2020
Deferred tax assets:		
Net operating loss carryforwards	$ 4,453	$ 3,146
Tax credit carryforwards	887	607
Stock-based compensation	29	24
Fixed assets/intangible assets	99	74
Others	7	1
	5,475	3,852
Valuation allowance	(5,475)	(3,852)
Total deferred tax assets	$ -	$ -

The Company has established a valuation allowance to offset net deferred tax assets as of December 31, 2021 and 2020 due to the uncertainty of realizing future tax benefits from such assets.

As of December 31, 2021, the Company had U.S. federal and state net operating loss ("NOL") carryforward amounts of $18.1 million and $11.7 million, respectively. The federal NOL carryforwards consists of $4.7 million generated before January 1, 2018, which will begin to expire in 2030 but are able to offset 100% of taxable income and $13.5 million generated after December 31, 2017 which can be carried forward indefinitely and may be able to be used against 100% of taxable income through the tax year ending December 31, 2020, as updated by the Coronavirus Aid, Relief, and Economic Security Act (P.L. 116-136), otherwise known as the CARES Act. Federal NOLs will then be subject to 80% limitation for tax years beginning on or after January 1, 2021.The state NOL carryforward will begin to expire in 2033.

As of December 31, 2021, the Company had federal and state tax credit carryforwards of $1.0 million which will begin to expire in 2033, and California tax credit carryforwards of $0.2 million which do not expire.

The Company follows Financial Accounting Standards Board No. 48,*Accounting for Uncertainty in Income Taxes – an interpretation of FASB No. 109*, as codified in FASB ASC 740-10, *Income Taxes.* At December 31, 2021, unrecognized tax benefits related to federal and state tax credits was $0.3 million. The Company did not have tax-related interest and penalties at December 31, 2021. The Company does not expect significant changes to its unrecognized tax benefits in the next twelve months. If recognized, none of the unrecognized tax benefits would affect the effective tax rate:

The following summarizes the activity related to the Company's unrecognized tax benefits for the years ended December 31, 2020 and December 31, 2021 (in thousands):

Balance at January 1, 2019	$ 142
Tax positions related to the current year:	
Additions	70
Balance at December 31, 2020	212
Tax positions related to the current year:	
Additions	97
Balance at December 31, 2021	$ 309

The utilization of NOLs and tax credit carryforwards to offset future taxable income may be subject to an annual limitation as a result of ownership changes that have occurred previously or that may occur in the future. Under Sections 382 and 383 of the Internal Revenue Code ("IRC") a corporation that undergoes an ownership change may be subject to limitations on its ability to utilize its pre-change NOLs and other tax attributes otherwise available to offset future taxable income and/or tax liability. An ownership change is defined as a cumulative change of 50% or more in the ownership positions of certain stockholders during a rolling three-year period. The Company has not completed a formal study to determine if any ownership changes within the meaning of IRC Section 382 and 383 have occurred. If an ownership change has occurred, the Company's ability to use its NOLs or tax credit carryforwards may be restricted, which could require the Company to pay federal or state income taxes earlier than would be required if such limitations were not in effect.

The Company files income tax returns in the U.S. federal jurisdiction and various state jurisdictions. The Company is subject to U.S. federal and state income tax examination for calendar tax years beginning in 2010 due to net operating losses that are being carried forward for tax purposes.

On March 27, 2020, the CARES Act was enacted and signed into law in response to the COVID-19 pandemic. GAAP requires recognition of the tax effects of new legislation during the reporting period that includes the enactment date. The CARES Act includes changes to the tax provisions that benefits business entities and makes certain technical corrections to the 2017 Tax Cuts and Jobs Act. The tax relief measures for businesses include a five-year net operating loss carryback, suspension of the annual deduction limitation of 80% of taxable income from net operating losses generated in a tax year beginning after December 31, 2017, changes in the deductibility of interest, acceleration of alternative minimum tax credit refunds, payroll tax relief, technical corrections on net operating loss carryforwards for fiscal year taxpayers and allows accelerated deduction qualified improvement property. The CARES Act also provides other non-tax benefits to assist those impacted by the pandemic. The Company filed for and received a PPP loan. We evaluated the impact of the CARES Act and determined that there was no material impact for the year ended December 31, 2020.

On June 29, 2020, California Assembly Bill 85 was signed into law. The legislation suspends the California net operating loss deductions for 2020, 2021, and 2022 for certain taxpayers and imposes a limitation of certain California tax credits for 2020, 2021, and 2022. The legislation disallows the use of California net operating loss deductions if the taxpayer recognizes business income and its adjusted gross income is greater than $1.0 million. The carryover periods for net operating loss deductions disallowed by this provision will be extended. Additionally, any business credit will only offset a maximum of $5.0 million of California tax. Given our loss position in the current year, the new

legislation did not impact the current year provision or our financial statements for the year ended December 31, 2020. We will continue to monitor possible California net operating loss and credit limitations in future periods.

On December 27, 2020, the Consolidated Appropriations Act, 2021 was enacted and signed into law to further COVID-19 economic relief and extend certain expiring tax provisions. The relief package includes a tax provision clarifying that businesses with forgiven PPP loans can deduct regular business expenses that are paid for with the loan proceeds. Additional pandemic relief tax measures include an expansion of the employee retention credit, enhanced charitable contribution deductions, and a temporary full deduction for business expenses for food and beverages provided by a restaurant. The provisions did not have a material impact on our financial statements for the year ended December 31, 2021.

11. Net Loss per Share

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

	Year Ended December 31,	
	2021	**2020**
Numerator:		
Net loss	$ (6,324)	$ (3,798)
Denominator:		
Weighted average shares used in computing net loss per share – basic and diluted	5,217	2,214
Net loss per share – basic and diluted	$ (1.21)	$ (1.72)

For the years ended December 31, 2021 and 2020, the Company had a net loss and as such, all outstanding shares of potentially dilutive securities were excluded from the calculation of diluted net loss per share as the inclusion would be anti-dilutive.

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

	Year ended December 31,	
	2021	**2020**
Convertible preferred stock	-	3,535,469
Options to purchase common stock	684,382	997,266
Total	684,382	4,532,735

12. Commitments and Contingencies

Operating Lease

The Company leases its headquarters in Los Altos, California under aone-year operating lease agreement which expires on May 31, 2022. As of December 31, 2021, the Company's operating lease liability was $30,000. Rent expense under the operating lease was $60,000 and $44,000 for the years ended December 31, 2021 and 2020, respectively.

Legal Proceedings

From time to time, the Company may become involved in legal proceedings arising in the ordinary course of business.

The Company was not subject to any material legal proceedings during the years ended December 31, 2021 and 2020, and no material legal proceedings are subsequently outstanding or pending.

Guarantees and Indemnifications

In the normal course of business, the Company enters into agreements that contain a variety of representations and provide for general indemnification. The Company's exposure under these agreements is unknown because it involves claims that may be made against the Company in the future. To date, the Company has not paid any claims or been required to defend any action related to its indemnification obligations. As of December 31, 2021, the Company is not subject to any material indemnification claims whose assertion is probable or reasonably possible. Consequently, the Company has not recorded any related liabilities.

13. Related Party Transactions

In January 2018, the Company entered into a consulting agreement with one of the Company's co-founders, Dr. Ramtin Agah, pursuant to which Dr. Agah provides consulting services as the Company's Chief Medical Officer by overseeing Company-sponsored clinical trials. The Agreement, which was amended on September 1, 2019, and November 11, 2021, continues in force for as long as Dr. Agah is providing consulting services and may be terminated by either party on thirty (30) days' notice. Dr. Agah was awarded (i) options to purchase 60,000 shares of the Company's common stock in May 2017, which have vested, (ii) options to purchase 40,000 shares of the Company's common stock in July 2018, of which 25% vested after one year and the remainder vests ratably over the 36 month period ending July 2022, (iii) options to purchase 20,000 shares of the Company's common stock in June 2021, which vest ratably over 24 months from the vesting commencement date of May 14, 2021, and (iv) options to purchase of 52,203 shares of the Company's common stock in September 2021, which vest ratably over 48 months from the vesting commencement date of August 26, 2021. In December 2018, Dr. Agah's agreement was amended to provide that he would receive cash compensation of $4,000 per month for certain proctoring services, and in September 2019, his compensation was increased to $10,000 per month to compensate for additional services he was providing.In November 2021, we entered into a third amendment to the Consulting Agreement with Dr. Agah which provides for a monthly consulting fee of $21,667.67, based on Dr. Agah spending no less than 24 hours per week on Company matters. Dr. Agah's monthly consulting fee was increased to $24,083.33 effective January 1, 2022. The Company may, in its discretion, proportionally adjust the monthly consulting fee if Dr. Agah's time commitment decreases. The Amendment also provides for Dr. Agah's eligibility for an annual target cash incentive bonus equal to 35% of his annualized base consulting fee. In November 2021, we entered into a Change in Control and Severance Agreement with Dr. Agah. Consulting fees paid to Dr. Agah for the years ending December 31, 2021 and 2020, were $227,000 and $120,000, respectively.

In July 2019, the Company entered into a consulting agreement with the Company's then Chief Financial Officer, Paul Manners. In February 2020, the Company granted Mr.

Manners an option to purchase 28,000 shares of the Company's common stock, of which 25% were vested at the grant date and the remainder vested ratably over the following 18 months. Mr. Manners' consulting agreement was amended in December 2020 to increase his hourly rate to $150. Consulting fees paid to Mr. Manners for the years ending December 31, 2021 and 2020, were $161,000 and $43,000, respectively. In August 2021, upon completion of the IPO, Mr. Manners stepped down from his role and Christopher J. Lehman, was appointed Chief Financial Officer. Mr. Manners consulting agreement with the Company terminated in December 2021.

Kamran Najmabadi, another co-founder of the Company, has served as our consulting technical engineering advisor on manufacturing and intellectual property matters since January 2020. Mr. Najmabadi served as the Company's Chief Executive Officer from its inception in December 2009 until January 2013; Chief Technical and Operations Officer from January 2013 until January 2019; and Chief Technology Officer from January 2019 to January 2020. He currently receives cash compensation of $3,000 per quarter. Consulting fees paid to Mr. Najmabadi for the years ending December 31, 2021 and 2020, were $13,000 and $12,000, respectively

14. Subsequent Events

In March 2022, non-qualified stock options to purchase an aggregate of 27,493 shares were granted to members of the Board of Directors, a non-qualified stock option to purchase 21,398 shares of common stock were granted to Dr. Agah and an incentive stock option to purchase 48,313 shares of common stock were granted to Mr. Bagai.

In March 2022, Mr. Bagai's annual base salary was increased to $495,000, retroactively effective to January 1, 2022, to align Mr. Bagai's compensation more closely to the 50th percentile of the peer group of companies that the Company benchmarks its compensation against. Mr. Bagai's annual bonus target was not changed.

Exhibit 3.2

RENOVORX, INC.
a Delaware Corporation
(the "***Corporation***")

AMENDED AND RESTATED BYLAWS

As Adopted March 24, 2022

ARTICLE I
MEETINGS OF STOCKHOLDERS

Section 1.1 **Place of Meetings**. Meetings of stockholders shall be held at any place, within or outside the State of Delaware, designated by the board of directors of the Corporation (the "***Board of Directors***"). The Board of Directors may, in its sole discretion, determine that a meeting of stockholders shall not be held at any place, but may instead be held solely by means of remote communication as authorized by Section 211(a) of the General Corporation Law of the State of Delaware (the "***DGCL***"). In the absence of any such designation or determination, stockholders' meetings shall be held at the Corporation's principal executive office.

Section 1.2 **Annual Meetings.** The Board of Directors shall designate the date and time of the annual meeting. At the annual meeting, directors shall be elected and other proper business properly brought before the meeting in accordance with Section 1.4 of these bylaws may be transacted.

Section 1.3 **Special Meetings.** Special meetings of stockholders for any purpose or purposes may be called at any time only by the Board of Directors, the chairperson of the Board of Directors, the chief executive officer or the president (in the absence of a chief executive officer) of the Corporation, and may not be called by any other person or persons. Business transacted at any special meeting of stockholders shall be limited to the purpose or purposes stated in the notice of meeting. Nothing contained in this paragraph of this Section 2.3 shall be construed as limiting, fixing, or affecting the time when a meeting of stockholders called by action of the Board may be held.

Section 1.4 **Notice of Meetings.** Notice of all meetings of stockholders shall be given in writing or by electronic transmission in the manner provided by law (including, without limitation, as set forth in Section 7.1.1 of these Bylaws) stating the date, time and place, if any, of the meeting and, in the case of a special meeting, the purpose or purposes for which the meeting is called. Unless otherwise required by applicable law or the Certificate of Incorporation of the Corporation (the "***Certificate of Incorporation***"), such notice shall be given not less than ten (10), nor more than sixty (60), days before the date of the meeting to each stockholder of record entitled to vote at such meeting. Notice of any meeting of stockholders shall be deemed given: (a) if mailed, when deposited in the United States mail, postage prepaid, directed to the stockholder at such stockholder's address as it appears on the Corporation's records; or (b) if electronically transmitted, as provided in Section 7.1.2 of these bylaws. An affidavit of the secretary or an assistant secretary of the Corporation or of the transfer agent or any other agent of the Corporation that the notice has been given by mail or by a form of electronic transmission, as applicable, shall, in the absence of fraud, be prima facie evidence of the facts stated therein.

Section 1.5 **Adjournments.** The chairperson of the meeting shall have the power to adjourn the meeting to another time, date and place (if any). Any meeting of stockholders may adjourn from time to time, and notice need not be given of any such adjourned meeting if the time, date and place (if any) thereof and the means of remote communications (if any) by which stockholders and proxy holders may be deemed to be present in person and vote at such adjourned meeting are announced at the meeting at which the adjournment is taken; *provided, however*, that if the adjournment is for more than thirty (30) days, or if a new record date is fixed for the adjourned meeting, then a notice of the adjourned meeting shall be given to each stockholder of record entitled to vote at the meeting. At the adjourned meeting the Corporation may transact any business that might have been transacted at the original meeting. To the fullest extent permitted by law, the Board may postpone or reschedule any previously scheduled special or annual meeting of stockholders before it is to be held, in which case notice shall be provided to the stockholders of the new date, time and place, if any, of the meeting as provided in Section 1.4 above. For the avoidance of doubt, any previously scheduled annual or special meeting of the stockholders may be postponed or adjourned, and any previously scheduled annual or special meeting of the stockholders may be canceled, by resolution of the Board of Directors.

Section 1.6 **Quorum.** Unless otherwise provided by law, the Certificate of Incorporation or these Bylaws, the holders of a majority in voting power of the capital stock issued and outstanding and entitled to vote, present in person, or by remote communication, if applicable, or represented by proxy, shall constitute a quorum for the transaction of business at all meetings of the stockholders. A quorum, once established at a meeting, shall not be broken by the withdrawal of enough votes to leave less than a quorum. If, however, a quorum is not present or represented at any meeting of the stockholders, then the chairperson of the meeting present in person, or by remote communication, if applicable, shall have power to adjourn the meeting from time to time in the manner provided in Section 1.5 of these bylaws until a quorum is present or represented. At such adjourned meeting at which a quorum is present or represented, any business may be transacted that might have been transacted at the meeting as originally noticed.

Section 1.7 **Organization.** The date and time of the opening and the closing of the polls for each matter upon which the stockholders will vote at a meeting shall be announced at the meeting by the person presiding over the meeting. The Board may adopt by resolution such rules and regulations for the conduct of the meeting of stockholders as it shall deem appropriate. Except to the extent inconsistent with such rules and regulations as adopted by the Board, the person presiding over any meeting of stockholders shall have the right and authority to convene and (for any or no reason) to recess and/or adjourn the meeting, to prescribe such rules, regulations and procedures (which need not be in writing) and to do all such acts as, in the judgment of such presiding person, are appropriate for the proper conduct of the meeting. Such rules, regulations or procedures, whether adopted by the Board or prescribed by the presiding person of the meeting, may include, without limitation, the following: (a) the establishment of an agenda or order of business for the meeting; (b) rules and procedures for maintaining order at the meeting and the safety of those present (including, without limitation, rules and procedures for removal of disruptive persons from the meeting); (c) limitations on attendance at or participation in the meeting to stockholders entitled to vote at the meeting, their duly authorized and constituted proxies or such other persons as the presiding person of the meeting shall determine; (d) restrictions on entry to the meeting after the time fixed for the commencement thereof; and (e) limitations on the time allotted to questions or comments by participants. The presiding person at any meeting of stockholders, in addition to making any other determinations that may be appropriate to the conduct of the meeting (including, without limitation, determinations with respect to the administration and/or interpretation of any of the rules, regulations or procedures of the meeting, whether adopted by the Board or prescribed by the person presiding over the meeting), shall, if the facts warrant, determine and declare to the meeting that a matter or business was not properly brought before the meeting and if such presiding person should so determine, such presiding person shall so declare to the meeting and any such matter or business not properly brought before the meeting shall not be transacted or considered. Unless and to the extent determined by the Board or the person presiding over the meeting, meetings of stockholders shall not be required to be held in accordance with the rules of parliamentary procedure.

Section 1.8 **Voting; Proxies.** Each stockholder entitled to vote at a meeting of stockholders may authorize another person or persons to act for such stockholder by proxy, but no such proxy shall be voted or acted upon after three (3) years from its date, unless the proxy provides for a longer period. The revocability of a proxy that states on its face that it is irrevocable shall be governed by the provisions of Section 212 of the DGCL. A proxy may be in the form of a telegram, cablegram or other means of electronic transmission, as permitted by applicable law, which sets forth or is submitted with information from which it can be determined that the telegram, cablegram or other means of electronic transmission was authorized by the stockholder. Except as may be otherwise provided in the Certificate of Incorporation or these Bylaws, each stockholder shall be entitled to one (1) vote for each share of capital stock held by such stockholder. At all duly called or convened meetings of stockholders, at which a quorum is present, for the election of directors, a plurality of the votes cast shall be sufficient to elect a director. All other elections and questions presented to the stockholders at a duly called or convened meeting,

at which a quorum is present, shall, unless a different or minimum vote is required by the certificate of incorporation, these bylaws, the rules or regulations of any stock exchange applicable to the Corporation, or any law or regulation applicable to the Corporation or its securities, in which case such different or minimum vote shall be the applicable vote on the matter, be decided by the affirmative vote of the holders of a majority in voting power of the votes cast affirmatively or negatively (excluding abstentions) at the meeting by the holders entitled to vote thereon.

Section 1.9 **Stockholder Action by Written Consent Without a Meeting**. Any action required or permitted to be taken by the stockholders of the Corporation must be effected at a duly called annual or special meeting of stockholders of the Corporation and may not be effected by any consent in writing by such stockholders.

Section 1.10 **Fixing Date for Determination of Stockholders of Record**. In order that the Corporation may determine the stockholders entitled to notice of any meeting of stockholders or any adjournment thereof, the Board of Directors may fix a record date, which record date shall not precede the date upon which the resolution fixing the record date is adopted by the Board of Directors, and which record date shall, unless otherwise required by law, not be more than sixty (60) nor less than ten (10) days before the date of such meeting. If the Board of Directors so fixes a date, such date shall also be the record date for determining the stockholders entitled to vote at such meeting unless the Board of Directors determines, at the time it fixes such record date, that a later date on or before the date of the meeting shall be the date for making such determination. If no record date is fixed by the Board of Directors, the record date for determining stockholders entitled to notice of or to vote at a meeting of stockholders shall be at the close of business on the day next preceding the day on which notice is given, or, if notice is waived, at the close of business on the day next preceding the day on which the meeting is held. A determination of stockholders of record entitled to notice of or to vote at a meeting of stockholders shall apply to any adjournment of the meeting; *provided, however*, that the Board of Directors may fix a new record date for determination of stockholders entitled to vote at the adjourned meeting, and in such case shall also fix as the record date for stockholders entitled to notice of such adjourned meeting the same or an earlier date as that fixed for determination of stockholders entitled to vote in accordance herewith at the adjourned meeting.

In order that the Corporation may determine the stockholders entitled to receive payment of any dividend or other distribution or allotment of any rights, or entitled to exercise any rights in respect of any change, conversion or exchange of stock or for the purpose of any other lawful action, the Board of Directors may fix a record date, which shall not be more than sixty (60) days prior to such other action. If no such record date is fixed, the record date for determining stockholders for any such purpose shall be at the close of business on the day on which the Board of Directors adopts the resolution relating thereto.

Section 1.11 **List of Stockholders Entitled to Vote**. The Corporation shall prepare, at least ten (10) days before every meeting of stockholders, a complete list of the stockholders entitled to vote at the meeting (provided, however, if the record date for determining the stockholders entitled to vote is less than ten (10) days before the date of the meeting, the list shall reflect the stockholders entitled to vote as of the tenth day before the date of the meeting), arranged in alphabetical order, and showing the address of each stockholder and the number of shares registered in the name of each stockholder. The Corporation shall not be required to include electronic mail addresses or other electronic contact information on such list. Such list shall be open to the examination of any stockholder, for any purpose germane to the meeting for a period of at least ten (10) days prior to the meeting: (a) on a reasonably accessible electronic network, provided that the information required to gain access to such list is provided with the notice of the meeting, or (b) during ordinary business hours, at the Corporation's principal executive office. In the event that the Corporation determines to make the list available on an electronic network, the Corporation may take reasonable steps to ensure that such information is available only to stockholders of the Corporation. If the meeting is to be held at a place, then the list shall be produced and kept at the time and place of the meeting during the whole time thereof, and may be inspected by any stockholder who is present. If the meeting is to be held solely by means of remote communication, then the list shall also be open to the examination of any stockholder during the whole time of the meeting on a reasonably accessible electronic network, and the information required to access such list shall be provided with the notice of the meeting. Except as otherwise provided by law, the stock ledger shall be the only evidence as to the identity of the stockholders entitled to vote in person or by proxy and the number of shares held by each of them, and as to the stockholders entitled to examine the list of stockholders.

