

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

FORM S-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

RenovoRx, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

2834
(Primary Standard Industrial
Classification Code Number)

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

4546 El Camino Real, Suite B1
Los Altos, CA 94022
(650)-284-4433

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Shaun Bagai
Chief Executive Officer
RenovoRx, Inc.
4546 El Camino Real, Suite B1
Los Altos, CA 94022
(650)-284-4433

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies of all communications to:

Jeffrey J. Fessler
Sheppard Mullin Richter & Hampton LLP
30 Rockefeller Plaza
New York, New York 10112
(212) 653-8700

Robert Charron
Charles Phillips
Ellenoff Grossman & Schole LLP
1345 Avenue of the Americas
New York, New York 10105
(212) 370-1300

Approximate date of commencement of proposed sale to the public:
As soon as practicable after this Registration Statement becomes effective.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act of 1933, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input checked="" type="checkbox"/>

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 7(a)(2)(B) of the Securities Act.

CALCULATION OF REGISTRATION FEE

	<u>Proposed Maximum Aggregate Offering Price⁽¹⁾⁽²⁾</u>	<u>Amount of Registration Fee</u>
Common Stock, \$0.0001 par value per share	\$	\$

Underwriter warrants to purchase shares of common stock ⁽³⁾	\$	\$
Total	\$	\$

(1) Estimated solely for the purpose of calculating the registration fee in accordance with Rule 457(o) under the Securities Act.

(2) Includes initial public offering price of shares that the underwriter has the option to purchase to cover over-allotments, if any.

(3) Represents warrants issuable to the representative or its designees to purchase a number of shares of common stock equal to 5% of the number of shares of common stock being offered at an exercise price equal to 120% of the initial public offering price. See “Underwriting.”

The registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine

The information in this preliminary prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED JUNE 15, 2021

PRELIMINARY PROSPECTUS



[] Shares of Common Stock

This is our initial public offering. We are offering up to [] of shares of common stock pursuant to this prospectus. Prior to this offering, there has been no public market for our common stock. We anticipate that the initial public offering price of our shares will be between \$[] and \$[].

We have applied to list our common stock on the Nasdaq Capital Market under the symbol “RNXT.”

We are an “emerging growth company” under the federal securities laws and have elected to comply with certain reduced public company reporting requirements.

Investing in our common stock involves a high degree of risk. See “Risk Factors” beginning on page 29.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

	Per Share	Total
Initial public offering price	\$	\$
Underwriting discounts and commissions ⁽¹⁾	\$	\$
Proceeds to us, before expenses	\$	\$

(1) We refer you to “Underwriting” beginning on page 111 for additional information regarding underwriter’s compensation.

We have granted a 45-day option to the representative of the underwriter to purchase up to [] additional shares of common stock solely to cover over-allotments, if any.

The underwriter expects to deliver the shares to purchasers on or about , 2021.

Roth Capital Partners

The date of this prospectus is , 2021

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Neither we nor the underwriter have authorized anyone to provide you with information other than that contained in this prospectus. We and the underwriter take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. We and the underwriter are offering to sell, and seeking offers to buy, the securities offered hereby only in jurisdictions where offers and sales are permitted. The information contained in this prospectus is accurate only as of the date on the front cover page of this prospectus, or other earlier date stated in this prospectus, regardless of the time of delivery of this prospectus or of any sale of our securities.

No action is being taken in any jurisdiction outside the United States to permit a public offering of our securities or possession or distribution of this prospectus in that jurisdiction. Persons who come into possession of this prospectus in jurisdictions outside the United States are required to inform themselves about and to observe any restrictions as to this offering and the distribution of this prospectus applicable to that jurisdiction.

This prospectus includes industry data and forecasts that we have obtained from industry publications and surveys, public filings and internal company sources. Industry publications and surveys and forecasts generally state that the information contained therein has been obtained from sources believed to be reliable, but there can be no assurance as to the accuracy or completeness of the included information. Statements as to our market position and market estimates are based on independent industry publications, government publications, third party forecasts, management’s estimates and assumptions about our markets and our internal research. While we are not aware of any misstatements regarding the market, industry or similar data presented herein, such data involve risks and uncertainties and are subject to change based on various factors, including those discussed under the headings “Risk Factors” and “Cautionary Statement Concerning Forward-Looking Statements” in this prospectus.

PROSPECTUS SUMMARY

The following summary highlights information contained elsewhere in this prospectus. It does not contain all of the information you need to consider in making your investment decision. Before making an investment decision, you should read this entire prospectus carefully and you should consider, among other things, the matters set forth under “Risk Factors” and our financial statements and related notes thereto appearing elsewhere in this prospectus. In this prospectus, except as otherwise indicated, “RenovoRx,” the “Company,” “we,” “our,” and “us” refer to RenovoRx, Inc., a Delaware corporation, and its subsidiaries.

Overview

We are a clinical-stage biopharmaceutical company focused on developing therapies for the local treatment of solid tumors and 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. RenovoTAMP combines our patented U.S. 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 drug. Our first product candidate, RenovoGem, is a drug and 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 our first 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 treated with RenovoGem and radiation. 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 RenovoTAMP. Based on FDA safety review of our Phase 1/2 study the FDA allowed us to proceed to evaluate RenovoGem within our Phase 3 registration Investigational New Drug, or IND, clinical trial. Our Phase 3 trial is 40% enrolled as of April 30, 2021 and we expect to report data from a planned interim data readout in the second half of 2022. We intend to evaluate RenovoGem in a second indication in a Phase 2/3 trial in hilar CCA (cancer that occurs in the bile ducts that lead out of the liver and join with the gallbladder, also called extrahepatic cholangiocarcinoma, or HCCA). We plan to propose the trial to the FDA and potentially launch in the first 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 have used gemcitabine, but in the future we may develop other chemotherapeutic agents for intra-arterial delivery via RenovoCath.

Our RenovoTAMP therapy platform is focused on optimizing drug concentration in solid tumors using approved small molecule chemotherapeutics that enable 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. More specifically, our patented approach combines local delivery via our patented RenovoCath delivery system utilizing pressure to force small molecule chemotherapy into the tumor tissue with pre-treatment of the local blood vessels and tissue with standard-of-care radiation therapy to decrease chemotherapy washout. We

believe there are many advantages to our approach:

- *Application of Approved Small Molecule Chemotherapeutic Agents:* We use approved small molecule chemotherapeutic agents such as gemcitabine.
- *Targeted Approach:* With our approach, we have demonstrated in our clinical studies up to 100 times higher local drug concentration compared to systemic chemotherapy. We believe our approach decreases systemic exposure and improves patient outcomes.
- *Delivery Method Independent of Tumor Vascularity:* We invented a novel combination platform and delivery system to deliver small molecule chemotherapeutic agents in solid tumors resistant to systemic chemotherapy due to lack of tumor blood vessels or tumor feeders.
- *Broad Application for Solid Tumor Indications:* Our platform is not restricted to a single small molecule chemotherapeutic agent or solid tumor type. As such, our platform and delivery system may be applied for use in additional solid tumor indications, including in solid tumors without identifiable tumor feeders.

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Our lead product candidate, RenovoGem, is a combination of gemcitabine and our patented delivery system, RenovoCath, and is regulated by the FDA as a novel oncology drug product. Our RenovoTAMP platform therapy utilizes pressure mediated delivery of gemcitabine across the arterial wall to bathe the pancreatic tumor tissue in 120mL of saline with 1,000mg/m² of the drug over a 20-minute delivery time (approximately a total of 1,500-2,000mg of drug dependent upon patient Body Surface Area). RenovoCath is an adjustable double balloon catheter designed to isolate the proximal and distal vessel and adjust the distance between the balloons to exclude any branching blood vessel offshoots.

While the field of oncology has seen progress in treating a handful of deadly cancers over the last few decades, there is a common limitation in chemotherapy: enhanced dosing of the drug to impact the tumor while minimizing systemic toxicity. The characteristics of the vasculature, within and surrounding the tumor, can be a limiting step in this goal. For example, LAPC and HCCA 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 certain solid tumors. A key component of this approach is to identify and isolate vessels feeding the tumor, known as tumor feeders. However, in patients with pancreatic cancer, no tumor feeder vessels are visible during angiography. In the absence of visible tumor feeders, we can introduce drugs directly across the arterial wall into the surrounding tissue via pressurized diffusion.

We are currently evaluating RenovoGem in patients with LAPC in a Phase 3 trial entitled “**T**argeted **I**ntra-arterial **G**emcitabine vs. Continuation of IV (intravenous) Gemcitabine Plus Nab-Paclitaxel Following Induction With Sequential IV Gemcitabine Plus Nab-Paclitaxel and **R**adiotherapy for Locally Advanced **P**ancreatic **C**ancer”, or TIGeR-PaC, trial at 28 US and Belgian sites. The trial is designed to enroll 340 subjects. 135 patients were enrolled as of April 30, 2021. A planned interim data readout is expected during the second half of 2022. We have secured Orphan Drug Designation for RenovoGem, which would provide us with seven years of exclusivity to market intra-arterial use of gemcitabine for LAPC upon New Drug Application, or NDA, approval.

In addition, we intend to evaluate RenovoGem in patients with HCCA, and we have secured FDA Orphan Drug Designation for this indication. We intend to potentially pursue additional indications including locally advanced lung cancer, locally advanced uterine tumors, and glioblastoma.

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. We established the maximum tolerated dose of 1000mg/m² of intra-arterial gemcitabine delivered via RenovoCath. The most common serious adverse events were neutropenia followed by sepsis. 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. The key inclusion criteria was a diagnosis of advanced or borderline resectable pancreatic adenocarcinoma confirmed by histology or cytology. The primary endpoints were survival, tumor response and performance of RenovoCath. 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. Looking at 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 both to IV chemotherapy alone, with 24-month survival of 12%, and to chemotherapy + radiation with 24-month survival of 5% and mOS of 12-15 months as demonstrated in historical studies.

We intend to submit our proposed Phase 2/3 clinical trial to evaluate RenovoGem in HCCA, BENEFICIAL, to the FDA as part of a pre-IND submission in the fourth quarter of 2021 and to launch the clinical trial in the first half of 2022. Intra-venous (IV), or systemic, delivery of gemcitabine has been considered standard of care for several solid tumors, and the drug’s anti-cancer tumor effects are well profiled. We intend to explore the application 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 pre-clinical studies, and additional pre-clinical experiments in lung cancer may be conducted. Beyond our initial anti-cancer product candidate, RenovoGem, multiple small molecule therapeutics could be incorporated into our RenovoTAMP platform, and we will opportunistically look to develop other potential product candidates.

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, has extensive experience running clinical trials as well as launching, creating, and developing new markets for novel therapies at Trans Vascular, 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 and Board experience including drug/device combination and oncology experience. Clinical advisors include experts in surgical oncology, interventional radiology, radiation oncology, and medical oncology. 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. Mike Pishvaian, also a medical oncologist, has extensive experience in running oncology studies and is an Associate Professor, and Department of Oncology 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. Peter Muscarella is a surgical oncologist and the Director of Pancreatic Surgery, General Surgery Site Director, Weiler Hospital Associate Program Director, and General Surgery Residency Training Program at Montefiore Medical Center, Bronx, NY. Dr. Karyn Goodman serves as our 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. We have two interventional radiology scientific advisors: Dr. Reza Malek, Neurointerventional Radiologist at Minimally Invasive Surgical Solutions and Dr. Jacob Cynamon, Professor of Clinical Radiology of the Albert Einstein College of Medicine, Chief of the Division of Vascular and Interventional Radiology, and Program Director of the Vascular and Interventional Radiology Fellowship Program at the Montefiore Medical Center, Bronx, NY.

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Summary Risk Factors

Our prospects should be considered in light of the risks, uncertainties, expenses and difficulties frequently encountered by similar companies. Our ability to realize our business objectives and execute our strategies is subject to risks and uncertainties, including, among others, the following:

- We are a clinical stage company and may never earn a profit.

- We will need to raise substantial additional capital to develop and commercialize RenovoGem, and our failure to obtain funding when needed may force us to delay, reduce or eliminate our product development programs or collaboration efforts. As a result, there is substantial doubt about our ability to operate as a going concern.
- Our product candidates' commercial viability remains subject to current and future preclinical studies, clinical trials, regulatory approvals, and the risks generally inherent in the development of a pharmaceutical product candidate. If we are unable to successfully advance or develop our product candidates, our business will be materially harmed.
- 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.
- 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 purchasers of our common stock in this offering.
- We have broad discretion in the use of our cash and cash equivalents, including the net proceeds we receive in this offering, and may not use them effectively.

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 elsewhere in this prospectus before investing in our common stock.

Corporate Information

We were incorporated in the State of Delaware on December 17, 2012. Our principal executive offices are located at 4546 El Camino Real, Suite B1, Los Altos, CA 94022. Our telephone number is (650) 284-4433. Our website address is <https://renovorx.com>. Information contained in our website does not constitute any part of, and is not incorporated into, this prospectus.

Implications of Being an Emerging Growth Company

Upon the completion of this offering, we will qualify as an "emerging growth company" under Jumpstart Our Business Act of 2012, as amended, or the JOBS Act. As a result, we will be permitted to, and intend to, rely on exemptions from certain disclosure requirements. For so long as we are an emerging growth company, we will not be required to:

- have an auditor report on our internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act;
- comply with 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 (i.e., an auditor discussion and analysis);
- submit certain executive compensation matters to stockholder advisory votes, such as "say-on-pay" and "say-on-frequency;" and
- disclose certain executive compensation related items such as the correlation between executive compensation and performance and comparisons of the chief executive officer's compensation to median employee compensation.

In addition, Section 107 of the JOBS Act also provides that an emerging growth company can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act of 1933, as amended, or the Securities Act, for complying with new or revised accounting standards. In other words, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to take advantage of the benefits of this extended transition period. Our financial statements may therefore not be comparable to those of companies that comply with such new or revised accounting standards.

We will remain an emerging growth company for up to five years from the date of the first sale of equity securities pursuant to an effective registration statement, or until the earliest of (i) the last day of the first fiscal year in which our total annual gross revenues exceed \$1.07 billion, (ii) the date that we become a "large accelerated filer" as defined in Rule 12b-2 under the Securities Exchange Act of 1934, as amended, or the Exchange Act, which would occur if the market value of our common stock that is held by non-affiliates exceeds \$700 million as of the last business day of our most recently completed second fiscal quarter or (iii) the date on which we have issued more than \$1 billion in non-convertible debt during the preceding three year period.

THE OFFERING

Common stock offered by us	[] shares of common stock, \$0.0001 par value per share.
Assumed initial public offering price	\$([]) per share, the midpoint of the range set forth on the cover page of this prospectus.
Over-allotment option	The underwriter has an option for a period of 45 days to acquire up to an additional [] shares of common stock from us at the public offering price, less the underwriting discount, solely for the purpose of covering over-allotments, if any.
Shares of common stock outstanding before this offering ⁽¹⁾	[] shares of common stock.
Shares outstanding after this offering	[] shares of common stock (or [] shares of common stock if the underwriter exercises its over-allotment option in full), after the sale of [] shares in this offering and after the Preferred Stock Conversions and the Note Conversions (as defined below).

Use of proceeds

We estimate that we will receive net proceeds of approximately \$[] (or approximately \$[] if the underwriter exercises its over-allotment option in full) from the sale of common stock by us in this offering assuming an initial public offering price of \$[] per share (the midpoint of the price range set forth on the cover of this prospectus). We plan to use the net proceeds of this offering primarily for completion of our currently ongoing Phase 3 trial for the locally advanced pancreatic cancer indication for RenovoGem, the launch of our Phase 2/3 trial for our second indication of hilar cholangiocarcinoma for RenovoGem, and working capital and general corporate purposes. See “Use of Proceeds.”

Risk factors

Investing in our common stock involves a high degree of risk and purchasers of our common stock may lose part or all of their investment. See “Risk Factors” for a discussion of factors you should carefully consider before deciding to invest in our common stock.

Proposed trading market and symbol

We have applied to list our common stock for trading on the Nasdaq Capital Market under the symbol “RNXT.” No assurance can be given that our application will be approved.

(1) The number of shares outstanding is based on shares outstanding as of March 31, 2021 and excludes the following:

- 4,755,668 shares of our common stock issuable upon the exercise of outstanding options with a weighted-average exercise price of \$0.08 per share;
- 3,542,669 shares of Series A-1 Preferred Stock, 3,546,095 shares of Series A-2 Preferred Stock, 2,660,230 shares of Series A-3 Preferred Stock and 7,928,359 shares of Series B Preferred Stock which will convert into 3,542,669, 3,546,095, 2,660,230 and 7,928,359 shares of common stock, respectively, upon the closing of this offering (the “Preferred Stock Conversions”);
- [] shares of common stock to be issued upon conversion of the March 2020 Notes upon the closing of this offering (the “Note Conversions”);
- up to an additional [] shares of our common stock issuable under our 2013 Equity Incentive Plan; and
- [] shares of our common stock underlying the warrants to be issued to the representative of the underwriters in connection with this offering.

SUMMARY FINANCIAL INFORMATION

The following tables set forth our summary financial data for the periods and as of the dates indicated. The summary statements of operations data for the years ended December 31, 2019 and 2020 have been derived from our audited financial statements included elsewhere in this prospectus. The summary statements of operations data for the three months ended March 31, 2020 and 2021 and the summary balance sheet data as of March 31, 2021 have been derived from our unaudited interim condensed financial statements included elsewhere in this prospectus. Our unaudited interim condensed financial statements have been prepared on a basis consistent with our audited financial statements and, in the opinion of management, reflect all adjustments, consisting only of normal recurring adjustments, necessary for a fair presentation of the financial information set forth in those statements. Our historical results are not necessarily indicative of the results that may be expected for any other period in the future and our interim results are not necessarily indicative of our expected results for the year ending December 31, 2021. You should read the following summary financial data set forth below in conjunction with our financial statements and the related notes included elsewhere in this prospectus and the information in the sections titled “Selected Financial Data” and Management’s Discussion and Analysis of Financial Condition and Results of Operations” contained elsewhere in this prospectus.

	<u>Year Ended December 31,</u>		<u>Three Months Ended March 31,</u>	
	2019	2020	2020	2021
			(unaudited)	
	(in thousands, except per share data)			
Statements of Operations Data:				
Operating expenses:				
Research and development	\$ 2,997	\$ 2,386	\$ 805	\$ 635
General and administrative	899	818	248	418
Total operating expenses	<u>3,896</u>	<u>3,204</u>	<u>1,053</u>	<u>1,053</u>
Loss from operations	(3,896)	(3,204)	(1,053)	(1,053)
Interest income (expense), net	63	(587)	2	(230)
Other income (expense), net	2	(7)	-	(5)
Loss on change in fair value of warrant liability	(8)	-	-	-
Gain on loan extinguishment	-	-	-	140
Total other income (expense), net	<u>57</u>	<u>(594)</u>	<u>2</u>	<u>(95)</u>
Net loss	<u>\$ (3,839)</u>	<u>\$ (3,798)</u>	<u>\$ (1,051)</u>	<u>\$ (1,148)</u>
Net loss per share – basic and diluted	<u>\$ (0.35)</u>	<u>\$ (0.34)</u>	<u>\$ (0.10)</u>	<u>\$ (0.10)</u>
Weighted average shares used to compute net loss per share – basic and diluted	<u>10,886</u>	<u>11,072</u>	<u>10,974</u>	<u>11,209</u>
Pro forma net loss per share – basic and diluted	<u>\$ []</u>	<u>\$ []</u>	<u>\$ []</u>	<u>\$ []</u>
Weighted average shares used to compute pro forma net loss per share – basic and diluted	<u>[]</u>	<u>[]</u>	<u>[]</u>	<u>[]</u>

(1) The unaudited pro forma net loss per share for the years ended December 31, 2019 and 2020 and the three months ended March 31, 2020 and 2021 was computed using the weighted-average number of shares of common stock outstanding, including the pro forma effect of the conversion of all outstanding shares of convertible preferred stock and convertible notes into shares of common stock, as if such conversion had occurred at the beginning of the period, or their issuance dates, if later.

	<u>As of March 31, 2021</u>		
	<u>Actual</u>	<u>Pro forma ⁽¹⁾</u>	<u>Pro forma as adjusted ⁽²⁾</u>
	(in thousands)		
Balance Sheet Data:			
Cash and cash equivalents	\$ 837	\$ 837	\$ 206
	(3,636)	206	
Working (deficit) capital			
Total assets	1,278	1,278	
Convertible note, net	2,843	-	
Total liabilities	4,589	747	
Convertible preferred stock	12,451	-	
Stockholders’ (deficit) equity	(15,762)	531	

- (1) The pro forma balance sheet data gives effect to the automatic conversion of all outstanding shares of our preferred stock, including the shares of preferred stock issuable upon the automatic conversion of our outstanding convertible notes, including the related accrued interest and derivative liability, into XX shares of common stock immediately prior to the closing of this offering.
- (2) The pro forma as adjusted balance sheet data gives effect to the issuance and sale of XXX shares of our common stock in this offering at an assumed initial public offering price of \$XX per share, which is the midpoint of the estimated price range set forth on the cover of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. The pro forma as adjusted information is illustrative only and will depend on the actual initial public offering price and other terms of this offering determined at pricing.

RISK FACTORS

An investment in our securities involve a high degree of risk. You should carefully consider the risks described below, together with the financial and other information contained in this prospectus, before you decide to purchase our securities. If any of the following risks actually occurs, our business, financial condition, results of operations, cash flows and prospects could be materially and adversely affected. In that event, the trading price of our common stock and the market value of the securities offered hereby could decline, and you may lose all or part of your investment.

Risks Related to Our Business

We are a clinical stage company and may never earn a profit.

We are a clinical stage company and have incurred losses since our formation. As of March 31, 2021, we have an accumulated total deficit of approximately \$16.1 million. For both three-month periods ended March 31, 2020 and 2021, we had a net loss of approximately \$1.1 million. To date, we have experienced negative cash flow from development of our product candidate, RenovoGem, our platform technology, Renovo Trans-Arterial Micro-Perfusion, or 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. We cannot predict the extent of these future net losses, or when we may attain profitability, if ever. If we are unable to generate significant revenue from RenovoGem or attain profitability, we will not be able to sustain operations.

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. We may never become profitable and you may never receive a return on an investment in our common stock. An investor 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.

We will need to raise substantial additional capital to develop and commercialize RenovoGem, and our failure to obtain funding when needed may force us to delay, reduce or eliminate our product development programs or collaboration efforts. If we do not obtain adequate and timely funding, we may not be able to continue as a going concern.

As of March 31, 2021, our cash and cash equivalents were approximately \$0.8 million, and our working capital deficit was approximately \$3.6 million. Due to our recurring losses from operations and the expectation that we will continue to incur 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 relied upon private sales of our equity as well as debt financings to fund our operations. In order 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, 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 candidate, restrict our operations or obtain funds by entering into agreements on unfavorable terms. Failure to obtain additional capital at acceptable terms would result in a material and adverse impact on our operations. As a result, there is substantial doubt about our ability to operate as a going concern.

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

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 our product candidate 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 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 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, our product candidates may not:

- offer therapeutic or other medical benefits over existing drugs or other product candidates in development to treat the same patient population;
- be proven to be safe and effective in current and future preclinical studies or clinical trials;
- have the desired effects;
- be free from undesirable or unexpected effects;
- meet applicable regulatory standards;

- be capable of being formulated and manufactured in commercially suitable quantities and at an acceptable cost; or
- be successfully commercialized by us or by collaborators.

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

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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. 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.

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 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 potential benefits. In preclinical studies and clinical trials we have conducted to date, 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.

Raising additional capital may cause dilution to our existing stockholders, including purchasers of common stock in this offering, 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.

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.

In order 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 and efficacy characteristics despite having favorably demonstrated such characteristics in preclinical studies or earlier stage clinical trials.

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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 we have difficulty recruiting patients 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; 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.

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.

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. 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 Practices. 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.

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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 bio-pharmaceutical 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, completion of our clinical trials and obtaining regulatory approvals, if at all, for our product candidates.