Section 1.12 **Inspectors of Elections**.

1.12.1 Appointment. The Corporation shall, in advance of any meeting of stockholders, appoint one or more inspectors of election to act at the meeting and make a written report thereof. The Corporation may designate one or more persons as alternate inspectors to replace any inspector who fails to act. If no inspector or alternate is able to act at a meeting of stockholders, the person presiding at the meeting shall appoint one or more inspectors to act at the meeting.

1.12.2 Inspector's Oath. Each inspector of election, before entering upon the discharge of his or her duties, shall take and sign an oath faithfully to execute the duties of inspector with strict impartiality and according to the best of such inspector's ability.

1.12.3 Duties of Inspectors. At a meeting of stockholders, the inspectors of election shall (a) ascertain the number of shares outstanding and the voting power of each share, (b) determine the shares represented at a meeting and the validity of proxies and ballots, (c) count all votes and ballots, (d) determine and retain for a reasonable period of time a record of the disposition of any challenges made to any determination by the inspectors, and (e) certify their determination of the number of shares represented at the meeting, and their count of all votes and ballots. The inspectors may appoint or retain other persons or entities to assist the inspectors in the performance of the duties of the inspectors.

1.12.4 Opening and Closing of Polls. The date and time of the opening and the closing of the polls for each matter upon which the stockholders will vote at a meeting shall be announced by the chairperson of the meeting at the meeting. No ballot, proxies or votes, nor any revocations thereof or changes thereto, shall be accepted by the inspectors after the closing of the polls unless the Court of Chancery upon application by a stockholder shall determine otherwise.

1.12.5 Determinations. In determining the validity and counting of proxies and ballots, the inspectors shall be limited to an examination of the proxies, any envelopes submitted with those proxies, any information provided in connection with proxies in accordance with any information provided pursuant to Section 211(a)(2)(B)(i) of the DGCL, or Sections 211(e) or 212(c)(2) of the DGCL, ballots and the regular books and records of the Corporation, except that the inspectors may consider other reliable information for the limited purpose of reconciling proxies and ballots submitted by or on behalf of banks, brokers, their nominees or similar persons which represent more votes than the holder of a proxy is authorized by the record owner to cast or more votes than the stockholder holds of record. If the inspectors consider other reliable information for the limited purpose permitted herein, the inspectors at the time they make their certification of their determinations pursuant to this Section 1.12 shall specify the precise information considered by them, including the person or persons from whom they obtained the information, when the information was obtained, the means by which the information was obtained and the basis for the inspectors' belief that such information is accurate and reliable.

Section 1.13 **Advance Notice Procedures**.

(a) Annual Meetings of Stockholders.

(i) Nominations of persons for election to the Board of Directors or the proposal of other business to be transacted by the stockholders at an annual meeting of stockholders may be made only (1) pursuant to the Corporation's notice of meeting (or any supplement thereto); (2) by or at the direction of the Board of Directors; (3) as may be provided in the certificate of designations for any class or series of preferred stock; or (4) by any stockholder of the Corporation who (A) is a stockholder of record at the time

of giving of the notice contemplated by Section 1.13(a)(ii); (B) is a stockholder of record on the record date for the determination of stockholders entitled to notice of the annual meeting; (C) is a stockholder of record on the record date for the determination of stockholders entitled to vote at the annual meeting; (D) is a stockholder of record at the time of the annual meeting; and (E) complies with the procedures set forth in this Section 1.13(a).

(ii) For nominations or other business to be properly brought before an annual meeting of stockholders by a stockholder pursuant to clause (4) of Section 1.13(a)(i), the stockholder must have given timely notice in writing to the secretary and any such nomination or proposed business must constitute a proper matter for stockholder action. To be timely, a stockholder's notice must be received by the secretary at the principal executive offices of the Corporation no earlier than 5:00 p.m., local time, on the 120th day and no later than 5:00 p.m., local time, on the 90th day prior to the day of the first anniversary of the preceding year's annual meeting of stockholders. However, if no annual meeting of stockholders was held in the preceding year, or if the date of the applicable annual meeting has been changed by more than 30 days before or more than 60 days after such anniversary date of the preceding year's annual meeting, then to be timely such notice must be received by the secretary at the principal executive offices of the Corporation no earlier than 5:00 p.m., local time, on the 120th day prior to the day of the annual meeting and no later than 5:00 p.m., local time, on the later of the 90th day prior to such annual meeting or the 10th day following the day on which public announcement of the date of the annual meeting was first made by the Corporation. In no event will the adjournment, rescheduling or postponement of any annual meeting, or any announcement thereof, commence a new time period (or extend any time period) for the giving of a stockholder's notice as described above. If the number of directors to be elected to the Board of Directors is increased and there is no public announcement naming all of the nominees for director or specifying the size of the increased Board of Directors at least 10 days before the last day that a stockholder may deliver a notice of nomination pursuant to the foregoing provisions, then a stockholder's notice required by this Section 1.13(a)(ii) will also be considered timely, but only with respect to nominees for any new positions created by such increase, if it is received by the secretary at the principal executive offices of the Corporation no later than 5:00 p.m., local time, on the 10th day following the day on which such public announcement is first made. "***Public announcement***" means disclosure in a press release reported by a national news service or in a document publicly filed by the Corporation with the Securities and Exchange Commission pursuant to Section 13, 14 or 15(d) of the Securities Exchange Act of 1934 (as amended and inclusive of rules and regulations thereunder, the "***1934 Act***").

(iii) A stockholder's notice to the secretary must set forth:

(1) as to each person whom the stockholder proposes to nominate for election as a director:

(A) such person's name, age, business address, residence address and principal occupation or employment; the class and number of shares of the Corporation that are held of record or are beneficially owned by such person and a description of any Derivative Instruments (defined below) held or beneficially owned thereby or of any other agreement, arrangement or understanding (including any short position or any borrowing or lending of shares), the effect or intent of which is to mitigate loss to, or to manage the risk or benefit of share price changes for, or to increase or decrease the voting power of such person; and all information relating to such person that is required to be disclosed in solicitations of proxies for the contested election of directors, or is otherwise required, in each case pursuant to the Section 14 of the 1934 Act;

(B) such person's written consent to being named in such stockholder's proxy statement as a nominee of such stockholder and to serving as a director of the Corporation if elected;

(C) a reasonably detailed description of any direct or indirect compensatory, payment, indemnification or other financial agreement, arrangement or understanding that such person has, or has had within the past three years, with any person or entity other than the Corporation (including the amount of any payment or payments received or receivable thereunder), in each case in connection with candidacy or service as a director of the Corporation (a "***Third-Party Compensation Arrangement***"); and

(D) a description of any other material relationships between such person and such person's respective affiliates and associates, or others acting in concert with them, on the one hand, and such stockholder giving the notice and the beneficial owner, if any, on whose behalf the nomination is made, and their respective affiliates and associates, or others acting in concert with them, on the other hand;

(2) as to any other business that the stockholder proposes to bring before the annual meeting:

(A) a brief description of the business desired to be brought before the annual meeting;

(B) the text of the proposal or business (including the text of any resolutions proposed for consideration and, if applicable, the text of any proposed amendment to these bylaws or the Corporation's certificate of incorporation);

(C) the reasons for conducting such business at the annual meeting;

(D) any material interest in such business of such stockholder giving the notice and the beneficial owner, if any, on whose behalf the proposal is made, and their respective affiliates and associates, or others acting in concert with them; and

(E) a description of all agreements, arrangements and understandings between such stockholder and the beneficial owner, if any, on whose behalf the proposal is made, and their respective affiliates or associates or others acting in concert with them, and any other person or persons (including their names) in connection with the proposal of such business by such stockholder; and

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(3) as to the stockholder giving the notice and the beneficial owner, if any, on whose behalf the nomination or proposal is made:

(A) the name and address of such stockholder (as they appear on the Corporation's books), of such beneficial owner and of their respective affiliates or associates or others acting in concert with them;

(B) for each class or series, the number of shares of stock of the Corporation that are, directly or indirectly, held of record or are beneficially owned by such stockholder, such beneficial owner or their respective affiliates or associates or others acting in concert with them;

(C) a description of any agreement, arrangement or understanding between such stockholder, such beneficial owner or their respective affiliates or associates or others acting in concert with them, and any other person or persons (including, in each case, their names) in connection with the proposal of such nomination or other business;

(D) a description of any agreement, arrangement or understanding (including, regardless of the form of settlement, any derivative, long or short positions, profit interests, forwards, futures, swaps, options, warrants, convertible securities, stock appreciation or similar rights, hedging transactions and borrowed or loaned shares) that has been entered into by or on behalf of such stockholder, such beneficial owner or their respective affiliates or associates or others acting in concert with them, with respect to the Corporation's securities (any of the foregoing, a "***Derivative Instrument***"), or any other agreement, arrangement or understanding that has been made the effect or intent of which is to create or mitigate loss to, manage risk or benefit of share price changes for or increase or decrease the voting power of such stockholder, such beneficial owner or their respective affiliates or associates or others acting in concert with them, with respect to the Corporation's securities;

(E) any rights to dividends on the Corporation's securities owned beneficially by such stockholder, such beneficial owner or their respective affiliates or associates or others acting in concert with them, that are separated or separable from the underlying security;

(F) any proportionate interest in the Corporation's securities or Derivative Instruments held, directly or indirectly, by a general or limited partnership in which such stockholder, such beneficial owner or their respective affiliates or associates or others acting in concert with them, is a general partner or, directly or indirectly, beneficially owns an interest in a general partner of such general or limited partnership;

(G) any performance-related fees (other than an asset-based fee) that such stockholder, such beneficial owner or their respective affiliates or associates or others acting in concert with, them is entitled to based on any increase or decrease in the value of the Corporation's securities or Derivative Instruments, including, without limitation, any such interests held by members of the immediate family of such persons sharing the same household;

(H) any significant equity interests or any Derivative Instruments in any principal competitor of the Corporation that are held by such stockholder, such beneficial owner or their respective affiliates or associates or others acting in concert with them;

(I) any direct or indirect interest of such stockholder, such beneficial owner or their respective affiliates or associates or others acting in concert with them, in any contract with the Corporation, any affiliate of the Corporation or any principal competitor of the Corporation (in each case, including any employment agreement, collective bargaining agreement or consulting agreement);

(J) a representation and undertaking that the stockholder is a holder of record of stock of the Corporation as of the date of submission of the stockholder's notice and intends to appear in person or by proxy at the meeting to bring such nomination or other business before the meeting;

(K) a representation and undertaking that such stockholder or any such beneficial owner intends, or is part of a group that intends, to (x) deliver a proxy statement or form of proxy to holders of at least the percentage of the voting power of the Corporation's then-outstanding stock required to approve or adopt the proposal or to elect each such nominee; or (y) otherwise solicit proxies from stockholders in support of such proposal or nomination;

(L) any other information relating to such stockholder, such beneficial owner, or their respective affiliates or associates or others acting in concert with them, or director nominee or proposed business that, in each case, would be required to be disclosed in a proxy statement or other filing required to be made in connection with the solicitation of proxies in support of such nominee (in a contested election of directors) or proposal pursuant to Section 14 of the 1934 Act; and

(M) such other information relating to any proposed item of business as the Corporation may reasonably require to determine whether such proposed item of business is a proper matter for stockholder action.

(iv) In addition to the requirements of this Section 1.13, to be timely, a stockholder's notice (and any additional information submitted to the Corporation in connection therewith) must further be updated and supplemented (1) if necessary, so that the information provided or required to be provided in such notice is true and correct as of the record date(s) for determining the stockholders entitled to notice of, and to vote at, the meeting and as of the date that is 10 business days prior to the meeting or any adjournment, rescheduling or postponement thereof and (2) to provide any additional information that the Corporation may reasonably request. Such update and supplement or additional information, if applicable, must be received by the secretary at the principal executive offices of the Corporation, in the case of a request for additional information, promptly following a request therefor, which response must be delivered not later than such reasonable time as is specified in any such request from the Corporation or, in the case of any other update or supplement of any information, not later than five business days after the record date(s) for the meeting (in the case of any update and supplement required to be made as of the record date(s)), and not later than eight business days prior to the date for the meeting or any adjournment, rescheduling or postponement thereof (in the case of the update and supplement required to be made as of 10 business days prior to the meeting or any adjournment, rescheduling or postponement thereof). The failure to timely provide such update, supplement or additional information shall result in the nomination or proposal no longer being eligible for consideration at the meeting.

(b) Special Meetings of Stockholders. Except to the extent required by the DGCL, special meetings of stockholders may be called only in accordance with the Corporation's certificate of incorporation and these bylaws. Only such business will be conducted at a special meeting of stockholders as has been brought before the special meeting pursuant to the Corporation's notice of meeting. If the election of directors is included as business to be brought before a special meeting in the Corporation's notice of meeting, then nominations of persons for election to the Board of Directors at such special meeting may be made by any stockholder who (i) is a stockholder of record at the time of giving of the notice contemplated by this Section 1.13(b); (ii) is a stockholder of record on the record date for the determination of stockholders entitled to notice of the special meeting; (iii) is a stockholder of record on the record date for the determination of stockholders entitled to vote at the special meeting; (iv) is a stockholder of record at the time of the special meeting; and (v) complies with the procedures set forth in this Section 1.13(b). For nominations to be properly brought by a stockholder before a special meeting pursuant to this Section 1.13(b), the stockholder's notice must be received by the secretary at the principal executive offices of the Corporation no earlier than 5:00 p.m., local time, on the 120th day prior to the day of the special meeting and no later than 5:00 p.m., local time, on the 10th day following the day on which public announcement of the date of the special meeting was first made. In no event will any adjournment, rescheduling or postponement of a special meeting or the announcement thereof commence a new time period (or extend any time period) for the giving of a stockholder's notice. A stockholder's notice to the Secretary must comply with the applicable notice requirements of Section 1.13(a)(iii).

(c) Other Requirements.

(i) To be eligible to be a nominee by any stockholder for election as a director of the Corporation, the proposed nominee must provide to the secretary, in accordance with the applicable time periods prescribed for delivery of notice under Section 1.13(a)(ii) or Section 1.13(b):

(1) a signed and completed written questionnaire (in the form provided by the secretary at the written request of the nominating stockholder, which form will be provided by the secretary within 10 days of receiving such request) containing information regarding such nominee's background and qualifications and such other information as may reasonably be required by the Corporation to determine the eligibility of such nominee to serve as a director of the Corporation or to serve as an independent director of the Corporation;

(2) a written representation and undertaking that, unless previously disclosed to the Corporation, such nominee is not, and will not become, a party to any voting agreement, arrangement, commitment, assurance or understanding with any person or entity as to how such nominee, if elected as a director, will vote on any issue;

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(3) a written representation and undertaking that, unless previously disclosed to the Corporation, such nominee is not, and will not become, a party to any Third-Party Compensation Arrangement;

(4) a written representation and undertaking that, if elected as a director, such nominee would be in compliance, and will continue to comply, with

the Corporation's corporate governance guidelines as disclosed on the Corporation's website, as amended from time to time; and

(5) a written representation and undertaking that such nominee, if elected, intends to serve a full term on the Board of Directors.

(ii) At the request of the Board of Directors, any person nominated by the Board of Directors for election as a director must furnish to the secretary the information that is required to be set forth in a stockholder's notice of nomination that pertains to such nominee.

(iii) No person will be eligible to be nominated by a stockholder for election as a director of the Corporation unless nominated in accordance with the procedures set forth in this Section 1.13. No business proposed by a stockholder will be conducted at a stockholder meeting except in accordance with this Section 1.13.

(iv) The chairperson of the applicable meeting of stockholders will, if the facts warrant, determine and declare to the meeting that a nomination was not made in accordance with the procedures prescribed by these bylaws or that business was not properly brought before the meeting. If the chairperson of the meeting should so determine, then the chairperson of the meeting will so declare to the meeting and the defective nomination will be disregarded or such business will not be transacted, as the case may be.

(v) Notwithstanding anything to the contrary in this Section 1.13, unless otherwise required by law, if the stockholder (or a qualified representative of the stockholder) does not appear in person at the meeting to present a nomination or other proposed business, such nomination will be disregarded or such proposed business will not be transacted, as the case may be, notwithstanding that proxies in respect of such nomination or business may have been received by the Corporation and counted for purposes of determining a quorum. For purposes of this Section 1.13, to be considered a qualified representative of the stockholder, a person must be a duly authorized officer, manager or partner of such stockholder or must be authorized by a writing executed by such stockholder or an electronic transmission delivered by such stockholder to act for such stockholder as proxy at the meeting, and such person must produce such writing or electronic transmission, or a reliable reproduction of the writing or electronic transmission, at the meeting.

(vi) Without limiting this Section 1.13, a stockholder must also comply with all applicable requirements of the 1934 Act with respect to the matters set forth in this Section 1.13, it being understood that (1) any references in these bylaws to the 1934 Act are not intended to, and will not, limit any requirements applicable to nominations or proposals as to any other business to be considered pursuant to this Section 1.13; and (2) compliance with clause (4) of Section 1.13(a)(i) and with Section 1.13(b) are the exclusive means for a stockholder to make nominations or submit other business (other than as provided in Section 1.13(c)(vii)).

(vii) Notwithstanding anything to the contrary in this Section 1.13, the notice requirements set forth in these bylaws with respect to the proposal of any business pursuant to this Section 1.13 will be deemed to be satisfied by a stockholder if (1) such stockholder has submitted a proposal to the Corporation in compliance with Rule 14a-8 under the 1934 Act; and (2) such stockholder's proposal has been included in a proxy statement that has been prepared by the Corporation to solicit proxies for the meeting of stockholders. Subject to Rule 14a-8 and other applicable rules and regulations under the 1934 Act, nothing in these bylaws will be construed to permit any stockholder, or give any stockholder the right, to include or have disseminated or described in the Corporation's proxy statement any nomination of a director or any other business proposal.

ARTICLE II
BOARD OF DIRECTORS

Section 2.1 **Powers**. Subject to the provisions of the DGCL and any limitations in the certificate of incorporation, the business and affairs of the Corporation shall be managed and all corporate powers shall be exercised by or under the direction of the Board of Directors.

Section 2.2 **Number of Directors.** The authorized number of directors shall be determined from time to time by resolution of the Board, provided the Board shall consist of at least one (1) member. No reduction of the authorized number of directors shall have the effect of removing any director before that director's term of office expires. Directors need not be stockholders of the Corporation.

Section 2.3 **Election; Qualification and Term of Office.** Except as provided in Section 2.4 and Section 2.5 of these Bylaws, each director, including, without limitation, a director elected to fill a vacancy, shall hold office until the expiration of the term for which elected and until such director's successor is elected and qualified or until such director's earlier death, resignation or removal. Directors need not be stockholders unless so required by the Certificate of Incorporation or these Bylaws. The Corporation may also have, at the discretion of the Board, a chairperson of the Board and a vice chairperson of the Board. The Certificate of Incorporation or these Bylaws may prescribe other qualifications for directors.

Section 2.4 **Resignation and Vacancies.** Any director may resign at any time upon notice given in writing or by electronic transmission to the chairperson of the Board of Directors or the Corporation's chief executive officer, president or secretary. When one or more directors so resigns and the resignation is effective at a future date, a majority of the directors then in office, including those who have so resigned, shall have power to fill such vacancy or vacancies, the vote thereon to take effect when such resignation or resignations shall become effective, and each director so chosen shall hold office as provided in this Section 2.4 in the filling of other vacancies.

Unless otherwise provided in the Certificate of Incorporation or these Bylaws, vacancies and newly created directorships resulting from any increase in the authorized number of directors shall, unless the Board of Directors determines by resolution that any such vacancies or newly created directorships shall be filled by stockholders, be filled only by a majority of the directors then in office, although less than a quorum, or by a sole remaining director. Any director elected in accordance with the preceding sentence shall hold office for the remainder of the full term of the director for which the vacancy was created or occurred and until such director's successor shall have been elected and qualified. A vacancy in the Board of Directors shall be deemed to exist under these Bylaws in the case of the death, removal or resignation of any director.

Section 2.5 **Removal of Directors**. Subject to the rights of the holders of the shares of any series of preferred stock of the Corporation, the Board or any individual director may be removed from office only for cause and only by the affirmative vote of the holders of at least two-thirds in voting power of the outstanding shares of capital stock of the Corporation entitled to vote thereon.

Section 2.6 **Regular Meetings.** Regular meetings of the Board may be held at such places, within or without the State of Delaware, and at such times as the Board may from time to time determine. Notice of regular meetings need not be given if the date, times and places thereof are fixed by resolution of the Board.

Section 2.7 **Special Meetings.** Special meetings of the Board may be called by the Chairperson of the Board, the President or a majority of the members of the Board then in office and may be held at any time, date or place, within or without the State of Delaware, as the person or persons calling the meeting shall fix. Notice of the time, date and place of such meeting shall be given, orally, in writing or by electronic transmission (including electronic mail), by the person or persons calling the meeting to all directors at least four (4) days before the meeting if the notice is mailed, or at least twenty-four (24) hours before the meeting if such notice is given by telephone, hand delivery, telegram, telex, mailgram, facsimile, electronic mail or other means of electronic transmission. Unless otherwise indicated in the notice, any and all business may be transacted at a special meeting.

Section 2.8 **Remote Meetings Permitted** Members of the Board, or any committee of the Board, may participate in a meeting of the Board or such committee by means of

conference telephone or other communications equipment by means of which all persons participating in the meeting can hear each other, and participation in a meeting pursuant to conference telephone or other communications equipment shall constitute presence in person at such meeting.