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

The product candidates that we, or our collaborators, are developing or may develop require regulatory approval to advance through clinical development and to ultimately be marketed and sold and are subject to extensive and rigorous domestic and foreign government regulation. In the U.S., the FDA regulates, among other things, the development, testing, manufacture, safety, efficacy, record-keeping, labeling, storage, approval, advertising, promotion, sale, and distribution of pharmaceutical and biopharmaceutical products. Our product candidates are also subject to similar regulation by foreign governments to the extent we seek to develop or market them in those countries. We, or our collaborators, must provide the FDA and foreign regulatory authorities, if applicable, with preclinical and clinical data, as well as data supporting an acceptable manufacturing process, that appropriately demonstrate 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 our product candidate 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 our product candidate through clinical development, and ultimately commercialize them, may:

- adversely impact our ability to raise sufficient capital 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; and

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- 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 products;
- 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; and
- 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.

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. In order to receive regulatory approval for the commercialization of our product candidates, we must conduct, at our own expense, extensive preclinical

testing and clinical trials to demonstrate safety and efficacy of our product candidate for the intended indication of use. Clinical testing is expensive, can take many years to complete, if at all, and its outcome is uncertain. Failure can occur at any time during the clinical trial process.

The results of preclinical studies and early clinical trials of new drugs do not necessarily predict the results of later-stage clinical trials. The design of our clinical trials is based on many assumptions about the expected effects of our product candidate, and if those assumptions are incorrect, they may not produce statistically significant results. Preliminary results may not be confirmed on full analysis of the detailed results of a clinical trial. Product candidates in later stages of clinical development may fail to show safety and efficacy sufficient to support intended use claims despite having progressed through earlier clinical testing. The data collected from clinical trials of our product candidate 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 approval, 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 candidate. 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. 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 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 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 our existing product candidate or any product candidate we may seek to develop in the future will ever obtain regulatory approval may fail to receive regulatory approval.

Our product candidate 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; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

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

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 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 safety and efficacy and governing, among other things, 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 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 our product candidate 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.

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.

As a developer of pharmaceuticals, certain federal and state healthcare laws and regulations pertaining to fraud and abuse, false claims and patients' privacy rights are and will be applicable to our business. We could be subject to healthcare fraud and abuse laws and patient 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;

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- 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 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; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers, and state 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.

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. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security and fraud laws may prove costly.

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

We need FDA approval prior to marketing our product candidates in the United States. If we fail to obtain FDA approval to market our product candidates, we will be unable to sell our product candidates in the United States and we will not generate any revenue.

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 pre-clinical 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 our product candidate 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, 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. 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.

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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 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.

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 qualified scientific and management personnel, establishing clinical trial sites, and patient enrollment for clinical trials, as well as in acquiring technologies and technology licenses complementary to our programs or advantageous to our business.

If approved and commercialized, RenovoGem would compete with several currently approved prescription therapies for the treatment of LAPC and hilar 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;

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- attract and retain key 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. Our resource allocation 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 GMP, FDA inspected contract manufacturers to manufacture our clinical supplies. Any curtailment in the availability of gemcitabine, 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. Gemcitabine is supplied from our clinical sites own 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 GMP.

The manufacture of pharmaceutical 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. 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 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 GMP 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 GMP requirements. We will be responsible for regularly assessing a contract manufacturer's compliance with GMP 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 GMP 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 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 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 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.

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 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. Our failure to achieve and maintain these high-quality manufacturing standards in collaboration with our third-party manufacturers, including the incidence of manufacturing errors, could result in patient injury or death, product recalls or withdrawals, delays or failures in product testing or delivery, cost overruns or other problems that could harm our business, financial condition and results of operations.

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

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

- demonstration of safety and efficacy;
- changes in the practice guidelines and the standard of care for the targeted indication;

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- 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 or 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.

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 GMP, 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 our product candidate, 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;

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- our contract manufacturers failing to manufacture our product candidates according to their own standards, our specifications or Current Good Manufacturing Practice ("cGMP"), 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 our product candidate. 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; and
- 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 candidate 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 our product candidate may need to be sourced. We currently obtain our RenovoCath delivery system from a single supplier. In accordance with cGMP regulations, 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. 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 our product candidate. Further, in order to maintain our development time lines in the event of a change in our third-party contract manufacturer, we may incur significantly higher costs to manufacture our product candidate.

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

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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 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 our product candidate is 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 an adverse effect on our business.

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

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

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 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. 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 6 employees as of April 30, 2021. 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 candidate 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;

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- integrate additional management, administrative, manufacturing, 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, or 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, for which we are predominantly self-insured. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses.

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.

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 security measures, however, any network infrastructure may be vulnerable to cyber-attacks by hackers and other security threats. We may face cyber-attacks that attempt to penetrate our network security, sabotage, or otherwise disable our research and development activities, products and services, misappropriate our or our customers' and partners' proprietary information, which may include personally identifiable information, or cause interruptions of our internal systems and services. 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.

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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: notification requirements to individuals, federal regulators, and in some cases, notification to local and national media. Notification is not required under HIPAA if the health information that is improperly used or disclosed is deemed secured in accordance with encryption or other standards developed by the U.S. Department of Health and Human Services. Most states have laws requiring notification of affected individuals and/or state regulators in the event of a breach of personal information, which is a broader class of information than the health information protected by HIPAA. Many state laws impose significant data security requirements, such as encryption or mandatory contractual terms, to ensure ongoing protection of personal information. Activities outside of the U.S. implicate local and national data protection standards, impose additional compliance requirements, and generate additional risks of enforcement for non-compliance. We may be required to expend significant capital and other resources to ensure ongoing compliance with applicable privacy and data security laws, to protect against security breaches and hackers or to alleviate problems caused by such breaches.

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

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

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

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

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

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

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

- multiple, conflicting and changing laws and regulations, such as privacy regulations, tax laws, export and import restrictions, employment laws, regulatory requirements and other governmental approvals, permits and licenses;

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- 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, the availability and cost of credit and government stimulus programs in the U.S. and other countries 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.

Healthcare reform measures could adversely affect our business.

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 U.S. federal and state levels that seek to reduce healthcare costs. In 2010, the Patient Protection and Affordable Care Act (the “PPACA”) was enacted, which includes measures to significantly change the way healthcare is financed by both governmental and private insurers. Among the provisions of the PPACA of greatest importance to the pharmaceutical and biotechnology industry are the following:

- an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;
- implementation of the federal physician payment transparency requirements, sometimes referred to as the “Physician Payments Sunshine Act”;

- a licensure framework for follow-on biologic products;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;
- establishment of a Center for Medicare Innovation at the Centers for Medicare & Medicaid Services to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program, to 23.1% and 13% of the average manufacturer price for most branded and generic drugs, respectively and capped the total rebate amount for innovator drugs at 100% of the AMP;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for certain drugs and biologics, including our product candidates, that are inhaled, infused, instilled, implanted or injected;
- extension of manufacturers’ Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for individuals with income at or below 133% of the federal poverty level, thereby potentially increasing manufacturers’ Medicaid rebate liability;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer’s outpatient drugs to be covered under Medicare Part D; and
- expansion of the entities eligible for discounts under the Public Health program.

Some of the provisions of the PPACA have yet to be implemented, and there have been legal and political challenges to certain aspects of the PPACA. During President Trump’s administration, he signed two executive orders and other directives designed to delay, circumvent, or loosen certain requirements mandated by the PPACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the PPACA. While Congress has not passed repeal legislation, the PPACA includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the PPACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the “individual mandate”. Congress may consider other legislation to repeal or replace elements of the PPACA.

Many of the details regarding the implementation of the PPACA are yet to be determined, and at this time, the full effect that the PPACA would have on our business remains unclear.

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. 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.

The outbreak of the novel coronavirus disease, COVID-19, 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 closely. The extent to which the COVID-19 outbreak will impact our operations or financial results is uncertain.

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, 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;

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- 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; and
- 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, with the status of operations and government restrictions evolving weekly. 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, travel restrictions and 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 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.

In addition, our business could be materially adversely affected by other business disruptions to us or our third-party providers that could materially adversely affect our potential future revenue and financial condition and increase our costs and expenses. Our operations, and those of our CROs, third party manufacturers, and other contractors, consultants and third parties could be subject to other global pandemics, 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, for which we are predominantly self-insured. The occurrence of any of these business disruptions could materially adversely affect our operations and financial condition and increase our costs and expenses. We rely on third-party manufacturers to produce and process our product candidate. Our ability to obtain clinical supplies of our product candidates could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption.

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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.

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. Any failure to protect our intellectual property rights could materially adversely affect our business, prospects and financial condition.

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. 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. In addition, there are numerous recent changes to the patent laws and proposed changes to the rules of the 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. Accordingly, 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.

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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 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.

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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. 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.

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 rely on trade secrets which 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.

Risks Related to this Offering and Our Common Stock

No active trading market for our common stock currently exists, and an active trading market may not develop.

Prior to this offering, there has not been an active trading market for our common stock. If an active trading market for our common stock does not develop following this offering, you may not be able to sell your shares quickly or at the market price. 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 also be impaired. The initial public offering price of our common stock will be determined by negotiations between us and the underwriters and may not be indicative of the market prices of our common stock that will prevail in the trading market.

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

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, including the following:

- any delay in the commencement, enrollment and ultimate completion of our clinical trials;
- any delay in submitting an NDA and any adverse development or perceived adverse development with respect to the FDA's review of that NDA;
- failure to successfully develop and commercialize RenovoGem;
- inability to obtain additional funding;

- regulatory or legal developments in the United States and other countries applicable to RenovoGem or any other product candidate;
- adverse regulatory decisions;
- changes in the structure of healthcare payment systems;
- inability to obtain adequate product supply for RenovoGem, RenovoCath or any other product candidate, or the inability to do so at acceptable prices;
- introduction of new products, services or technologies by our competitors;
- failure to meet or exceed financial projections we provide to the public;
- failure to meet or exceed the estimates and projections of the investment community;
- changes in the market valuations of companies similar to ours;
- market conditions in the pharmaceutical and biotechnology sectors, and the issuance of new or changed securities analysts' reports or recommendations;
- announcements of significant acquisitions, strategic collaborations, joint ventures or capital commitments by us or our competitors;
- significant lawsuits, including patent or stockholder litigation, and disputes or other developments relating to our proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- additions or departures of key scientific or management personnel;
- sales of our common stock by us or our stockholders in the future;
- trading volume of our common stock;
- 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. The market price of our common stock may decline below the initial public offering price, and you may lose some or all of your investment. In particular, stock markets have

experienced extreme volatility due to the ongoing COVID-19 pandemic and investor concerns and uncertainty related to the impact of the pandemic on the economies of countries worldwide.

We have broad discretion in the use of our cash and cash equivalents, including the net proceeds we receive in this offering, and may not use them effectively.

Our management has broad discretion to use our cash and cash equivalents, including the net proceeds we receive in this offering, to fund our operations and could spend these funds in ways that do not improve our results of operations or enhance the value of our common stock, and you will not have the opportunity as part of your investment decision to assess whether the net proceeds are being used appropriately. The failure by our management to apply these funds effectively could result in financial losses that could have a material adverse effect on our business, cause the price of our common stock to decline. Pending their use to fund our operations, we may invest our cash and cash equivalents, including the net proceeds from this offering, in a manner that does not produce income or that loses value.

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We could be subject to securities class action litigation.

In the past, securities class action litigation has often been brought against companies following a decline in the market price of their securities. 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 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 will depend in part on the research and reports that securities or industry analysts publish about us or our business. If research analysts do not establish and maintain adequate research coverage or 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 after this offering, 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 after price appreciation to earn an investment return, which may never occur. Investors seeking cash dividends should not purchase our shares. 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.

As our initial public offering price is substantially higher than our net tangible book value per share, you will experience immediate and substantial dilution.

If you purchase shares in this offering, you will pay more for your shares of common stock than the amount paid by our existing stockholders for their shares on a per share basis. As a result, you will experience immediate and substantial dilution in net tangible book value per share in relation to the price that you paid for your shares. We expect the dilution as a result of the offering and the automatic conversion of all outstanding shares of our preferred stock, including the shares of preferred stock issuable upon the automatic conversion of our outstanding convertible note immediately prior to the closing of this offering, to be \$[] per share to new investors purchasing our shares in this offering. In addition, you will experience further dilution to the extent that our shares are issued upon the exercise of any warrants or exercise of stock options under any stock incentive plans. See "Dilution" for a more complete description of how the value of your investment in our shares will be diluted upon completion of this offering.

We will incur increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives and corporate governance practices.

As a public company, and particularly after we no longer qualify as an emerging growth company, we will incur significant legal, accounting and other expenses that we did not incur previously. 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 devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make 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.

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

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

Effective internal control over financial reporting is necessary for us to provide reliable financial reports in a timely manner. In connection with the audit of our financial statements as of and for the years ended December 31, 2019 and 2020 and the review of our financial statements for the three month periods ended March 31, 2020 and 2021, 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 have determined that we lack 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 GAAP, and adequate management review controls. In addition, 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.

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.

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

We are an “emerging growth company,” as defined in the Jumpstart Our Business Startups Act (“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, 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. 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 this offering, (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, and (2) the date on which we have issued more than \$1.0 billion in non-convertible debt during the prior three-year period.

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

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

Anti-takeover provisions contained in our certificate of incorporation and bylaws to be adopted upon the closing of this offering, as well as provisions of Delaware law, could impair a takeover attempt.

Our certificate of incorporation, bylaws and Delaware law contain or will contain provisions which 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 or will include provisions:

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

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

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

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

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

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

- any derivative action or proceeding brought on our behalf;

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

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

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

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

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

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

CAUTIONARY STATEMENT CONCERNING FORWARD-LOOKING STATEMENTS

This prospectus contains certain “forward-looking statements” with respect to our business, financial condition, liquidity and results of operations. Words such as “anticipates,” “expects,” “intends,” “plans,” “predicts,” “believes,” “seeks,” “estimates,” “could,” “would,” “will,” “may,” “can,” “continue,” “potential,” “should,” and the negative of these terms or other comparable terminology often identify forward-looking statements. These forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties that could cause actual results to differ materially from the results contemplated by the forward-looking statements. See “Risk Factors” beginning on page 9.

- our estimates regarding sufficiency of our cash resources, anticipated capital requirements and our need for additional financing;
- the commencement of clinical trials and the results and timing of those clinical trials;
- our ability to successfully commercialize our product candidates and generate revenue;
- submission and timing of applications for regulatory approval and approval thereof;
- our ability to successfully negotiate and enter into agreements with distribution, strategic and corporate partners; and
- our estimates of potential market opportunities and our ability to successfully realize these opportunities.

Many of the important factors that will determine these results are beyond our ability to control or predict. You are cautioned not to put undue reliance on any forward-looking statements, which speak only as of the date of this prospectus. Except as otherwise required by law, we do not assume any obligation to publicly update or release any revisions to these forward-looking statements to reflect events or circumstances after such applicable date or to reflect the occurrence of unanticipated events. You should, however, review the factors and risks we describe in the “Risk Factors” section hereof beginning on page 9 and in reports we will file from time to time with the SEC after the date of this prospectus.

MARKET AND INDUSTRY DATA

We obtained the industry, statistical and market data included in this prospectus from our own internal estimates and research as well as from industry and general publications and research, surveys and studies conducted by third parties. All of the market data used in this prospectus involve a number of assumptions and limitations, and the sources of such data cannot guarantee the accuracy or completeness of such information. While we are not aware of any misstatements regarding the third-party information and we believe that each of these studies and publications is reliable, the industry in which we operate is subject to a high degree of uncertainty and risk due to a variety of important factors, including those described in the section titled “Risk Factors.” These and other factors could cause results to differ materially from those expressed in the estimates made by third parties and by us.

TRADEMARKS, SERVICE MARKS AND TRADE NAMES

We own or have rights to use a number of registered and common law trademarks, service marks and/or trade names in connection with our business in the United States and/or in certain foreign jurisdictions.

Solely for convenience, the trademarks, service marks, logos and trade names referred to in this prospectus are without the® and™ symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensors to these trademarks, service marks and trade names. This prospectus contains additional trademarks, service marks and trade names of others, which are the property of their respective owners. All trademarks, service marks and trade names appearing in this prospectus are, to our knowledge, the property of their respective owners. We do not intend our use or display of

other companies' trademarks, service marks, copyrights or trade names to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

We have trademarks for the names RENOVORX, RENOVOGEM, RENOVOCATH, TAMP and DELIVERING THERAPY WHERE IT MATTERS. We have a trademark pending for RenovoTAMP.

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USE OF PROCEEDS

We estimate that the net proceeds from this offering will be approximately \$ (\$ million if the underwriter exercises its over-allotment option in full), after deducting the underwriting discount and estimated offering expenses payable by us, based on an assumed initial public offering price of \$[] per share (the midpoint of the price range set forth on the cover of this prospectus).

We intend to use:

- approximately \$8.4 million to fund our ongoing TIGeR-PaC Phase 3 clinical trial of RenovoGem in LAPC patients through mid 2023, including our planned interim analysis in our TIGeR-PaC Phase 3 clinical trial which we expect will take place in the second half of 2022;
- approximately \$3.6 million to fund the launch of our planned BENEFICIAL Phase 2/3 clinical trial of RenovoGem in HCCA patients, which we expect to commence in the first half of 2022, through mid 2023; and
- the balance for working capital and general corporate purposes, including the costs of operating as a public company.

We estimate that our current capital resources, along with the net proceeds from this offering, will be sufficient to fund our operating expenses and capital expenditure requirements through mid 2023. However, the net proceeds from this offering, together with our current cash, will not be sufficient for us to fund the development of RenovoGem through regulatory approval, and we will need to raise additional capital to complete the development and commercialization of RenovoGem. At this time, we cannot predict with certainty the amount of capital needed to complete the development and commercialization of RenovoGem, but we anticipate seeking additional capital in the future to fund such capital needs through further equity offerings and/or debt borrowings. We cannot guarantee that we will be able to raise additional capital on reasonable terms or at all.

We may also use a portion of the net proceeds of this offering to acquire or invest in complementary businesses, products, or technologies, or to obtain the right to use such complementary technologies. We have no commitments with respect to any acquisition or investment, and we are not currently involved in any negotiations with respect to any such transaction.

As of the date of this prospectus, we cannot specify with certainty all of the particular uses for the net proceeds to be received upon the completion of this offering. The amounts and timing of our actual expenditures will depend on numerous factors, including the status of our product development efforts, sales and marketing activities, technological advances, amount of cash generated or used by our operations and competition. Accordingly, our management will have broad discretion in the application of the net proceeds and investors will be relying on the judgment of our management regarding the application of the proceeds of this offering. Pending such use, we intend to invest the net proceeds in interest-bearing investment-grade securities or government securities.

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DIVIDEND POLICY

We have never declared or paid cash dividends on our common stock. We currently intend to retain all available funds and any future earnings for use in the operation of our business and do not anticipate paying any cash dividends on our common stock in the near future. We may enter into credit agreements or other borrowing arrangements in the future that will restrict our ability to declare or pay cash dividends on our common stock.

Any future determination to declare dividends will be made at the discretion of our board of directors and will depend on our financial condition, operating results, capital requirements, contractual restrictions, general business conditions and other factors that our board of directors may deem relevant.

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CAPITALIZATION

The following table sets forth our total capitalization as of March 31, 2021:

- on an actual basis;
- on a pro forma basis giving effect to the automatic conversion of all outstanding shares of our preferred stock, including the shares of preferred stock issuable upon the automatic conversion of our outstanding convertible note into [] shares of common stock immediately prior to the closing of this offering;
- on a pro forma as adjusted basis giving further effect to the sale and issuance by us of [] shares of common stock in this offering at the assumed initial public offering price of \$[] per share (the midpoint of the price range set forth on the cover of this prospectus) and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

You should read this table together with our financial statements, the related notes included elsewhere in this prospectus and the information under "Management's Discussion and Analysis of Financial Condition and Results of Operations."

	March 31, 2021		
	Actual	Pro forma	Pro forma as adjusted
	(in thousands, except for share and per share data)		
Cash and cash equivalents	\$ 837	\$ 837	\$
Convertible note	\$ 2,843	\$	-
Convertible preferred stock:			
Series A-1 Preferred Stock, \$0.0001 par value, 3,542,669 shares authorized and issued and outstanding, actual; no shares authorized or issued and outstanding, pro forma and pro forma as adjusted	\$ 639	\$	-

Series A-2 Preferred Stock, \$0.0001 par value, 3,546,095 shares authorized and issued and outstanding, actual; no shares authorized or issued and outstanding, pro forma and pro forma as adjusted	1,099	-
Series A-3 Preferred Stock, \$0.0001 par value, 2,660,230 shares authorized and issued and outstanding, actual; no shares authorized or issued and outstanding, pro forma and pro forma as adjusted	2,166	-
Series B Preferred Stock, \$0.0001 par value, 12,611,461 shares authorized and 7,928,359 shares issued and outstanding, actual; no shares authorized or issued and outstanding, pro forma and pro forma as adjusted	8,547	-
Stockholders' (deficit) equity:		
Common stock, \$0.0001 par value, 42,000,000 shares authorized and 11,415,994 shares issued and outstanding, actual; [] shares authorized, pro forma and pro forma as adjusted; [] shares issued and outstanding, pro forma; and [] shares issued and outstanding, pro forma as adjusted	1	3
Additional paid-in capital	345	16,636
Accumulated deficit	(16,108)	(16,108)
Total stockholders' (deficit) equity	(15,762)	531
Total capitalization	\$ (3,311)	\$ 531

Each \$1.00 increase (decrease) in the assumed initial public offering price of \$[] per share, the midpoint of the price range listed on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of cash and cash equivalents, working capital, total assets and total stockholders' equity by approximately \$[], assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase (decrease) of [] shares in the number of shares offered by us at the assumed initial public offering price of \$[] per share, the midpoint of the price range listed on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of cash and cash equivalents, working capital, total assets and total stockholders' equity by approximately \$[].

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DILUTION

If you purchase shares of our common stock in this offering, your interest will be diluted to the extent of the difference between the initial public offering price per share and our net tangible book value per share after this offering. Dilution results from the fact that the assumed initial public offering price per share is substantially in excess of the net tangible book value per share attributable to the existing stockholders for our presently outstanding common stock.

Our net tangible book value (deficit) was approximately \$(3.3) million or \$(0.29) per share, as of March 31, 2021. Our net tangible book value represents the amount of our total tangible assets (which is calculated by subtracting net intangible assets, deferred tax assets, and prepaid offering expenses from our total assets), less the amount of our total liabilities.

Our pro forma net tangible book value as of March 31, 2021, was \$[] million, or \$[] per share of our common stock. Pro forma net tangible book value represents the amount of our total tangible assets less our total liabilities. Pro forma net tangible book value per share represents pro forma net tangible book value divided by the total number of shares outstanding as of March 31, 2021, after giving effect to the automatic conversion of all outstanding shares of our preferred stock, including the shares of preferred stock issuable upon the automatic conversion of our outstanding convertible note into [] shares of common stock immediately prior to the closing of this offering as if such conversions had occurred on March 31, 2021.

After giving further effect to the sale and issuance by us of [] shares of common stock in this offering at the assumed initial public offering price of \$[] per share, (the midpoint of the price range as set forth on the cover page of this prospectus), after deducting underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of March 31, 2021 would have been \$[] or \$[] per share. This represents an immediate increase in pro forma net tangible book value of \$[] per share to our existing stockholders, and an immediate dilution in pro forma as adjusted net tangible book value of \$[] per share to new investors. The following table illustrates this per share dilution:

Assumed initial public offering price per share		\$
Historical net tangible book value deficit per share as of March 31, 2021	\$	0.29
Increase in net tangible book value per share attributable to pro forma adjustment described above		
Pro forma as adjusted net tangible book value per share (deficit) as of March 31, 2021		
Increase in pro forma net tangible book value per share attributable to this offering	\$	
Pro forma as adjusted net tangible book value per share, after this offering		
Dilution per share to new investors in this offering		\$

If the underwriter's over-allotment option is exercised in full, our pro forma as adjusted net tangible book value per share after this offering would be \$[] and dilution per share to new investors purchasing common stock in this offering would be \$[] at the assumed initial public offering price of \$[] per share, (the midpoint of the price range as set forth on the cover page of this prospectus) and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The pro forma as adjusted information discussed above is illustrative only. Our pro forma as adjusted net tangible book value following the completion of this offering is subject to adjustment based on the actual initial public offering price of our shares and other terms of this offering determined at pricing.

The following tables summarize the differences between our existing stockholders and the investors purchasing shares in this offering with respect to the number of shares purchased from us, the total consideration paid and the average price per share paid, at the assumed initial public offering price of \$[] per share, (the midpoint of the price range as set forth on the cover page of this prospectus) before deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

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	Shares Purchased		Total Consideration		Average Price per Share
	Number	Percent	Amount	Percent	
Common Stock	11,415,994		\$ 45,000		\$ -
Series A-1 Preferred Stock	3,542,669		660,000		\$ 0.19
Series A-2 Preferred Stock	3,546,095		1,150,000		\$ 0.32

Series A-3 Preferred Stock	2,660,230	2,100,000	\$	0.79
Series B Preferred Stock	7,928,359	8,308,000	\$	1.05
New investors				

The table above assumes no exercise of the underwriter's over-allotment option. If the underwriter's over-allotment option is exercised in full, upon completion of this offering, the percentage of common stock held by existing holders would be reduced to []%, and the percentage of common stock held by new investors purchasing common stock in this offering would be increased to []%.

The number of shares outstanding is based on shares outstanding as of March 31, 2021 and except as noted above excludes the following:

- 4,755,668 shares of our common stock issuable upon the exercise of outstanding options with a weighted-average exercise price of \$0.08 per share;
- 3,542,669 shares of Series A-1 Preferred Stock, 3,546,095 shares of Series A-2 Preferred Stock, 2,660,230 shares of Series A-3 Preferred Stock and 7,928,359 shares of Series B Preferred Stock which will convert into 3,542,669, 3,546,095, 2,660,230 and 7,928,359 shares of common stock, respectively, upon the closing of this offering (the "Preferred Stock Conversions");
- [] shares of common stock to be issued upon conversion of the March 2020 Notes upon the closing of this offering (the "Note Conversions");
- up to an additional [] shares of our common stock issuable under our 2013 Equity Incentive Plan; and
- [] shares of our common stock underlying the warrants to be issued to the representative of the underwriter in connection with this offering.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Unless the context otherwise requires, all references in this section to the "Company," "we," "us, or "our" refer to the business of RenovoRx, Inc. You should read the following discussion and analysis of our financial condition and results of operations together with the "Selected Financial Data" section of this prospectus and our financial statements and the related notes appearing elsewhere in this prospectus. This discussion contains forward-looking statements that reflect our plans, estimates, and beliefs that involve risks and uncertainties. As a result of many factors, such as those set forth under the "Risk Factors" and "Special Note Regarding Forward-Looking Statements" sections and elsewhere in this proxy statement/prospectus, our actual results may differ materially from those anticipated in these forward-looking statements.

Overview

We are a clinical-stage biopharmaceutical company focused on developing therapies for the local treatment of solid tumors and 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. 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 drug. Our first product candidate, RenovoGem, is a drug and 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 our first 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 treated with RenovoGem and radiation. 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 RenovoTAMP. Based on FDA safety review of our Phase 1/2 study the FDA allowed us to proceed to evaluate RenovoGem within our Phase 3 registration Investigational New Drug, or IND, clinical trial. Our Phase 3 trial is 40% enrolled as of April 30, 2021 and we expect to report data from a planned interim data readout in the second half of 2022. We intend to evaluate RenovoGem in a second indication in a Phase 2/3 trial in hilar CCA (cancer that occurs in the bile ducts that lead out of the liver and join with the gallbladder, also called extrahepatic cholangiocarcinoma, or HCCA). We plan to propose the trial to the FDA and potentially launch in the first 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 have used gemcitabine, but in the future we may develop other chemotherapeutic agents for intra-arterial delivery via RenovoCath.

Since our inception, we have devoted substantially all of our efforts to developing our cancer therapy platform and product candidates, raising capital and organizing and staffing our company. To date, we have funded our operations with proceeds from the issuance of convertible preferred stock and convertible notes. Through March 31, 2021, we received total net proceeds of \$15.0 million of which \$11.8 million was from the issuance of convertible preferred stock, \$3.0 million from convertible notes and \$140,000 from a loan under the Paycheck Protection Program, or PPP. In April 2021, the Company entered into a series of convertible note agreements with certain current and new investors to provide an aggregate \$2.0 million in cash proceeds.

We have incurred significant operating losses and generated negative cash flows from operations since our inception. As of March 31, 2021, we had cash and cash equivalents of \$837,000. We also had net losses of \$1.1 million in each of the three months ended March 31, 2020 and March 31, 2021. As of March 31, 2021, we had an accumulated deficit of \$16.1 million. We expect to continue to incur significant expenses, increasing operating losses and negative cash flows from operations in 2021 and for the foreseeable future. We do not expect to generate revenues from product sales unless and until we successfully complete development and obtain regulatory approval for one or more product candidates. We expect that our expenses will increase substantially in connection with our ongoing research and development activities, particularly as we:

- Advance clinical development of RenovoGem and our platform technology by continuing to enroll patients in our ongoing 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.

Without giving effect to the anticipated net proceeds from this offering, we expect that our existing cash on hand will be insufficient to fund our operating expenses and capital expenditures for at least one year from the date of our financial statements. We will need to raise additional capital to finance our operations, which cannot be assured. We have concluded that this circumstance raises substantial doubt about our ability to continue as a going concern for at least one year from the date of issuance date of our financial statements. See Note 2 to our audited financial statements and Note 2 to our unaudited interim condensed financial statements, each included elsewhere in this prospectus, for additional information on our assessment. Similarly, our independent registered public accounting firm included an explanatory paragraph in its report on our audited financial statements as of and for the year ended December 31, 2020, describing the existence of substantial doubt about our ability to continue as a going concern.

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 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 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 work-from home 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 global pandemic of COVID-19 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 ultimate geographic spread of the disease, the duration of the 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.

In April 2020, we received \$140,000 in funding as a promissory note under the PPP. This promissory note was subsequently forgiven in February 2021. See Note 6 to the unaudited condensed interim financial statements appearing at the end of this prospectus for additional information.

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 were able to charge our clinical trial sites for the RenovoCath delivery device. To date, proceeds from clinical trial sites have been adequate to cover our direct costs of manufacturing the RenovoCath delivery devices for which they have paid. Any proceeds we receive from the clinical trial sites for their purchase of the RenovoCath delivery device are offset against 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 trials, initiate future clinical trials and pursue regulatory approval of our product candidates. It is difficult to predict with any certainty the duration and completion costs of our current or future clinical trials of our product candidates or if, when or to what extent we will achieve regulatory approval and generate revenue from the commercialization and sale of our product candidates. The duration, costs and timing of clinical trials and other development of our product candidates will depend on a variety of factors, including uncertainties in clinical trial enrollment, timing and extent of future clinical trials, development of new product candidates and significant and changing government regulation. We may never succeed in achieving regulatory approval for any of our product candidates.

Our research and development expenses include:

- expenses incurred under agreements with clinical trial sites, contract research organizations, and consultants that conduct 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,
- travel expenses, and

- facilities, insurance, and other allocated expenses which include direct and allocated expenses for rent, insurance and other general overhead costs.

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

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Other Income (Expense), Net

Interest Income (Expense) Net

Interest income (expense), net consists of interest income earned from our cash and cash equivalents net of interest expense. 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.

Other Income (Expense), Net

Other income (expense), net comprise primarily investment expenses and foreign currency exchange gains and losses. We expect our foreign currency exchange gains and losses to fluctuate in the future due to changes in foreign currency exchange rates.

Gain on Loan Extinguishment

Gain on loan extinguishment resulted from the forgiveness and cancellation of the Company's PPP loan.

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 not reasonably assured.

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 Coronavirus Aid, Relief, and Economic Security Act, or 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

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

	Years Ended December 31,		Three Months Ended March 31,	
	2019	2020	2020	2021
Statements of Operations Data:			(unaudited)	
Operating expenses:				
Research and development	\$ 2,997	\$ 2,386	\$ 805	\$ 635
General and administrative	899	818	248	418
Total operating expenses	<u>3,896</u>	<u>3,204</u>	<u>1,053</u>	<u>1,053</u>
Loss from operations	(3,896)	(3,204)	(1,053)	(1,053)
Other income (expense), net				
Interest income (expense), net	63	(587)	2	(230)
Other income (expense), net	2	(7)	-	(5)
Loss on change in fair value of warrant liability	(8)	-	-	-
Gain on loan extinguishment	-	-	-	140
Total other income (expense), net	<u>57</u>	<u>(594)</u>	<u>2</u>	<u>(95)</u>
Net loss	<u>\$ (3,839)</u>	<u>\$ (3,798)</u>	<u>\$ (1,051)</u>	<u>\$ (1,148)</u>

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Comparison of the Three Months Ended March 31, 2020 and 2021

The following table summarizes our results of operations for the three months ended March 31, 2020 and 2021 (in thousands, except percentages):

Three Months Ended March 31,

Change

	(unaudited)		\$	%
	2020	2021		
Operating expenses:				
Research and development	\$ 805	\$ 635	\$ (170)	(21)%
General and administrative	248	418	170	69%
Total operating expenses	1,053	1,053	-	-
Loss from operations	(1,053)	(1,053)	-	-
Other income (expense), net				
Interest income (expense), net	2	(230)	(232)	(116)%
Other expense, net	-	(5)	(5)	100%
Gain on loan extinguishment	-	140	140	100%
Total other income (expense), net	2	(95)	(97)	(4,850)%
Net loss	\$ (1,051)	\$ (1,148)	\$ 97	9%

Research and Development

Research and development expenses decreased \$170,000, or 21%, in the three months ended March 31, 2021 compared to the three months ended March 31, 2020. This decrease was due a reduction of \$50,000 in clinical development spending related to travel and off-site meetings due to the COVID-19 pandemic, a \$42,000 reduction in expenses for preclinical studies due to the completion of sample analysis activities, and a \$12,000 reduction in regulatory expenses due to lower support for European filings and vendor audits. Also contributing to the decrease in research and development expense was an increase of \$45,000 in offsetting clinical supply usage and corresponding vendor payments from clinical trial sites. Vendor payments for delivery devices represents the cash payment made by vendors for the RenovoCath delivery devices used in clinical trials.

General and Administrative Expenses

General and administrative expenses increased \$170,000, or 69%, in the three months ended March 31, 2021 compared to the three months ended March 31, 2020. This increase was due to an increase in professional expenses of \$285,000 primarily as a result of preparing for this offering offset by a reduction in spending on legal costs of \$68,000 due to reduced spending on intellectual property and a decrease of \$37,000 in executive-level clinical support costs.

Interest Income (Expense), Net

The interest expense for the three-month period ended March 31, 2021 comprises both the stated interest on the note of 5% per annum, or \$37,000, as well as the amortization of the discount and debt issuance costs associated with the 2020 Convertible Notes of \$193,000. Interest income for the three months ended March 31, 2020 was de minimis.

Other Expense, Net

Other expense, net for the three months ended March 31, 2021 was de minimis. There was no other expense for the three months ended March 31, 2020.

On March 1, 2021, the Company entered into an amendment to the 2020 Convertible Notes which extends the maturity date of the 2020 Convertible Notes from March 31, 2021 to October 30, 2021 and provides for the conversion of the 2020 Convertible Notes into shares of the Company's common stock upon a Qualified Financing. 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.

Gain on Loan Extinguishment

The gain on loan extinguishment of \$140,000 for the three months ended March 31, 2021 resulted from the forgiveness and cancellation of the Company's PPP loan.

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Comparison of the Years Ended December 31, 2019 and 2020

	Year Ended December 31,		Change	
	2019	2020	\$	%
(in thousands, except percentages)				
Operating expenses:				
Research and development	\$ 2,997	\$ 2,386	\$ (611)	(20)%
General and administrative	899	818	(81)	(9)%
Total operating expenses	3,896	3,204	(692)	(18)%
Loss from operations	(3,896)	(3,204)	692	18%
Other income (expense), net				
Interest income (expense), net	63	(587)	(650)	(1,032)%
Other income (expense), net	2	(7)	(9)	(450)%
Loss on change in fair value of warrant liability	(8)	-	8	(100)%
Total other income (expense), net	57	(594)	(651)	(1,142)%
Net loss	\$ (3,839)	\$ (3,798)	\$ 41	1%

Research and Development

The following table summarizes our research and development expenses, personnel and our outsourced spending by functional area (in thousands):

	Year Ended December 31,		Increase/
	2019	2020	(Decrease)
Clinical development	\$ 2,021	\$ 1,518	\$ (503)
Vendor payments for delivery devices	(113)	(241)	(128)
Preclinical research and development	416	238	(178)
Regulatory	247	339	92
Personnel	426	532	106

Total research and development expenses	<u>\$ 2,997</u>	<u>\$ 2,386</u>	<u>\$ (611)</u>
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Research and development expenses were \$3.0 million for the year ended December 31, 2019 compared to \$2.4 million for the year ended December 31, 2020, a net decrease of \$0.6 million. This net decrease can be attributed to a number of factors. The decrease in clinical development costs of \$0.5 million for the year ended December 31, 2020 is primarily due to the initiation of the European portion of our clinical trial and startup of clinical trial sites in the U.S. in 2019 that did not recur in 2020. Vendor payments for delivery devices represents the cash payment made by vendors for the RenovoCath delivery devices used in clinical trials. To date, proceeds from clinical trial sites have been adequate to cover our direct costs of manufacturing the RenovoCath delivery devices for which they have paid. Preclinical research and development decreased by \$0.2 million for the year ended December 31, 2020 due to higher costs associated with early-stage product development in 2019. Regulatory expenses increased by approximately \$0.1 million for the year ended December 31, 2020 due to a higher level of support required for communications and filings with the FDA. Our personnel-related expenses increased by \$0.1 million in the year ended December 31, 2020 driven primarily by increased staffing costs to support our ongoing clinical trials.

General and Administrative Expenses

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

	<u>Year Ended December 31,</u>		<u>Increase/</u>
	<u>2019</u>	<u>2020</u>	<u>(Decrease)</u>
Personnel	\$ 560	\$ 576	\$ 16
Legal fees	201	170	(31)
Professional services and other	138	72	(66)
Total general and administrative expenses	<u>\$ 899</u>	<u>\$ 818</u>	<u>\$ (81)</u>

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General and administrative expenses were \$0.9 million for the year ended December 31, 2019 compared to \$0.8 million for the year ended December 31, 2020, a decrease of \$0.1 million. The decrease in general and administrative expenses was primarily attributable to reductions in expenses related to legal, professional services, consulting, recruiting, medical conferences and communications.

Interest Income (Expense), Net (in thousands)

	<u>Year Ended December 31,</u>		<u>Increase/</u>
	<u>2019</u>	<u>2020</u>	<u>(Decrease)</u>
Interest income	\$ 63	\$ 3	\$ (60)
Interest expense	-	(590)	(590)
Interest income (expense), net	<u>\$ 63</u>	<u>(587)</u>	<u>\$ (650)</u>

Interest income (expense), net decreased by \$0.7 million from the year ended December 31, 2019 to the year ended December 31, 2020. The decrease in interest income is due to interest earned on lower cash balances and lower interest rates throughout 2020 compared to 2019. Interest expense increased by \$0.6 million during the year ended December 31, 2020 primarily as a result of the 2020 Convertible Notes we issued in 2020. Interest expense comprises both the stated interest on the note of 5% per annum or \$0.1 million as well as the amortization of the discount and debt issuance costs associated with the 2020 Convertible Notes of \$0.5 million.

Other Expense, Net

Other expense, net increased by \$9,000 from the year ended December 31, 2019 to the year ended December 31, 2020, a de minimis amount

Loss on Change in Fair Value of Warrant Liability

Loss on change in fair value of warrant liability decreased by \$8,000 from the year ended December 31, 2019 to the year ended December 31, 2020, a de minimis amount.

Liquidity and Capital Resources

For the years ended December 31, 2019 and December 31, 2020, our net losses were \$3.8 million in each of those years, and for the three months ended March 31, 2020 and March 31, 2021 we incurred net losses of \$1.1 million in each of those periods. As of March 31, 2021, we had an accumulated deficit of \$16.1 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 and convertible notes.

As of December 31, 2020 and March 31, 2021, we had \$1.8 million and \$837,000 in cash and cash equivalents, respectively. During the three months ended March 31, 2021, we used \$1.0 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. Our cash and cash equivalents at these dates was primarily from \$3.0 million in net proceeds from convertible notes and a promissory note with Silicon Valley Bank for proceeds of \$140,000 pursuant to the PPP under the CARES Act. In February 2021, we received notification and confirmation from Silicon Valley Bank that our PPP loan including related accrued interest has been forgiven in its entirety by the U.S. Small Business Administration and automatically cancelled.

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Based on our planned operations, we expect that the proceeds from this offering plus our current cash and cash equivalents will be sufficient to fund our operations for at least 12 months after the date of this prospectus. After this offering, we intend to raise additional capital through equity offerings and/or debt financings. Adequate funding may not be available to us on acceptable terms, or at all. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our clinical trials 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 terms favorable to us, or at all.

Sources of Liquidity

Since our inception, we have not generated any revenue from product sales and we have incurred significant operating losses. 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.

To date, we have funded our operations primarily through the issuance and sale of convertible preferred stock and debt. From our inception through March 31, 2021, we had raised net cash proceeds of \$14.9 million from the issuance and sale of our convertible preferred stock and convertible notes. We also received \$140,000 from a loan under the PPP which was forgiven in February 2021. As of March 31, 2021, we had cash and cash equivalents of \$837,000 and an accumulated deficit of \$16.1 million. In April 2021, we entered into a series of convertible note agreements with certain existing and new investors to provide an aggregate \$2.0 million in cash proceeds.

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 this offering, 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.

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

	Years Ended December 31,		Three Months Ended March 31,	
	2019	2020	2020	2021
			(unaudited)	
Net cash provided by (used in):				
Operating activities	\$ (3,350)	\$ (3,528)	\$ (1,039)	\$ (992)
Investing activities	(1)	-	-	-
Financing activities	-	3,199	1,312	34
(Decrease) increase in cash and cash equivalents	<u>\$ (3,351)</u>	<u>\$ (329)</u>	<u>\$ 273</u>	<u>\$ (958)</u>

Cash Used in Operating Activities

Net cash used in operating activities for the three months ended March 31, 2020 and 2021 was approximately \$1.0 million in each of the periods, consisting primarily of our net losses in both periods of \$1.1 million.

Net cash used in operating activities for the year ended December 31, 2019 of \$3.4 million was primarily attributable to a \$3.8 million net loss, partially offset by a net increase in operating assets and liabilities of \$0.4 million.

Net cash used in operating activities for the year ended December 31, 2020 of \$3.5 million was primarily attributable to a \$3.8 million net loss and a decrease in operating assets and liabilities of \$0.2 million, partially offset by amortization of debt issuance costs and amortization of debt discount of \$0.5 million.

Cash Used in Investing Activities

There were no investing activities for the three months ended March 31, 2020 and March 31, 2021.

Net cash used in investing activities during the year ended December 31, 2019 was insignificant. There were no investing activities during the year ended December 31, 2020.

Cash Provided by Financing Activities

Net cash provided by financing activities in the three months ended March 31, 2020 was \$1.3 million, consisting primarily of \$1.3 million in proceeds from the issuance of convertible notes.

Net cash provided by financing in the three months ended March 31, 2021 was \$34,000 and consisted of proceeds from the exercise of stock options.

We had no financing activities in 2019.

Net cash provided by financing activities during the year ended December 31, 2020 of \$3.2 million was primarily attributable to \$3.0 million in proceeds from the issuance of the 2020 Convertible Notes and \$140,000 in proceeds from the PPP loan.

Contractual Obligations and Other Commitments

The following table summarizes our contractual obligations as of December 31, 2020 (in thousands):

	Payments due by period			
	Total	Less than 1 year	1 to 3 years	3 to 5 years
2020 Convertible Notes	\$ 3,038	\$ 3,038	\$ -	\$ -
PPP loan	140	117	23	-
Total	<u>\$ 3,178</u>	<u>\$ 3,155</u>	<u>\$ 23</u>	<u>\$ -</u>

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On February 6, 2021, the Company received notification and confirmation from Silicon Valley Bank that its PPP loan totaling \$140,000 has been forgiven in its entirety by the U.S. Small Business Administration and automatically cancelled. There have been no other significant changes in our contractual obligations as of March 31, 2021 compared to December 31, 2020.

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 financial statements requires us to make estimates, assumptions and judgments that affect the reported amounts in our 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 prospectus, we believe that the following critical accounting policies are most important to understanding and evaluating our reported financial results.

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.

We believe the following policies to be the most critical to an understanding of our financial condition and results of operations because they require us to make estimates, assumptions and judgments about matters that are inherently uncertain.

Clinical Trial Expenses

We make payments in connection with clinical trials 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 calculate the fair value of stock options using the Black-Scholes option pricing model, which incorporates various assumptions including assumptions including the fair value of our common stock, volatility, expected life, 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.

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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, our Board of Directors 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.

Following this offering, we will 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 will be 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. 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 to non-employees, the expected term equals the remaining contractual term of the option from the vesting date.

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 (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 and March 31, 2021, our only derivative financial instrument was related to the 2020 Convertible Notes, which contained certain redemptive features.

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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 in this prospectus;
- 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 the registration statement of which this prospectus is a part 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 after this offering 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, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation

Recently Issued and Adopted Accounting Pronouncements

See Note 2 to our audited financial statements included elsewhere in this prospectus for more information.

Off-Balance Sheet Arrangements

During the periods presented, we did not have any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

Quantitative and Qualitative Disclosures about Market Risk

We are exposed to market risks in the ordinary course of our business. These risks primarily include interest rate risks, foreign currency exchange, risks and inflation risks. Periodically, we maintain deposits in accredited financial institutions in excess of federally insured limits. We deposit our cash in financial institutions that we believe have high credit quality and have not experienced any losses on such accounts and do not believe we are exposed to any unusual credit risk beyond the normal credit risk associated with commercial banking relationships.

Interest Rate Risk

Our cash and cash equivalents consisted primarily of cash on hand at December 31, 2020 and March 31, 2021. The fair value of our cash and cash equivalents would not be significantly affected by either an increase or decrease in interest rates.

Our exposure to risks related to interest rates is minimal. The interest rate for our 2020 Convertible Note is a fixed rate.

Foreign Currency Exchange Risk

We are not currently exposed to significant market risk related to changes in foreign currency exchange rates. However, we have contracted with and may continue to contract with vendors such as contract research organizations and clinical trial sites that are located in Europe. We may be subject to fluctuations in foreign currency rates in connection with certain of these agreements. Transactions denominated in currencies other than the U.S. dollar are recorded based on exchange rates at the time such transactions arise. While we have not engaged in hedging our foreign currency transactions to date, we may evaluate the costs and benefits of initiating such a program and may in the future, hedge selected significant transactions denominated in currencies other than the U.S. dollar as we expand our clinical trial sites globally.

Inflation Risk

Inflation generally affects us by increasing our labor and clinical trial costs. We do not believe that inflation had a material effect on our business, financial condition or results of operations during the year ended December 31, 2020 and the three-month period ended March 31, 2021.

Internal Control Over Financial Reporting

Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with generally accepted accounting principles in the United States, or GAAP. Under standards established by the Public Company Accounting Oversight Board, or PCAOB, a deficiency in internal control over financial reporting exists when the design or operation of a control does not allow management or personnel, in the normal course of performing their assigned functions, to prevent or detect misstatements on a timely basis. The PCAOB defines a material weakness as a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of annual or interim financial statements will not be prevented or detected on a timely basis.

In preparation for our initial public offering, we identified material weaknesses in our internal control over financial reporting related to our control environment. Specifically, we have determined that we lack 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 GAAP, and adequate management review controls. In addition, 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.

To address these material weaknesses, we have implemented, and are continuing to implement, measures designed to improve internal controls 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 have implemented 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.