Section 2.9 **Quorum; Vote Required for Action.** The majority of the directors at any time in office shall constitute a quorum of the Board of Directors for the transaction of business. The vote of a majority of the directors present at any meeting at which a quorum is present shall be the act of the Board of Directors, except as may be otherwise specifically provided by statute, the Certificate of Incorporation or these Bylaws. If a quorum is not present at any meeting of the Board of Directors, then the directors present thereat may adjourn the meeting from time to time, without notice other than announcement at the meeting, until a quorum is present.

Section 2.10 **Organization.** Meetings of the Board shall be presided over by the Chairperson of the Board, or in such person's absence by a chairperson chosen at the meeting. The Secretary shall act as secretary of the meeting, but in such person's absence the chairperson of the meeting may appoint any person to act as secretary of the meeting.

Section 2.11 **Written Action by Directors.** Any action required or permitted to be taken at any meeting of the Board, or of any committee thereof, may be taken without a meeting if all members of the Board or such committee, as the case may be, consent thereto in writing or by electronic transmission, and the writing or writings or electronic transmission or transmissions are filed with the minutes of proceedings of the Board or committee, respectively, in the minute books of the Corporation. Such filing shall be in paper form if the minutes are maintained in paper form and shall be in electronic form if the minutes are maintained in electronic form.

Section 2.12 **Compensation of Directors.** Members of the Board, as such, may receive, pursuant to a resolution of the Board, fees and other compensation for their services as directors, including without limitation their services as members of committees of the Board.

Section 2.13 **Execution of Corporate Contracts and Instruments**. The Board of Directors, except as otherwise provided in these bylaws, may authorize any officer or officers, or agent or agents, to enter into any contract or execute any instrument in the name of and on behalf of the Corporation; such authority may be general or confined to specific instances. Unless so authorized or ratified by the Board of Directors or within the agency power of an officer, no officer, agent or employee shall have any power or authority to bind the Corporation by any contract or engagement or to pledge its credit or to render it liable for any purpose or for any amount.

ARTICLE III
COMMITTEES

Section 3.1 **Committees.** The Board may designate one or more committees, each committee to consist of one or more of the directors of the Corporation. The Board may designate one or more directors as alternate members of any committee, who may replace any absent or disqualified member at any meeting of the committee. In the absence or disqualification of a member of the committee, the member or members thereof present at any meeting of such committee who are not disqualified from voting, whether or not such member or members constitute a quorum, may unanimously appoint another member of the Board to act at the meeting in place of any such absent or disqualified member. Any such committee, to the extent provided in a resolution of the Board, shall have and may exercise all the powers and authority of the Board in the management of the business and affairs of the Corporation and may authorize the seal of the Corporation to be affixed to all papers that may require it; but no such committee shall have the power or authority in reference to the following matters: (a) approving, adopting, or recommending to the stockholders any action or matter (other than the election or removal of members of the Board) expressly required by the DGCL to be submitted to stockholders for approval or (b) adopting, amending or repealing any bylaw of the Corporation.

Section 3.2 **Committee Rules**. Unless the Board otherwise provides, each committee designated by the Board may make, alter and repeal rules for the conduct of its business. In the absence of such rules each committee shall conduct its business in the same manner as the Board conducts its business pursuant to Article II of these Bylaws.

ARTICLE IV
OFFICERS

Section 4.1 **Generally.** The officers of the Corporation shall consist of a Chief Executive Officer (who may be the Chairperson of the Board or the President), a Secretary and a Treasurer and may consist of such other officers, including a Chief Financial Officer, Chief Medical Officer and one or more Vice Presidents, as may from time to time be appointed by the Board. All officers shall be elected by the Board; *provided, however*, that the Board may empower the Chief Executive Officer of the Corporation to appoint any officer other than the Chairperson of the Board, the Chief Executive Officer, the President, the Chief Financial Officer or the Treasurer. Each officer shall hold office until such person's successor is appointed or until such person's earlier resignation, death or removal. Any number of offices may be held by the same person. Any officer may resign at any time upon written notice to the Corporation. Any vacancy occurring in any office of the Corporation by death, resignation, removal or otherwise may be filled by the Board.

Section 4.2 **Chief Executive Officer.** Subject to the control of the Board and such supervisory powers, if any, as may be given by the Board, the powers and duties of the Chief Executive Officer of the Corporation are:

(a) To act as the general manager and, subject to the control of the Board, to have general supervision, direction and control of the business and affairs of the Corporation;

(b) Subject to Article I, Section 1.6, to preside at all meetings of the stockholders;

(c) Subject to Article I, Section 1.3, to call special meetings of the stockholders to be held at such times and, subject to the limitations prescribed by law or by these Bylaws, at such places as he or she shall deem proper; and

(d) To affix the signature of the Corporation to all deeds, conveyances, mortgages, guarantees, leases, obligations, bonds, certificates and other papers and instruments in writing which have been authorized by the Board or which, in the judgment of the Chief Executive Officer, should be executed on behalf of the Corporation; to sign certificates for shares of stock of the Corporation; and, subject to the direction of the Board, to have general charge of the property of the Corporation and to supervise and control all officers, agents and employees of the Corporation.

The President shall be the Chief Executive Officer of the Corporation unless the Board shall designate another officer to be the Chief Executive Officer. If there is no President, and the Board has not designated any other officer to be the Chief Executive Officer, then the Chairperson of the Board shall be the Chief Executive Officer.

Section 4.3 **Chairperson of the Board.** The Chairperson of the Board shall have the power to preside at all meetings of the Board and shall have such other powers and duties as provided in these Bylaws and as the Board may from time to time prescribe.

Section 4.4 **President.** The President shall be the Chief Executive Officer of the Corporation unless the Board shall have designated another officer as the Chief Executive Officer of the Corporation. Subject to the provisions of these Bylaws and to the direction of the Board, and subject to the supervisory powers of the Chief Executive Officer (if

the Chief Executive Officer is an officer other than the President), and subject to such supervisory powers and authority as may be given by the Board to the Chairperson of the Board, and/or to any other officer, the President shall have the responsibility for the general management and control of the business and affairs of the Corporation and the general supervision and direction of all of the officers, employees and agents of the Corporation (other than the Chief Executive Officer, if the Chief Executive Officer is an officer other than the President) and shall perform all duties and have all powers that are commonly incident to the office of President or that are delegated to the President by the Board.

Section 4.5 **Vice President.** Each Vice President shall have all such powers and duties as are commonly incident to the office of Vice President, or that are delegated to him or her by the Board or the Chief Executive Officer. A Vice President may be designated by the Board to perform the duties and exercise the powers of the Chief Executive Officer in the event of the Chief Executive Officer's absence or disability.

Section 4.6 **Chief Financial Officer.** The Chief Financial Officer shall be the Treasurer of the Corporation unless the Board shall have designated another officer as the Treasurer of the Corporation. Subject to the direction of the Board and the Chief Executive Officer, the Chief Financial Officer shall perform all duties and have all powers that are commonly incident to the office of Chief Financial Officer.

Section 4.7 **Treasurer.** The Treasurer shall have custody of all moneys and securities of the Corporation. The Treasurer shall make such disbursements of the funds of the Corporation as are authorized and shall render from time to time an account of all such transactions. The Treasurer shall also perform such other duties and have such other powers as are commonly incident to the office of Treasurer, or as the Board or the Chief Executive Officer may from time to time prescribe.

Section 4.8 **Secretary.** The Secretary shall issue or cause to be issued all authorized notices for, and shall keep, or cause to be kept, minutes of all meetings of the stockholders the Board. The Secretary shall have charge of the corporate minute books and similar records and shall perform such other duties and have such other powers as are commonly incident to the office of Secretary, or as the Board or the Chief Executive Officer may from time to time prescribe.

Section 4.9 **Delegation of Authority.** The Board may from time to time delegate the powers or duties of any officer to any other officers or agents, notwithstanding any provision hereof.

Section 4.10 **Removal.** Any officer of the Corporation shall serve at the pleasure of the Board and may be removed at any time, with or without cause, by the Board; provided that if the Board has empowered the Chief Executive Officer to appoint any Vice Presidents of the Corporation, then such Vice Presidents may be removed by the Chief Executive Officer. Such removal shall be without prejudice to the contractual rights of such officer, if any, with the Corporation.

ARTICLE V
STOCK

Section 5.1 **Certificates.** The shares of capital stock of the Corporation shall be represented by certificates;*provided, however*, that the Board may provide by resolution or resolutions that some or all of any or all classes or series of its stock may be uncertificated shares. Any such resolution shall not apply to shares represented by a certificate until such certificate is surrendered to the Corporation (or the transfer agent or registrar, as the case may be). Notwithstanding the adoption of such resolution by the Board, every holder of stock that is a certificated security shall be entitled to have a certificate signed by or in the name of the Corporation by the Chairperson or Vice-Chairperson of the Board, or the President or a Vice President, and by the Treasurer or an Assistant Treasurer, or the Secretary or an Assistant Secretary, of the Corporation, certifying the number of shares owned by such stockholder in the Corporation. Any or all of the signatures on the certificate may be a facsimile. In case any officer, transfer agent or registrar who has signed or whose facsimile signature has been placed upon a certificate shall have ceased to be such officer, transfer agent or registrar before such certificate is issued, it may be issued by the Corporation with the same effect as if such person were an officer, transfer agent or registrar at the date of issue. If any holder of uncertificated shares elects to receive a certificate, the Corporation (or the transfer agent or registrar, as the case may be) shall, to the extent permitted under applicable law and rules, regulations and listing requirements of any stock exchange or stock market on which the Corporation's shares are listed or traded, cease to provide annual statements indicating such holder's holdings of shares in the Corporation.

Section 5.2 **Lost, Stolen or Destroyed Stock Certificates; Issuance of New Certificates.** Except as provided in this Section 5.2, no new certificates for shares shall be issued to replace a previously issued certificate unless the latter is surrendered to the Corporation in accordance with applicable law. The Corporation may issue a new certificate of stock or uncertificated shares in the place of any certificate theretofore issued by it, alleged to have been lost, stolen or destroyed, and the Corporation may require the owner of the lost, stolen or destroyed certificate, or such owner's legal representative, to give the Corporation a bond sufficient to indemnify it against any claim that may be made against it on account of the alleged loss, theft or destruction of any such certificate or the issuance of such new certificate or uncertificated shares.

Section 5.3 **Multiple Classes or Series of Stock.** If the Corporation is authorized to issue more than one class of stock or more than one series of any class, then the powers, the designations, the preferences and the relative, participating, optional or other special rights of each class of stock or series thereof and the qualifications, limitations or restrictions of such preferences and/or rights shall be set forth in full or summarized on the face or back of the certificate that the Corporation shall issue to represent such class or series of stock; *provided, however*, that, except as otherwise provided in Section 202 of the DGCL, in lieu of the foregoing requirements, there may be set forth on the face or back of the certificate that the Corporation shall issue to represent such class or series of stock a statement that the Corporation will furnish without charge to each stockholder who so requests the powers, the designations, the preferences and the relative, participating, optional or other special rights of each class of stock or series thereof and the qualifications, limitations or restrictions of such preferences and/or rights. Within a reasonable time after the issuance or transfer of uncertificated stock, the Corporation shall send to the registered owner thereof a written notice containing the information required to be set forth or stated on certificates pursuant to the DGCL or a statement that the Corporation will furnish without charge to each stockholder who so requests the powers, designations, preferences and relative participating, optional or other special rights of each class of stock or series thereof and the qualifications, limitations or restrictions of such preferences and/or rights.

Section 5.4 **Other Regulations.** The issue, transfer, conversion and registration of stock certificates and uncertificated securities shall be governed by such other regulations as the Board of Directors may establish.

ARTICLE VI
INDEMNIFICATION

Section 6.1 **Indemnification of Officers and Directors.** Each person who was or is made a party to, or is threatened to be made a party to, or is involved in any action, suit or proceeding, whether civil, criminal, administrative or investigative (a "***Proceeding***"), by reason of the fact that such person (or a person of whom such person is the legal representative), is or was a member of the Board or officer of the Corporation or a Reincorporated Predecessor (as defined below) or is or was serving at the request of the Corporation or a Reincorporated Predecessor as a member of the board of directors, officer or trustee of another corporation, or of a partnership, joint venture, trust or other enterprise, including service with respect to employee benefit plans (for purposes of this Article VI, an "***Indemnitee***"), shall be indemnified and held harmless by the Corporation to the fullest extent permitted by applicable law, as the same exists or may hereafter be amended (but, in the case of any such amendment, only to the extent that such amendment permits the Corporation to provide broader indemnification rights than such law permitted the Corporation to provide prior to such amendment), against all expenses, liability and loss (including attorneys' fees, judgments, fines, Employee Retirement Income Security Act of 1974, as amended ("***ERISA***") excise taxes and penalties and amounts paid or to be paid in settlement) reasonably incurred or suffered by such Indemnitee in connection therewith, provided such Indemnitee acted in good faith and in a manner that the Indemnitee reasonably believed to be in or not opposed to the best interests of the Corporation, and, with respect to any criminal action or Proceeding, had no

reasonable cause to believe the Indemnitee's conduct was unlawful. Such indemnification shall continue as to an Indemnitee who has ceased to be a director or officer and shall inure to the benefit of such Indemnitees' heirs, executors and administrators. Notwithstanding the foregoing, the Corporation shall indemnify any such Indemnitee seeking indemnity in connection with a Proceeding (or part thereof) initiated by such Indemnitee only if such Proceeding (or part thereof) was authorized by the Board or such indemnification is authorized by an agreement approved by the Board. As used herein, the term the "***Reincorporated Predecessor***" means a corporation that is merged with and into the Corporation in a statutory merger where (a) the Corporation is the surviving corporation of such merger; (b) the primary purpose of such merger is to change the corporate domicile of the Reincorporated Predecessor to Delaware.

Section 6.2 **Partial Indemnification**. If an Indemnitee is entitled under any provision of this Article VI to indemnification by the Corporation for some or a portion of the expenses (including, without limitation, attorneys' fees), liabilities, losses, judgments, fines (including, without limitation, excise taxes and penalties arising under ERISA or amounts paid in settlement actually and reasonably incurred by or on behalf of Indemnitee in connection with any action, suit, proceeding or investigation and any appeal therefrom but not, however, for the total amount thereof, the Corporation shall nevertheless indemnify Indemnitee for the portion of such expenses (including, without limitation, attorneys' fees), liabilities, losses, judgments, fines (including, without limitation, excise taxes and penalties arising ERISA or amounts paid in settlement to which Indemnitee is entitled.

Section 6.3 **Advance of Expenses.** The Corporation shall pay all expenses (including attorneys' fees) incurred by such an Indemnitee in defending any such Proceeding as they are incurred in advance of its final disposition; *provided, however*, that (a) if the DGCL then so requires, the payment of such expenses incurred by such an Indemnitee in advance of the final disposition of such Proceeding shall be made only upon delivery to the Corporation of an undertaking, by or on behalf of such Indemnitee, to repay all amounts so advanced if it should be determined ultimately by final judicial decision from which there is no appeal that such Indemnitee is not entitled to be indemnified under this Article VI or otherwise; and (b) the Corporation shall not be required to advance any expenses to a person against whom the Corporation directly brings a claim, in a Proceeding, alleging that such person has breached such person's duty of loyalty to the Corporation, committed an act or omission not in good faith or that involves intentional misconduct or a knowing violation of law, or derived an improper personal benefit from a transaction.

Section 6.4 **Non-Exclusivity of Rights**. The rights conferred on any person in this Article VI shall not be exclusive of any other right that such person may have or hereafter acquire under any statute, provision of the Certificate of Incorporation, Bylaw, agreement, vote or consent of stockholders or disinterested directors, or otherwise. Additionally, nothing in this Article VI shall limit the ability of the Corporation, in its discretion, to indemnify or advance expenses to persons whom the Corporation is not obligated to indemnify or advance expenses pursuant to this Article VI.

Section 6.5 **Indemnification Contracts.** The Board is authorized to cause the Corporation to enter into indemnification contracts with any director, officer, employee or agent of the Corporation, or any person serving at the request of the Corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, including employee benefit plans, providing indemnification or advancement rights to such person. Such rights may be greater than those provided in this Article VI.

Section 6.6 **Right of Indemnitee to Bring Suit.** The following shall apply to the extent not in conflict with any indemnification contract provided for in Section 6.5 above.

6.6.1 Right to Bring Suit. If a claim under Section 6.1 or Section 6.2 of this Article VI is not paid in full by the Corporation within sixty (60) days after a written claim has been received by the Corporation, except in the case of a claim for an advancement of expenses, in which case the applicable period shall be twenty (20) days, the Indemnitee may at any time thereafter bring suit against the Corporation to recover the unpaid amount of the claim. If successful in whole or in part in any such suit, or in a suit brought by the Corporation to recover an advancement of expenses pursuant to the terms of an undertaking, the Indemnitee shall be entitled to be paid also the expense of prosecuting or defending such suit. In (a) any suit brought by the Indemnitee to enforce a right to indemnification hereunder (but not in a suit brought by the Indemnitee to enforce a right to an advancement of expenses) it shall be a defense that, and (b) in any suit brought by the Corporation to recover an advancement of expenses pursuant to the terms of an undertaking, the Corporation shall be entitled to recover such expenses upon a final adjudication that, the Indemnitee has not met any applicable standard for indemnification set forth in applicable law.

6.6.2 Effect of Determination. Neither the failure of the Corporation (including its directors who are not parties to such action, a committee of such directors, independent legal counsel or its stockholders) to have made a determination prior to the commencement of such suit that indemnification of the Indemnitee is proper in the circumstances because the Indemnitee has met the applicable standard of conduct set forth in applicable law, nor an actual determination by the Corporation (including its directors who are not parties to such action, a committee of such directors, independent legal counsel or its stockholders) that the Indemnitee has not met such applicable standard of conduct, shall create a presumption that the Indemnitee has not met the applicable standard of conduct or, in the case of such a suit brought by the Indemnitee, be a defense to such suit.

6.6.3 Burden of Proof. In any suit brought by the Indemnitee to enforce a right to indemnification or to an advancement of expenses hereunder, or brought by the Corporation to recover an advancement of expenses pursuant to the terms of an undertaking, the burden of proving that the Indemnitee is not entitled to be indemnified, or to such advancement of expenses, under this Article VI, or otherwise, shall be on the Corporation.

Section 6.7 **Nature of Rights.** The rights conferred upon Indemnitees in this Article VI shall be contract rights and such rights shall continue as to an Indemnitee who has ceased to be a director, officer or trustee and shall inure to the benefit of the Indemnitee's heirs, executors and administrators.

Section 6.8 **Subsequent Amendment**. No amendment, termination or repeal of this Article VI or of the relevant provisions of the DGCL or any other applicable laws shall adversely affect or diminish in any way the rights of any Indemnitee to indemnification or advancement of expenses under the provisions hereof with respect to any action, suit, proceeding or investigation arising out of or relating to any actions, transactions or facts occurring prior to the final adoption of such amendment, termination or repeal.

Section 6.9 **Insurance**. The Corporation may purchase and maintain insurance, at its expense, to protect itself and any director, officer, employee or agent of the Corporation or another corporation, partnership, joint venture, trust or other enterprise (including, without limitation, any employee benefit plan) against any expense, liability or loss incurred by him or her in any such capacity, or arising out of his or her status as such, whether or not the Corporation would have the power to indemnify such person against such expense, liability or loss under the DGCL.

Section 6.10 **Savings Clause**. If this Article VI or any portion hereof shall be invalidated on any ground by any court of competent jurisdiction, then the Corporation shall nevertheless indemnify each Indemnitee as to any expenses (including, without limitation, attorneys' fees), liabilities, losses, judgments, fines (including, without limitation, excise taxes and penalties arising under the Employee Retirement Income Security Act of 1974, as amended) and amounts paid in settlement in connection with any action, suit, proceeding or investigation, whether civil, criminal or administrative, including, without limitation, an action by or in the right of the Corporation, to the fullest extent permitted by any applicable portion of this Article IX that shall not have been invalidated and to the fullest extent permitted by applicable law.

ARTICLE VII
NOTICES

Section 7.1 **Notice**.

7.1.1 Form and Delivery. Except as otherwise specifically required in these Bylaws (including, without limitation, Section 7.1.2 below) or by law, all notices required to be given pursuant to these Bylaws shall be in writing and may, (a) in every instance in connection with any delivery to a member of the Board, be effectively given by hand delivery (including use of a delivery service), by depositing such notice in the mail, postage prepaid, or by sending such notice by prepaid telegram, cablegram, overnight express courier, facsimile, electronic mail or other form of electronic transmission and (b) be effectively be delivered to a stockholder when given by hand delivery, by depositing such notice in the mail, postage prepaid or, if specifically consented to by the stockholder as described in Section 7.1.2 of this Article VII by sending such notice by telegram, cablegram, facsimile, electronic mail or other form of electronic transmission. Any such notice shall be addressed to the person to whom notice is to be given at such person's address as it appears on the records of the Corporation. The notice shall be deemed given (a) in the case of hand delivery, when received by the person to whom notice is to be given or by any person accepting such notice on behalf of such person, (b) in the case of delivery by mail, upon deposit in the mail, (c) in the case of delivery by overnight express courier, when dispatched, and (d) in the case of delivery via telegram, cablegram, facsimile, electronic mail or other form of electronic transmission, when dispatched.