The process of designing and implementing an effective accounting and financial reporting system is a continuous effort that requires us to anticipate and react to changes in our business and the economic and regulatory environments and to expend significant resources to maintain an accounting and financial reporting system that is

adequate to satisfy our reporting obligations. As we continue to evaluate and take actions to improve our internal control over financial reporting, we may determine to take additional actions to address control deficiencies or determine to modify certain of the remediation measures described above. We cannot assure you that the measures we have taken to date, or any measures we may take in the future, will be sufficient to remediate the material weakness we have identified or avoid potential future material weaknesses.

BUSINESS

Overview

We are a clinical-stage biopharmaceutical company focused on developing therapies for the local treatment of solid tumors and 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. 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 drug. Our first product candidate, RenovoGem, is a drug and 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 our first 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 treated with RenovoGem and radiation. 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 RenovoTAMP. Based on FDA safety review of our Phase 1/2 study the FDA allowed us to proceed to evaluate RenovoGem within our Phase 3 registration Investigational New Drug, or IND, clinical trial. Our Phase 3 trial is 40% enrolled as of April 30, 2021 and we expect to report data from a planned interim data readout in the second half of 2022. We intend to evaluate RenovoGem in a second indication in a Phase 2/3 trial in hilar CCA (cancer that occurs in the bile ducts that lead out of the liver and join with the gallbladder, also called extrahepatic cholangiocarcinoma, or HCCA). We plan to propose the trial to the FDA and potentially launch in the first 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 have used gemcitabine, but in the future we may develop other chemotherapeutic agents for intra-arterial delivery via RenovoCath.

Our RenovoTAMP therapy platform is focused on optimizing drug concentration in solid tumors using approved small molecule chemotherapeutics that enable 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. More specifically, our patented approach combines local delivery via our patented RenovoCath delivery system utilizing pressure to force small molecule chemotherapy into the tumor tissue with pre-treatment of the local blood vessels and tissue with standard-of-care radiation therapy to decrease chemotherapy washout. We believe there are many advantages to our approach:

- *Application of Approved Small Molecule Chemotherapeutic Agents:* We use approved small molecule chemotherapeutic agents such as gemcitabine.
- *Targeted Approach:* With our approach, we have demonstrated in our clinical studies up to 100 times higher local drug concentration compared to systemic chemotherapy. We believe our approach decreases systemic exposure and improves patient outcomes.
- *Delivery Method Independent of Tumor Vascularity:* We invented a novel combination platform and delivery system to deliver small molecule chemotherapeutic agents in solid tumors resistant to systemic chemotherapy due to lack of tumor blood vessels or tumor feeders.
- *Broad Application for Solid Tumor Indications:* Our platform is not restricted to a single small molecule chemotherapeutic agent or solid tumor type. As such, our platform and delivery system may be applied for use in additional solid tumor indications, including in solid tumors without identifiable tumor feeders.

Our lead product candidate, RenovoGem, is a combination of gemcitabine and our patented delivery system, RenovoCath, and is regulated by the FDA as a novel oncology drug product. Our RenovoTAMP platform therapy utilizes pressure mediated delivery of the small molecule gemcitabine across the arterial wall to bathe the pancreatic tumor tissue in 120mL of saline with 1,000mg/m² of the drug over a 20-minute delivery time (approximately a total of 1,500-2,000mg of drug dependent upon patient Body Surface Area). RenovoCath is an adjustable double balloon catheter designed to isolate the proximal and distal vessel and adjust the distance between the balloons to exclude any branching blood vessel offshoots.

While the field of oncology has seen progress in treating a handful of deadly cancers over the last few decades, there is a common limitation in chemotherapy: enhanced dosing of the drug to impact the tumor while minimizing systemic toxicity. The characteristics of the vasculature, within and surrounding the tumor, can be a limiting step in this goal. For example, LAPC and HCCA 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 feeders. However, in patients with pancreatic cancer, no tumor feeder vessels are visible during angiography. In the absence of visible tumor feeders, we can introduce drugs directly across the arterial wall into the surrounding tissue via pressurized diffusion.

We are currently evaluating RenovoGem in patients with LAPC in our TIGeR-PaC Phase 3 trial at 28 US and Belgian sites. The trial is designed to enroll 340 subjects. As of April 30, 2021, 135 patients were enrolled, accounting for 40% of expected total enrollment. A planned interim data readout is expected during the second half of 2022. We have secured Orphan Drug Designation for RenovoGem; which would provide us with seven years of exclusivity to market intra-arterial use of gemcitabine for LAPC upon NDA approval.

In addition, we intend to evaluate RenovoGem in patients with HCCA, and we have secured FDA Orphan Drug Designation for the broader CCA indication. We intend to potentially pursue additional indications including locally advanced lung cancer, locally advanced uterine tumors and glioblastoma.

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. Looking at 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 24-month survival of 12%, and to chemotherapy + radiation with 24-month survival of 5% and mOS of 12-15 months as demonstrated in historical studies.

We intend to submit our proposed Phase 2/3 clinical trial to evaluate RenovoGem in HCCA, BENEFICIAL, to the FDA as part of a pre-IND submission in the fourth quarter of 2021 and to launch the clinical trial in the first half of 2022. Gemcitabine has been considered standard of care for several solid tumors, and the drug’s anti-cancer tumor effects are well profiled. 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 pre-clinical studies, and additional pre-clinical 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.

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, has extensive experience running clinical trials and launching, creating, and developing new markets for novel therapies at Trans Vascular, 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 and Board experience including drug/device combination and oncology experience. Clinical advisors include experts in surgical oncology, interventional radiology, radiation oncology, and medical oncology. 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. Mike Pishvaian, also a medical oncologist, has extensive experience in running oncology studies and is an Associate Professor, and Department of Oncology Director of the Gastrointestinal, Developmental Therapeutics, and Clinical Research Programs at the NCI 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. Peter Muscarella is a surgical oncologist and the Director of Pancreatic Surgery, General Surgery Site Director, Weiler Hospital Associate Program Director, and General Surgery Residency Training Program at Montefiore Medical Center, Bronx, NY. Dr. Karyn Goodman serves as our 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. We have two interventional radiology scientific advisors: Dr. Reza Malek, Neurointerventional Radiologist at Minimally Invasive Surgical Solutions and Dr. Jacob Cynamon, Professor of Clinical Radiology of the Albert Einstein College of Medicine, Chief of the Division of Vascular and Interventional Radiology, and Program Director of the Vascular and Interventional Radiology Fellowship Program at the Montefiore Medical Center, Bronx, NY.

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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.

Strategy

RenovoGem is a combination of intra-arterial gemcitabine and our patented delivery system, RenovoCath, and is regulated by the FDA as a novel oncology drug product. Our near-term goal is to develop RenovoGem utilizing our RenovoTAMP platform to address the unmet medical needs of LAPC and HCCA patients. We intend to broaden application of our 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 our first indication, LAPC.** 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 locally advanced pancreatic cancer patients. We are currently conducting our TIGeR-PaC Phase 3 clinical trial with a target enrollment of 340 patients. As of April 30, 2021, we have enrolled 135 patients. We expect to receive an interim data readout on the primary endpoint of overall survival by the second half of 2022.
- **Advance RenovoGem for use in our second indication, HCCA.** We have secured Orphan Drug Designation for the broader CCA indication and intend to launch a Phase 2/3 trial for the treatment of HCCA in the first half of 2022.
- **Expand RenovoGem for use in additional solid tumors indications.** We plan to potentially launch IND studies to explore the application of RenovoGem for the treatment of locally advanced lung cancer and other solid tumor indications with data on the use of systemic or intravenously administered gemcitabine such as locally advanced uterine tumors and glioblastoma.
- **Use 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 use our platform to develop products with drugs that are available generically or we may enter strategic collaborations to access other companies' proprietary drugs.
- **Explore collaborations with biotechnology and pharmaceutical companies.** We have exclusive global development and commercialization rights for RenovoGem and RenovoCath including issued patents on methods of RenovoTAMP for all indications that we may pursue. While we may develop these products independently, we may also enter strategic relationships with 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 delivers anti-cancer drugs directly to the tumor and does not rely on the existence of extensive vasculature also known as tumor feeders. We believe that RenovoTAMP, which locally delivers directly to the tumor a drug that is standard of care in systemic administration, 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 via the RenovoTAMP therapy platform is well tolerated with multiple survival signals.
- **Pipeline with broad utility.** 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, our platform has been used throughout the duration of our clinical trials with demonstrated adoption of the RenovoTAMP technique by physicians.

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, surgery may be an effective and potentially curative treatment of the entire tumor is removed. In most cases, surgery is initially completed prior to commencing additional treatment approaches. However, multiple solid tumor types, including LAPC and HCCA are diagnosed at stages that preclude surgery as a treatment approach. In many of these circumstances, the tumor has grown into adjacent anatomical structures making the surgery difficult or impossible.

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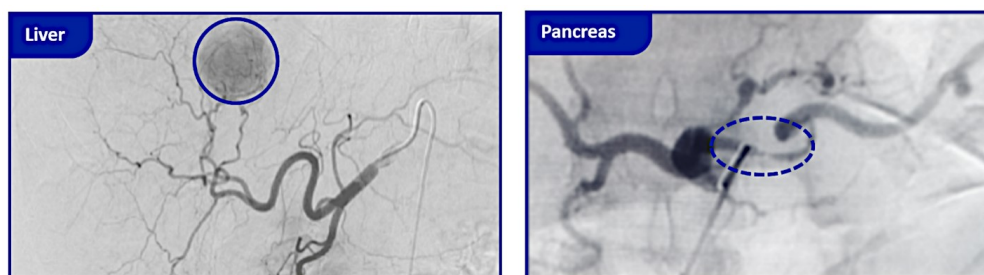
Intra-venous (IV), or systemic chemotherapy, is considered standard of care for most solid tumors, but limitations include less than acceptable efficacy, systemic toxicities, and side effects.

For the treatment of localized solid tumors, TACE is an established first line therapy. Many companies have used this approach to treat tumors of the liver, uterus, and prostate. Many solid tumors have a dedicated blood supply; small blood vessels, called tumor feeders, 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 feeders during x-ray angiography and then deliver the desired therapy including chemotherapy and embolic agents. In patients LAPC, no tumor feeder 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, HCCA, and with a subset of other solid tumors. The limitations of TACE translate to low survival rates in these tumor subtypes despite attempts with novel therapies including targeted therapies that address a specific molecule on one or more tumor types and immuno-oncology treatment approaches, which harness the body's immune system to treat cancer. For example, early studies targeting immunotherapies in pancreatic cancer have limited success due to the inability of immune cells to penetrate the tumor tissue.

Our Platform: RenovoTAMP

In Figure 2 below, the panel on the left depicts visualization of the actual tumor, hepatocellular carcinoma, or primary liver cancer, under x-ray angiography as dye injected through the arteries reaches the tumor itself. Further, visible tumor feeders can be reached by simple end-hole catheters to deliver targeted therapy to these liver tumors. The panel on the right demonstrates the typical lack of tumor feeders to the pancreatic tumor. Given the lack of tumor feeders, the dye does not reach the tumor, rendering the tumor “invisible” under x-ray angiography. Rather one can see the native/large blood vessel being “pinched” by the tumor.

Tumors in Liver are Different from Hypovascular Tumors in the Pancreas



Liver tumors are highly vascularized:

Large tumor feeders – excellent targets for therapy
Large branches within tumor - easily visualize tumor

Pancreas tumors are hypovascular:

Inability to identify or engage tumor feeder vessels

Figure 2 Liver tumors are highly vascularized versus pancreas tumors that are avascular, therefore systemic chemotherapy and local TACE approaches can more easily deliver chemotherapy to liver tumors than to pancreatic tumors. The panel on the left depicts tumor feeders originating from the native liver arteries. Under x-ray angiography, dye injected in the native liver arteries drain into the tumor feeders and clearly define the tumor. The panel on the right depicts the “invisible” pancreatic tumor. From a dye injection through the arteries near the pancreas, one can only visualize a narrowing of the artery due to the tumor pinching on the artery, but tumor feeders, and thus, the tumor itself are not visible.

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In 2009 our founder Dr. Ramtin Agah, an experienced interventional cardiologist with a degree in biomedical engineering, invented 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. We contracted with a contract manufacturer to prototype and manufacture its 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, and a further clearance for use with a power-injector in 2019. We are evaluating RenovoGem under an IND and expect that RenovoGem, if approved, will be regulated and reimbursed as a drug.

To overcome the limitation of lack of tumor feeder 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 (TAMP[®]). To isolate the vessel and create this pressure gradient, we developed a patented adjustable double balloon catheter to occlude the proximal and distal part of the vessel (RenovoCath). Using this technique with the RenovoCath delivery system we were able to validate our hypothesis by demonstrating >99% gemcitabine pressurized diffusion in explanted pig aorta and iliac arteries across the arterial wall in the absence of feeder vessels. This mechanism of action was further supported via 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.

RenovoCath Pressurizes Isolated Vessel Segment, Allowing RenovoTAMP

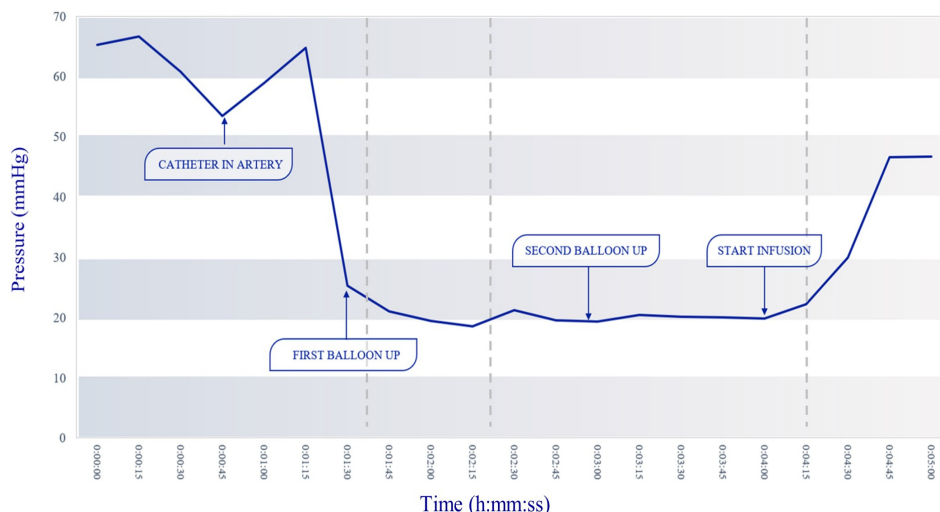


Figure 3 Occluding the vessel with the *RenovoCath* while changing the balloon-to-balloon distance to exclude all branches established an intravascular interstitial pressure in the isolated segment of approximately 20mmHg. With subsequent infusion of fluids between the balloons at 6mls/minute, the intravascular pressure increases until above 45mmHg, trans-arterially forcing the small molecule drug across the arterial wall via diffusion (RenovoTAMP).

Our RenovoTAMP platform therapy utilizes pressure mediated delivery of the small molecule gemcitabine across the arterial wall to bathe the pancreatic tumor tissue in 120mL of saline with 1,000mg/m² of the drug over a 20-minute delivery time (approximately a total of 1,500-2,000mg of drug dependent 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 vessels to deliver the drug. These generally do not exist in avascular or hypovascular tumors such as LAPC and HCCA
- In solid tumors without identifiable feeder vessels, technically easier than direct cannulation of small tumor feeders
- High local concentration of drug into the tumor tissue
- Potential for decreased systemic exposure of drug due to local metabolism prior to systemic exposure

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 with the ability to adjust the balloon-to-balloon distance to tailor the treatment zone to each patient's unique anatomy. The RenovoCath delivery system is inserted into the body through the femoral artery and positioned in the artery closest to the tumor using standard interventional technique, by an interventional radiologist. Once the balloons are inflated and the position is confirmed, chemotherapy is delivered through the handle, exiting the device between the balloons and forced through the vessel wall into the tissue over 20 minutes, depicted below in Figure 4.

RenovoCath Delivers Therapeutic Agent Between Two Balloons

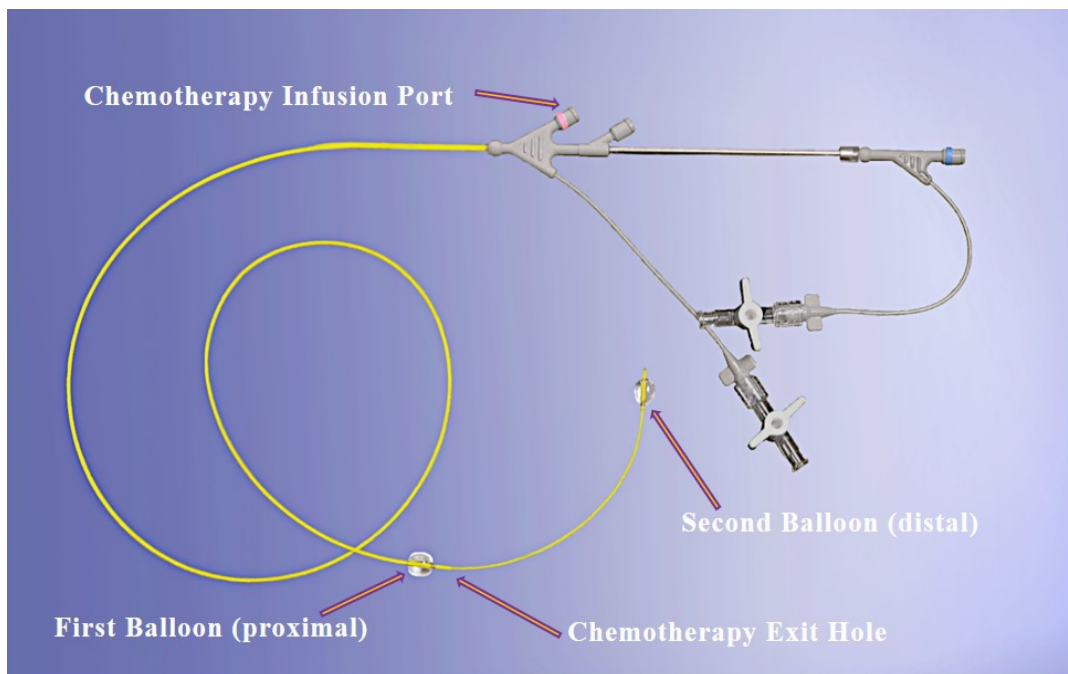


Figure 4 RenovoCath delivery system illustrating two balloon configuration to isolate the target vessel segment, and Chemotherapy delivery port/exit hole to infuse target vessel segment.

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After the procedure is complete, RenovoCath is discarded, and the patient is generally discharged the same day. The average procedure is 90 minutes, and the procedure is repeated every two weeks for as long as local chemotherapy is warranted. 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 with ease.

RenovoGem for LAPC

Disease Overview

Pancreatic cancer is one of the deadliest cancers in the U.S. with very poor outcomes. In 2021, it is estimated that 60,430 Americans will be diagnosed with pancreatic cancer in the US and more than 48,220 will die of the disease. Pancreatic cancer currently has a 5-year overall survival rate of 5-10% (Stages I-IV) and is expected to quickly become the second leading cause of cancer-related deaths.

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 at the time of presentation (Stage I-II: 15-20%); the rest are distributed between having tumors with unresectable LAPC (Stage III: 30%) and metastatic pancreatic cancer (Stage IV: 50%). The curative prognosis for these patients is poor with a 5-year survival of only 7%.

Chemotherapy, which can be used in the neoadjuvant setting (before surgery) to attempt to decrease tumor size in the borderline resectable or resectable patients, in the adjuvant setting (after surgery), or first line in the metastatic/advanced setting, is the forefront of systemic therapy. Specifically, 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, or metastatic PC, since its introduction in the US as Gemzar® (gemcitabine for injection) in 1996 with an FDA approved indication as such and 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 PC 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.

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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 chemo resistant.

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. Despite these modest advances, there is room for improvement.

A major focus of clinicians is to determine the most 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, attempts at local injection of drugs directly, and use of adenoviral vector to deliver toxic agents. The aforementioned 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. More recently, the addition of Abraxane to gemcitabine was approved in 2013 with immediate deep market penetration based on an 8-week survival benefit.

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 and device combination therapy of intra-arterial gemcitabine and our proprietary RenovoCath delivery system which forces anti-cancer drug into the tissue. RenovoGem is regulated by the FDA as a novel oncology drug product. We do not intend to sell RenovoCath alone. Instead, we intend to sell RenovoCath only in combination with intra-arterial gemcitabine or potentially with other therapeutic agents.

Based on third-party primary research/market analysis of the U.S. market, we believe that over 5,000 patients per year would be excellent candidates and undergo RenovoGem treatment once approved in the U.S. 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.

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RenovoTAMP Therapy Platform and First Product Candidate, RenovoGem

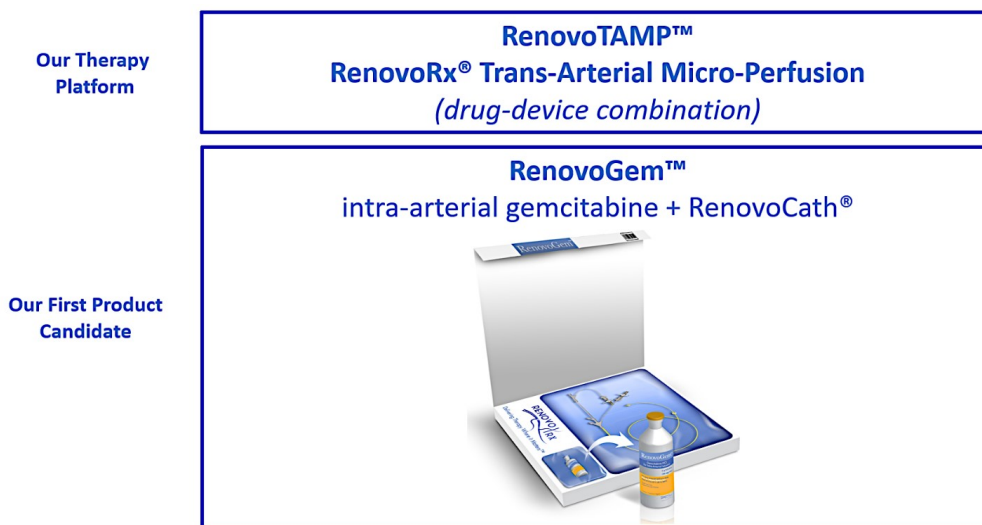


Figure 5 We invented a new therapy platform, RenovoTAMP, that uses pressure to force small molecule chemotherapeutics across the vessel wall into the tissue using our patented RenovoCath delivery system. Our first product candidate, RenovoGem, is a drug-device combination of intra-arterial gemcitabine and the RenovoCath delivery system and is in development for LAPC and HCCA with Orphan Drug Designation secured for both indications.

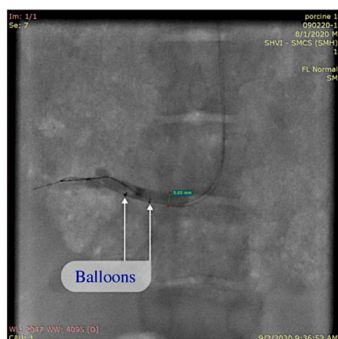
Clinical Development of RenovoGem in LAPC

Pre-Clinical Studies and Data

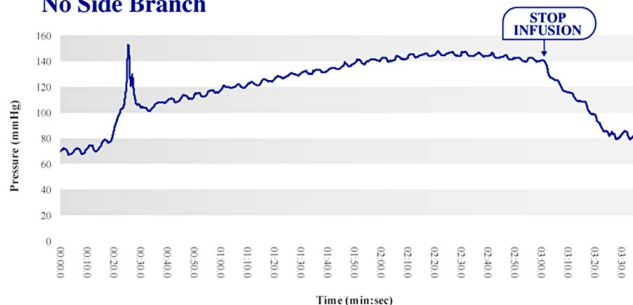
Once RenovoCath is introduced via standard interventional technique to the arterial vessel segment next to the targeted tissue, both balloons are inflated and the vessel segment is isolated from the rest of the circulatory system. With inflation of balloons, the pressure is observed to drop within the vessel. However, with infusion of fluids between the balloons, the intravascular pressure increases beyond 45mmHg 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 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 between proper balloon positioning with no side branches allowing drug across the arterial wall versus improper balloon positioning with side branches washing out drug via the side branches in an animal study.