7.1.2 Electronic Transmission. Without limiting the manner by which notice otherwise may be given effectively to stockholders, any notice to stockholders given by the Corporation under any provision of the DGCL, the Certificate of Incorporation, or these Bylaws shall be effective if given by a form of electronic transmission consented to by the stockholder to whom the notice is given in accordance with Section 232 of the DGCL. Any such consent shall be revocable by the stockholder by written notice to the Corporation. Any such consent shall be deemed revoked if (a) the Corporation is unable to deliver by electronic transmission two consecutive notices given by the Corporation in accordance with such consent and (b) such inability becomes known to the Secretary or an Assistant Secretary of the Corporation or to the transfer agent, or other person responsible for the giving of notice; *provided, however*, the inadvertent failure to treat such inability as a revocation shall not invalidate any meeting or other action. Notice given pursuant to this Section 7.1.2 shall be deemed given: (i) if by facsimile telecommunication, when directed to a number at which the stockholder has consented to receive notice; (ii) if by electronic mail, when directed to an electronic mail address at which the stockholder has consented to receive notice; (iii) if by a posting on an electronic network together with separate notice to the stockholder of such specific posting, upon the later of such posting and the giving of such separate notice; and (iv) if by any other form of electronic transmission, when directed to the stockholder.

7.1.3 Affidavit of Giving Notice. An affidavit of the Secretary or an Assistant Secretary or of the transfer agent or other agent of the Corporation that the notice has been given in writing or by a form of electronic transmission shall, in the absence of fraud, be prima facie evidence of the facts stated therein.

Section 7.2 **Waiver of Notice.** Whenever notice is required to be given under any provision of the DGCL, the Certificate of Incorporation or these Bylaws, a written waiver of notice, signed by the person entitled to notice, or waiver by electronic transmission by such person, whether before or after the time stated therein, shall be deemed equivalent to notice. Attendance of a person at a meeting shall constitute a waiver of notice of such meeting, except when the person attends a meeting for the express purpose of objecting at the beginning of the meeting to the transaction of any business because the meeting is not lawfully called or convened. Neither the business to be transacted at, nor the purpose of, any regular or special meeting of the stockholders, directors or members of a committee of directors need be specified in any waiver of notice.

ARTICLE VIII
INTERESTED DIRECTORS

Section 8.1 **Interested Directors.** No contract or transaction between the Corporation and one or more of its members of the Board or officers, or between the Corporation and any other corporation, partnership, association or other organization in which one or more of its directors or officers are members of the board of directors or officers, or have a financial interest, shall be void or voidable solely for this reason, or solely because the director or officer is present at or participates in the meeting of the Board or committee thereof that authorizes the contract or transaction, or solely because his, her or their votes are counted for such purpose, if: (a) the material facts as to his, her or their relationship or interest and as to the contract or transaction are disclosed or are known to the Board or the committee, and the Board or committee in good faith authorizes the contract or transaction by the affirmative votes of a majority of the disinterested directors, even though the disinterested directors be less than a quorum; (b) the material facts as to his, her or their relationship or interest and as to the contract or transaction are disclosed or are known to the stockholders entitled to vote thereon, and the contract or transaction is specifically approved in good faith by vote of the stockholders; or (c) the contract or transaction is fair as to the Corporation as of the time it is authorized, approved or ratified by the Board, a committee thereof, or the stockholders.

Section 8.2 **Quorum.** Interested directors may be counted in determining the presence of a quorum at a meeting of the Board or of a committee which authorizes the contract or transaction.

ARTICLE IX
MISCELLANEOUS

Section 9.1 **Fiscal Year.** The fiscal year of the Corporation shall be determined by resolution of the Board of Directors and may be changed by the Board of Directors.

Section 9.2 **Seal.** The Corporation may adopt a corporate seal, which shall be adopted and which may be altered by the Board. The Corporation may use the corporate seal by causing it or a facsimile thereof to be impressed or affixed or in any other manner reproduced.

Section 9.3 **Dividends**. The Board of Directors, subject to any restrictions contained in either (a) the DGCL or (b) the Certificate of Incorporation, may declare and pay dividends upon the shares of its capital stock. Dividends may be paid in cash, in property or in shares of the Corporation's capital stock.

The Board of Directors may set apart out of any of the funds of the Corporation available for dividends a reserve or reserves for any proper purpose and may abolish any such reserve. Such purposes shall include but not be limited to equalizing dividends, repairing or maintaining any property of the Corporation, and meeting contingencies.

Section 9.4 **Form of Records.** Any records maintained by the Corporation in the regular course of its business, including its stock ledger, books of account and minute books, may be kept on or by means of, or be in the form of, diskettes, CDs, or any other information storage device or method, provided that the records so kept can be converted into clearly legible paper form within a reasonable time. The Corporation shall so convert any records so kept upon the request of any person entitled to inspect such records pursuant to any provision of the DGCL.

Section 9.5 **Reliance upon Books and Records.** A member of the Board, or a member of any committee designated by the Board shall, in the performance of such person's duties, be fully protected in relying in good faith upon records of the Corporation and upon such information, opinions, reports or statements presented to the Corporation by any of the Corporation's officers or employees, or committees of the Board, or by any other person as to matters the member reasonably believes are within such other person's professional or expert competence and who has been selected with reasonable care by or on behalf of the Corporation.

Section 9.6 **Certificate of Incorporation Governs.** In the event of any conflict between the provisions of the Certificate of Incorporation and Bylaws, the provisions of the Certificate of Incorporation shall govern.

Section 9.7 **Severability.** If any provision of these Bylaws shall be held to be invalid, illegal, unenforceable or in conflict with the provisions of the Certificate of Incorporation, then such provision shall nonetheless be enforced to the maximum extent possible consistent with such holding and the remaining provisions of these Bylaws (including without limitation, all portions of any section of these Bylaws containing any such provision held to be invalid, illegal, unenforceable or in conflict with the Certificate of Incorporation, that are not themselves invalid, illegal, unenforceable or in conflict with the Certificate of Incorporation) shall remain in full force and effect.

ARTICLE X
TRANSFERS OF CAPITAL STOCK

Section 10.1 **Restriction on Transfer**. Shares of the Corporation shall be transferable in the manner prescribed by law and in these bylaws. Shares of stock of the Corporation shall be transferred on the books of the Corporation only by the holder of record thereof or by such holder's attorney duly authorized in writing, upon surrender to the Corporation of the certificate or certificates representing such shares endorsed by the appropriate person or persons (or by delivery of duly executed instructions with respect to uncertificated shares), with such evidence of the authenticity of such endorsement or execution, transfer, authorization and other matters as the Corporation may reasonably require, and accompanied by all necessary stock transfer stamps. To the fullest extent permitted by law, no transfer of stock shall be valid as against the Corporation for any purpose until it shall have been entered in the stock records of the Corporation by an entry showing the names of the persons from and to whom it was transferred.

Section 10.2 **Stock Transfer Agreements.** The Corporation shall have power to enter into and perform any agreement with any number of stockholders of any one or more classes of stock of the Corporation to restrict the transfer of shares of stock of the Corporation of any one or more classes owned by such stockholders in any manner not prohibited by the DGCL.

Section 10.3 **Registered Stockholders**. The Corporation, to the fullest extent permitted by law,

(a) shall be entitled to recognize the exclusive right of a person registered on its books as the owner of shares to receive dividends and to vote as such owner;

(b) shall be entitled to hold liable for calls and assessments the person registered on its books as the owner of shares; and

(c) shall not be bound to recognize any equitable or other claim to or interest in such share or shares on the part of another person, whether or not it shall have express or other notice thereof, except as otherwise provided by the laws of Delaware

Section 10.4 **Waiver of Notice**. Whenever notice is required to be given under any provision of the DGCL, the certificate of incorporation or these bylaws, a written waiver, signed by the person entitled to notice, or a waiver by electronic transmission by the person entitled to notice, whether before or after the time of the event for which notice is to be given, shall be deemed equivalent to notice. Attendance of a person at a meeting shall constitute a waiver of notice of such meeting, except when the person attends a meeting for the express purpose of objecting at the beginning of the meeting, to the transaction of any business because the meeting is not lawfully called or convened. Neither the business to be transacted at, nor the purpose of, any regular or special meeting of the stockholders need be specified in any written waiver of notice or any waiver by electronic transmission unless so required by the certificate of incorporation or these bylaws.

ARTICLE XI
AMENDMENT

Subject to the limitations set forth in Section 6.8 of these Bylaws or the provisions of the Certificate of Incorporation, the Board of Directors is expressly empowered to adopt, amend or repeal the bylaws of the Corporation.

CERTIFICATION OF BYLAWS OF
RENOVORX, INC.

a Delaware Corporation

I, _____, certify that I am Secretary of RenovoRx, Inc., a Delaware corporation (the "***Corporation***"), that I am duly authorized to make and deliver this certification, that the attached Bylaws are a true and complete copy of the Bylaws of the Corporation in effect as of the date of this certificate.

Dated: _____, 2022

Exhibit 4.6

Description of Securities

The following summary of the material terms of the capital stock of RenovoRx, Inc. ("we," "our," "us" or the "Company") is not intended to be a complete description of all of the rights and preferences of such securities. Because it is only a summary, it does not contain all of the information that may be important to you, and is qualified in its entirety by reference to our Sixth Amended and Restated Certificate of Incorporation, the Amended and Restated Bylaws, and the Warrant Agent Agreement, which are exhibits to this Annual Report on Form 10-K, as well as by the applicable provisions of the Delaware General Corporation Law ("DGCL"). We urge you to read each of the Sixth Amended and Restated Certificate of Incorporation, the Amended and Restated Bylaws, and the Warrant Agent Agreement in their entirety for a complete description of the rights and preferences of our securities.

Authorized Capital Stock

Our authorized capital stock consists of 265,000,000 shares, $0.0001 par value per share, of which:

- 250,000,000 shares are designated as common stock; and
- 15,000,000 shares are designated as preferred stock.

All of our outstanding shares of common stock are fully paid and non-assessable.

Common Stock

Our common stock is listed on the Nasdaq Capital Market under the trading symbol "RNXT." The transfer agent and registrar for our common stock is Philadelphia Stock Transfer, Inc. The transfer agent and registrar's address is 2320 Haverford Road, Suite 230, Ardmore, Pennsylvania 19003.

Voting Rights

Holders of our common stock are entitled to one vote per share on matters to be voted on by stockholders and also are entitled to receive such dividends, if any, as may be declared from time to time by our board of directors in its discretion out of funds legally available therefor. Holders of our common stock have exclusive voting rights for the election of our directors and all other matters requiring stockholder action, except with respect to amendments to our certificate of incorporation that alter or change the powers, preferences, rights or other terms of any outstanding preferred stock if the holders of such affected series of preferred stock are entitled to vote on such an amendment or filling vacancies on the board of directors.

Dividends

Holders of common stock are entitled to share ratably in any dividends declared by our board of directors, if any, subject to any preferential dividend rights of any outstanding preferred stock. Dividends consisting of shares of common stock may be paid to holders of shares of common stock. We do not intend to pay cash dividends in the foreseeable future.

Liquidation and Dissolution

Upon our liquidation or dissolution, the holders of our common stock will be entitled to receive pro rata all assets remaining available for distribution to stockholders after payment of all liabilities and provision for the liquidation of any shares of preferred stock at the time outstanding.

Rights and Preferences

Holders of our common stock have no preemptive, conversion or subscription rights, and there are no redemption or sinking fund provisions applicable to our common stock. The rights, preferences and privileges of the holders of our common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of preferred stock that we may designate and issue in the future.

Preferred Stock

Our board of directors will have the authority, without further action by the stockholders, to issue up to 15,000,000 shares of preferred stock in one or more series and to fix the designations, powers, preferences, privileges, and relative participating, optional, or special rights as well as the qualifications, limitations, or restrictions of the preferred stock, including dividend rights, conversion rights, voting rights, terms of redemption, and liquidation preferences, any or all of which may be greater than the rights of the common stock. Our board of directors, without stockholder approval, will be able to issue convertible preferred stock with voting, conversion, or other rights that could adversely affect the voting power and other rights of the holders of common stock. Preferred stock could be issued quickly with terms calculated to delay or prevent a change of control or make removal of management more difficult. Additionally, the issuance of preferred stock may have the effect of decreasing the market price of our common stock, and may adversely affect the voting and other rights of the holders of common stock. We have no present plans to issue any shares of preferred stock.

Public Warrants

On August 25, 2021, the Company's Registration Statement on Form S-1 relating to its initial public offering ("IPO") of units of securities, or Units, was declared effective by the U.S. Securities and Exchange Commission, (or "SEC"). In connection with the IPO, the Company issued and sold an aggregate of 1,850,000 units at a price of $9.00 per unit. Each unit consisted of (a) one share of common stock and (b) one warrant to purchase one share of common stock at an exercise price equal to $10.80 per share, which is exercisable for a period of five years after the issuance date ("Warrant(s)"). The Company also granted the underwriters an over-allotment option, exercisable for 45 days after August 25, 2021, to purchase any combination of up to 277,500 shares of its common stock and/or common stock warrants to purchase 277,500 shares of common stock with an exercise price of $10.80 per share. The underwriters exercised their over-allotment option to purchase 277,500 common stock warrants on August 30, 2021. In connection with the IPO, the underwriters were issued a five-year warrant, exercisable on or after February 25, 2022, to purchase up to 198,875 shares of the Company's common stock at an exercise price of $10.80 (the "Underwriter's Warrant").

Warrant Agent

The Warrants were issued in registered form under a warrant agent agreement (the "Warrant Agent Agreement") between us and our warrant agent, Philadelphia Stock Transfer, Inc. (the "Warrant Agent"). The material provisions of the warrants are set forth herein and a copy of the Warrant Agent Agreement has been filed as an exhibit to the

Registration Statement on Form S-1. The Company and the Warrant Agent may amend or supplement the Warrant Agent Agreement without the consent of any holder for the purpose of curing any ambiguity, or curing, correcting or supplementing any defective provision contained therein or adding or changing any other provisions with respect to matters or questions arising under the Warrant Agent Agreement as the parties thereto may deem necessary or desirable and that the parties determine, in good faith, shall not adversely affect the interest of the Warrant holders. All other amendments and supplements to the Warrant Agent Agreement shall require the vote or written consent of holders of at least 50.1% of the Warrants.

Warrant Terms

The Warrants entitle the registered holder to purchase one share of our common stock at a price equal to $10.80 per share, subject to adjustment as discussed below, terminating at 5:00 p.m., New York City time, on the fifth (5^{th}) anniversary of the date of issuance.

The exercise price and number of shares of common stock issuable upon exercise of the Warrants may be adjusted in certain circumstances, including in the event of a stock dividend, extraordinary dividend or recapitalization, reorganization, merger or consolidation.

The Warrants may be exercised upon surrender of the warrant certificate on or prior to the expiration date at the offices of the Warrant Agent, with the exercise form attached to the warrant certificate completed and executed as indicated, accompanied by full payment of the exercise price, by certified or official bank check payable to us, for the number of warrants being exercised. The Warrant holders do not have the rights or privileges of holders of common stock or any voting rights until they exercise their Warrants and receive shares of common stock, except as set forth in the Warrants. After the issuance of shares of common stock upon exercise of the Warrants, each holder will be entitled to one vote for each share held of record on all matters to be voted on by stockholders.

No Warrants will be exercisable for cash unless at the time of the exercise a prospectus or prospectus relating to common stock issuable upon exercise of the Warrants is current and the common stock has been registered or qualified or deemed to be exempt under the securities laws of the state of residence of the holder of the warrants. Under the terms of the Warrant Agent Agreement, we have agreed to use our best efforts to maintain a current prospectus or prospectus relating to common stock issuable upon exercise of the Warrants until the expiration of the Warrants. Additionally, the market for the Warrants may be limited if the prospectus or prospectus relating to the common stock issuable upon exercise of the Warrants is not current or if the common stock is not qualified or exempt from qualification in the jurisdictions in which the holders of such Warrants reside. In no event will the registered holders of a Warrant be entitled to receive a net-cash settlement in lieu of physical settlement in shares of our common stock.

No fractional shares of common stock will be issued upon exercise of the Warrants. If, upon exercise of the Warrants, a holder would be entitled to receive a fractional interest in a share, we will, upon exercise, round down to the nearest whole number the number of shares of common stock to be issued to the Warrant holder. If multiple Warrants are exercised by the holder at the same time, we will aggregate the number of whole shares issuable upon exercise of all the Warrants.

Private Warrants

In the IPO, the Company triggered the automatic conversion of certain outstanding convertible notes plus accrued interest into an aggregate of 708,820 private units, each unit consisting of one share of common stock and one five-year warrant to purchase one share of common stock at an exercise price equal to $10.80 per share. The private warrants have substantially the same terms as the public Warrants except that the private warrants were issued in a transaction exempt from the registration requirements of the Securities Act of 1933, as amended.

Registration Rights of Certain Stockholders

The Underwriter's Warrant contains a right to require us to register the offer and sale of their shares, or to include their shares in any registration statement we file, in each case as described below.

Demand Registration Rights

The Underwriter's Warrant will provide for one demand registration right at our expense and an additional demand registration right at the holder's expense for a period of five years following the date of commencement of the IPO.

Piggyback Registration Rights

The Underwriter's Warrant will provide for unlimited piggyback registration rights at our expense for a period of five years following the date of commencement of the IPO.

Anti-Takeover Effects of Delaware law and Our Sixth Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws

Certain provisions of Delaware law and certain provisions that are included in our Sixth Amended and Restated Certificate of Incorporation and our Amended and Restated Bylaws may have the effect of delaying, deferring or discouraging another party from acquiring control of us.

Section 203 of the Delaware General Corporation Law

We are subject to Section 203 of the DGCL, which prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years after the date that such stockholder became an interested stockholder, with the following exceptions:

- before such date, the board of directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;

- upon completion of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction began, excluding for purposes of determining the voting stock outstanding (but not the outstanding voting stock owned by the interested stockholder) those shares owned (i) by persons who are directors and also officers and (ii) employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or

- on or after such date, the business combination is approved by the board of directors and authorized at an annual or special meeting of the stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock that is not owned by the interested stockholder.

In general, Section 203 defines business combination to include the following:

- any merger or consolidation involving the corporation and the interested stockholder;

● any sale, transfer, pledge or other disposition of 10% or more of the assets of the corporation involving the interested stockholder;

● subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;

● any transaction involving the corporation that has the effect of increasing the proportionate share of the stock or any class or series of the corporation owned by the interested stockholder; or

● any receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits by or through the corporation.

In general, Section 203 defines an "interested stockholder" as an entity or person who, together with the person's affiliates and associates, beneficially owns, or within three years prior to the time of determination of interested stockholder status (subject to certain other requirements) did own, 15% or more of the outstanding voting stock of the corporation.

Board of Directors Vacancies

Our Sixth Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws authorize only our board of directors to fill vacant directorships. In addition, the number of directors constituting our board of directors may be set only by resolution of the majority of the incumbent directors.

Removal of Directors

Our Sixth Amended and Restated Certificate of Incorporation provides that stockholders may only remove a director for cause by the affirmative vote of the holders of at least two-thirds in voting power of the outstanding shares of capital stock of the Company entitled to vote at an election of directors.

No Cumulative Voting

Our Sixth Amended and Restated Certificate of Incorporation provides that stockholders do not have the right to cumulate votes in the election of directors.

Stockholder Action; Special Meeting of Stockholders

Our Sixth Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws provide that our stockholders may not take action by written consent. Our Sixth Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws further provide that special meetings of our stockholders may be called by a majority of the board of directors, the Chief Executive Officer, or the Chairman of the board of directors.

Advance Notice Requirements for Stockholder Proposals and Director Nominations

Our Amended and Restated Bylaws provide that stockholders seeking to bring business before our annual meeting of stockholders, or to nominate candidates for election as directors at our annual meeting of stockholders, must provide timely notice of their intent in writing. To be timely, a stockholder's notice must be delivered to the secretary at our principal executive offices not later than 5 p.m., local time, on the 90th day nor earlier than the close of business on the 120th day prior to the first anniversary of the preceding year's annual meeting; provided, however, that in the event the date of the annual meeting is more than 30 days before or more than 60 days after such anniversary date, or if no annual meeting was held in the preceding year, notice by the stockholder to be timely must be so delivered not earlier than 5 p.m., local time, on the 120th day prior to such annual meeting and not later than 5 p.m., local time, on the later of the 90th day prior to such annual meeting or the 10th day following the day on which a public announcement of the date of such meeting is first made by us. These provisions may preclude our stockholders from bringing matters before our annual meeting of stockholders or from making nominations for directors at our annual meeting of stockholders.

Authorized but Unissued Shares

Our authorized but unissued shares of common stock and preferred stock are available for future issuance without stockholder approval and may be utilized for a variety of corporate purposes, including future public offerings to raise additional capital, corporate acquisitions and employee benefit plans. The existence of authorized but unissued and unreserved common stock and preferred stock could render more difficult or discourage an attempt to obtain control of us by means of a proxy contest, tender offer, merger or otherwise. If we issue such shares without stockholder approval and in violation of limitations imposed by the Nasdaq Capital Market or any stock exchange on which our stock may then be trading, our stock could be delisted.

Exclusive Forum

Our Sixth Amended and Restated Certificate of Incorporation provides that unless we consent in writing to the selection of an alternative forum, the State of Delaware is the sole and exclusive forum for: (i) any derivative action or proceeding brought on behalf of us, (ii) any action asserting a claim of breach of a fiduciary duty owed by any director, officer or other employee of our Company to us or our stockholders, (iii) any action asserting a claim against us, our directors, officers or employees arising pursuant to any provision of the DGCL or our Sixth Amended and Restated Certificate of Incorporation or our Amended and Restated Bylaws, or (iv) any action asserting a claim against us, our directors, officers, employees or agents governed by the internal affairs doctrine, except for, as to each of (i) through (iv) above, any claim as to which the Court of Chancery determines that there is an indispensable party not subject to the jurisdiction of the Court of Chancery (and the indispensable party does not consent to the personal jurisdiction of the Court of Chancery within ten days following such determination), which is vested in the exclusive jurisdiction of a court or forum other than the Court of Chancery, or for which the Court of Chancery does not have subject matter jurisdiction.