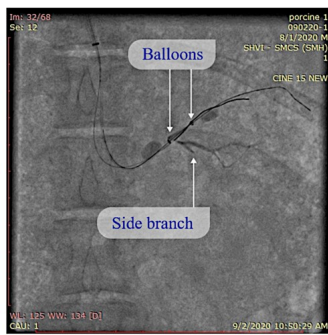
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Infusion Pressure Achieved When Side Branches Are Excluded



Mean Pressure Starting at Infusion No Side Branch





Mean Pressure Starting at Infusion With Side Branch

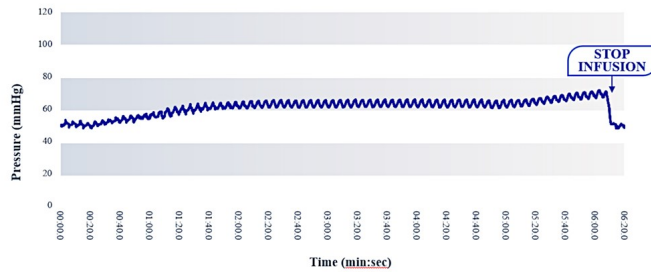


Figure 6 Top panel demonstrates proper balloon positioning with no side branch. Pressure increases with infusion and reaches plateau of approximately 75mmHg higher than initial pressure. Bottom panel demonstrates improper balloon positioning with side branch between the balloons. Pressure increases with 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 following studies to validate this hypothesis:

- 1) Gemcitabine can cross the arterial wall via RenovoTAMP, with 99% crossing the arterial wall into the tissue.

In explanted (dissected out of the animal and used separately in a saline water bath) pig iliac and aortic artery, with 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 60mg/minute of gemcitabine into the isolated area over 20 minutes. By the end of the infusion, we measured 1188 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).

99% of Chemotherapy Crosses Arterial Wall with RenovoTAMP Delivery

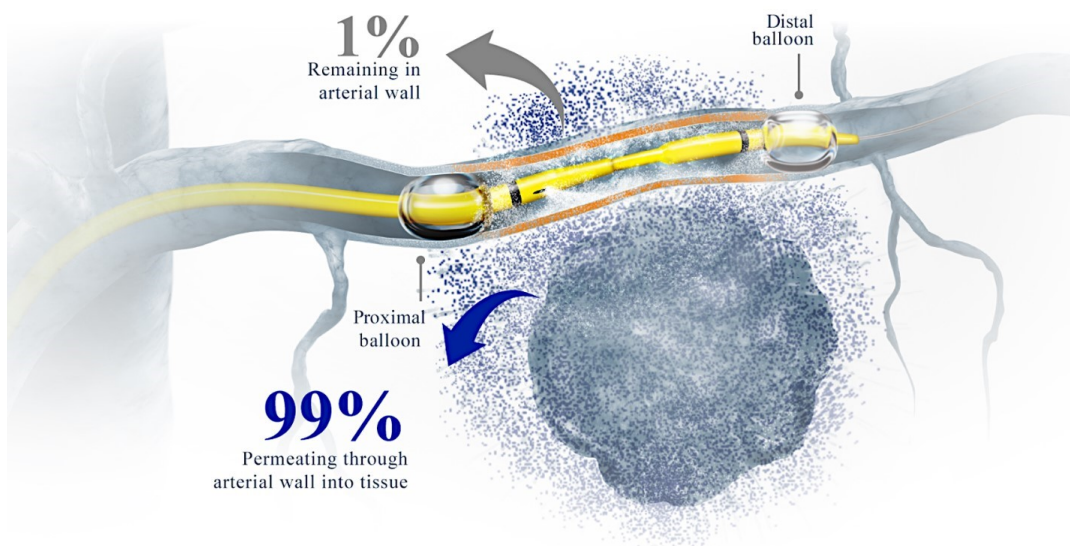


Figure 7 RenovoTAMP: delivery of chemotherapy through the RenovoCath and into the tissue to bathe the tumor in chemotherapy. With gemcitabine, 99% of the drug crosses the arterial wall and less than 0.75% is retained in the arterial tissue.

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

Six pigs were treated with gemcitabine via RenovoTAMP (6mL/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) RenovoTAMP can achieve 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 with the RenovoCath double balloons as well as side branches) 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 cm² (2.2 cm x 4.8 cm) of the

pancreas.

Dye Demonstrates RenovoTAMP Delivery of Agent into Pancreatic Tissue

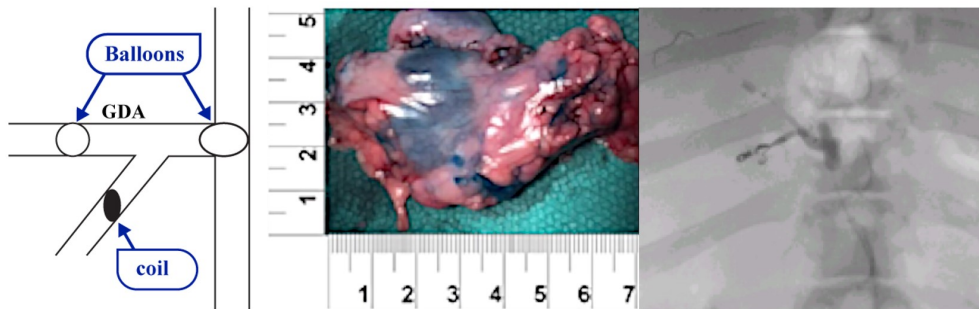


Figure 8 RenovoCath was introduced into the GDA and a side branch was excluded by coiling. This test was conducted in an acute porcine model and demonstrated a dye coverage area of approximately 10.56 cm² for a 2-minute dye infusion. All dimensions in above figure are in cm.

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 6mls/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 (4cm). 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

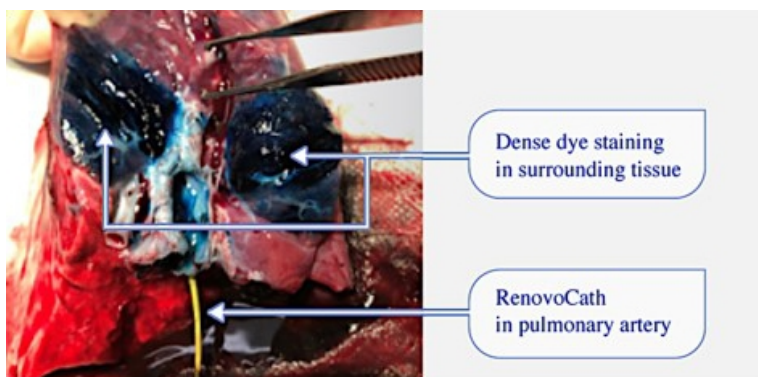


Figure 9 Dense dye staining localized to the area of the isolated pulmonary artery segment and penetrating 4cm into surrounding tissue following 1 minute dye infusion. In addition, gemcitabine was delivered via RenovoTAMP for 20 minutes demonstrating 100-fold increase in tissue concentration of gemcitabine 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 of local tissue concentration. The tissue concentration with intravenous infusion and/or distant from RenovoTAMP site (likely after recirculation through systemic system) are two orders of magnitudes lower than tissue levels achieved with RenovoTAMP ($p < 0.02$).

RenovoTAMP Increases Local Tissue Concentration of Gemcitabine Compared to IV Infusion.

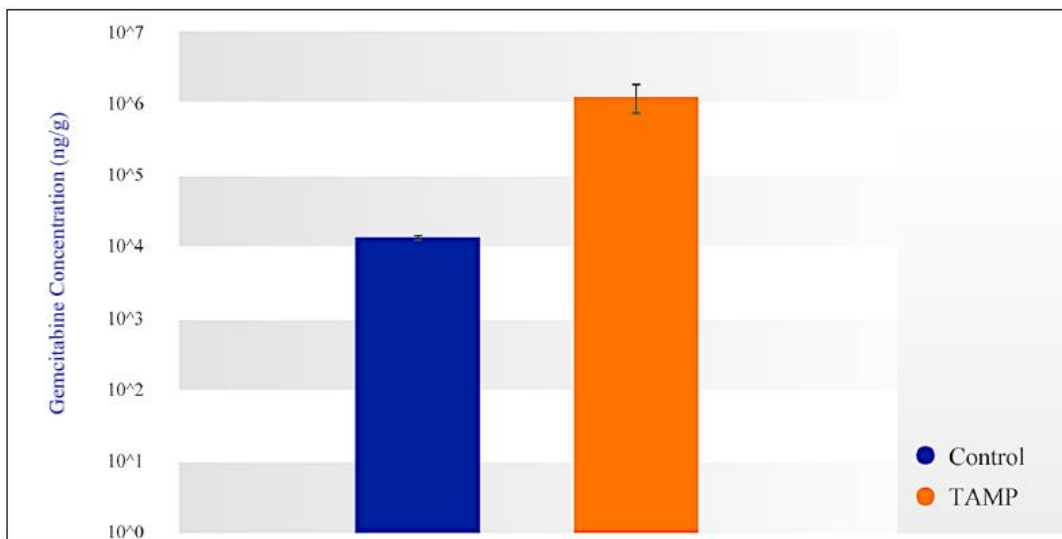


Figure 10 Local tissue concentration of gemcitabine. control (Blue): IV infusion versus RenovoTAMP (Orange): RenovoTAMP: intra-arterial infusion. The tissue concentration with intravenous infusion and/or distant from RenovoTAMP site (likely after recirculation through systemic system) are 100-fold lower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

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This animal lung study successfully validated the efficacy and ability for RenovoCath to deliver small molecules locally to lung tissue with the RenovoTAMP therapy.

III. Increase in local tissue delivery of gemcitabine in LAPC should 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 (IV) injection. To achieve a comparable reduction in tumor growth as seen with IA treatment, gemcitabine had to be given IV at over 300 times the dose which was associated with some toxicity.

RenovoTAMP and Radiation

Traditionally the goal of radiation includes a) debulking the tumor and/or b) acting as a chemo-sensitizer. In our RR1 dose escalation safety study and RR2 observational registry study, the benefit of RenovoTAMP seems to be enhanced in patients with prior radiation. As we were observing this effect months after radiation and 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.

RenovoTAMP Combined with Radiation Reduces Venous Outflow by Decreasing the Microvasculature

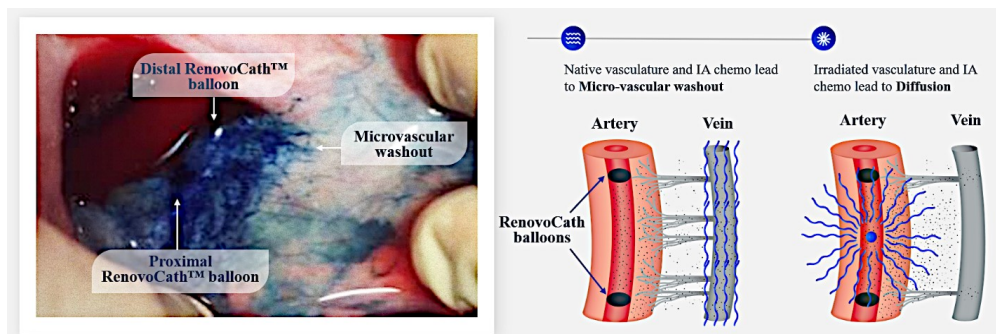
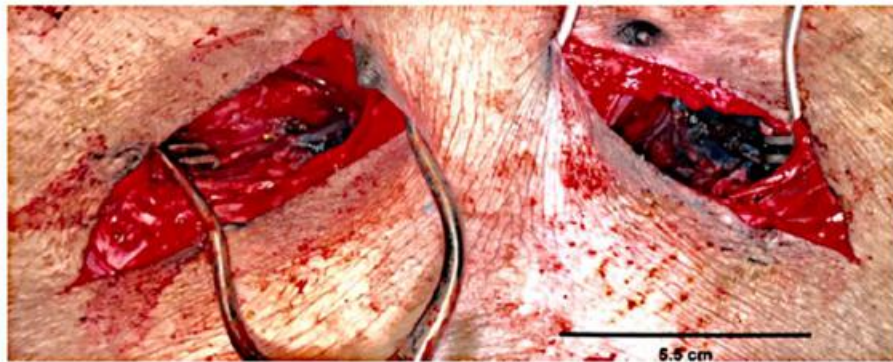
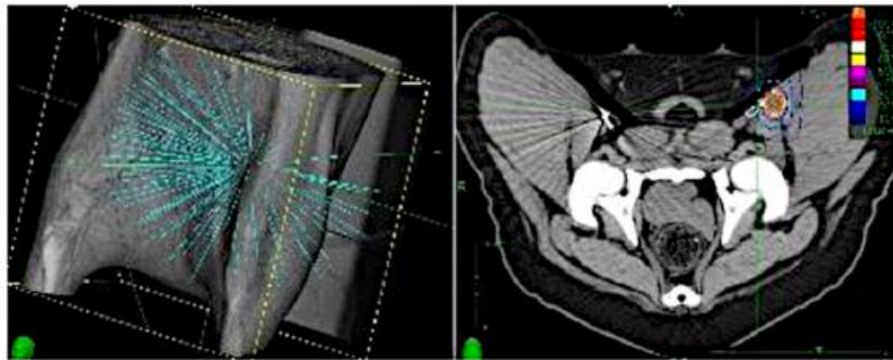


Figure 11 Mechanism of RenovoTAMP and radiation reduces venous outflow by decreasing the microvasculature networks that could act as an “escape route” for the drugs. The photo on the left illustrates this effect in a dye infusion study in the porcine animal model. The panel on the right demonstrates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

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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.

Left Leg Radiation



Increase in Blue Staining and Gemcitabine on Radiation Leg

Figure 12 To demonstrate the effect of radiation pre-treatment, we delivered radiation therapy to the left leg of a pig. After waiting for one month for the vascular effect to take place, 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.

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 feeders. The mechanism of action is the exclusion of distal (downstream) and side branch vessels in the isolated segment and subsequently achieving 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 4cm-tissue penetration and 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 through its effect on 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 April 30, 2021 we have enrolled 135 patients in this study.

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 locally advanced pancreatic cancer. 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/m² to 1000 mg /m². 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 anticoagulants (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 doses of 250mg/m², and doses increased by 250 mg/m² in each subsequent cycle culminating with the full dose of 1,000 mg/m². After the initial six subjects, the starting dose increased to 500 mg/m² for one cycle, after which dosing increased to 750 mg/m² for the second cycle, and then the full 1,000 mg/m² 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. Importantly, 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. 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) away from the treatment site and site complications (2) out of 101 procedures.

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.

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 Cycles Survived Longer

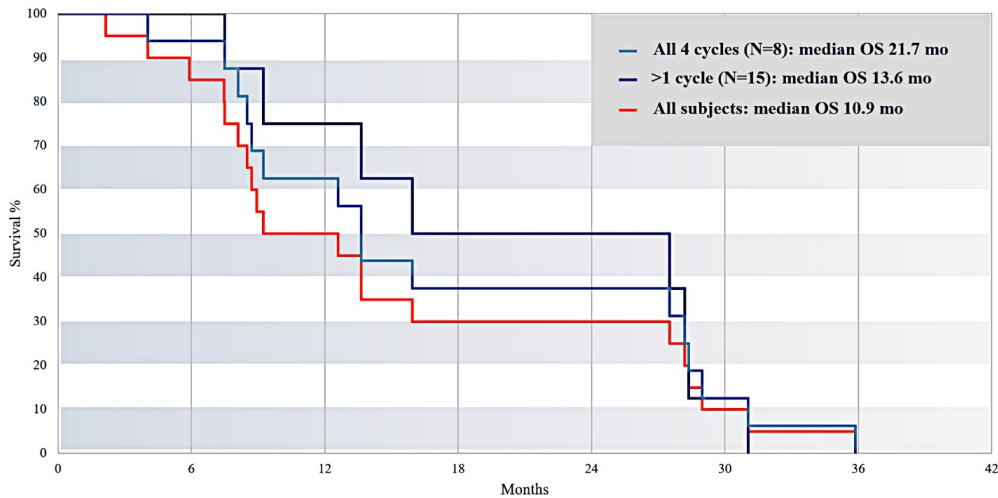


Figure 13 This chart shows survival as a function of total number of IA treatment cycles received. Subjects receiving all 4 cycles (n=8) had a median survival time of 21.7 months, compared to a median survival time of 10.9 months for all subjects (n=20).

Subjects Who Received Greater Cumulative Exposure Survived Longer

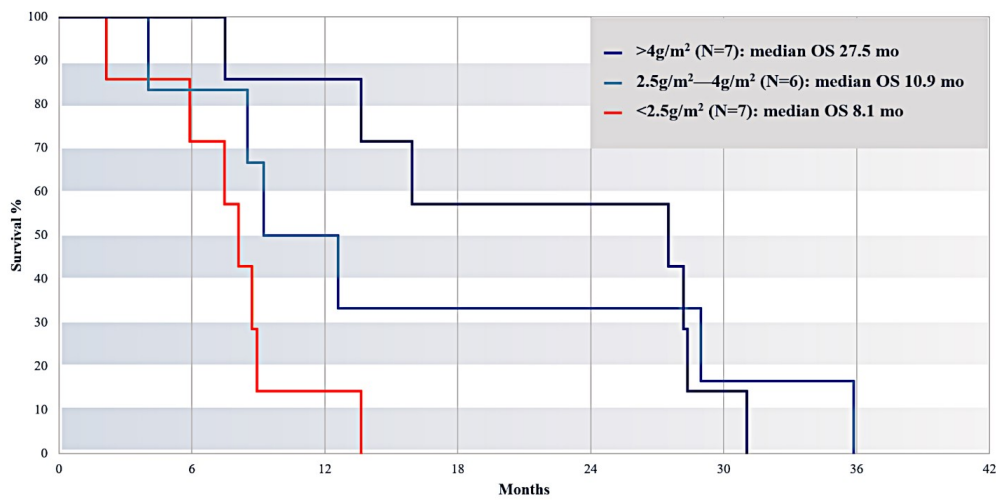


Figure 14 Splitting the entire cohort into equal tertiles based on total dose received, patients receiving the lowest total dose (<2.5g/m²; n=7) demonstrated the lowest median overall survival (8.1 months) compared to patients in the group receiving the next higher total dose (>2.5g/m², but <4g/m²; n=6; 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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Fifteen subjects received more than 1 cycle of intra-arterial gemcitabine treatment. The blue line depicts subjects without any prior treatment or received prior chemotherapy only (n=10; median OS=13.6 months). The 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 as shown below.

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

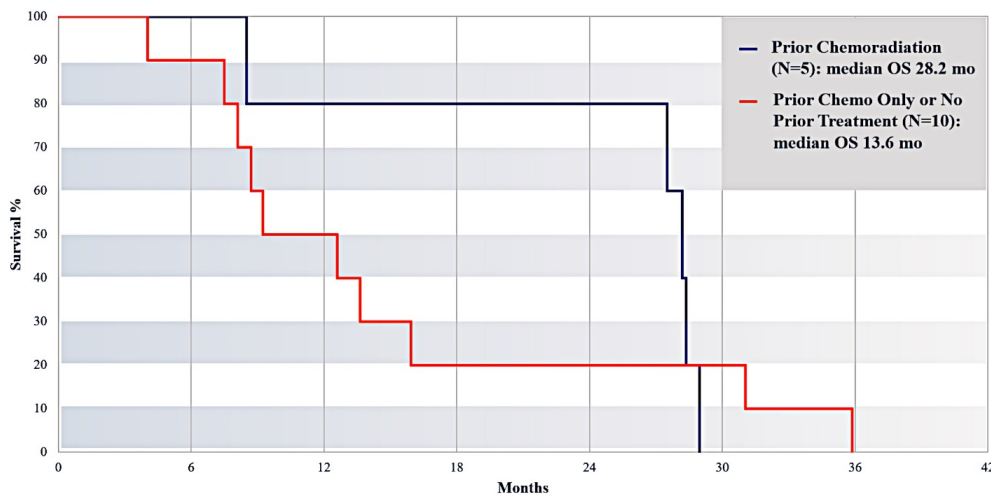


Figure 15 Survival of subjects with or without Prior Chemoradiation. Subjects with prior chemoradiation (n=5) had a median survival time of 28.2 months, compared with a median survival time of 13.6 months for subjects without prior chemoradiation (n=10).

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 included 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 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 the subjects participated in our Phase 1/2 RenovoCath/Gem RR1 trial, in which each received 8 IA gemcitabine infusions prior to enrollment in the RR2 study for observation of additional IA gemcitabine infusions. A summary of data updated through January 2021 is presented below.

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The study initially enrolled LAPC subjects without regard to prior radiation or chemotherapy; 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 beginning April 2017. 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 post-last procedure but reporting of non-serious adverse events was optional. All subjects received gemcitabine 1000 mg/m² every two weeks, except one who received 500 mg/m², typically for a total of 8 doses. Subjects were followed post treatment for survival.

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 radiotherapy and chemotherapy, 6 had 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 Tally 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).

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 similar to that of pancreatic cancer subjects receiving myelosuppressive chemotherapeutic regiment in other studies.

Efficacy

Excluding the subject 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 and median overall survival was 13.0 months.

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

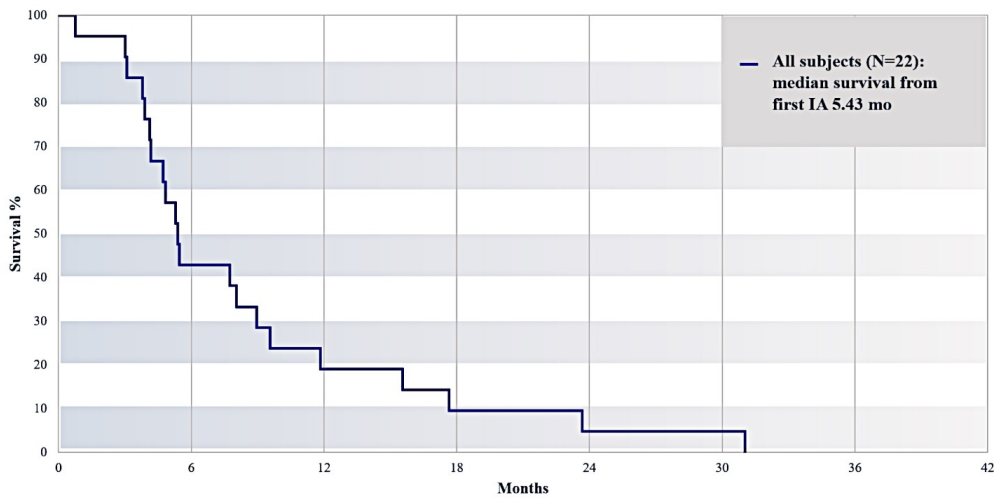


Figure 16 Overall RR2 observational registry study cohort (N=22) survival from first IA treatment until date of death.

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

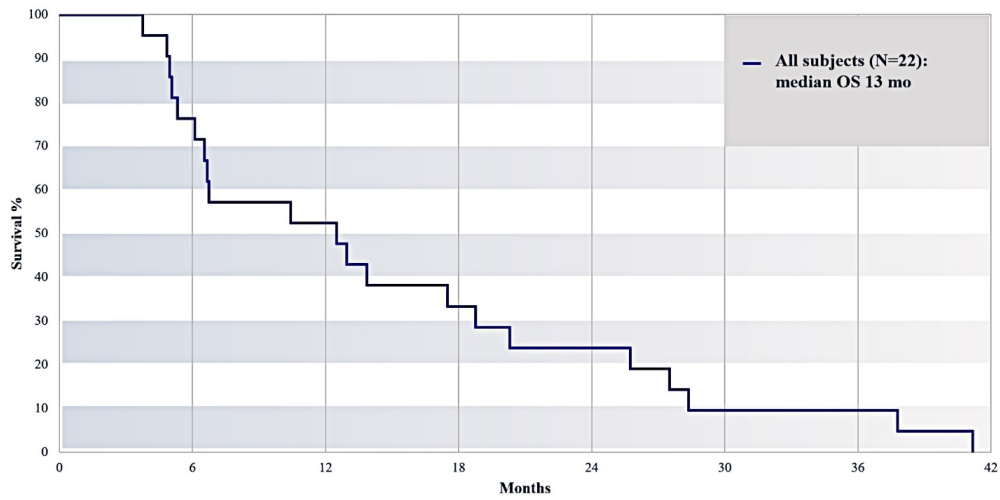


Figure 17 Overall RR2 observational registry study cohort (N=22) overall survival from date of diagnosis.