Additionally, our Sixth Amended and Restated Certificate of Incorporation provides that unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States of America will be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock are deemed to have notice of and consented to this provision.

Limitation of Liability and Indemnification of Officers and Directors

Our Sixth Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws provide that we must indemnify our directors and officers to the fullest extent authorized by the DGCL.

Exhibit 10.2

RENOVORX, INC.
2021 OMNIBUS EQUITY INCENTIVE PLAN

Section 1. **Purpose of Plan.**

The name of the Plan is the RenovoRx, Inc. 2021 Omnibus Equity Incentive Plan (the "Plan"). The purposes of the Plan are to (i) provide an additional incentive to selected employees, directors, and independent contractors of the Company or its Affiliates whose contributions are essential to the growth and success of the Company, (ii) strengthen the commitment of such individuals to the Company and its Affiliates, (iii) motivate those individuals to faithfully and diligently perform their responsibilities and (iv) attract and retain competent and dedicated individuals whose efforts will result in the long-term growth and profitability of the Company. To accomplish these purposes, the Plan provides that the Company may grant Options, Stock Appreciation Rights, Restricted Stock, Restricted Stock Units, Other Stock-Based Awards or any combination of the foregoing.

Section 2. **Definitions.**

For purposes of the Plan, the following terms shall be defined as set forth below:

(a) "Administrator" means the Board, or, if and to the extent the Board does not administer the Plan, the Committee in accordance with Section 3 hereof.

(b) "Affiliate" means a Person that directly, or indirectly through one or more intermediaries, controls, or is controlled by, or is under common control with, the Person specified as of any date of determination.

(c) "Applicable Laws" means the applicable requirements under U.S. federal and state corporate laws, U.S. federal and state securities laws, including the Code, any stock exchange or quotation system on which the Common Stock is listed or quoted and the applicable laws of any other country or jurisdiction where Awards are granted under the Plan, as are in effect from time to time.

(d) "Award" means any Option, Stock Appreciation Right, Restricted Stock, Restricted Stock Unit or Other Stock-Based Award granted under the Plan.

(e) "Award Agreement" means any written notice, agreement, contract or other instrument or document evidencing an Award, including through electronic medium, which shall contain such terms and conditions with respect to an Award as the Administrator shall determine, consistent with the Plan.

(f) "Beneficial Owner" (or any variant thereof) has the meaning defined in Rule 13d-3 under the Exchange Act.

(g) "Board" means the Board of Directors of the Company.

(h) "Bylaws" mean the bylaws of the Company, as may be amended and/or restated from time to time.

(i) "Cause" has the meaning assigned to such term in any individual service, employment or severance agreement or Award Agreement with the Participant or, if no such agreement exists or if such agreement does not define "Cause," then "Cause" means a Participant's (i) conviction of a felony or a crime involving fraud or moral turpitude; (ii) theft, material act of dishonesty or fraud, intentional falsification of any employment or Company records, or commission of any criminal act which impairs Participant's ability to perform appropriate employment duties for the Company; (iii) intentional or reckless conduct or gross negligence materially harmful to the Company or the successor to the Company after a Change in Control, including violation of a non-competition or confidentiality agreement; (iv) willful failure to follow lawful instructions of the person or body to which Participant reports; or (v) gross negligence or willful misconduct in the performance of Participant's assigned duties. Cause shall not include mere unsatisfactory performance in the achievement of a Participant's job objectives. Any voluntary termination of employment or service by the Participant in anticipation of an involuntary termination of the Participant's employment or service, as applicable, for Cause shall be deemed to be a termination for Cause.

(j) "Change in Capitalization" means any (i) merger, consolidation, reclassification, recapitalization, spin-off, spin-out, repurchase or other reorganization or corporate transaction or event, (ii) special or extraordinary dividend or other extraordinary distribution (whether in the form of cash, Common Stock or other property), stock split, reverse stock split, share subdivision or consolidation, (iii) combination or exchange of shares or (iv) other change in corporate structure, which, in any such case, the Administrator determines, in its sole discretion, affects the Shares such that an adjustment pursuant to Section 5 hereof is appropriate.

(k) "Change in Control" means the first occurrence of an event set forth in any one of the following paragraphs following the Effective Date:

(1) any Person is or becomes the Beneficial Owner, directly or indirectly, of securities of the Company (not including in the securities Beneficially Owned by such Person which were acquired directly from the Company or any Affiliate thereof) representing more than fifty percent (50%) of the combined voting power of the Company's then outstanding securities, excluding any Person who becomes such a Beneficial Owner in connection with a transaction described in clause (i) of paragraph (3) below; or

(2) the date on which individuals who constitute the Board as of the Effective Date and any new director (other than a director whose initial assumption of office is in connection with an actual or threatened election contest, including, but not limited to, a consent solicitation, relating to the election of directors of the Company) whose appointment or election by the Board or nomination for election by the Company's stockholders was approved or recommended by a vote of at least two-thirds (2/3) of the directors then still in office who either were directors on the Effective Date or whose appointment, election or nomination for election was previously so approved or recommended cease for any reason to constitute a majority of the number of directors serving on the Board; or

(3) there is consummated a merger or consolidation of the Company or any direct or indirect Subsidiary with any other corporation or other entity, other than (i) a merger or consolidation (A) which results in the voting securities of the Company outstanding immediately prior to such merger or consolidation continuing to represent (either by remaining outstanding or by being converted into voting securities of the surviving entity or any parent thereof), in combination with the ownership of any trustee or other fiduciary holding securities under an employee benefit plan of the Company or any Subsidiary, fifty percent (50%) or more of the combined voting power of the securities of the Company or such surviving entity or any parent thereof outstanding immediately after such merger or consolidation and (B) following which the individuals who comprise the Board immediately prior thereto constitute at least a majority of the board of directors of the Company, the entity surviving such merger or consolidation or, if the Company or the entity surviving such merger or consolidation is then a Subsidiary, the ultimate parent thereof, or (ii) a merger or consolidation effected to implement a recapitalization of the Company (or similar transaction) in which no Person is or becomes the Beneficial Owner, directly or indirectly, of securities of the Company (not including in the securities Beneficially Owned by such Person any securities acquired directly from the Company or its Affiliates) representing more than fifty percent (50%) of the combined voting power of the Company's then outstanding securities; or

(4) the stockholders of the Company approve a plan of complete liquidation or dissolution of the Company or there is consummated an agreement for the sale or disposition by the Company of all or substantially all of the Company's assets, other than (A) a sale or disposition by the Company of all or substantially all of the

Company's assets to an entity, more than fifty percent (50%) of the combined voting power of the voting securities of which are owned by stockholders of the Company following the completion of such transaction in substantially the same proportions as their ownership of the Company immediately prior to such sale or (B) a sale or disposition of all or substantially all of the Company's assets immediately following which the individuals who comprise the Board immediately prior thereto constitute at least a majority of the board of directors of the entity to which such assets are sold or disposed or, if such entity is a subsidiary, the ultimate parent thereof.

Notwithstanding the foregoing, (i) a Change in Control shall not be deemed to have occurred by virtue of the consummation of any transaction or series of integrated transactions immediately following which the holders of Common Stock immediately prior to such transaction or series of transactions continue to have substantially the same proportionate ownership in an entity which owns all or substantially all of the assets of the Company immediately following such transaction or series of transactions and (ii) to the extent required to avoid accelerated taxation and/or tax penalties under Section 409A of the Code, a Change in Control shall be deemed to have occurred under the Plan with respect to any Award that constitutes deferred compensation under Section 409A of the Code only if a change in the ownership or effective control of the Company or a change in ownership of a substantial portion of the assets of the Company shall also be deemed to have occurred under Section 409A of the Code. For purposes of this definition of Change in Control, the term "Person" shall not include (i) the Company or any Subsidiary thereof, (ii) a trustee or other fiduciary holding securities under an employee benefit plan of the Company or any Subsidiary thereof, (iii) an underwriter temporarily holding securities pursuant to an offering of such securities, or (iv) a corporation owned, directly or indirectly, by the stockholders of the Company in substantially the same proportions as their ownership of shares of the Company.

(l) "Code" means the Internal Revenue Code of 1986, as amended from time to time, or any successor thereto.

(m) "Committee" means any committee or subcommittee the Board may appoint to administer the Plan. Subject to the discretion of the Board, the Committee shall be composed entirely of individuals who meet the qualifications of a "non-employee director" within the meaning of Rule 16b-3 under the Exchange Act and any other qualifications required by the applicable stock exchange on which the Common Stock is traded.

(n) "Common Stock" means the common stock of the Company, par value $0.0001.

(o) "Company" means RenovoRx, Inc., a Delaware corporation (or any successor company, except as the term "Company" is used in the definition of "Change in Control" above).

(p) "Disability" has the meaning assigned to such term in any individual service, employment or severance agreement or Award Agreement with the Participant or, if no such agreement exists or if such agreement does not define "Disability," then "Disability" means that a Participant, as determined by the Administrator in its sole discretion, (i) is unable to engage in any substantial gainful activity by reason of any medically determinable physical or mental impairment which can be expected to result in death or can be expected to last for a continuous period of not less than twelve (12) months, or (ii) is, by reason of any medically determinable physical or mental impairment which can be expected to result in death or can be expected to last for a continuous period of not less than twelve (12) months, receiving income replacement benefits for a period of not less than three (3) months under an accident and health plan covering employees of the Company or an Affiliate thereof.

(q) "Effective Date" has the meaning set forth in Section 17 hereof.

(r) "Eligible Recipient" means an employee, director or independent contractor of the Company or any Affiliate of the Company who has been selected as an eligible participant by the Administrator; provided, however, to the extent required to avoid accelerated taxation and/or tax penalties under Section 409A of the Code, an Eligible Recipient of an Option or a Stock Appreciation Right means an employee, non-employee director or independent contractor of the Company or any Affiliate of the Company with respect to whom the Company is an "eligible issuer of service recipient stock" within the meaning of Section 409A of the Code. Further, for the avoidance of doubt, an Eligible Recipient will include only those persons to whom the issuance of Shares may be registered under Form S-8 promulgated under the Securities Act.

(s) "Exchange Act" means the Securities Exchange Act of 1934, as amended from time to time.

(t) "Exempt Award" shall mean the following:

(1) An Award granted in assumption of, or in substitution for, outstanding awards previously granted by a corporation or other entity acquired by the Company or any of its Subsidiaries or with which the Company or any of its Subsidiaries combines by merger or otherwise. The terms and conditions of any such Awards may vary from the terms and conditions set forth in the Plan to the extent the Administrator at the time of grant may deem appropriate, subject to Applicable Laws.

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(2) An award that an Eligible Recipient purchases at Fair Market Value (including awards that an Eligible Recipient elects to receive in lieu of fully vested compensation that is otherwise due) whether or not the Shares are delivered immediately or on a deferred basis.

(u) "Exercise Price" means, (i) with respect to any Option, the per share price at which a holder of such Option may purchase Shares issuable upon exercise of such Award, and (ii) with respect to a Stock Appreciation Right, the base price per share of such Stock Appreciation Right.

(v) "Fair Market Value" of a share of Common Stock or another security as of a particular date shall mean the fair market value as determined by the Administrator in its sole discretion; provided, that, (i) if the Common Stock or other security is admitted to trading on a national securities exchange, the fair market value on any date shall be the closing sale price reported on such date, or if no shares were traded on such date, on the last preceding date for which there was a sale of a share of Common Stock on such exchange, or (ii) if the Common Stock or other security is then traded in an over-the-counter market, the fair market value on any date shall be the average of the closing bid and asked prices for such share in such over-the-counter market for the last preceding date on which there was a sale of such share in such market.

(w) "Free Standing Rights" has the meaning set forth in Section 8.

(x) "Good Reason" has the meaning assigned to such term in any individual service, employment or severance agreement or Award Agreement with the Participant or, if no such agreement exists or if such agreement does not define "Good Reason," "Good Reason" and any provision of this Plan that refers to "Good Reason" shall not be applicable to such Participant.

(y) "Grandfathered Arrangement" means an Award which is provided pursuant to a written binding contract in effect on November 2, 2017, and which was not modified in any material respect on or after November 2, 2017, within the meaning of Section 13601(e)(2) of P.L. 115.97, as may be amended from time to time (including any rules and regulations promulgated thereunder).

(z) "Incentive Compensation" means annual cash bonus and any Award.

(aa) "ISO" means an Option intended to be and designated as an "incentive stock option" within the meaning of Section 422 of the Code.

(bb) "Nonqualified Stock Option" shall mean an Option that is not designated as an ISO.

(cc) "Option" means an option to purchase shares of Common Stock granted pursuant to Section 7 hereof. The term "Option" as used in the Plan includes the terms "Nonqualified Stock Option" and "ISO."

(dd) "Other Stock-Based Award" means a right or other interest granted pursuant to Section 10 hereof that may be denominated or payable in, valued in whole or in part by reference to, or otherwise based on or related to, Common Stock, including, but not limited to, unrestricted Shares, dividend equivalents or performance units, each of which may be subject to the attainment of performance goals or a period of continued provision of service or employment or other terms or conditions as permitted under the Plan.

(ee) "Participant" means any Eligible Recipient selected by the Administrator, pursuant to the Administrator's authority provided for in Section 3 below, to receive grants of Awards, and, upon his or her death, his or her successors, heirs, executors and administrators, as the case may be.

(ff) "Person" shall have the meaning given in Section 3(a)(9) of the Exchange Act, as modified and used in Sections 13(d) and 14(d) thereof.

(gg) "Plan" means this 2021 Omnibus Equity Incentive Plan, as amended and/or restated from time to time.

(hh) "Prior Plan" means the Company's Amended and Restated 2013 Equity Incentive Plan, as in effect immediately prior to the Effective Date.

(ii) "Related Rights" has the meaning set forth in Section 8.

(jj) "Restricted Period" has the meaning set forth in Section 9.

(kk) "Restricted Stock" means a Share granted pursuant to Section 9 below subject to certain restrictions that lapse at the end of a specified period (or periods) of time and/or upon attainment of specified performance objectives.

(ll) "Restricted Stock Unit" means the right granted pursuant to Section 9 hereof to receive a Share at the end of a specified restricted period (or periods) of time and/or upon attainment of specified performance objectives.

(mm) "Rule 16b-3" has the meaning set forth in Section 3.

(nn) "Section 16 Officer" means any officer of the Company whom the Board has determined is subject to the reporting requirements of Section 16 of the Exchange Act, whether or not such individual is a Section 16 Officer at the time the determination to recoup compensation is made.

(oo) "Share" means a share of Common Stock, as adjusted pursuant to the Plan, and any successor (pursuant to a merger, consolidation or other reorganization) security.

(pp) "Stock Appreciation Right" means a right granted pursuant to Section 8 hereof to receive an amount equal to the excess, if any, of (i) the aggregate Fair Market Value, as of the date such Award or portion thereof is surrendered, of the Shares covered by such Award or such portion thereof, over (ii) the aggregate Exercise Price of such Award or such portion thereof.

(qq) "Subsidiary" means, with respect to any Person, as of any date of determination, any other Person as to which such first Person owns or otherwise controls, directly or indirectly, more than 50% of the voting shares or other similar interests or a sole general partner interest or managing member or similar interest of such other Person.

(rr) "Transfer" has the meaning set forth in Section 15.

Section 3. **Administration.**

(a) The Plan shall be administered by the Administrator and shall be administered, to the extent applicable, in accordance with Rule 16b-3 under the Exchange Act ("Rule 16b-3").

(b) Pursuant to the terms of the Plan, the Administrator, subject, in the case of any Committee, to any restrictions on the authority delegated to it by the Board, shall have the power and authority, without limitation:

(1) to select those Eligible Recipients who shall be Participants;

(2) to determine whether and to what extent Options, Stock Appreciation Rights, Restricted Stock, Restricted Stock Units, Other Stock-Based Awards or a combination of any of the foregoing, are to be granted hereunder to Participants;

(3) to determine the number of Shares to be covered by each Award granted hereunder;

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(4) to determine the terms and conditions, not inconsistent with the terms of the Plan, of each Award granted hereunder (including, but not limited to, (i) the restrictions applicable to Restricted Stock or Restricted Stock Units and the conditions under which restrictions applicable to such Restricted Stock or Restricted Stock Units shall lapse, (ii) the performance goals and periods applicable to Awards, (iii) the Exercise Price of each Option and each Stock Appreciation Right or the purchase price of any other Award, (iv) the vesting schedule and terms applicable to each Award, (v) the number of Shares or amount of cash or other property subject to each Award, and (vi) subject to the requirements of Section 409A of the Code (to the extent applicable), any amendments to the terms and conditions of outstanding Awards, including, but not limited to, extending the exercise period of such Awards and accelerating the payment schedules of such Awards and/or accelerating the vesting schedules of such Awards);

(5) to determine the terms and conditions, not inconsistent with the terms of the Plan, which shall govern all written instruments evidencing Awards;

(6) to determine the Fair Market Value in accordance with the terms of the Plan;

(7) to determine the duration and purpose of leaves of absence which may be granted to a Participant without constituting termination of the Participant's service or employment for purposes of Awards granted under the Plan;

(8) to adopt, alter and repeal such administrative rules, regulations, guidelines and practices governing the Plan as it shall from time to time deem advisable;

(9) to construe and interpret the terms and provisions of, and supply or correct omissions in, the Plan and any Award issued under the Plan (and any Award Agreement relating thereto), and to otherwise supervise the administration of the Plan and to exercise all powers and authorities either specifically granted under the Plan or necessary or advisable in the administration of the Plan; and

(10) to prescribe, amend and rescind rules and regulations relating to sub-plans established for the purpose of satisfying applicable non-United States laws or for qualifying for favorable tax treatment under applicable non-United States laws, which rules and regulations may be set forth in an appendix or appendixes to the Plan.

(c) Subject to Section 5, neither the Board nor the Committee shall have the authority to reprice or cancel and regrant any Award at a lower exercise, base or purchase price or cancel any Award with an exercise, base or purchase price in exchange for cash, property or other Awards without first obtaining the approval of the Company's stockholders.

(d) All decisions made by the Administrator pursuant to the provisions of the Plan shall be final, conclusive and binding on all Persons, including the Company and the Participants.

(e) The expenses of administering the Plan shall be borne by the Company and its Affiliates.

(f) If at any time or to any extent the Board shall not administer the Plan, then the functions of the Administrator specified in the Plan shall be exercised by the Committee. Except as otherwise provided in the Articles of Incorporation or Bylaws of the Company, any action of the Committee with respect to the administration of the Plan shall be taken by a majority vote at a meeting at which a quorum is duly constituted or unanimous written consent of the Committee's members.

Section 4. **Shares Reserved for Issuance Under the Plan.**

(a) Subject to Section 5 hereof, the number of shares of Common Stock that are reserved and available for issuance pursuant to Awards granted under the Plan shall be equal to the sum of (i) 2,175,000 shares, plus (ii) the number of shares of Common Stock reserved, but unissued under the Prior Plan (for the avoidance of doubt, this equals 10,832 shares); (iii) the number of shares of Common Stock underlying forfeited awards under the Prior Plan (for avoidance of doubt, the maximum number of shares of Common Stock that could underly forfeited awards under the Prior Plan is 754,838); and (iv) an annual increase on the first day of each calendar year beginning with the first January 1 following the Effective Date and ending with the last January 1 during the initial ten-year term of the Plan, equal to the lesser of (A) three percent (3%) of the Shares outstanding on the final day of the immediately preceding calendar year and (B) such lesser number of Shares as determined by the Board; provided, that, shares of Common Stock issued under the Plan with respect to an Exempt Award shall not count against such share limit. Following the Effective Date, no further awards shall be issued under the Prior Plan, but all awards under the Prior Plan which are outstanding as of the Effective Date (including any Grandfathered Arrangement) shall continue to be governed by the terms, conditions and procedures set forth in the Prior Plan and any applicable Award Agreement.

(b) Shares issued under the Plan may, in whole or in part, be authorized but unissued Shares or Shares that shall have been or may be reacquired by the Company in the open market, in private transactions or otherwise. If an Award entitles the Participant to receive or purchase Shares, the number of Shares covered by such Award or to which such Award relates shall be counted on the date of grant of such Award against the aggregate number of Shares available for granting Awards under the Plan. If any Shares subject to an Award are forfeited, cancelled, exchanged or surrendered or if an Award otherwise terminates or expires without a distribution of Shares to the Participant, the Shares with respect to such Award shall, to the extent of any such forfeiture, cancellation, exchange, surrender, termination or expiration, again be available for granting Awards under the Plan. Notwithstanding the foregoing, (i) Shares surrendered or withheld as payment of either the Exercise Price of an Award (including Shares otherwise underlying a Stock Appreciation Right that are retained by the Company to account for the Exercise Price of such Stock Appreciation Right) and/or withholding taxes in respect of an Award and (ii) any Shares reacquired by the Company on the open market or otherwise using cash proceeds from the exercise of Options shall no longer be available for grant under the Plan. In addition, (i) to the extent an Award is denominated in shares of Common Stock, but paid or settled in cash, the number of shares of Common Stock with respect to which such payment or settlement is made shall again be available for grants of Awards pursuant to the Plan and (ii) shares of Common Stock underlying Awards that can only be settled in cash shall not be counted against the aggregate number of shares of Common Stock available for Awards under the Plan. Upon the exercise of any Award granted in tandem with any other Awards, such related Awards shall be cancelled to the extent of the number of Shares as to which the Award is exercised and, notwithstanding the foregoing, such number of Shares shall no longer be available for grant under the Plan.

(c) No more than 2,175,000 Shares (as increased on an annual basis, on the first day of each calendar year beginning with the first January 1 following the Effective Date and ending with the last January 1 during the initial ten-year term of the Plan, by the lesser of (A) three percent (3%) of the Shares outstanding on the final day of the immediately preceding calendar year; (B) 343,734 Shares; and (C) such lesser number of Shares as determined by the Board) shall be issued pursuant to the exercise of ISOs.

Section 5. **Equitable Adjustments.**

In the event of any Change in Capitalization, an equitable substitution or proportionate adjustment shall be made in (i) the aggregate number and kind of securities reserved for issuance under the Plan pursuant to Section 4, (ii) the kind, number of securities subject to, and the Exercise Price subject to outstanding Options and Stock Appreciation Rights granted under the Plan, (iii) the kind, number and purchase price of Shares or other securities or the amount of cash or amount or type of other property subject to outstanding Restricted Stock, Restricted Stock Units or Other Stock-Based Awards granted under the Plan; and/or (iv) the terms and conditions of any outstanding Awards (including, without limitation, any applicable performance targets or criteria with respect thereto); provided, however, that any fractional shares resulting from the adjustment shall be eliminated. Such other equitable substitutions or adjustments shall be made as may be determined by the Administrator, in its sole discretion. Without limiting the generality of the foregoing, in connection with a Change in Capitalization, the Administrator may provide, in its sole discretion, but subject in all events to the requirements of Section 409A of the Code, for the cancellation of any outstanding Award granted hereunder in exchange for payment in cash or other property having an aggregate Fair Market Value equal to the Fair Market Value of the Shares, cash or other property covered by such Award, reduced by the aggregate Exercise Price or purchase price thereof, if any; provided, however, that if the Exercise Price or purchase price of any outstanding Award is equal to or greater than the Fair Market Value of the shares of Common Stock, cash or other property covered by such Award, the Administrator may cancel such Award without the payment of any consideration to the Participant. Further, without limiting the generality of the foregoing, with respect to Awards subject to foreign laws, adjustments made hereunder shall be made in compliance with applicable requirements. Except to the extent determined by the Administrator, any adjustments to ISOs under this Section 5 shall be made only to the extent not constituting a "modification" within the meaning of Section 424(h)(3) of the Code. The Administrator's determinations pursuant to this Section 5 shall be final, binding and conclusive.

Section 6. **Eligibility.**

The Participants in the Plan shall be selected from time to time by the Administrator, in its sole discretion, from those individuals that qualify as Eligible Recipients. No Participant who is a director, but is not also an employee or consultant, of the Company shall receive Awards and be paid cash compensation during any calendar year that exceed, in the aggregate, $300,000 in total value (with cash compensation measured for this purpose at its value upon payment and any Awards measured for this purpose at their grant date fair value, as determined for the Company's financial reporting purposes). For the avoidance of doubt, any cash compensation paid or equity compensation award (including any Awards) granted to an individual for his or her services as an employee, or for his or her services as a consultant (other than as a non-employee director), will not count for purposes of the limitation contained in the immediately preceding sentence.

Section 7. **Options.**

(a) General. Options granted under the Plan shall be designated as Nonqualified Stock Options or ISOs. Each Participant who is granted an Option shall enter into an Award Agreement with the Company, containing such terms and conditions as the Administrator shall determine, in its sole discretion, including, among other things, the Exercise Price of the Option, the term of the Option and provisions regarding exercisability of the Option, and whether the Option is intended to be an ISO or a Nonqualified Stock Option (and in the event the Award Agreement has no such designation, the Option shall be a Nonqualified Stock Option). The provisions of each Option need not be the same with respect to each Participant. More than one Option may be granted to the same Participant and be outstanding concurrently hereunder. Options granted under the Plan shall be subject to the terms and conditions set forth in this Section 7 and shall contain such additional terms and conditions, not inconsistent with the terms of the Plan, as the Administrator shall deem desirable and set forth in the applicable Award Agreement.

(b) Exercise Price. The Exercise Price of Shares purchasable under an Option shall be determined by the Administrator in its sole discretion at the time of grant, but in no event shall the exercise price of an Option be less than one hundred percent (100%) of the Fair Market Value of a share of Common Stock on the date of grant.

(c) Option Term. The maximum term of each Option shall be fixed by the Administrator, but no Option shall be exercisable more than ten (10) years after the date such Option is granted. Each Option's term is subject to earlier expiration pursuant to the applicable provisions in the Plan and the Award Agreement. Notwithstanding the foregoing, the Administrator shall have the authority to accelerate the vesting and/or exercisability of any outstanding Option at such time and under such circumstances as the Administrator, in its sole discretion, deems appropriate.

(d) Exercisability. Each Option shall be exercisable at such time or times and subject to such terms and conditions, including the attainment of performance goals, as shall be determined by the Administrator in the applicable Award Agreement. The Administrator may also provide that any Option shall be exercisable only in installments, and the Administrator may waive such installment exercise provisions at any time, in whole or in part, based on such factors as the Administrator may determine in its sole discretion.

(e) Method of Exercise. Options may be exercised in whole or in part by giving written notice of exercise to the Company specifying the number of whole Shares to be purchased, accompanied by payment in full of the aggregate Exercise Price of the Shares so purchased in cash or its equivalent, as determined by the Administrator. As determined by the Administrator, in its sole discretion, with respect to any Option or category of Options, payment in whole or in part may also be made (i) by means of consideration received under any cashless exercise procedure approved by the Administrator (including the withholding of Shares otherwise issuable upon exercise), (ii) in the form of unrestricted Shares already owned by the Participant which have a Fair Market Value on the date of surrender equal to the aggregate exercise price of the Shares as to which such Option shall be exercised, (iii) any other form of consideration approved by the Administrator and permitted by Applicable Laws or (iv) any combination of the foregoing.

(f) ISOs. The terms and conditions of ISOs granted hereunder shall be subject to the provisions of Section 422 of the Code and the terms, conditions, limitations and administrative procedures established by the Administrator from time to time in accordance with the Plan. At the discretion of the Administrator, ISOs may be granted only to an employee of the Company, its "parent corporation" (as such term is defined in Section 424(e) of the Code) or a Subsidiary of the Company.

(1) *ISO Grants to 10% Stockholders.* Notwithstanding anything to the contrary in the Plan, if an ISO is granted to a Participant who owns shares representing more than ten percent (10%) of the voting power of all classes of shares of the Company, its "parent corporation" (as such term is defined in Section 424(e) of the Code) or a Subsidiary of the Company, the term of the ISO shall not exceed five (5) years from the time of grant of such ISO and the Exercise Price shall be at least one hundred and ten percent (110%) of the Fair Market Value of the Shares on the date of grant.

(2) *$100,000 Per Year Limitation For ISOs*. To the extent the aggregate Fair Market Value (determined on the date of grant) of the Shares for which ISOs are exercisable for the first time by any Participant during any calendar year (under all plans of the Company) exceeds $100,000, such excess ISOs shall be treated as Nonqualified Stock Options.

(3) *Disqualifying Dispositions*. Each Participant awarded an ISO under the Plan shall notify the Company in writing immediately after the date the Participant makes a "disqualifying disposition" of any Share acquired pursuant to the exercise of such ISO. A "disqualifying disposition" is any disposition (including any sale) of such Shares before the later of (i) two years after the date of grant of the ISO and (ii) one year after the date the Participant acquired the Shares by exercising the ISO. The Company may, if determined by the Administrator and in accordance with procedures established by it, retain possession of any Shares acquired pursuant to the exercise of an ISO as agent for the applicable Participant until the end of the period described in the preceding sentence, subject to complying with any instructions from such Participant as to the sale of such Shares.

(g) Rights as Stockholder. A Participant shall have no rights to dividends, dividend equivalents or distributions or any other rights of a stockholder with respect to the Shares subject to an Option until the Participant has given written notice of the exercise thereof, and has paid in full for such Shares and has satisfied the requirements of Section 14 hereof.

(h) Termination of Employment or Service. Treatment of an Option upon termination of employment of a Participant shall be provided for by the Administrator in the Award Agreement.

(i) Other Change in Employment or Service Status. An Option shall be affected, both with regard to vesting schedule and termination, by leaves of absence, including unpaid and un-protected leaves of absence, changes from full-time to part-time employment, partial Disability or other changes in the employment status or service status of a Participant, in the discretion of the Administrator.

Section 8. **Stock Appreciation Rights.**

(a) General. Stock Appreciation Rights may be granted either alone ("Free Standing Rights") or in conjunction with all or part of any Option granted under the Plan ("Related Rights"). Related Rights may be granted either at or after the time of the grant of such Option. The Administrator shall determine the Eligible Recipients to whom, and the time or times at which, grants of Stock Appreciation Rights shall be made. Each Participant who is granted a Stock Appreciation Right shall enter into an Award Agreement with the Company, containing such terms and conditions as the Administrator shall determine, in its sole discretion, including, among other things, the number of Shares to be awarded, the Exercise Price per Share, and all other conditions of Stock Appreciation Rights. Notwithstanding the foregoing, no Related Right may be granted for more Shares than are subject to the Option to which it relates. The provisions of Stock Appreciation Rights need not be the same with respect to each Participant. Stock Appreciation Rights granted under the Plan shall be subject to the following terms and conditions set forth in this Section 8 and shall contain such additional terms and conditions, not inconsistent with the terms of the Plan, as the Administrator shall deem desirable, as set forth in the applicable Award Agreement.

(b) Awards; Rights as Stockholder. A Participant shall have no rights to dividends or any other rights of a stockholder with respect to the shares of Common Stock, if any, subject to a Stock Appreciation Right until the Participant has given written notice of the exercise thereof and has satisfied the requirements of Section 14 hereof.

(c) Exercise Price. The Exercise Price of Shares purchasable under a Stock Appreciation Right shall be determined by the Administrator in its sole discretion at the time of grant, but in no event shall the exercise price of a Stock Appreciation Right be less than one hundred percent (100%) of the Fair Market Value of a share of Common Stock on the date of grant.

(d) Exercisability.

(1) Stock Appreciation Rights that are Free Standing Rights shall be exercisable at such time or times and subject to such terms and conditions as shall be determined by the Administrator in the applicable Award Agreement.

(2) Stock Appreciation Rights that are Related Rights shall be exercisable only at such time or times and to the extent that the Options to which they relate shall be exercisable in accordance with the provisions of Section 7 hereof and this Section 8 of the Plan.

(e) Payment Upon Exercise.

(1) Upon the exercise of a Free Standing Right, the Participant shall be entitled to receive up to, but not more than, that number of Shares equal in value to the excess of the Fair Market Value as of the date of exercise over the Exercise Price per share specified in the Free Standing Right multiplied by the number of Shares in respect of which the Free Standing Right is being exercised.

(2) A Related Right may be exercised by a Participant by surrendering the applicable portion of the related Option. Upon such exercise and surrender, the Participant shall be entitled to receive up to, but not more than, that number of Shares equal in value to the excess of the Fair Market Value as of the date of exercise over the Exercise Price specified in the related Option multiplied by the number of Shares in respect of which the Related Right is being exercised. Options which have been so surrendered, in whole or in part, shall no longer be exercisable to the extent the Related Rights have been so exercised.

(3) Notwithstanding the foregoing, the Administrator may determine to settle the exercise of a Stock Appreciation Right in cash (or in any combination of Shares and cash).

(f) Termination of Employment or Service. Treatment of a Stock Appreciation Right upon termination of employment of a Participant shall be provided for by the Administrator in the Award Agreement.

(g) Term.

(1) The term of each Free Standing Right shall be fixed by the Administrator, but no Free Standing Right shall be exercisable more than ten (10) years after the date such right is granted.

(2) The term of each Related Right shall be the term of the Option to which it relates, but no Related Right shall be exercisable more than ten (10) years after the date such right is granted.

(h) Other Change in Employment or Service Status. Stock Appreciation Rights shall be affected, both with regard to vesting schedule and termination, by leaves of absence, including unpaid and un-protected leaves of absence, changes from full-time to part-time employment, partial Disability or other changes in the employment or service status of a Participant, in the discretion of the Administrator.

Section 9. **Restricted Stock and Restricted Stock Units.**

(a) General. Restricted Stock or Restricted Stock Units may be issued under the Plan. The Administrator shall determine the Eligible Recipients to whom, and the time or times at which, Restricted Stock or Restricted Stock Units shall be made. Each Participant who is granted Restricted Stock or Restricted Stock Units shall enter into an Award Agreement with the Company, containing such terms and conditions as the Administrator shall determine, in its sole discretion, including, among other things, the number of Shares to be awarded; the price, if any, to be paid by the Participant for the acquisition of Restricted Stock or Restricted Stock Units; the period of time restrictions, performance goals or other conditions that apply to the Transfer (or ability to Transfer), delivery or vesting of such Awards (the "Restricted Period"); and all other conditions applicable to the Restricted Stock and Restricted Stock Units. If the restrictions, performance goals or conditions established by the Administrator are not attained, a Participant shall forfeit his or her Restricted Stock or Restricted Stock Units, in accordance with the terms of the grant. The provisions of the Restricted Stock or Restricted Stock Units need not be the same with respect to each Participant.

(b) Awards and Certificates. Except as otherwise provided below in Section 9(c), (i) each Participant who is granted an Award of Restricted Stock may, in the Company's sole discretion, be issued a share certificate in respect of such Restricted Stock; and (ii) any such certificate so issued shall be registered in the name of the Participant, and shall bear an appropriate legend referring to the terms, conditions and restrictions applicable to any such Award. The Company may require that the share certificates, if any, evidencing Restricted Stock granted hereunder be held in the custody of the Company until the restrictions thereon shall have lapsed, and that, as a condition of any Award of Restricted Stock, the Participant shall have delivered a share transfer form, endorsed in blank, relating to the Shares covered by such Award. Certificates for shares of unrestricted Common Stock may, in the Company's sole discretion, be delivered to the Participant only after the Restricted Period has expired without forfeiture in such Restricted Stock Award. With respect to Restricted Stock Units to be settled in Shares, at the expiration of the Restricted Period, share certificates in respect of the shares of Common Stock underlying such Restricted Stock Units may, in the Company's sole discretion, be delivered to the Participant, or his legal representative, in a number equal to the number of shares of Common Stock underlying the Restricted Stock Units Award. Notwithstanding anything in the Plan to the contrary, any Restricted Stock or Restricted Stock Units to be settled in Shares (at the expiration of the Restricted Period, and whether before or after any vesting conditions have been satisfied) may, in the Company's sole discretion, be issued in uncertificated form or by the appropriate entry on the books of the Company or of a duly authorized transfer agent of the Company. Further, notwithstanding anything in the Plan to the contrary, with respect to Restricted Stock Units, at the expiration of the Restricted Period, Shares, or cash, as applicable, shall promptly be issued (either in certificated or uncertificated form) to the Participant, unless otherwise deferred in accordance with procedures established by the Company in accordance with Section 409A of the Code, and such issuance or payment shall in any event be made within such period as is required to avoid the imposition of a tax under Section 409A of the Code.

(c) Restrictions and Conditions. The Restricted Stock or Restricted Stock Units granted pursuant to this Section 9 shall be subject to the following restrictions and conditions and any additional restrictions or conditions as determined by the Administrator at the time of grant or, subject to Section 409A of the Code where applicable, thereafter:

(1) The Administrator may, in its sole discretion, provide for the lapse of restrictions in installments and may accelerate or waive such restrictions in whole or in part based on such factors and such circumstances as the Administrator may determine, in its sole discretion, including, but not limited to, the attainment of certain performance goals, the Participant's termination of employment or service with the Company or any Affiliate thereof, or the Participant's death or Disability. Notwithstanding the foregoing, upon a Change in Control, the outstanding Awards shall be subject to Section 11 hereof.

(2) Except as provided in the applicable Award Agreement, the Participant shall generally have the rights of a stockholder of the Company with respect to Restricted Stock during the Restricted Period; provided, however, that dividends declared during the Restricted Period with respect to an Award, shall only become payable if (and to the extent) the underlying Restricted Stock vests. Except as provided in the applicable Award Agreement, the Participant shall generally not have the rights of a stockholder with respect to Shares subject to Restricted Stock Units during the Restricted Period; provided, however, that, subject to Section 409A of the Code, an amount equal to dividends declared during the Restricted Period with respect to the number of Shares covered by Restricted Stock Units shall, unless otherwise set forth in an Award

Agreement, be paid to the Participant at the time (and to the extent) Shares in respect of the related Restricted Stock Units are delivered to the Participant. Certificates for Shares of unrestricted Common Stock may, in the Company's sole discretion, be delivered to the Participant only after the Restricted Period has expired without forfeiture in respect of such Restricted Stock or Restricted Stock Units, except as the Administrator, in its sole discretion, shall otherwise determine.

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(3) The rights of Participants granted Restricted Stock or Restricted Stock Units upon termination of employment or service as a director or independent contractor to the Company or to any Affiliate thereof terminates for any reason during the Restricted Period shall be set forth in the Award Agreement.

(d) Form of Settlement. The Administrator reserves the right in its sole discretion to provide (either at or after the grant thereof) that any Restricted Stock Unit represents the right to receive the amount of cash per unit that is determined by the Administrator in connection with the Award.

Section 10. **Other Stock-Based Awards.**

Other Stock-Based Awards may be issued under the Plan. Subject to the provisions of the Plan, the Administrator shall have sole and complete authority to determine the individuals to whom and the time or times at which such Other Stock-Based Awards shall be granted. Each Participant who is granted an Other Stock-Based Award shall enter into an Award Agreement with the Company, containing such terms and conditions as the Administrator shall determine, in its sole discretion, including, among other things, the number of shares of Common Stock to be granted pursuant to such Other Stock-Based Awards, or the manner in which such Other Stock-Based Awards shall be settled (e.g., in shares of Common Stock, cash or other property), or the conditions to the vesting and/or payment or settlement of such Other Stock-Based Awards (which may include, but not be limited to, achievement of performance criteria) and all other terms and conditions of such Other Stock-Based Awards. In the event that the Administrator grants a bonus in the form of Shares, the Shares constituting such bonus shall, as determined by the Administrator, be evidenced in uncertificated form or by a book entry record or a certificate issued in the name of the Participant to whom such grant was made and delivered to such Participant as soon as practicable after the date on which such bonus is payable. Notwithstanding anything set forth in the Plan to the contrary, any dividend or dividend equivalent Award issued hereunder shall be subject to the same restrictions, conditions and risks of forfeiture as apply to the underlying Award.

Section 11. **Change in Control.**

Unless otherwise determined by the Administrator and evidenced in an Award Agreement, in the event that a Change in Control occurs, the Administrator, in its sole and absolute discretion, may:

(a) provide that any unvested or unexercisable portion of any Award carrying a right to exercise become fully vested and exercisable; and

(b) cause the restrictions, deferral limitations, payment conditions and forfeiture conditions applicable to an Award granted under the Plan to lapse and such Awards shall be deemed fully vested and any performance conditions imposed with respect to such Awards shall be deemed to be fully achieved at target performance levels.

If the Administrator determines in its discretion pursuant to Section 3(b)(4) hereof to accelerate the vesting of Options and/or Share Appreciation Rights in connection with a Change in Control (or, for the avoidance of doubt, if Options and/or Share Appreciation rights are already vested), the Administrator shall also have discretion in connection with such action to provide that any or all of such Options and/or Stock Appreciation Rights outstanding immediately prior to such Change in Control shall expire on the effective date of such Change in Control. For the avoidance of doubt, in the event of a merger of the Company with or into another corporation or other entity or a Change in Control, the Administrator may provide, without a Participant's consent, that the successor corporation (which may include the Company) (or a parent entity thereof) may assume or substitute for any portion of an Award, with such assumed or substituted Award adjusted in accordance with Section 5. For purposes of this Plan, an Award will be considered assumed if, following the merger or Change in Control, the Award confers the right to purchase or receive, for each Share subject to the Award immediately prior to the merger or Change in Control, the consideration (whether shares, cash, or other securities or property) received in the merger or Change in Control by holders of Common Stock for each Share held on the effective date of the transaction (and if holders were offered a choice of consideration, the type of consideration chosen by the holders of a majority of the outstanding Shares); provided, however, that if such consideration received in the merger or Change in Control is not solely common stock of the successor corporation or its parent entity, the Administrator may, with the consent of the successor corporation, provide for the consideration to be received upon the exercise of an Option or Stock Appreciation Right or upon the payout of a Restricted Stock Unit or Other Stock-Based Award, for each Share subject to such Award, to be solely common stock of the successor corporation or its Parent equal in fair market value to the per share consideration received by holders of Common Stock in the merger or Change in Control. Notwithstanding anything in this Section 11 to the contrary, an Award that vests, is earned or paid out upon the satisfaction of one or more performance goals will not be considered assumed if the Company or its successor modifies any of such performance goals without the Participant's consent, in all cases, unless specifically provided otherwise under the applicable Award Agreement or other written agreement authorized by the Administrator between the Participant and the Company any of its Affiliates; provided, however, a modification to such performance goals only to reflect the successor corporation's post-Change in Control corporate structure will not be deemed to invalidate an otherwise valid Award assumption.

Section 12. **Amendment and Termination.**

The Board may amend, alter or terminate the Plan at any time, but no amendment, alteration or termination shall be made that would impair the rights of a Participant under any Award theretofore granted without such Participant's consent. The Board shall obtain approval of the Company's stockholders for any amendment that would require such approval in order to satisfy the requirements of any rules of the stock exchange on which the Common Stock is traded or other Applicable Law. Subject to Section 3(c), the Administrator may amend the terms of any Award theretofore granted, prospectively or retroactively, but, subject to Section 5 of the Plan and the immediately preceding sentence, no such amendment shall materially impair the rights of any Participant without his or her consent.