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

Subjects with Prior Chemo or Prior Chemoradiation Survive Longer

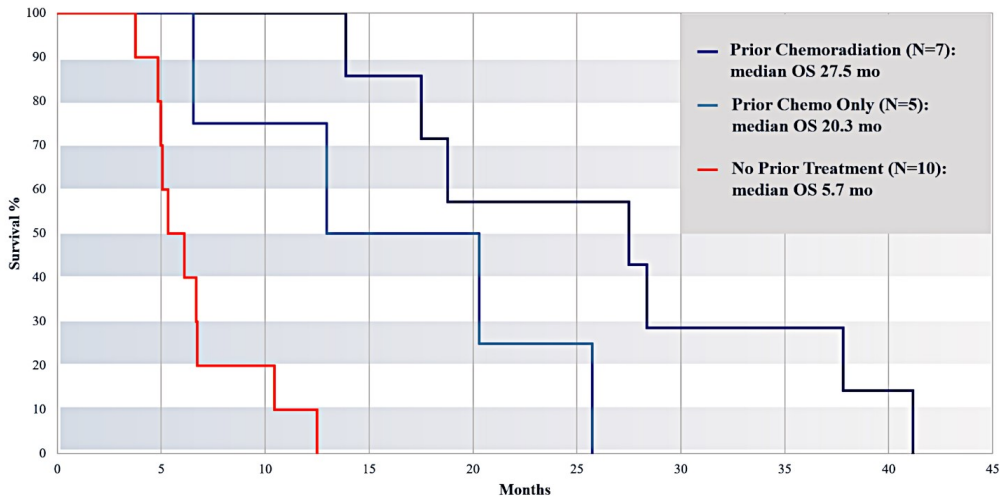


Figure 18 Survival as function of previous treatment received for RR2 registry study subjects. As in RR1 study, subjects with prior radiation and chemotherapy demonstrated longer survival than other subjects.

In summary the results of RR2 observational registry, build on the finding of the Phase 1/2 RenovoCath/Gem RR1 study, where 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 guide catheter to prevent arterial dissection, and 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.

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 registration clinical trial.

TIGeR-PaC Phase 3 Trial (RR3)

With completion of RR1 and RR2 we obtained FDA approval for Phase 3 IND study in Feb 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. Simultaneously in April 2018 we obtained Orphan drug designation for use of RenovoGem in patients with LAPC.

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 and Belgium.

The study design is 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. 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. The TIGeR-PaC SAP includes an interim analysis with the potential of early FDA approval or Breakthrough Status with a strong efficacy signal early in the study. 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

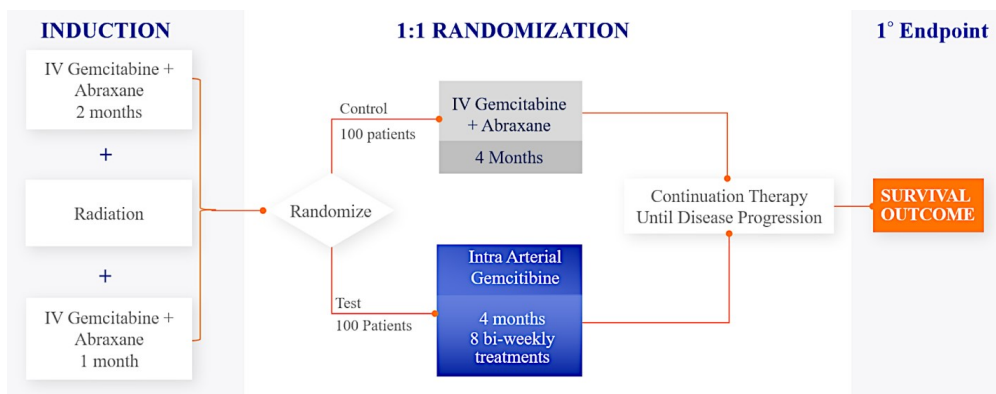


Figure 19 TIGeR-PaC Study Flowchart. All subjects undergo a 4-month induction phase that includes IV gemcitabine + Abraxane and radiation therapy. If the subjects are stable with LAPC post-induction, they are randomized 1:1 into control group (IV gemcitabine + Abraxane) versus treatment group (intra-arterial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

The study currently has 28 active clinical sites. As of April 30, 2021, 135 participants have enrolled in the study and ultimately approximately 340 participants are expected to be enrolled in the study with 200 participants randomized in the US and Europe. An interim analysis is planned when a total of 65 deaths (randomized patients) have been observed and is projected to be in the second half of 2022.

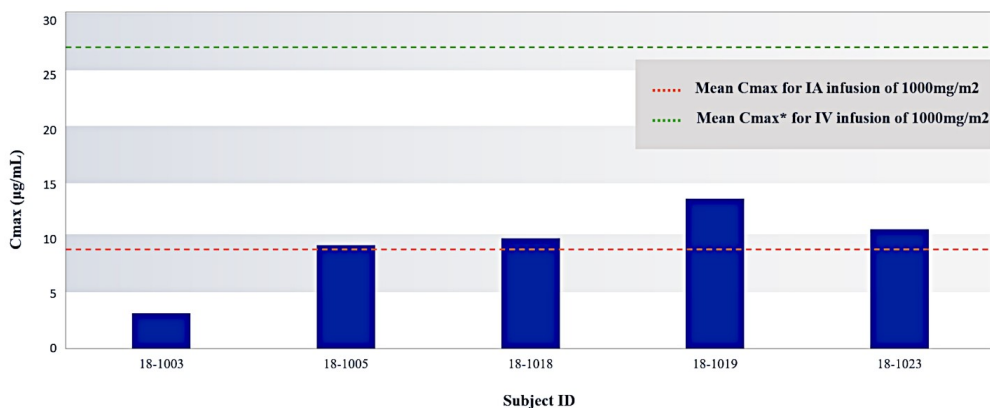
It is projected that enrollment and randomization of the entire cohort will be completed in 2023.

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 distinct PK from IV gemcitabine dosing. Furthermore, with local delivery of gemcitabine into the tissue via RenovoTAMP and drainage into the liver prior to systemic circulation, lower systemic levels of gemcitabine would be anticipated.

We are collecting blood samples for PK analysis in 15 patients from our TIGeR-PaC Phase 3 study (Figure 20, below). Our initial data on the first 5 patients demonstrate a 3-fold decrease in C_{max}, or maximum serum concentration of a drug, with RenovoTAMP compared to established levels for IV 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

HCCA 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, and extra-hepatic, or hilar. The HCCA subset of CCA patients are about 3000 cases per year. HCCA is a disease with an exceptionally poor prognosis.

HCCA Current Treatment Landscape and Limitations

Most patients with HCCA 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 HCCA; 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 both intrahepatic, within the liver, and hilar 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 1000mg/m² and cisplatin at 25mg/m². Reported median O.S. for patients on such a regimen (11.7 months) was greater than patients receiving gemcitabine alone (8.1 months). Commonly observed Grade 3-4 toxicity of this standard of care treatment 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 hilar cholangiocarcinoma. For this reason, a practice standard of care has not been established for hilar cholangiocarcinoma.

RenovoGem for the Treatment of HCCA

Similar to RenovoGem for LAPC, we believe that RenovoGem may overcome the current treatment limitations of HCCA. In this setting, patients with HCCA have several features that make them attractive for treatment via our RenovoTAMP therapy.

- 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
- The bile duct around the hilum is usually within 1-14mm (mean of 3.8 mm) of the hepatic artery: a reasonable target for RenovoTAMP therapy given the potential 4cm tissue penetration of drug

Clinical Development of RenovoGem in HCCA

BENEFICIAL Study Design and Rationale

The FDA granted us Orphan Drug Designation in June of 2020 for the treatment of CCA with RenovoTAMP. Shortly after the granted designation we began working on the BENEFICIAL study protocol. We intend to meet with the FDA to propose a phase 2/3 trial for approval of RenovoTAMP for HCCA and, if approved by the FDA, to initiate such a study in the first half of 2022.

We expect the study duration will be up to 4.5 years, with an estimated 30 months of enrollment and 2 years of follow-up to have 150 subjects enrolled and 100 subjects randomized. The study is a multi-center, open-label, randomized active-controlled study of subjects with hilar cholangiocarcinoma which is unresectable according to NCCN guidelines. We intend to conduct the study in up to 8 U.S. sites.

The primary endpoint of the study is time to treatment failure (progression or if the subject can no longer tolerate treatment) from randomization. Secondary endpoints include, but not limited to, overall survival, time to progression from randomization to radiologic progression, progression free survival and tumor response by RECIST 1.1 guidelines.

There are four phases to the study after screening: Induction, Randomization Treatment, Continuing Therapy and Survival follow-up. All subjects receive an initial four-month induction phase of IV chemotherapy (gemcitabine + cisplatin) and radiation. Subjects with stable or responding disease after approximately 3 months of induction therapy, and who are not surgical candidates, will then be randomized 1:1 to either 4 cycles (8 treatments) of RenovoTAMP or 5 cycles of IV chemotherapy in addition to the 3 received during induction. Subjects will receive capecitabine during continuing therapy after completion of randomization treatment without disease progression or treatment intolerance. Subjects will be followed for up to three years for survival.

Key inclusion criteria include biopsy proven cholangiocarcinoma within 6 weeks of consent, unresectable cholangiocarcinoma (stage 4A included), measurable disease as per RECIST 1.1 must be present, and ECOG Performance Status score of 0-1. Key exclusion criteria include contraindications to angiography and selective visceral catheterization, location of tumor more than 15mm from targeted IA therapy location as per imaging, cirrhosis (Child-Pugh > Class B7) and clinically evident ascites.

BENEFICIAL Study Flowchart

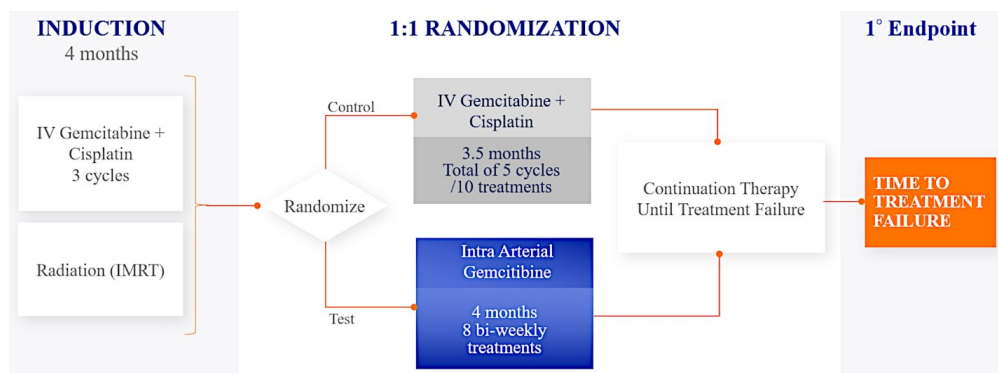


Figure 21 BENEFICIAL study flowchart. All subjects undergo a 4-month induction phase that includes IV gemcitabine + Cisplatin and radiation therapy. If the subjects are stable with LAPC post-induction, they are randomized 1:1 into control group (IV gemcitabine + Cisplatin) versus treatment group (intra-arterial gemcitabine via RenovoTAMP therapy). Subjects are then administered continuation therapy until treatment failure (cessation of continuation therapy, change in continuation therapy, progression, and/or death).

Market Opportunity

We are currently developing RenovoGem for LAPC, intend to develop it for HCCA, 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 can exceed \$1 billion based on a third-party market research analysis. The total cost of care of 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 U.S. 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. From third-party market research, a number of physicians mentioned a role for local therapy as an adjunct for systemic chemotherapy as well as for patients who decline systemic chemotherapy. Beyond pancreatic cancer, there are additional markets we will be exploring.

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.

Market Opportunity for RenovoTAMP

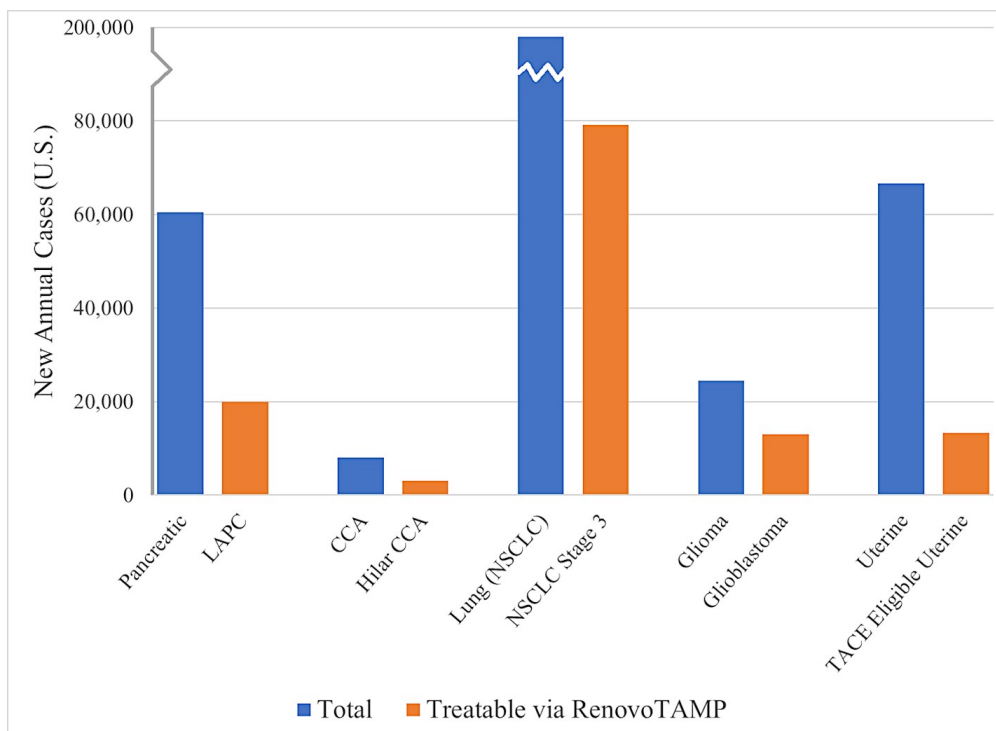


Figure 22 Market Opportunity of target cancers, showing overall incidence in blue, and those treatable via RenovoTAMP in orange.

- All Pancreatic Cancers compared to Locally Advanced Pancreatic Cancers (LAPC)
- All Cholangiocarcinoma (CCA) compared to Hilar 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

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 6 US patents issued, 1 European patent issued, and 1 patent pending in each of China, Japan, Europe, and India. In addition, we have two pending US patents, one of which is allowed, that we expect will be issued in the second or third quarter of 2021. 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.

Table 3 RenovoRx has Significant Patent Protection with 7 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	U.S. Utility patent	Methods: isolating splenic artery with 2 balloons (sliding inner catheter) Apparatus: 2 balloons, seal to isolate lumen, and infusion aperture	U.S. 8,821,476	January 25, 2033
Dual Balloon Methods and Apparatuses	14/870833 Filed: 9/30/2015	U.S. Utility patent	Apparatus: 2 balloons (sliding inner catheter), 2 ports for fluid handling	U.S. 9,463,304	December 2, 2030
Dual Balloon Methods and Apparatuses	14/293603 Filed: 6/2/2014	U.S. Utility patent	Kits for chemotherapy including catheter with 2 balloons, an infusion aperture and 2 ports	U.S. 9,457,171	April 16, 2031
Dual Balloon Methods and Apparatuses	15/351922 File: 11/15/2016	U.S. Utility patent	A two occlusion element, adjustable delivery apparatus having inner and outer catheter, seal to isolate lumen	U.S. 10,512,761	April 16, 2031
Dual Balloon Methods and Apparatuses	10/8351107 Filed: 12/2/2010	E.U. Utility patent, nationalized in BE, CH, DE, ES, FR, GB, IE, IT and NL	Apparatuses and Methods: 3 balloon catheters for isolating side branches	E.U. 2506913	December 2, 2030
Side Branch Isolation Device and Methods	14/958428 Filed: 12/3/2015	U.S. Utility patent	Methods delivering radiation to devascularize then TAMP	U.S. 10,099,040	December 3, 2035
Trans-Arterial Micro-Perfusion (TAMP)	15/807011 Filed: 11/8/2017	U.S. Utility patent		U.S., 10,695,543	August 28, 2038

Dual Balloon Methods and Apparatuses	16/685950 Filed: 11/15/2019	U.S. Utility patent (Pending application)	Methods of treating bile duct	PENDING	April 16, 2031*
Trans-Arterial Micro-Perfusion (TAMP)	16/685974 Filed: 11/15/2019	U.S. Utility patent (Pending application)	Devascularization in conjunction with TAMP	PENDING and ALLOWED	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*

We have additional market exclusivity protection with Orphan Drug Designation for seven years post-approval. Gemcitabine is generic; however, we have exclusivity for the intra-arterial route of administration. RenovoGem is regulated by the FDA as a novel 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 beyond the treatment of cancers in the liver.

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.

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.

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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

We rely on a single-source contract manufacturer, Medical Murray, North Barrington, IL, for the device component, RenovoCath, of the drug-device combination and 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 and amendments, or MDD, 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 contract manufacturer. Our European Union Notified Body, British Standards Institute (BSI), monitors compliance with the MDD 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 own 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 the 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.

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United States Regulatory Environment

In the US, the FDA regulates drug and device products 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. 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. Combination products where the drug provides the primary mechanism of action are often referred to as “drug-led combination” products.

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 current good manufacturing practice, or 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 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.

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.

Prior to initiating our currently ongoing Phase 3 clinical trial(s), we submitted a proposal for the design, execution and analysis under a SPA.

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. The FDA may deny approval of an NDA by issuing a Complete Response Letter, or CRL, if the applicable regulatory criteria are not satisfied. 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.

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.

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 LAPC and for HCCA.

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.

Other 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), 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, 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, lists conditions the FDA investigators believe may have violated cGMP 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 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, 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 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, 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, 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.

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.

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.

Reimbursement

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.

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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.

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. In addition, 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

As of April 30, 2021, we had 6 full-time employees. None of our employees is represented by a labor union or covered by a collective bargaining agreement. We believe our relationship with our employees is good. We have 8 key consultants in the areas of quality, regulatory, finance, legal, IT, clinical, and marketing.

Facilities

Our administrative headquarters is located at 4546 El Camino Real, Ste. 223, Los Altos, CA 94019. The office space is approximately 900 square feet, and the rent is \$3,600/month. We believe that our facilities are adequate for our operations.

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.

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MANAGEMENT, EXECUTIVE COMPENSATION AND CORPORATE GOVERNANCE

Directors and Executive Officers

The following sets forth information about our directors, director nominees, and executive officers as of the date of this prospectus:

Name	Age	Position
Shaun R. Bagai	44	Chief Executive Officer and Director
Paul Manners	70	Chief Financial Officer
Ramtin Agah	55	Chief Medical Officer, Founder, Director
Laurence J. Marton	77	Director
Una S. Ryan	79	Director
Maky Zanganeh	50	Director
Kristen Angela Macfarlane	56	Director
David Diamond	71	Director

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 new 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 which led 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 was selected to serve on our board of directors due to his tenure with our company and his industry experience.

Paul Manners. Mr. Manners has served as our Chief Financial Officer since July 2019. In addition, since 2011 he has held several positions for Sandstone Diagnostics, an early stage medical device company, and is currently Senior Director Finance. Previously, Mr. Manners was a VP Finance & Marketing in Chiron/Novartis' Diagnostic Division

from 2003 to 2010 and the Chief Financial Officer, VP Sales & Customer Service for Amira Medical from 1997 to 2002. In addition, he has previously held various accounting and finance positions in various units for Johnson & Johnson from 1973 until 1996. Mr. Manners received an MBA from Rider University and a BBA from Northeastern University.

Ramtin Agah, MD Dr. Agah has served as the Chief Medical Officer and Co-Founder of the Company since December 2009 and has acted as Chairman of the Board of Directors 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, Houston, Texas, and a Fellowship in Cardiology with U.C.S.F. in San Francisco, CA. He is a MD graduate of University of Texas Southwestern Medical School. Dr. Agah was selected to serve on our board of directors due to his tenure with our company and his industry experience.

Laurence J. Marton. Dr. Marton has served as our director since December 2012. Dr. Marton is currently the Executive Chairman of Omnio, Pharma, a role he began in July 2020. 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, Rapid Science, and the Bay Area American Committee for the Weizmann Institute of Science. In the for-profit sector, he serves on the Board of Directors of TOMA Biosciences, Microsonic Systems and Pathologica, is Chair of the Scientific Advisory Board of PharmaJet, and is on the Advisory Boards of Gem Pharmaceuticals and Silicom Ventures. 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. His research has resulted in more than 195 original publications, 60 scientific reviews and chapters, four books, and numerous patents. Dr. Marton received his MD from the Albert Einstein College of Medicine and his BA from Yeshiva University. Mr. Marton was selected to serve on our board of directors due to his tenure with our company and his industry experience.

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Una S. Ryan, PhD, OBE. Dr. Ryan has served as our director since 2013. Dr. Ryan is currently the Managing Director of Golden Seeds (Silicon Valley), an angel investing group focused on women-led companies since 2009. Her board positions include Cortexyme, Inc., Elemental Machines, and Cambridge America. From 2010 until 2013, Dr. Ryan acted as President and CEO of Diagnostics For All, a nonprofit organization developing inexpensive diagnostics for global health and agricultural uses. Previously, from 1993 to 2008, she was President and CEO of AVANT Immunotherapeutics, Inc. a company developing vaccines and immunotherapeutics for cancer, travelers, food safety, and global health, and also a member of its Board of Directors. Dr. Ryan has held a number of positions in academia, including Research Professor of Surgery at Washington University School of Medicine in St. Louis and Professor of Medicine at the University of Miami School of Medicine. She was also Chair of the Massachusetts Biotechnology Council, served on its Board, as well as the Biotechnology Industry Organization, New England Healthcare Institute, Board of Associates of the Whitehead Institute, Strategy & Policy Council of the MIT Center for Biomedical Innovation, Massachusetts Life Sciences Collaborative Leadership Council and the Goddard Council on science, technology, engineering and mathematics education. Dr. Ryan holds a PhD in Cellular and Molecular Biology from Cambridge University and BS degrees in Zoology, Microbiology and Chemistry from Bristol University. In 2007, Dr. Ryan received the Albert Einstein Award for outstanding achievement in the life sciences, and in 2009, she received an Honorary Doctor of Science degree from Bristol University. Dr. Ryan was selected to serve on our board of directors due to her tenure with our company and her industry experience.

Maky Zanganeh, DDS, MBA. Dr. Zanganeh has served as our director since 2018. Dr. Zanganeh has more than 16 years of strategic planning, management, corporate, clinical, business and marketing experience in the pharmaceutical, medical device and technology industries. She has been the Chief Operating Officer of Summit Therapeutics since 2020 and the Founder and Chief Executive Officer of Maky Zanganeh and Associates, Inc., an investment, consulting and management group since 2016. Previously, from 2008 to 2016, Dr. Zanganeh was the Chief Operating Officer at Pharmacyclics, Inc., where she oversaw all clinical, research, commercial and business-related matters. In addition, from 1997 to 2002 Dr. Zanganeh held senior and executive positions including International Product Manager for IRCAD-EITS, General Director Pos De Competitive for Therapeutic Innovation and President Director General (Chief Executive Officer) of Europe, Middle East and Africa and World-Wide Vice President of Training and Education for Computer Motion. Dr. Zanganeh's current directorships include Human Longevity Inc., Radial Medical and Pulse Biosciences. Dr. Zanganeh earned her Doctor of Dental Surgery and her Master of Business Administration in International Business in France. She is a licensed investment advisor (Series 65) and has her dentistry license. She earned the Fierce Biotech "2013 Top Women in Biotech" Award and the Ernst & Young Entrepreneur of the Year Award in 2013. Dr. Zanganeh was selected to serve on our board of directors due to her industry experience.