Section 13. **Unfunded Status of Plan.**

The Plan is intended to constitute an "unfunded" plan for incentive compensation. With respect to any payments not yet made to a Participant by the Company, nothing contained herein shall give any such Participant any rights that are greater than those of a general creditor of the Company.

Section 14. **Withholding Taxes.**

Each Participant shall, no later than the date as of which the value of an Award first becomes includible in the gross income of such Participant for purposes of applicable taxes, pay to the Company, or make arrangements satisfactory to the Administrator regarding payment of an amount up to the maximum statutory tax rates in the Participant's applicable jurisdiction with respect to the Award, as determined by the Company. The obligations of the Company under the Plan shall be conditional on the making of such payments or arrangements, and the Company shall, to the extent permitted by Applicable Laws, have the right to deduct any such taxes from any payment of any kind otherwise due to such Participant. Whenever cash is to be paid pursuant to an Award, the Company shall have the right to deduct therefrom an amount sufficient to satisfy any applicable withholding tax requirements related thereto. Whenever Shares or property other than cash are to be delivered pursuant to an Award, the Company shall have the right to require the Participant to remit to the Company in cash an amount sufficient to satisfy any related taxes to be withheld and applied to the tax obligations; provided, that, with the approval of the Administrator, a Participant may satisfy the foregoing requirement by either (i) electing to have the Company withhold from delivery of Shares or other property, as applicable, or (ii) delivering already owned unrestricted shares of Common Stock, in each case, having a value not exceeding the applicable taxes to be withheld and applied to the tax obligations. Such already owned and unrestricted shares of Common Stock shall be valued at their Fair Market Value on the date on which

the amount of tax to be withheld is determined and any fractional share amounts resulting therefrom shall be settled in cash. Such an election may be made with respect to all or any portion of the Shares to be delivered pursuant to an award. The Company may also use any other method of obtaining the necessary payment or proceeds, as permitted by Applicable Laws, to satisfy its withholding obligation with respect to any Award.

Section 15. **Transfer of Awards.**

Until such time as the Awards are fully vested and/or exercisable in accordance with the Plan or an Award Agreement, no purported sale, assignment, mortgage, hypothecation, transfer, charge, pledge, encumbrance, gift, transfer in trust (voting or other) or other disposition of, or creation of a security interest in or lien on, any Award or any agreement or commitment to do any of the foregoing (each, a "Transfer") by any holder thereof in violation of the provisions of the Plan or an Award Agreement will be valid, except with the prior written consent of the Administrator, which consent may be granted or withheld in the sole discretion of the Administrator. Any purported Transfer of an Award or any economic benefit or interest therein in violation of the Plan or an Award Agreement shall be null and void *ab initio* and shall not create any obligation or liability of the Company, and any Person purportedly acquiring any Award or any economic benefit or interest therein transferred in violation of the Plan or an Award Agreement shall not be entitled to be recognized as a holder of such Shares or other property underlying such Award. Unless otherwise determined by the Administrator in accordance with the provisions of the immediately preceding sentence, an Option or a Stock Appreciation Right may be exercised, during the lifetime of the Participant, only by the Participant or, during any period during which the Participant is under a legal Disability, by the Participant's guardian or legal representative.

Section 16. **Continued Employment or Service.**

Neither the adoption of the Plan nor the grant of an Award shall confer upon any Eligible Recipient any right to continued employment or service with the Company or any Affiliate thereof, as the case may be, nor shall it interfere in any way with the right of the Company or any Affiliate thereof to terminate the employment or service of any of its Eligible Recipients at any time.

Section 17. **Effective Date.**

The Plan was initially approved by the Board on July 19, 2021 and was adopted and became effective on the date that it was first approved by the Company's stockholders (the "Effective Date").

Section 18. **Electronic Signature.**

Participant's electronic signature of an Award Agreement shall have the same validity and effect as a signature affixed by hand.

Section 19. **Term of Plan.**

No Award shall be granted pursuant to the Plan on or after the tenth anniversary of the Effective Date, but Awards theretofore granted may extend beyond that date, and no ISO may be granted after the tenth anniversary of the earlier of the initial Board adoption of the Plan or initial shareholder approval of the Plan.

Section 20. **Securities Matters and Regulations.**

(a) Notwithstanding anything herein to the contrary, the obligation of the Company to sell or deliver Shares with respect to any Award granted under the Plan shall be subject to all Applicable Laws, rules and regulations, including all applicable federal and state securities laws, and the obtaining of all such approvals by governmental agencies as may be deemed necessary or appropriate by the Administrator. The Administrator may require, as a condition of the issuance and delivery of certificates evidencing shares of Common Stock pursuant to the terms hereof, that the recipient of such shares make such agreements and representations, and that such certificates bear such legends, as the Administrator, in its sole discretion, deems necessary or advisable.

(b) Each Award is subject to the requirement that, if at any time the Administrator determines that the listing, registration or qualification of Shares is required by any securities exchange or under any state or federal law, or the consent or approval of any governmental regulatory body is necessary or desirable as a condition of, or in connection with, the grant of an Award or the issuance of Shares, no such Award shall be granted or payment made or Shares issued, in whole or in part, unless listing, registration, qualification, consent or approval has been effected or obtained free of any conditions not acceptable to the Administrator.

(c) In the event that the disposition of Shares acquired pursuant to the Plan is not covered by a then current registration statement under the Securities Act and is not otherwise exempt from such registration, such Shares shall be restricted against transfer to the extent required by the Securities Act or regulations thereunder, and the Administrator may require a Participant receiving Common Stock pursuant to the Plan, as a condition precedent to receipt of such Common Stock, to represent to the Company in writing that the Common Stock acquired by such Participant is acquired for investment only and not with a view to distribution.

Section 21. **Section 409A of the Code.**

The Plan as well as payments and benefits under the Plan are intended to be exempt from, or to the extent subject thereto, to comply with Section 409A of the Code, and, accordingly, to the maximum extent permitted, the Plan shall be interpreted in accordance therewith. Notwithstanding anything contained herein to the contrary, to the extent required in order to avoid accelerated taxation and/or tax penalties under Section 409A of the Code, the Participant shall not be considered to have terminated employment or service with the Company for purposes of the Plan and no payment shall be due to the Participant under the Plan or any Award until the Participant would be considered to have incurred a "separation from service" from the Company and its Affiliates within the meaning of Section 409A of the Code. Any payments described in the Plan that are due within the "short term deferral period" as defined in Section 409A of the Code shall not be treated as deferred compensation unless Applicable Law requires otherwise. Notwithstanding anything to the contrary in the Plan, to the extent that any Awards (or any other amounts payable under any plan, program or arrangement of the Company or any of its Affiliates) are payable upon a separation from service and such payment would result in the imposition of any individual tax and penalty interest charges imposed under Section 409A of the Code, the settlement and payment of such awards (or other amounts) shall instead be made on the first business day after the date that is six (6) months following such separation from service (or death, if earlier). Each amount to be paid or benefit to be provided under this Plan shall be construed as a separate identified payment for purposes of Section 409A of the Code. The Company makes no representation that any or all of the payments or benefits described in this Plan will be exempt from or comply with Section 409A of the Code and makes no undertaking to preclude Section 409A of the Code from applying to any such payment. The Participant shall be solely responsible for the payment of any taxes and penalties incurred under Section 409A.

Section 22. **Notification of Election Under Section 83(b) of the Code.**

If any Participant shall, in connection with the acquisition of shares of Common Stock under the Plan, make the election permitted under Section 83(b) of the Code, such Participant shall notify the Company of such election within ten (10) days after filing notice of the election with the Internal Revenue Service.

Section 23. **No Fractional Shares.**

No fractional shares of Common Stock shall be issued or delivered pursuant to the Plan. The Administrator shall determine whether cash, other Awards, or other property shall be issued or paid in lieu of such fractional shares or whether such fractional shares or any rights thereto shall be forfeited or otherwise eliminated.

Section 24. **Beneficiary.**

A Participant may file with the Administrator a written designation of a beneficiary on such form as may be prescribed by the Administrator and may, from time to time, amend or revoke such designation. If no designated beneficiary survives the Participant, the executor or administrator of the Participant's estate shall be deemed to be the Participant's beneficiary.

Section 25. **Paperless Administration.**

In the event that the Company establishes, for itself or using the services of a third party, an automated system for the documentation, granting or exercise of Awards, such as a system using an internet website or interactive voice response, then the paperless documentation, granting or exercise of Awards by a Participant may be permitted through the use of such an automated system.

Section 26. **Severability.**

If any provision of the Plan is held to be invalid or unenforceable, the other provisions of the Plan shall not be affected but shall be applied as if the invalid or unenforceable provision had not been included in the Plan.

Section 27. **Clawback.**

(a) If the Company is required to prepare a financial restatement due to the material non-compliance of the Company with any financial reporting requirement, then the Committee may require any Section 16 Officer to repay or forfeit to the Company, and each Section 16 Officer agrees to so repay or forfeit, that part of the Incentive Compensation received by that Section 16 Officer during the three-year period preceding the publication of the restated financial statement that the Committee determines was in excess of the amount that such Section 16 Officer would have received had such Incentive Compensation been calculated based on the financial results reported in the restated financial statement. The Committee may take into account any factors it deems reasonable in determining whether to seek recoupment of previously paid Incentive Compensation and how much Incentive Compensation to recoup from each Section 16 Officer (which need not be the same amount or proportion for each Section 16 Officer), including any determination by the Committee that a Section 16 Officer engaged in fraud, willful misconduct or committed grossly negligent acts or omissions which materially contributed to the events that led to the financial restatement. The amount and form of the Incentive Compensation to be recouped shall be determined by the Committee in its sole and absolute discretion, and recoupment of Incentive Compensation may be made, in the Committee's sole and absolute discretion, through the cancellation of vested or unvested Awards, cash repayment or both.

(b) Notwithstanding any other provisions in this Plan, any Award which is subject to recovery under any Applicable Laws, government regulation or stock exchange listing requirement, will be subject to such deductions and clawback as may be required to be made pursuant to such Applicable Law, government regulation or stock exchange listing requirement (or any policy adopted by the Company pursuant to any such law, government regulation or stock exchange listing requirement).

Section 28. **Governing Law.**

The Plan shall be governed by, and construed in accordance with, the laws of the State of Delaware, without giving effect to principles of conflicts of law of such state.

Section 29. **Indemnification.**

To the extent allowable pursuant to applicable law, each member of the Board and the Administrator and any officer or other employee to whom authority to administer any component of the Plan is designated shall be indemnified and held harmless by the Company from any loss, cost, liability, or expense that may be imposed upon or reasonably incurred by such member in connection with or resulting from any claim, action, suit, or proceeding to which he or she may be a party or in which he or she may be a party or in which he or she may be involved by reason of any action or failure to act pursuant to the Plan and against and from any and all amounts paid by him or her in satisfaction of judgment in such action, suit, or proceeding against him or her; provided, however, that he or she gives the Company an opportunity, at its own expense, to handle and defend the same before he or she undertakes to handle and defend it on his or her own behalf. The foregoing right of indemnification shall not be exclusive of any other rights of indemnification to which such individuals may be entitled pursuant to the Company's Articles of Incorporation or Bylaws, as a matter of law, or otherwise, or any power that the Company may have to indemnify them or hold them harmless.

Section 30. **Titles and Headings, References to Sections of the Code or Exchange Act.**

The titles and headings of the sections in the Plan are for convenience of reference only and, in the event of any conflict, the text of the Plan, rather than such titles or headings, shall control. References to sections of the Code or the Exchange Act shall include any amendment or successor thereto.

Section 31. **Successors.**

The obligations of the Company under the Plan shall be binding upon any successor corporation or organization resulting from the merger, consolidation or other reorganization of the Company, or upon any successor corporation or organization succeeding to substantially all of the assets and business of the Company.

Section 32. **Relationship to other Benefits.**

No payment pursuant to the Plan shall be taken into account in determining any benefits under any pension, retirement, savings, profit sharing, group insurance, welfare, or other benefit plan of the Company or any Affiliate except to the extent otherwise expressly provided in writing in such other plan or an agreement thereunder.

RENOVORX, INC.
STOCK OPTION GRANT NOTICE AND OPTION AGREEMENT
(2021 Omnibus Equity Incentive Plan)

As a key leader in our business, you are in a position to have significant influence on the performance and success of RenovoRx, Inc. (the "**Company**"). I am pleased to inform you that, in recognition of the role you play in our collective success, you have been granted an option to purchase shares of the Company's Common Stock. This award is subject to the terms and conditions of the RenovoRx, Inc. 2021 Omnibus Equity Incentive Plan, this Grant Notice, and the following Stock Option Agreement. The details of this award are indicated below.

Optionee:	[_____]
Date of Grant:	[_____]
Number of Shares subject to the Option:	[_____]
Exercise Price Per Share:	[_____]
Term of Option:	[ISO/Nonqualified Stock Option]
Vesting:	[_____]

Name:_____
Title:_____

Acknowledged and agreed as of the Date of Grant

_____
Name: _____

STOCK OPTION AGREEMENT

THIS STOCK OPTION AGREEMENT (together with the above grant notice (the "**Grant Notice**"), the "**Agreement**") is made and entered into as of the date set forth on the Grant Notice by and between RenovoRx, Inc., a Delaware corporation (the "**Company**"), and the individual (the "**Optionee**") set forth on the Grant Notice.

A. Pursuant to the RenovoRx, Inc. 2021 Omnibus Equity Incentive Plan (the "**Plan**"), the Administrator has determined that it is to the advantage and best interest of the Company to grant to the Optionee an option to purchase the number of Shares (the "**Shares**") set forth on the Grant Notice, at the exercise price per Share set forth on the Grant Notice, and in all respects subject to the terms, definitions and provisions of the Plan, which is incorporated herein by reference, and this Agreement (the "**Option**").

B. Unless otherwise defined herein, capitalized terms used in this Agreement shall have the meanings set forth in the Plan. For purposes of this Agreement, the following definitions shall apply:

(i) "**Termination**" shall mean the termination of the employment or service of the Optionee with the Company and all Affiliates thereof (including because of the Optionee's employer ceasing to be an affiliate of the Company). For purposes of this Agreement, Termination will not occur when Optionee goes on a military leave, a sick leave or another bona fide leave of absence that was approved by the Company in writing if the terms of the leave provide for continued service crediting, or when continued service crediting is required by Applicable Laws. Notwithstanding the foregoing, an approved leave of absence for six months or less, which does not in fact exceed six months, will not result in Termination for purposes of this Agreement. However, Termination will occur when an approved leave described in this Section A ends, unless Optionee immediately returns to active work.

(ii) "**Termination Date**" shall mean the date of the Optionee's Termination of Service.

NOW, THEREFORE, in consideration of the mutual agreements contained herein, the Optionee and the Company hereby agree as follows:

1. Acceptance of Agreement. Optionee has reviewed all of the provisions of the Plan and this Agreement. Optionee hereby agrees to accept as binding, conclusive and final all decisions or interpretations of the Administrator on questions relating to the Plan and this Agreement, and, solely as they relate to this Option, the applicable provisions (if any) contained in a written employment agreement between the Company or an Affiliate and the Optionee. The Optionee's electronic signature of this Agreement shall have the same validity and effect as a signature affixed by hand.

2. Grant and Terms of Stock Option.

2.1 Grant of Option. Pursuant to this Agreement, the Company has granted to the Optionee the right and option to purchase, subject to the terms and conditions set forth in the Plan and this Agreement, all or any part of the number of Shares set forth on the Grant Notice at a purchase price per Share equal to the exercise price per Share set forth on the Grant Notice. An Option granted pursuant to the Grant Notice and this Agreement shall be [an ISO/a Nonqualified Stock Option].

2.2 Vesting and Term of Option. This Section 2.2 is subject to the provisions of the Plan and the other provisions of this Agreement.

2.2.1 This Option shall vest and become exercisable as described in the Grant Notice.

2.2.2 The "**Term**" of this Option shall begin on the Date of Grant set forth in the Grant Notice and end on the expiration of the Term specified in the Grant Notice. No portion of this Option may be exercised after the expiration of the Term.

2.2.3 In the event of Optionee's Termination for any reason other than death, Disability, or Cause:

2.2.3.1 the portion of this Option that is not vested and exercisable as of the Termination Date shall not continue to vest and shall be immediately cancelled and terminated; and

2.2.3.2 the portion of this Option that is vested and exercisable as of the Termination Date shall terminate and be cancelled on the earlier of:

(a) the expiration of the Term and

(b) ninety (90) days after such Termination Date.

2.2.4 In the event of Termination due to death or Disability:

2.2.4.1 the portion of this Option that is not vested and exercisable as of the Termination Date shall not continue to vest and shall be immediately cancelled and terminated; and

2.2.4.2 the portion of this Option that is vested and exercisable as of the Termination Date shall terminate and be cancelled on the earlier of (a) the expiration of the Term and (b) the date that is twelve (12) months after the Termination Date.

2.2.5 In the event of Optionee's Termination for Cause, or if, after the Termination, the Administrator determines that Cause existed before such Termination, this entire Option shall not continue to vest, shall be cancelled and terminated as of the Termination Date, and shall no longer be exercisable as to any Shares,

whether or not previously vested.

3. Method of Exercise.

3.1 Method of Exercise. Each election to exercise the Option shall be subject to the terms and conditions of the Plan and shall be in writing, signed by the Optionee or by his or her executor, administrator, or permitted transferee (subject to any restrictions provided under the Plan), made pursuant to and in accordance with the terms and conditions set forth in the Plan and received by the Company at its principal offices, accompanied by payment in full as provided in the Plan or in this Agreement. Notwithstanding any of the foregoing, the Administrator shall have the right to specify all conditions of the manner of exercise. Upon the Company's determination that the Option has been validly exercised as to any of the Shares, the Company may issue certificates in the Optionee's name for such Shares. However, the Company shall not be liable to the Optionee for damages relating to any reasonable delays in issuing the certificates to the Optionee, any loss of the certificates, or any mistakes or errors in the issuance of the certificates or in the certificates themselves which it promptly undertakes to correct.

3.2 Restrictions on Exercise. No Shares will be issued pursuant to the exercise of this Option unless and until there shall have been full compliance with all applicable requirements of the Securities Act of 1933 ("**Securities Act**"), as amended (whether by registration or satisfaction of exemption conditions), all applicable listing requirements of any national securities exchange or other market system on which the Common Stock is then listed and all applicable requirements of any Applicable Laws and of any regulatory bodies having jurisdiction over such issuance. As a condition to the exercise of this Option, the Company may require the Optionee to make any representation and warranty to the Company as may be necessary or appropriate, in the judgment of the Administrator, to comply with any Applicable Law. In addition, Optionee shall not sell any Shares acquired upon exercise of this Option at a time when Applicable Laws, regulations or Company's or underwriter trading policies prohibit such sale. Any other provision of this Agreement notwithstanding, the Company shall have the right to designate one or more periods of time, each of which shall not exceed 180 days in length, during which this Option shall not be exercisable if the Administrator determines (in its sole discretion) that such limitation on exercise could in any way facilitate a lessening of any restriction on transfer pursuant to the Securities Act or any state securities laws with respect to any issuance of securities by the Company, facilitate the registration or qualification of any securities by the Company under the Securities Act or any state securities laws, or facilitate the perfection of any exemption from the registration or qualification requirements of the Securities Act or any applicable state securities laws for the issuance or transfer of any securities. Such limitation on exercise shall not alter the vesting schedule set forth in this Agreement other than to limit the periods during which this Option shall be exercisable.

3.3 Method of Payment. Payment of the exercise price shall be made in full at the time of exercise (a) by the delivery of cash or check acceptable to the Administrator, including an amount to cover the withholding taxes (as provided in Section 7.11) with respect to such exercise, or (b) any other method, if any, approved by the Administrator, including (i) by means of consideration received under any cashless exercise procedure, if any, approved by the Administrator (including the withholding of Shares otherwise issuable upon exercise) or (ii) any other form of consideration approved by the Administrator and permitted by Applicable Laws.

3.4 No Rights as a Shareholder. Until the Shares are issued to the Optionee (as evidenced by the appropriate entry on the books of the Company or of a duly authorized transfer agent of the Company), no right to vote or receive dividends or any other rights as a shareholder will exist with respect to the Shares, notwithstanding the exercise of the Option.

4. Non-Transferability of Option. Except as provided below, this Option may not be sold, assigned or transferred in any manner, pledged or otherwise encumbered other than by will or by the laws of descent or distribution or to a beneficiary designated pursuant to the Plan, and may be exercised during the lifetime of Optionee only by Optionee or the Optionee's guardian or legal representative. Subject to all of the other terms and conditions of this Agreement, following the death of Optionee, this Option may, to the extent it is vested and exercisable by Optionee in accordance with its terms on the Termination Date, be exercised by Optionee's executor or administrator, or the person or persons to whom the Optionee's rights under this Agreement shall pass by will or by the laws of descent and distribution as the case may be. Any heir or legatee of the Optionee shall take rights herein granted subject to the terms and conditions hereof.

5. Restrictions; Restrictive Legends. Ownership and transfer of Shares issued pursuant to the exercise of this Option will be subject to the provisions of, including ownership and transfer restrictions contained in, the Company's Certificate of Incorporation or Bylaws, as amended from time to time, restrictions imposed by Applicable Laws and restrictions set forth or referenced in legends imprinted on certificates representing such Shares.

6. Dissolution or Liquidation. In the event of the proposed dissolution or liquidation of the Company, to the extent that this Option had not been previously exercised, it will terminate immediately prior to the consummation of such proposed dissolution or liquidation. In such instance, the Administrator may, in the exercise of its sole discretion, declare that this Option will terminate as of a date fixed by the Administrator and give the Optionee the right to exercise this Option prior to such date as to all or any part of the optioned stock, including Shares as to which this Option would not otherwise be exercisable.

7. General.

7.1 Governing Law. This Agreement shall be governed by and construed under the laws of the State of Delaware applicable to agreements made and to be performed entirely in Delaware, without regard to the conflicts of law provisions of Delaware or any other jurisdiction.

7.2 Community Property. Without prejudice to the actual rights of the spouses as between each other, for all purposes of this Agreement, the Optionee shall be treated as agent and attorney-in-fact for that interest held or claimed by his or her spouse with respect to this Option and the parties hereto shall act in all matters as if the Optionee was the sole owner of this Option. This appointment is coupled with an interest and is irrevocable.

7.3 No Employment Rights. Nothing herein contained shall be construed as an agreement by the Company or any of its Subsidiaries, express or implied, to employ the Optionee or contract for the Optionee's services, to restrict the Company's or such Subsidiary's right to discharge the Optionee or cease contracting for the Optionee's services or to modify, extend or otherwise affect in any manner whatsoever the terms of any employment agreement or contract for services which may exist between the Optionee and the Company or any Affiliate.

7.4 Application to Other Stock. In the event any capital stock of the Company or any other corporation shall be distributed on, with respect to, or in exchange for Shares as a stock dividend, stock split, reclassification or recapitalization in connection with any merger or reorganization or otherwise, all restrictions, rights and obligations set forth in this Agreement shall apply with respect to such other capital stock to the same extent as they are, or would have been applicable, to the Shares on or with respect to which such other capital stock was distributed, and references to "Company" in respect of such distributed stock shall be deemed to refer to the company to which such distributed stock relates.

7.5 No Third-Party Benefits. Except as otherwise expressly provided in this Agreement, none of the provisions of this Agreement shall be for the benefit of, or enforceable by, any third-party beneficiary.

7.6 Successors and Assigns. Except as provided herein to the contrary, this Agreement shall be binding upon and inure to the benefit of the parties, their

respective successors and permitted assigns.

7.7 No Assignment. Except as otherwise provided in this Agreement, the Optionee may not assign any of his or her rights under this Agreement without the prior written consent of the Company, which consent may be withheld in its sole discretion. The Company shall be permitted to assign its rights or obligations under this Agreement so long as such assignee agrees to perform all of the Company's obligations hereunder.

7.8 Severability. The validity, legality or enforceability of the remainder of this Agreement shall not be affected even if one or more of the provisions of this Agreement shall be held to be invalid, illegal or unenforceable in any respect.

7.9 Equitable Relief. The Optionee acknowledges that, in the event of a threatened or actual breach of any of the provisions of this Agreement, damages alone will be an inadequate remedy, and such breach will cause the Company great, immediate and irreparable injury and damage. Accordingly, the Optionee agrees that the Company shall be entitled to injunctive and other equitable relief, and that such relief shall be in addition to, and not in lieu of, any remedies it may have at law or under this Agreement.

7.10 Jurisdiction. Any suit, action or proceeding with respect to this Agreement, or any judgment entered by any court in respect of any thereof, shall be brought in any court of competent jurisdiction in the State of Delaware, and the Company and the Optionee hereby submit to the exclusive jurisdiction of such courts for the purpose of any such suit, action, proceeding or judgment. The Optionee and the Company hereby irrevocably waive (i) any objections which it may now or hereafter have to the laying of the venue of any suit, action or proceeding arising out of or relating to this Agreement brought in any court of competent jurisdiction in the State of Delaware, (ii) any claim that any such suit, action or proceeding brought in any such court has been brought in any inconvenient forum and (iii) any right to a jury trial.

7.11 Taxes. By agreeing to this Agreement, the Optionee represents that he or she has reviewed with his or her own tax advisors the federal, state, local and foreign tax consequences of the transactions contemplated by this Agreement and that he or she is relying solely on such advisors and not on any statements or representations of the Company or any of its agents. The Company shall be entitled to require a cash payment by or on behalf of the Optionee and/or to deduct from the Shares or cash otherwise issuable hereunder or other compensation payable to the Optionee the minimum amount of any sums required by federal, state or local tax law to be withheld (or other such sums that will not cause adverse accounting consequences for the Company and is permitted under applicable withholding rules promulgated by the Internal Revenue Service or another applicable governmental entity) in respect of the Option, its exercise or any payment or transfer under or with respect to the Option.

7.12 Headings. The section headings in this Agreement are inserted only as a matter of convenience, and in no way define, limit, extend or interpret the scope of this Agreement or of any particular section.

7.13 Number and Gender. Throughout this Agreement, as the context may require, (a) the masculine gender includes the feminine and the neuter gender includes the masculine and the feminine; (b) the singular tense and number includes the plural, and the plural tense and number includes the singular; (c) the past tense includes the present, and the present tense includes the past; (d) references to parties, sections, paragraphs and exhibits mean the parties, sections, paragraphs and exhibits of and to this Agreement; and (e) periods of days, weeks or months mean calendar days, weeks or months.

7.14 Data Privacy. Optionee agrees that all of Optionee's information that is described or referenced in this Agreement and the Plan may be used by the Company, its affiliates and the designated broker and its affiliates to administer and manage Optionee's participation in the Plan.

7.15 Acknowledgments of Optionee. Optionee has reviewed the Plan and this Agreement in their entirety, has had an opportunity to obtain the advice of counsel prior to executing this Agreement, fully understands all provisions of the Plan and this Agreement and, by accepting the Notice of Grant, acknowledges and agrees to all of the provisions of the Grant Notice, the Plan and this Agreement.

7.16 Complete Agreement. The Grant Notice, this Stock Option Agreement, the Plan, and the applicable provisions (if any) contained in a written employment agreement between the Company or an Affiliate and the Optionee constitute the parties' entire agreement with respect to the subject matter hereof and supersede all agreements, representations, warranties, statements, promises and understandings, whether oral or written, with respect to the subject matter hereof. In the event of any inconsistency between the Plan and this Agreement, the terms of the Plan shall control.

7.17 Waiver. The Optionee acknowledges that a waiver by the Company of a breach of any provision of this Agreement shall not operate or be construed as a waiver of any other provision of this Agreement, or of any subsequent breach by the Optionee.

7.18 Signature in Counterparts. This Agreement may be signed in counterparts, each of which shall be an original, with the same effect as if the signatures thereto and hereto were upon the same instrument.

7.19 Amendments and Termination. To the extent permitted by the Plan, this Agreement may be wholly or partially amended, altered or terminated at any time or from time to time by the Administrator or the Board, but no amendment, alteration or termination shall be made that would materially impair the rights of an Optionee under the Option without such Optionee's consent. If it is determined that the terms of this Agreement have been structured in a manner that would result in adverse tax treatment under Section 409A of the Code, the parties agree to cooperate in taking all reasonable measures to restructure the arrangement to minimize or avoid such adverse tax treatment without materially impairing Optionee's economic rights.

7.20 Waiver of Jury Trial. TO THE EXTENT EITHER PARTY INITIATES LITIGATION INVOLVING THIS AGREEMENT OR ANY ASPECT OF THE RELATIONSHIP BETWEEN US (EVEN IF OTHER PARTIES OR OTHER CLAIMS ARE INCLUDED IN SUCH LITIGATION), ALL OF THE PARTIES WAIVE THEIR RIGHT TO A TRIAL BY JURY. THIS WAIVER WILL APPLY TO ALL CAUSES OF ACTION THAT ARE OR MIGHT BE INCLUDED IN SUCH ACTION, INCLUDING CLAIMS RELATED TO THE ENFORCEMENT OR INTERPRETATION OF THIS AGREEMENT, ALLEGATIONS OF STATE OR FEDERAL STATUTORY VIOLATIONS, FRAUD, MISREPRESENTATION, OR SIMILAR CAUSES OF ACTION, AND IN CONNECTION WITH ANY LEGAL ACTION INITIATED FOR THE RECOVERY OF DAMAGES BETWEEN OR AMONG US OR BETWEEN OR AMONG ANY OF OUR OWNERS, AFFILIATES, OFFICERS, EMPLOYEES OR AGENTS.

7.21 **Electronic Delivery and Disclosure**. The Company may, in its sole discretion, decide to deliver or disclose, as applicable, any documents related to this Award granted under the Plan, future awards that may be granted under the Plan, the prospectus related to the Plan, the Company's annual reports or proxy statements by electronic means or to request Optionee's consent to participate in the Plan by electronic means, including, but not limited to, the Securities and Exchange Commission's Electronic Data Gathering, Analysis, and Retrieval system or any successor system ("**EDGAR**"). Optionee hereby consents to receive such documents delivered electronically or to retrieve such documents furnished electronically (including on EDGAR), as applicable, and agrees to participate in the Plan through any online or electronic system established and maintained by the Company or another third party designated by the Company.

7.22 Section 409A. The parties intend for the Option to be exempt from Section 409A of the Code or, if not so exempt, to be treated in a manner which complies with the requirements of such section, and intend that this Agreement be construed and administered in accordance with such intention. In the event that the parties determine that the terms of this Agreement or the Option needs to be modified in order to comply with Section 409A of the Code, the parties shall cooperate reasonably to do so

in a manner intended to best preserve the economic benefits of this Agreement. Any payments that qualify for the "short-term deferral" exception or another exception under Section 409A of the Code shall be paid under the applicable exception. For purposes of the limitations on nonqualified deferred compensation under Section 409A of the Code, each payment of compensation under this Agreement shall be treated as a separate payment of compensation. Notwithstanding anything contained herein to the contrary, to the extent required in order to avoid accelerated taxation and/or tax penalties under Section 409A of the Code, amounts that would otherwise be payable and benefits that would otherwise be provided pursuant to this Agreement during the six-month period immediately following the Participant's separation from service shall instead be paid on the first business day after the date that is six months following the Participant's termination date (or death, if earlier).

Exhibit 10.3

RENOVORX, INC.
OUTSIDE DIRECTOR COMPENSATION POLICY

*Initially Adopted and Approved by the Board of Directors on September 30, 2021; most recently amended and restated February 10, 2022 (the "**Restatement Date**")*

RenovoRx, Inc. (the "**Company**") believes that providing cash and equity compensation to its members of the Board of Directors (the "**Board**," and members of the Board, the "**Directors**") represents an effective tool to attract, retain and reward Directors who are not employees of the Company (the "**Outside Directors**"). This Outside Director Compensation Policy as amended and restated (the "**Policy**") is intended to formalize the Company's policy regarding the compensation to its Outside Directors. Unless otherwise defined herein, capitalized terms used in this Policy will have the meaning given to such terms in the Company's 2021 Omnibus Equity Incentive Plan (the "**Plan**"), or if the Plan is no longer in place, the meaning given to such terms or any similar terms in the equity plan then in place. Each Outside Director will be solely responsible for any tax obligations incurred by such Outside Director as a result of the equity and cash payments such Outside Director receives under this Policy.

This amended and restated Policy is effective as of the Restatement Date.

1. Cash Compensation

Annual Cash Retainer

Each Outside Director will be paid an annual cash retainer of $36,000. There are no per-meeting attendance fees for attending Board meetings. This cash compensation will be paid quarterly in arrears on a prorated basis to each Outside Director who has served in the relevant capacity at any point during the immediately preceding fiscal quarter, and such payment shall be made no later than forty-five (45) days following the end of such immediately preceding fiscal quarter.

Committee Annual Cash Retainer

Effective as of the Restatement Date, each Outside Director who serves as the chair or a member of a committee of the Board listed below will be eligible to earn additional annual cash fees (paid quarterly in arrears on a prorated basis to each Outside Director who has served in the relevant capacity at any point during the immediately preceding fiscal quarter, and such payment shall be made no later than forty-five (45) days following the end of such immediately preceding fiscal quarter) as follows:

Chair of Audit Committee:	$	15,000
Chair of Compensation Committee:	$	10,000
Chair of Corporate Governance and Nominating Committee:	$	10,000
Non-Chair Members of Various Committees:	$	5,000

For clarity, each Outside Director who serves as the chair of a committee shall receive only the additional annual cash fee as the chair of the committee, and not the additional annual cash fee as a member of the committee. For purposes of further clarification, an Outside Director who has served as an Outside Director, or as a member of an applicable committee (or chair thereof), as applicable, during only a portion of the relevant Company fiscal quarter will receive a pro-rated payment of the quarterly payment of the applicable annual cash retainer(s), calculated based on the number of days during such fiscal quarter such Outside Director has served in the relevant capacities.

2. Equity Compensation

Outside Directors will be eligible to receive all types of Awards (except Incentive Stock Options) under the Plan (or the applicable equity plan in place at the time of grant), including discretionary Awards not covered under this Policy. All grants of Awards to Outside Directors pursuant to Section 2 of this Policy will be automatic and nondiscretionary, except as otherwise provided herein, and will be made in accordance with the following provisions:

(a) No Discretion. No person will have any discretion to select which Outside Directors will be granted any Awards under this Policy or to determine the number of Shares to be covered by such Awards.

(b) Initial Award. Each individual who first becomes an Outside Director following the Restatement Date will be granted Options having a Value of $120,000 in the aggregate (an "**Initial Award**"), on the date on which such individual first becomes an Outside Director, whether through election by the stockholders of the Company or appointment by the Board to fill a vacancy. Subject to Section 11 of the Plan and Section 3 of this Policy, each Initial Award will vest and become exercisable over three years, with 1/36th of the Initial Award vesting each month on the same day of the month as the commencement of the applicable Outside Director's service as an Outside Director, subject to the Outside Director continuing to be a Participant (as defined in the Plan) through such date.

(c) Annual Award. On October 1 of each year, commencing October 1, 2022, each Outside Director will be automatically granted Options having a Value of $70,000 in the aggregate (an "**Annual Award**"). Subject to Section 11 of the Plan and Section 3 of this Policy, 1/12th of each Annual Award will vest monthly after October 1 on the first day of each subsequent month, subject to the applicable Outside Director continuing to be a Participant through such date.

(c) Terms. The terms and conditions of each Initial Award or Annual Award will be as follows:

(i) Exercise Price. The per Share exercise price for an Option granted under this Policy will be 100% of the Fair Market Value on the grant date.

(ii) Term. The maximum term to expiration of an Option granted under this Policy will be 10 years, subject to earlier termination as provided in the Plan.

(d) Value. For purposes of this Policy, "Value" means the grant date fair value as determined for the Company's financial reporting purposes.

3. Change in Control

In the event of a Change in Control, each Outside Director will fully vest in his or her outstanding Company equity Awards, including any Initial Award or Annual Award, provided that the Outside Director continues to be an Outside Director through such date.

4. Annual Compensation Limit

In any fiscal year, other than the fiscal year in which he or she joins the Board, no Outside Director may be paid, issued or granted compensation (including in the

form of cash or equity compensation, with cash compensation measured for this purpose at its value upon payment and any equity compensation measured for this purpose at its Value) with an aggregate value greater than $250,000 (increased to $300,000 for an Outside Director's first fiscal year of service). Any cash compensation paid or equity compensation award (including any Awards) granted to an individual for his or her services as an employee, or for his or her services as a consultant (other than as an Outside Director), will not count for purposes of the limitation under this Section 4.

5. Travel Expenses

Each Outside Director's reasonable, customary and documented travel expenses to Board or Board committee meetings will be reimbursed by the Company.

6. Additional Provisions

All provisions of the Plan not inconsistent with this Policy will apply to Awards granted to Outside Directors.

7. Adjustments

In the event that that any extraordinary dividend or other extraordinary distribution (whether in the form of cash, Shares, other securities or other property), recapitalization, stock split, reverse stock split, reorganization, merger, consolidation, split-up, spin-off, combination, repurchase, or exchange of Shares or other securities of the Company, or other change in the corporate structure of the Company affecting the Shares occurs, the Administrator, in order to prevent diminution or enlargement of the benefits or potential benefits intended to be made available under this Policy, will adjust the number of Shares issuable pursuant to Awards granted under this Policy.

8. Section 409A

In no event will cash compensation or expense reimbursement payments under this Policy be paid after the later of (i) 15th day of the third month following the end of the Company's fiscal year in which the compensation is earned or expenses are incurred, as applicable, or (ii) 15th day of the third month following the end of the calendar year in which the compensation is earned or expenses are incurred, as applicable, in compliance with the "short-term deferral" exception under Section 409A of the Internal Revenue Code of 1986, as amended, and the final regulations and guidance thereunder, as may be amended from time to time (together, "**Section 409A**"). It is the intent of this Policy that this Policy and all payments hereunder be exempt from or otherwise comply with the requirements of Section 409A so that none of the compensation to be provided hereunder will be subject to the additional tax imposed under Section 409A, and any ambiguities or ambiguous terms herein will be interpreted to be so exempt or comply. In no event will the Company reimburse an Outside Director for any taxes imposed or other costs incurred as a result of Section 409A.

9. Revisions

The Board may amend, alter, suspend or terminate this Policy at any time and for any reason. No amendment, alteration, suspension or termination of this Policy will materially impair the rights of an Outside Director with respect to compensation that already has been paid or awarded, unless otherwise mutually agreed between the Outside Director and the Company. Termination of this Policy will not affect the Board's or the Compensation Committee's ability to exercise the powers granted to it under the Plan with respect to Awards granted under the Plan pursuant to this Policy prior to the date of such termination.

Exhibit 10.7

AMENDMENT TO CONSULTING AGREEMENT

This Fourth Amendment (the "***Fourth Amendment***") by and between RenovoRx, Inc. (the "***Company***") and Ramtin Agah ("***Consultant***") (together, the "***Parties***") amends the Consulting Agreement by and between the Parties dated January 1, 2018 ("***Consulting Agreement***"), as amended by the Second Amendment to the Consulting Agreement, effective August 1, 2019 (the "***Second Amendment***"), and the Third Amendment to the Consulting Agreement, effective November 11, 2021 (the "***Third Amendment***", and together with the Second Amendment (as amended by the Third Amendment) and the Consulting Agreement, the "***Agreement***"). This Amendment is entered into as of January 25, 2022 ("***Amendment Effective Date***").

1. Amendment to Statement of Work. The following replaces and supersedes Section 2.1 of the SOW.

2.1 **Base Consulting Fee**. Effective January 1, 2022, the Company will pay Consultant a monthly consulting fee of $24,083.33 ("***Base Consulting Fee***"), based on Consultant spending no less than 24 hours per week on Company matters (the "***Allocated Time")***. If Consultant's Allocated Time decreases, the Company may, in its discretion, proportionally adjust the Base Consulting Fee. Consultant agrees that any such reduction in the Base Consulting Fee will not constitute "Good Reason" or any similar definition or concept in any agreement, contract, or arrangement between Consultant and the Company notwithstanding any language to the contrary in any such agreement, contract, or arrangement, nor serves as a trigger for any related benefits.

2. Miscellaneous

A. **Full Force and Effect**. To the extent not expressly amended hereby, the Agreement, shall remain in full force and effect.

B. **Entire Agreement**. This Fourth Amendment, together with the Agreement, constitutes the full and entire understanding and agreement between Company and Consultant with respect to the subjects hereof and thereof.

C. **No Oral Modification**. No modification of or amendment to this Fourth Amendment (or the Agreement) will be effective unless in a writing signed by Consultant and an authorized signatory of the Company.

Company	**Consultant:**
By: /s/ *Shaun R. Bagai*	**By:** /s/ *Ramtin Agah*
Name:Shaun R. Bagai	**Name:Ramtin Agah, MD**
Title: Chief Executive Officer	**Title: Chief Medical Officer**
Date: January 25, 2022	**Date: January 25, 2022**

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statement (No. 333-260573) on Form S-8 of RenovoRx, Inc. of our report dated March 29, 2022, relating to the financial statements of RenovoRx, Inc., appearing in this Annual Report on Form 10-K of RenovoRx, Inc. for the year ended December 31, 2021.

/s/ BAKER TILLY US, LLP

Campbell, California

March 29, 2022

Exhibit 23.2

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation in this Annual Report on Form 10-K of RenovoRx, Inc. for the year ended December 31, 2021, of our report dated May 12, 2021 (August 19, 2021 as to the effects of the reverse stock split described in Note 1 and the effects of the amendment to the 2013 Plan in addition to the adoption of the RenovoRx, Inc. 2021 Omnibus Equity Incentive Plan described in Note 9), relating to the financial statements for the year ended December 31, 2020.

/s/ Frank, Rimerman + Co. LLP

San Francisco, California
March 29, 2022

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 of RenovoRx, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) 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) 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

c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's fourth fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors:

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: March 29, 2022

By: */s/ Shaun R. Bagai*
Chief 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, Christopher J. Lehman, certify that:

1. I have reviewed this Annual Report on Form 10-K of RenovoRx, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) 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) 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

c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's fourth fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors:

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: March 29, 2022

By: */s/ Christopher J. Lehman*
Chief 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 on Form 10-K for the year ended December 31, 2021 (the "*Annual Report*") of RenovoRx, Inc. (the "*Company*"), as filed with the Securities and Exchange Commission on the date hereof, I, Shaun R. Bagai, hereby certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that:

1) The Annual Report of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

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

Date: March 29, 2022

By: */s/ Shaun R. Bagai*
Chief 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 on Form 10-K for the year ended December 31, 2021 (the "*Annual Report*") of RenovoRx, Inc. (the "*Company*"), as filed with the Securities and Exchange Commission on the date hereof, I, Christopher J. Lehman, hereby certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that:

1) The Annual Report of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

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

Date: March 29, 2022

By: */s/ Christopher J. Lehman*
Chief Financial Officer