Kristen Angela Macfarlane. Ms. Macfarlane has served as our director since September 2018. She currently acts as Chief Executive Officer for Voyant Biotherapeutics, LLC, an early-stage biotech company dedicated to solving age-related macular degeneration since 2018. In addition to serving as CEO of ForSight Labs, LLC an ophthalmic incubator formed in 2005, from 2007 to 2016, from 2008 to 2016, Ms. Macfarlane served as the operating Chief Executive Officer for three ForSight companies, which included acting as a founding Chief Executive Officer through the acquisition of ForSight VISION4, Inc. (acquired by ROCHE), and ForSight VISION5, Inc., (Acquired by Allergan). Previously, Ms. Macfarlane served as Chief Technology Counsel to The Foundry, 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 and 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 the Fogarty Institute for Innovation and is a mentor in the Ferolyn Powell Leadership Program. Ms. Macfarlane was selected to serve on our board of directors due to her industry experience.

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 significant 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 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 also serves as a director of Oncolytics Biotech, Inc. Mr. Diamond previously served as a Board member for Kreston International (\$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 was selected to serve on our board of directors due to his extensive experience extensive experience as a strategic guide and oversight to CEOs and Boards of companies in the life sciences space.

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Family Relationships

There are no other family relationships among any of our officers or directors.

Involvement in Certain Legal Proceedings

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

Corporate Governance

The Board's Role in Risk Oversight

The board of directors oversees that the assets of our company are properly safeguarded, that the appropriate financial and other controls are maintained, and that our business is conducted wisely and in compliance with applicable laws and regulations and proper governance. Included in these responsibilities is the board's oversight of the various risks facing our company. In this regard, our board seeks to understand and oversee critical business risks. Our board does not view risk in isolation. Risks are considered in virtually every business decision and as part of our business strategy. Our board recognizes that it is neither possible nor prudent to eliminate all risk. Indeed, purposeful and appropriate risk-taking is essential for our company to be competitive on a global basis and to achieve its objectives.

While the board oversees risk management, company management is charged with managing risk. Management communicates routinely with the board and individual directors on the significant risks identified and how they are being managed. Directors are free to, and indeed often do, communicate directly with senior management.

Our board administers its risk oversight function as a whole by making risk oversight a matter of collective consideration. Once the board establishes committees, it is anticipated that much of the work will be delegated to such committees, which will meet regularly and report back to the full board. It is anticipated that the audit committee will oversee risks related to our financial statements, the financial reporting process, accounting and legal matters, that the compensation committee will evaluate the risks and rewards associated with our compensation philosophy and programs, and that the nominating and corporate governance committee will evaluate risk associated with management decisions and strategic direction.

Director Independence

Our board of directors has undertaken a review of the independence of each director. Based on information provided by each director concerning his background, employment and affiliations, our board of directors has determined that Mr. Marton, Mr. Diamond and Ms. Ryan, Zanganeh and Macfarlane do not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that each of these directors is "independent" as that term is defined under the listing standards of the Nasdaq Capital Market. In making these determinations, our board of directors considered the current and prior relationships that each non-employee director has with our company and all other facts and circumstances our board of directors deemed relevant in determining their independence, including the beneficial ownership of our capital stock by each non-employee director, and the transactions involving them described in the section titled "Certain Relationships and Related Person Transactions."

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Committees of the Board of Directors

Our board has established an audit committee, a compensation and nominating and corporate governance committee, each with its own charter that has been approved by the board. Upon completion of this offering, we intend to make each committee's charter available on our website at www.renovorx.com.

Our board of directors may, from time to time, designate one or more additional committees, which shall have the duties and powers granted to it by our board of directors.

Audit Committee

The members of our audit committee are Una Ryan and Laurence Marton. [] serves as chairperson of the committee. All members of our audit committee meet the independence requirements of Rule 10A-3 under the Exchange Act and the applicable rules of the Nasdaq Capital Market, or the Nasdaq rules. Our board of directors has determined that [] is an audit committee financial expert, as defined by the rules of the SEC, and satisfies the financial sophistication requirements of the Nasdaq rules.

The audit committee will oversee our accounting and financial reporting processes and the audits of the financial statements of our company.

The audit committee will be responsible for, among other things: (i) retaining and overseeing our independent registered public accounting firm; (ii) assisting the board in its oversight of the integrity of our financial statements, the qualifications, independence and performance of our independent registered public accounting firm and our compliance with legal and regulatory requirements; (iii) reviewing and approving the plan and scope of the internal and external audit; (iv) pre-approving any audit and non-audit services provided by our independent registered public accounting firm; (v) approving the fees to be paid to our independent registered public accounting firm; (vi) reviewing with our chief executive officer and chief financial officer and independent registered public accounting firm the adequacy and effectiveness of our internal controls; (vii) reviewing hedging transactions; and (viii) reviewing and assessing annually the audit committee's performance and the adequacy of its charter.

Compensation Committee

The members of our compensation committee are Maky Zanganeh and Kristen Angela Macfarlane. Maky Zanganeh serves as the chairperson of the committee. The compensation committee will assist the board in reviewing and approving the compensation structure, including all forms of compensation, relating to our directors and executive officers.

The compensation committee will be responsible for, among other things: (i) reviewing and approving the remuneration of our executive officers; (ii) reviewing the compensation of our independent directors; (iii) making recommendations to the board regarding equity-based and incentive compensation plans, policies and programs; and (iv) reviewing and assessing annually the compensation committee's performance and the adequacy of its charter.

Nominating and Corporate Governance Committee

The members of our nominating and governance committee are Una Ryan, Kristen Angela Macfarlane and Laurence Marton. Una Ryan serves as the chairperson of the committee. The nominating and corporate governance committee will assist the board of directors in selecting individuals qualified to become our directors and in determining the composition of the board and its committees.

The nominating and corporate governance committee will be responsible for, among other things: (i) identifying and evaluating individuals qualified to become members of the board by reviewing nominees for election to the board submitted by stockholders and recommending to the board director nominees for each annual meeting of stockholders and for election to fill any vacancies on the board, (ii) advising the board with respect to board organization, desired qualifications of board members, the membership, function, operation, structure and composition of committees (including any committee authority to delegate to subcommittees), and self-evaluation and policies, (iii) advising on matters relating to corporate governance and monitoring developments in the law and practice of corporate governance, (iv) overseeing compliance with our code of ethics, and (v) approving any related party transactions.

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The nominating and corporate governance committee's methods for identifying candidates for election to our board of directors (other than those proposed by our stockholders, as discussed below) will include the solicitation of ideas for possible candidates from a number of sources—members of our board of directors, our executives, individuals personally known to the members of our board of directors, and other research. The nominating and corporate governance committee may also, from time-to-time, retain one or more third-party search firms to identify suitable candidates.

In making director recommendations, the nominating and corporate governance committee may consider some or all of the following factors: (i) the candidate's

judgment, skill, experience with other organizations of comparable purpose, complexity and size, and subject to similar legal restrictions and oversight; (ii) the interplay of the candidate's experience with the experience of other board members; (iii) the extent to which the candidate would be a desirable addition to the board and any committee thereof; (iv) whether or not the person has any relationships that might impair his or her independence; and (v) the candidate's ability to contribute to the effective management of our company, taking into account the needs of our company and such factors as the individual's experience, perspective, skills and knowledge of the industry in which we operate.

Code of Business Conduct and Ethics

We plan to adopt a code of ethics that applies to all of our directors, officers and employees, including our principal executive officer, principal financial officer and principal accounting officer. Such code of ethics addresses, among other things, honesty and ethical conduct, conflicts of interest, compliance with laws, regulations and policies, including disclosure requirements under the federal securities laws, and reporting of violations of the code. Upon our listing on the Nasdaq Capital Market, our code of business conduct and ethics will be available under the Corporate Governance section of our website.

We will be required to disclose any amendment to, or waiver from, a provision of our code of ethics applicable to our principal executive officer, principal financial officer, principal accounting officer, controller, or persons performing similar functions. We intend to use our website as a method of disseminating this disclosure, as permitted by applicable SEC rules. Any such disclosure will be posted to our website within four business days following the date of any such amendment to, or waiver from, a provision of our code of ethics.

Executive and Director Compensation

As an emerging growth company under the JOBS Act we have opted to comply with the executive compensation disclosure rules applicable to "smaller reporting companies," which require compensation disclosure for our principal executive officer and the two most highly compensated executive officers (other than our principal executive officer) serving as executive officers at the end of our most recently completed fiscal year (collectively, our "Named Executive Officers"). This section describes the executive compensation program in place for our Named Executive Officers during the year ended December 31, 2020, who are the individuals who served as our principal executive officer and two most highly compensated executive officers.

This section discusses the material components of the executive compensation program for our executive officers who are named in the "Summary Compensation Table" below and the non-employee members of our board of directors. In 2020, our "Named Executive Officers" and their positions were:

- Shaun Bagai, Chief Executive Officer;
- Paul Manners, Chief Financial Officer; and
- Ramtin Agah, MD, Chief Medical Officer.

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2020 Summary Compensation Table

The following table sets forth information concerning the compensation of our Named Executive Officers for the year ended December 31, 2020 and 2019 ~~in~~ thousands).

Name & Principal Position	Year	Salary (\$)	Salary/ Bonus (\$)	Option Awards (\$)⁽¹⁾	Total (\$)
Shaun Bagai, CEO	2020	253			\$ 253
	2019	240	30		\$ 270
Paul Manners, CFO	2020	37			\$ 37
	2019	19		20	\$ 39
Ramtin Agah, MD, CMO	2020	120			\$ 120
	2019	78			\$ 78

- (1) The amount disclosed represents the aggregate grant date fair value of the award as calculated in accordance with ASC 718. The assumptions used in calculating the grant date fair value of the award disclosed in this column are set forth in the notes to our audited financial statements included elsewhere in this prospectus. This amount does not correspond to the actual value that may be recognized upon vesting of the award.

Compensation Arrangements with our Executive Officers

Shaun R. Bagai

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

Paul Manners

We entered into a consulting agreement in July 2019 with Paul Manners, our Chief Financial Officer that set forth the terms and conditions of the services he was to render. The agreement was amended in December 2020. The amended agreement establishes an hourly consulting rate of one hundred and fifty dollars (\$150) per hour. We also agreed to reimburse Mr. Manners for any reasonable out-of-pocket business expenses incurred in connection with the services, provided such expenses are approved in advance by us and fully documented our satisfaction. For the years ended December 31, 2019 and 2020 and the three months ended March 31, 2020 and 2021, we paid Mr. Manners \$19,000, \$37,000, \$12,000 and \$54,000, respectively.

Mr. Manners was also granted an option to purchase one hundred and forty thousand (140,000) shares of our common stock at the fair market value as determined by the Board as of the grant date, pursuant to our 2013 Equity Incentive Plan. The option will fully vest July 9, 2021.

Ramtin Agah

In January 2013, we entered into a consulting agreement with Dr. Agah, one of our co-founders, whereby he would provide consulting services as our Chief Medical Officer by overseeing Company-sponsored clinical trials. The agreement is for a term of 15 years with automatic one-year renewals. The sole compensation payable to Dr. Agah

is the continued vesting of shares of common stock held by Dr. Agah. In July 2018, he was awarded options for the purchase of 200,000 shares of our common stock with 25% vested after one year and the remaining 75% vesting ratably over 36 months. We entered into an amendment to the agreement with Dr. Agah in 2019 providing cash compensation to Dr. Agah of \$10,000 per month for additional services. Consulting fees paid to Dr. Agah were \$78,000, \$120,000, \$30,000 and \$30,000 for the years ended December 31, 2019 and 2020 and March 31, 2020 and 2021, respectively. Upon consummation of the offering, Dr. Agah's compensation will be \$260,000 per year provided he spends 60% of his time on Company matters. On June 7, 2021 we granted to Dr. Agah options to purchase 100,000 shares of common stock at an exercise price of \$0.49 per share which vests in 24 equal consecutive monthly installments commencing on June 14, 2021.

Director Compensation

None of our non-employee directors received option awards during the year ended December 31, 2020. We did not compensate our board during the last fiscal year. Under our non-employee director compensation policy, each non-employee director received the following annual compensation for his or her service:

	Annual retainer non- employee board member	Committee membership		
		Audit	Compensation	Corporate Governance/Nominating
Chair	\$ 36,000	\$ 15,000	\$ 10,000	\$ 10,000
Member	\$ 36,000	\$ 5,000	\$ 5,000	\$ 5,000

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Equity compensation

Outstanding equity awards at March 31, 2021

The following table sets forth information concerning the outstanding equity awards held by each of our Named Executive Officers as of March 31, 2021:

Name	Option Grant Date	Option Awards ⁽¹⁾			Option Expiration Date
		Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price (\$)	
Shaun Bagai	August 6, 2014 ⁽²⁾	1,230,285	0	\$ 0.03	August 5, 2024
	May 19, 2017 ⁽³⁾	281,250	18,750	\$ 0.10	May 18, 2027
	July 11, 2018 ⁽⁴⁾	437,500	162,500	\$ 0.13	July 10, 2028
Paul Manners	February 5, 2020 ⁽⁵⁾	0	23,334	\$ 0.14	February 4, 2030
Ramtin Agah, MD	May 19, 2017 ⁽²⁾	300,000	0	\$ 0.10	May 18, 2027
	July 11, 2018 ⁽⁶⁾	145,833	54,167	\$ 0.13	July 10, 2028

- (1) Each of the outstanding equity awards was granted pursuant to our 2013 Equity Incentive Plan.
- (2) The shares underlying this option are fully vested and immediately exercisable.
- (3) The shares underlying this option vest, subject to Mr. Bagai's continued role as a service provider to us, 25% on the one-year anniversary of the June 1, 2017 vesting commencement date and then in 48 equal monthly installments.
- (4) The shares underlying this option vest, subject to Mr. Bagai's continued role as a service provider to us, 25% on the one-year anniversary of the April, 19, 2018 vesting commencement date and then in 48 equal monthly installments.
- (5) The shares underlying this option vest, subject to Mr. Manner's continued role as a service provider to us, 25% on the six-month anniversary of the July 9, 2019 vesting commencement date and then in 24 equal monthly installments. On March 19, 2021 Mr. Manners exercised 116,666 options.
- (6) The shares underlying this option vest, subject to Dr. Agah's continued role as a service provider to us, 25% on the one-year anniversary of the April 19, 2018 vesting commencement date and then in 36 equal monthly installments.

Incentive plan

Equity Incentive Plans

2021 Omnibus Equity Incentive Plan

In [] 2021 our board of directors adopted, and our stockholders approved, the RenovoRx, Inc. 2021 Omnibus Equity Incentive Plan, or the 2021 Plan, which will become effective immediately prior to the closing of this offering. We intend to use the 2021 Plan following the closing of this offering to provide incentives that will assist us to attract, retain, and motivate employees, including officers, consultants, and directors. We may provide these incentives through the grant of stock options, stock appreciation rights, restricted stock, RSUs, performance shares, and units and other cash-based or share-based awards

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Shares Available

The maximum number of shares of common stock reserved and available for issuance under the 2021 Plan will be equal to the sum of (i) _____ shares of common stock; (ii) the number of shares of common stock reserved, but unissued under the 2013 Plan, and (iii) the number of shares of common stock underlying forfeited awards under the 2013 Plan; provided that shares of common stock issued under the 2021 Plan with respect to an Exempt Award will not count against the share limit. We use the term "Exempt Award" to mean (i) an award granted in assumption of, or in substitution for, outstanding awards previously granted by another business entity acquired by us or any of our subsidiaries or with which we or any of our subsidiaries merge, or (ii) an award that a participant purchases at fair market value.

Administration

The 2021 Plan is administered by the Board or by one or more committees of directors appointed by the Board (the “**Administrator**”). The Board may delegate different levels of authority to different committees with administrative and grant authority under the 2021 Plan. Any committee delegated administrative authority under the 2021 Plan may further delegate its authority under the Plan to another committee of directors, and any such delegate shall be deemed to be an Administrator of the 2021 Plan. The Administrator comprised solely of directors may also delegate, to the extent permitted by Section 157 of the Delaware General Corporation Law and any other applicable law, to one or more officers of the Company, its powers under this Plan (a) to designate Eligible Persons who will receive grants of awards under this Plan, and (b) to determine the number of shares subject to, and the other terms and conditions of, such awards. It is anticipated that the Administrator (either generally or with respect to specific transactions) will be constituted so as to comply, as necessary or desirable, with the requirements of Section 162(m) of Internal Revenue Code of 1986, as amended (the “**Code**”), and Rule 16b-3 promulgated under the Exchange Act.

Eligibility

Awards may be granted pursuant to the 2021 Plan only to persons who are eligible persons. Under the 2021 Plan, “Eligible Person” means any person who is either: (a) an officer (whether or not a director) or employee of the Company or one of its subsidiaries; (b) a director of the Company or one of its subsidiaries; or (c) a consultant who renders bona fide services to the Company or one of its subsidiaries; provided, however, that Incentive Stock Options (“**ISOs**”) may be granted only to employees.

Awards

The 2021 Plan permits the grant of: (a) stock options, which may be intended as ISOs or as nonqualified stock options (options not meeting the requirements to qualify as ISOs); (b) stock appreciation rights (“**SARs**”); (c) restricted stock; (d) restricted stock units; (e) cash incentive awards; or (f) other awards, including: (i) stock bonuses, performance stock, performance units, dividend equivalents, or similar rights to purchase or acquire shares, whether at a fixed or variable price or ratio related to the common stock, upon the passage of time, the occurrence of one or more events, or the satisfaction of performance criteria or other conditions, or any combination thereof; or (ii) any similar securities with a value derived from the value of or related to the common stock and/or returns thereon.

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Consideration for Awards

The purchase price for any award granted under the 2021 Plan or the common stock to be delivered pursuant to any such award, as applicable, may be paid by means of any lawful consideration as determined by the Administrator, including, without limitation, one or a combination of the following methods:

- services rendered by the recipient of such award;
- cash, check payable to the order of the Company, or electronic funds transfer;
- notice and third party payment in such manner as may be authorized by the Administrator;
- the delivery of previously owned and fully vested shares of common stock;
- by a reduction in the number of shares otherwise deliverable pursuant to the award; or
- subject to such procedures as the Administrator may adopt, pursuant to a “cashless exercise” with a third party who provides financing for the purposes of (or who otherwise facilitates) the purchase or exercise of awards.

Certain Federal Tax Consequences

The following summary of the federal income tax consequences of the 2021 Plan transactions is based upon federal income tax laws in effect as of April 2, 2021. This summary does not purport to be complete, and does not discuss state, local or non-U.S. tax consequences.

Nonqualified Stock Options. The grant of a nonqualified stock option under the 2021 Plan will not result in any federal income tax consequences to the participant or to the Company. Upon exercise of a nonqualified stock option, the participant will recognize ordinary compensation income equal to the excess of the fair market value of the shares of Common stock at the time of exercise over the option exercise price. If the participant is an employee, this income is subject to withholding for federal income and employment tax purposes. The Company is entitled to an income tax deduction in the amount of the income recognized by the participant, subject to possible limitations imposed by the Code, including Section 162(m) thereof. Any gain or loss on the participant’s subsequent disposition of the shares will be treated as long-term or short-term capital gain or loss, depending on the sales proceeds received and whether the shares are held for more than one year following exercise. The Company does not receive a tax deduction for any subsequent capital gain.

Incentive Options. The grant of an ISO under the 2021 Plan will not result in any federal income tax consequences to the participant or to the Company. A participant recognizes no federal taxable income upon exercising an ISO (subject to the alternative minimum tax rules discussed below), and the Company receives no deduction at the time of exercise. In the event of a disposition of stock acquired upon exercise of an ISO, the tax consequences depend upon how long the participant has held the shares. If the participant does not dispose of the shares within two years after the ISO was granted, nor within one year after the ISO was exercised, the participant will recognize a long-term capital gain (or loss) equal to the difference between the sale price of the shares and the exercise price. The Company is not entitled to any deduction under these circumstances.

If the participant fails to satisfy either of the foregoing holding periods (referred to as a “disqualifying disposition”), he or she will recognize ordinary compensation income in the year of the disposition. The amount of ordinary compensation income generally is the lesser of (i) the difference between the amount realized on the disposition and the exercise price or (ii) the difference between the fair market value of the stock at the time of exercise and the exercise price. Such amount is not subject to withholding for federal income and employment tax purposes, even if the participant is an employee of the Company. Any gain in excess of the amount taxed as ordinary income will generally be treated as a short-term capital gain. The Company, in the year of the disqualifying disposition, is entitled to a deduction equal to the amount of ordinary compensation income recognized by the participant, subject to possible limitations imposed by the Code, including Section 162(m) thereof.

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The “spread” under an ISO — i.e., the difference between the fair market value of the shares at exercise and the exercise price — is classified as an item of adjustment in the year of exercise for purposes of the alternative minimum tax. If a participant’s alternative minimum tax liability exceeds such participant’s regular income tax liability, the participant will owe the alternative minimum tax liability.

Restricted Stock. Restricted stock is generally taxable to the participant as ordinary compensation income on the date that the restrictions lapse (i.e. the date that the stock vests), in an amount equal to the excess of the fair market value of the shares on such date over the amount paid for such stock (if any). If the participant is an employee, this income is subject to withholding for federal income and employment tax purposes. The Company is entitled to an income tax deduction in the amount of the ordinary income recognized by the participant, subject to possible limitations imposed by the Code, including Section 162(m) thereof. Any gain or loss on the participant’s subsequent disposition of the shares will be treated as long-term or short-term capital gain or loss treatment depending on the sales price and how long the stock has been held since the restrictions lapsed. The Company does not receive a tax deduction for any subsequent gain.

Participants receiving restricted stock awards may make an election under Section 83(b) of the Code (**Section 83(b) Election**) to recognize as ordinary compensation

income in the year that such restricted stock is granted, the amount equal to the excess of the fair market value on the date of the issuance of the stock over the amount paid for such stock. If such an election is made, the recipient recognizes no further amounts of compensation income upon the lapse of any restrictions and any gain or loss on subsequent disposition will be long-term or short-term capital gain or loss to the recipient. The Section 83(b) Election must be made within 30 days from the time the restricted stock is issued.

Other Awards. Other awards (such as restricted stock units) are generally treated as ordinary compensation income as and when common stock or cash are paid to the participant upon vesting or settlement of such awards. If the participant is an employee, this income is subject to withholding for income and employment tax purposes. The Company is generally entitled to an income tax deduction equal to the amount of ordinary income recognized by the recipient, subject to possible limitations imposed by the Code, including Section 162(m) thereof.

Section 162(m) Limitation. In general, under Section 162(m), income tax deductions of publicly-held corporations may be limited to the extent total compensation (including base salary, annual bonus, stock option exercises and non-qualified benefits paid) for certain executive officers exceeds \$1 million (less the amount of any “excess parachute payments” as defined in Section 280G of the Code) in any one year. Prior to the Tax Cuts and Jobs Act of 2017 (the “TCJA”), covered employees generally consisted of our Chief Executive Officer and each of the next three highest compensated officers serving at the end of the taxable year other than our Chief Financial Officer, and compensation that qualified as “performance-based” under Section 162(m) was exempt from this \$1 million deduction limitation. As part of the TCJA, the ability to rely on this exemption was, with certain limited exceptions, eliminated; in addition, the definition of covered employees was expanded to generally include all named executive officers. Certain awards under the 2013 Plan granted prior to November 2, 2017 may be grandfathered from the changes made by the TCJA under certain limited transition relief, however, for grants after that date and any grants which are not grandfathered, we will no longer be able to take a deduction for any compensation in excess of \$1 million that is paid to a covered employee. There is no guarantee that we will be able to take a deduction for any compensation in excess of \$1 million that is paid to a covered employee under the 2013 Plan.

Amended and Restated 2013 Equity Incentive Plan

The 2013 Plan was originally adopted by our board of directors and approved by our stockholders in January 23, 2013. The maximum aggregate number of shares of common stock that may be issued under the 2013 Plan is 6,606,504. Upon the closing of this offering, our board of directors will terminate the 2013 Plan and we will not grant any further awards under such plan, but the 2013 Plan will continue to govern outstanding awards granted thereunder. Our compensation committee administers the 2013 Plan and has the authority, among other things, to construe and interpret the terms of the 2013 Plan and awards granted thereunder.

On January 23, 2013, our Board of Directors adopted the 2013 Equity Incentive Plan, or the 2013 Plan. The following summary describes the material terms of the 2013 Plan. This summary is not a complete description of all provisions of the 2013 Plan and is qualified in its entirety by reference to the 2013 Plan, which is filed as an exhibit to the registration statement of which this prospectus is a part.

The purpose of the 2013 Plan is to secure and retain the services of the eligible recipients, to provide incentives for such persons to exert maximum efforts for the success of the Company, and to provide a means by which such eligible recipients may be given an opportunity to benefit from increases in value of the common stock of the Company.

Administration. The plan is administered by the Board. The Board shall have authority in its discretion to determine the eligible persons to whom, and the time or times at which, awards may be granted, the number of shares, units or other rights subject to each award, the exercise, base or purchase price of an award (if any), the time or times at which an award will become vested, exercisable or payable, the performance criteria, performance goals and other conditions of an award, the duration of the award, and all other terms of the award, including the fair market value thereof.

Available shares. The maximum aggregate number of shares of common stock which may be issued under all awards granted to participants under the plan initially shall be 6,346,504 shares. All 6,346,504 of such authorized shares initially available may be issued in respect of incentive stock options.

Eligibility for participation. An incentive stock option may only be granted to an employee of ours or any subsidiary of ours. Awards other than incentive stock options may be granted to employees, directors and consultants.

Types of awards. The 2013 Plan provides for the grant of nonqualified stock options, incentive stock options (“ISOs”), stock appreciation rights (“SARs”), restricted stock and stock units.

- **Stock options and SARs.** The Board may grant stock options, including ISOs, and SARs. A stock option is a right entitling the holder to acquire our common shares upon payment of the applicable exercise price. A SAR is a right entitling the holder upon exercise to receive an amount (payable in cash or shares of equivalent value) equal to the excess of the fair market value of the shares subject to the right over the base value from which appreciation is measured. The exercise price of each stock option, and the base value of each SAR, granted under the 2013 Plan shall be no less than 100% of the fair market value of a share of common stock on the date of grant. Each stock option and SAR will have a maximum term of not more than ten years from the date of grant.

- **Restricted and unrestricted stock and stock units.** The administrator of the 2013 Plan may grant awards of shares, stock units, restricted stock and restricted stock units. A stock unit is an unfunded and unsecured promise, denominated in shares, to deliver shares or cash measured by the value of shares in the future, and a restricted stock unit is a stock unit that is subject to the satisfaction of specified performance or other vesting conditions. Restricted stock are shares subject to restrictions requiring that they be redelivered or forfeited to the company if specified conditions are not satisfied.

Change in control. An award under the 2013 Plan may be subject to additional acceleration of vesting and exercisability upon or after a ‘Change in Control’ as may be provided in the applicable award agreement for such stock award or as may be provided in any other written agreement between the Company and the participant, but in the absence of such provision, no such acceleration shall occur.

Stockholder rights. Except as otherwise provided in the applicable award agreement, and with respect to an award of restricted stock, a participant will have no rights as a stockholder with respect to shares of our common stock covered by any award until the participant becomes the record holder of such shares.

Amendments and termination. The Board of Directors may suspend or terminate the 2013 Plan at any time and may amend the 2013 Plan at any time and from time to time in such respects as the Board of Directors may deem advisable or in our best interests; provided, however, that stockholder approval is required for any amendment to the 2013 Plan that (i) increases the number of shares of common stock available for issuance under the 2013 Plan, or (ii) changes the persons or class of persons eligible to receive awards under the 2013 Plan.

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

Based solely upon information made available to us, the following table sets forth information regarding the beneficial ownership of our common stock as of the date of this prospectus, held by: (i) each director and director nominees; (ii) each of the named executive officers; (iii) all of our directors and executive officers as a group; and (iv) each additional person or group who is known by us to own beneficially more than 5% of our common stock. 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.

The percentage of shares beneficially owned is computed on the basis of 11,357,661 shares of our common stock outstanding as of March 31, 2021. Shares of our common stock that a person has the right to acquire within 60 days after March 31, 2021 are deemed outstanding for purposes of computing the percentage ownership of the person holding such rights, but are not deemed outstanding for purposes of computing the percentage ownership of any other person, except with respect to the percentage ownership of all directors and executive officers as a group.

Name of Beneficial Owner	Number of Shares Beneficially Owned Prior to Offering	Percentage of Shares Beneficially Owned	
		Prior to Offering	After Offering
5% or Greater Stockholders			
Kamran Najmabadi ⁽¹⁾	5,225,000	44.6	
Executive Officers and Directors			
Shaun R. Bagai ⁽²⁾	1,992,785	14.9	
Paul Manners ⁽³⁾	128,333	1.1	
Ramtin Agah ⁽⁴⁾	5,329,166	45.1	
Laurence J. Marton ⁽⁵⁾	366,256	3.1	
Una S. Ryan ⁽⁶⁾	53,333	*	
Maky Zanganeh ⁽⁷⁾	106,666	*	
Kristen Angela Macfarlane ⁽⁸⁾	106,666	*	
Directors and Officers as a Group (7 persons)	8,083,205	55.9	

* Represents less than 1% of the beneficial ownership of the outstanding shares of our common stock.

- (1) Consists of 4,875,000 shares held of record by Mr. Najmabadi, our founder and technical engineering advisor, and 350,000 shares subject to options exercisable within 60 days of April 1, 2021. The address for Mr. Najmabadi is c/o RenovoRx, 4546 El Camino Real, Ste. B1, Los Altos, CA 94022.
- (2) Consists of 1,992,785 shares subject to options exercisable within 60 days of April 1, 2021 held by Mr. Bagai.
- (3) Consists of 116,666 shares held of record by Mr. Manners and 11,167 shares subject to options exercisable within 60 days of April 1, 2021.
- (4) Consists of 4,875,000 shares held of record by Dr. Agah and 454,166 shares subject to options exercisable within 60 days of April 1, 2021.
- (5) Consists of 366,256 shares subject to options exercisable within 60 days of April 1, 2021 held by Dr. Marton.
- (6) Consists of 53,333 shares subject to options exercisable within 60 days of April 1, 2021 held by Dr. Ryan.
- (7) Consists of 106,666 shares subject to options exercisable within 60 days of April 1, 2021 held by Dr. Zanganeh.
- (8) Consists of 106,666 shares subject to options exercisable within 60 days of April 1, 2021 held by Ms. Macfarlane.

CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

The following includes a summary of transactions since January 1, 2019 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, 2020 and 2019, 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 "Executive and Director Compensation." We also describe below certain other transactions with our directors, executive officers, and stockholder.

In January 2013, we entered into an agreement, or the Agreement, with Dr. Agah, one of our co-founders, whereby he would provide consulting services as our Chief Medical Officer by overseeing Company-sponsored clinical trials. The Agreement is for a term of 15 years with automatic one-year renewals. The sole compensation payable to Dr. Agah was continued vesting of shares of common stock held by Dr. Agah. We entered into an amendment to the Agreement in 2019 providing cash compensation to Dr. Agah of \$10,000 per month for additional services. Consulting fees paid to Dr. Agah were \$78,000, \$120,000 and \$30,000 for the years ended December 31, 2019 and 2020 and the three months ended March 31, 2021, respectively. On June 7, 2021 we granted to Dr. Agah options to purchase 100,000 shares of common stock at an exercise price of \$0.49 per share which vests in 24 equal consecutive monthly installments commencing on June 14, 2021.

In July 2019, we entered into a consulting agreement, the CFO Agreement, with the Mr. Manners, our Chief Financial Officer. In February 2020, we granted Mr. Manners an option to purchase 140,000 shares of common stock, of which 25% were vested upon grant and the remaining 75% vested ratably over 18 months. We entered into an amendment to the CFO Agreement in December 2020 providing for cash compensation of \$150 per hour. Consulting fees paid to Mr. Manners were \$19,000, \$37,000 and \$54,000 for the years ended December 31, 2019 and 2020 and the three months ended March 31, 2021, respectively.

Mr. Kamran Najmabadi, another 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 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. 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 of directors intends to adopt a written related person transaction policy, to be effective upon the closing of this offering, setting forth the policies and procedures for the review and approval or ratification of related person transactions. This policy will cover, 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 as of December 31, 2019 and 2020 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

DESCRIPTION OF SECURITIES

General

Upon completion of this offering, our authorized capital stock will consist of _____ shares of common stock, par value \$0.001 per share, and _____ shares of preferred stock, par value \$0.001 per share.

As of March 31, 2021, there were 11,415,994 shares of common stock issued and outstanding. In addition, as of March 31, 2021, the following series of convertible preferred stock was authorized and issued and outstanding, which shares of preferred stock are convertible into an aggregate of 17,677,353 shares of common stock upon closing of this offering.

Preferred Series	Shares Authorized	Shares Issued and Outstanding	Liquidation Value
B	12,611,461	7,928,359	\$ 8,745,000
A-3	2,660,230	2,660,230	2,227,000
A-2	3,546,095	3,546,095	1,150,000
A-1	3,542,669	3,542,669	660,000
	<u>22,360,455</u>	<u>17,677,353</u>	<u>\$ 12,782,000</u>

The following description of our capital stock and provisions of our Second Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws to be effective upon the completion of this offering is only a summary. You should also refer to our Second Amended and Restated Certificate of Incorporation, a copy of which is filed as an exhibit to the registration statement of which this prospectus is a part, and our Amended and Restated Bylaws, a copy of which is filed as an exhibit to the registration statement of which this prospectus is a part.

Common Stock

Voting

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, 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.

Preferred Stock

Our board of directors will have the authority, without further action by the stockholders, to issue up to _____ 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. At present, we have no plans to issue any shares of preferred stock following this offering.

Exclusive Forum

Our Sixth Amended and Restated Certificate of Incorporation to be effective upon completion of this offering 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 to be effective upon completion of this offering, 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 to be effective upon completion of this offering provide 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 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.

Anti-Takeover Effects of Delaware law and Our Sixth Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws

The provisions of Delaware law, our Sixth Amended and Restated Certificate of Incorporation and our Amended and Restated Bylaws to be adopted upon the closing of this offering, described below 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 Delaware General Corporation Law, 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 stockholder, 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.

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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 beneficially owned by the interested stockholder; or
- the receipt by the interested stockholder of the benefit of any loss, 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 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.

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 the close of business 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 the close of business on the 120th day prior to such annual meeting and not later than the close of business 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.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is [].

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SHARES ELIGIBLE FOR FUTURE SALE

Upon completion of this offering, we will have [] shares of common stock issued and outstanding. All of the shares sold in this offering will be freely transferable without restriction under the Securities Act unless purchased by one of our affiliates as that term is defined in Rule 144 under the Securities Act, which generally includes directors, executive officers and 10% stockholders. Sales of substantial amounts of our shares in the public market could adversely affect prevailing market prices of our shares.

All outstanding shares prior to this offering are “restricted securities” as that term is defined in Rule 144 and may be sold only if they are sold pursuant to an effective registration statement under the Securities Act or an exemption from the registration requirements of the Securities Act such as those provided in Rules 144 and 701 promulgated under the Securities Act, which rules are summarized below. Restricted shares may also be sold outside of the United States in accordance with Regulation S under the Securities Act. This prospectus may not be used in connection with any resale of our shares acquired in this offering by our affiliates.

Rule 144

In general, under Rule 144 of the Securities Act, a person or entity that has beneficially owned our common stock for at least six months and is not our “affiliate” will be entitled to sell our common stock, subject only to the availability of current public information about us, and will be entitled to sell shares held for at least one year without any restriction. A person or entity that is our “affiliate” and has beneficially owned our common stock for at least six months will be able to sell, within a rolling three month period, the number of shares that does not exceed the greater of the following:

- (i) 1% of the then outstanding common stock, which immediately after this offering will equal approximately [] shares if the maximum number of shares being offered by us; and
- (ii) the average weekly trading volume of our common stock on the Nasdaq Capital Market during the four calendar weeks preceding the date on which notice of the sale is filed with the SEC.

Sales by affiliates under Rule 144 must be made through unsolicited brokers’ transactions. They are also subject to manner of sale provisions, notice requirements and the availability of current public information about us.

Rule 701

In general, under Rule 701 of the Securities Act as currently in effect, each of our employees, directors or consultants who purchases our common stock from us pursuant to a compensatory stock or option plan or other written agreement relating to compensation is eligible to resell such common stock 90 days after we become a reporting company under the Exchange Act in reliance on Rule 144, but without compliance with some of the restrictions, such as the holding period, contained in Rule 144. However, the Rule 701 shares would remain subject to lock-up arrangements and would only become eligible for sale when the lock-up period expires.

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MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES TO NON-U.S. HOLDERS OF THE COMPANY’S COMMON STOCK

The following is a summary of the material U.S. federal income tax consequences to non-U.S. holders (as defined below) of the ownership and disposition of the Company’s common stock but does not purport to be a complete analysis of all the potential tax considerations relating thereto. This summary is based upon the provisions of the Internal Revenue Code of 1986, as amended, or the Internal Revenue Code, Treasury regulations promulgated thereunder, administrative rulings and judicial decisions, all as of the date hereof. These authorities may be changed, possibly retroactively, so as to result in U.S. federal income tax consequences different from those set forth below. No ruling on the U.S. federal, state, or local tax considerations relevant to the Company’s operations or to the purchase, ownership or disposition of its shares, has been requested from the IRS or other tax authority. No assurance can be given that the IRS would not assert, or that a court would not sustain, a position contrary to any of the tax consequences described below.

This summary also does not address the tax considerations arising under the laws of any non-U.S., state or local jurisdiction, or under U.S. federal gift and estate tax laws, except to the limited extent set forth below. In addition, this discussion does not address tax considerations applicable to an investor’s particular circumstances or to investors that may be subject to special tax rules, including, without limitation:

- banks, insurance companies or other financial institutions, regulated investment companies or real estate investment trusts;
- persons subject to the alternative minimum tax or Medicare contribution tax on net investment income;
- tax-exempt organizations or governmental organizations;
- controlled foreign corporations, passive foreign investment companies and corporations that accumulate earnings to avoid U.S. federal income tax;
- brokers or dealers in securities or currencies;
- traders in securities that elect to use a mark-to-market method of accounting for their securities holdings;
- persons that own, or are deemed to own, more than five percent of the Company’s capital stock (except to the extent specifically set forth below);
- US expatriates and certain former citizens or long-term residents of the United States;
- partnerships or entities classified as partnerships for U.S. federal income tax purposes or other pass-through entities (and investors therein);
- persons who hold the Company’s common stock as a position in a hedging transaction, “straddle,” “conversion transaction” or other risk reduction transaction or integrated investment;
- persons who hold or receive the Company’s common stock pursuant to the exercise of any employee stock option or otherwise as compensation;
- persons who do not hold the Company’s common stock as a capital asset within the meaning of Section 1221 of the Internal Revenue Code; or
- persons deemed to sell the Company’s common stock under the constructive sale provisions of the Internal Revenue Code.

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In addition, if a partnership or entity classified as a partnership for U.S. federal income tax purposes holds the Company’s common stock, the tax treatment of a partner generally will depend on the status of the partner and upon the activities of the partnership. Accordingly, partnerships that hold the Company’s common stock, and partners in such partnerships, should consult their tax advisors.

You are urged to consult your tax advisor with respect to the application of the U.S. federal income tax laws to your particular situation, as well as any tax consequences of the purchase, ownership and disposition of the Company’s common stock arising under the U.S. federal estate or gift tax rules or under the laws of any state, local, non-U.S., or other taxing jurisdiction or under any applicable tax treaty.

For purposes of this discussion, you are a non-U.S. holder (other than a partnership) if you are any holder other than:

- an individual citizen or resident of the United States (for U.S. federal income tax purposes);
- a corporation or other entity taxable as a corporation created or organized in the United States or under the laws of the United States, any state thereof, or the District of Columbia;
- an estate whose income is subject to U.S. federal income tax regardless of its source; or
- a trust (x) whose administration is subject to the primary supervision of a U.S. court and which has one or more “U.S. persons” (within the meaning of Section 7701(a) (30) of the Internal Revenue Code) who have the authority to control all substantial decisions of the trust or (y) which has made a valid election to be treated as a U.S. person

Distributions

As described in “Dividend Policy,” we have never declared or paid cash dividends on our common stock and does not anticipate paying any dividends on our common stock in the foreseeable future. However, if we do make distributions on our common stock, those payments will constitute dividends for U.S. tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. To the extent those distributions exceed both our current and accumulated earnings and profits, they will constitute a return of capital and will first reduce your basis in our common stock, but not below zero, and then will be treated as gain from the sale of stock as described below under “—Gain on Disposition of Common Stock.”

Subject to the discussion below on effectively connected income, backup withholding and foreign accounts, any dividend paid to a non-U.S. holder generally will be subject to U.S. withholding tax either at a rate of 30% of the gross amount of the dividend or such lower rate as may be specified by an applicable income tax treaty. In order to receive a reduced treaty rate, a non-U.S. holder must provide us with an IRS Form W-8BEN, IRS Form W-8BEN-E, or other appropriate version of IRS Form W-8 certifying qualification for the reduced rate. A non-U.S. holder of shares of our common stock eligible for a reduced rate of U.S. withholding tax pursuant to an income tax treaty may obtain a refund of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS. If the non-U.S. holder holds the stock through a financial institution or other agent acting on the non-U.S. holder’s behalf, the non-U.S. holder will be required to provide appropriate documentation to the agent, which then will be required to provide certification to us or our paying agent, either directly or through other intermediaries.

Dividends received by a non-U.S. holder that are effectively connected with such non-U.S. holder’s conduct of a U.S. trade or business (and, if required by an applicable income tax treaty, attributable to a permanent establishment maintained by a non-U.S. holder in the United States) are generally exempt from the withholding tax described above. In order to obtain this exemption, a non-U.S. holder must provide us with an IRS Form W-8ECI or other applicable IRS Form W-8 properly certifying such exemption. Such effectively connected dividends, although not subject to withholding tax, are taxed at the same graduated rates applicable to U.S. persons, net of certain deductions and credits. In addition, if a non-U.S. holder is a corporate non-U.S. holder, dividends received by such non-U.S. holder that are effectively connected with such non-U.S. holder’s conduct of a U.S. trade or business may also be subject to a branch profits tax at a rate of 30% or such lower rate as may be specified by an applicable income tax treaty. You should consult your tax advisor regarding any applicable tax treaties that may provide for different rules.

Gain on Disposition of Common Stock

Subject to the discussion below regarding backup withholding and foreign accounts, a non-U.S. holder generally will not be required to pay U.S. federal income tax on any gain realized upon the sale or other disposition of our common stock unless:

- the gain is effectively connected with the non-U.S. holder’s conduct of a U.S. trade or business (and, if required by an applicable income tax treaty, the gain is attributable to a permanent establishment maintained by such non-U.S. holder in the United States);
- the gain is effectively connected with the non-U.S. holder’s conduct of a U.S. trade or business (and, if required by an applicable income tax treaty, the gain is attributable to a permanent establishment maintained by such non-U.S. holder in the United States);
- the non-U.S. holders are a non-resident alien individual who is present in the United States for a period or periods aggregating 183 days or more during the taxable year in which the sale or disposition occurs and certain other conditions are met; or
- our common stock constitutes a United States real property interest by reason of its status as a “United States real property holding corporation,” or USRPHC, for U.S. federal income tax purposes at any time within the shorter of (i) the five-year period preceding the non-U.S. holder’s disposition of our common stock, or (ii) the non-U.S. holder’s holding period for our common stock.

We believe that we are not currently and will not become a USRPHC for U.S. federal income tax purposes, and the remainder of this discussion so assumes. However, because the determination of whether we are a USRPHC depends on the fair market value of our U.S. real property relative to the fair market value of our other business assets, there can be no assurance that we will not become a USRPHC in the future. Even if we become a USRPHC, however, as long as our common stock is regularly traded on an established securities market, such common stock will be treated as U.S. real property interests only if the non-U.S. holder’s actually or constructively hold more than five percent of such regularly traded common stock at any time during the shorter of (i) the five-year period preceding the non-U.S. holder’s disposition of our common stock, or (ii) the non-U.S. holder’s holding period for our common stock.

Gains described in the first bullet point above, generally will be subject to U.S. federal income tax on a net income basis at the regular graduated U.S. federal income tax rates, and a corporate non-U.S. holder described in the first bullet above also may be subject to the branch profits tax at a 30% rate, or such lower rate as may be specified by an applicable income tax treaty. An individual non-U.S. holder described in the second bullet above, you will be required to pay a flat 30% tax (or such lower rate specified by an applicable income tax treaty) on the gain derived from the sale, which gain may be offset by U.S. source capital losses for the year (provided the non-U.S. holder has timely filed U.S. federal income tax returns with respect to such losses). You should consult any applicable income tax or other treaties that may provide for different rules.

Backup Withholding and Information Reporting

Generally, we must report annually to the IRS, regardless of whether any tax was withheld, the amount of dividends paid to a non-U.S. holder, the non-U.S. holder’s name and address and the amount of tax withheld, if any. A similar report will be sent to the non-U.S. holder. Pursuant to applicable income tax treaties or other agreements, the IRS may make these reports available to tax authorities in the non-U.S. holder’s country of residence.

Payments of dividends or of proceeds on the disposition of stock made to a non-U.S. holder may be subject to information reporting and backup withholding at a current rate of 24% unless such non-U.S. holder establishes an exemption, for example, by properly certifying such non-U.S. holder’s non-U.S. status on an IRS Form W-8BEN, IRS Form W-8BEN-E, or another appropriate version of IRS Form W-8.

Backup withholding is not an additional tax; rather, the U.S. federal income tax liability of persons subject to backup withholding will be reduced by the amount of tax withheld. If withholding results in an overpayment of taxes, a refund or credit may generally be obtained from the IRS, provided that the required information is furnished to the IRS in a timely manner.

Foreign Account Tax Compliance

The Foreign Account Tax Compliance Act, or FATCA, imposes withholding tax at a rate of 30% on dividends on and gross proceeds from the sale or other disposition of our common stock paid to “foreign financial institutions” (as specially defined under these rules), unless such institution enters into an agreement with the U.S. government to withhold on certain payments and to collect and provide to the U.S. tax authorities substantial information regarding the U.S. account holders of such institution (which includes certain equity and debt holders of such institution, as well as certain account holders that are foreign entities with U.S. owners) or otherwise establishes an exemption. FATCA also generally imposes a U.S. federal withholding tax of 30% on dividends on and gross proceeds from the sale or other disposition of our common stock paid to a “non-financial foreign entity” (as specially defined for purposes of these rules) unless such entity provides the withholding agent with a certification identifying certain substantial direct and indirect U.S. owners of the entity, certifies that there are none or otherwise establishes an exemption. The withholding provisions under FATCA generally apply to dividends on our common stock, and under current transition rules, are expected to apply with respect to the gross proceeds from the sale or other disposition of our common stock on or after January 1, 2019. An intergovernmental agreement between the United States and an applicable foreign country may modify the requirements described in this paragraph. Non-U.S. holders should consult their own tax advisors regarding the possible implications of this legislation on their investment in our common stock.

Each prospective investor should consult its own tax advisor regarding the particular U.S. federal, state and local and non-U.S. tax consequences of purchasing, holding and disposing of our common stock, including the consequences of any proposed change in applicable laws.

UNDERWRITING

We have entered into an underwriting agreement with Roth Capital Partners, LLC. Subject to the terms and conditions of the underwriting agreement, we have agreed to sell to the underwriter, and the underwriter has agreed to purchase from us, shares of our common stock. We have applied to list our common stock on the Nasdaq Capital Market under the symbol “RNXT.”

Pursuant to the terms and subject to the conditions contained in the underwriting agreement, we have agreed to sell to the underwriter named below, and the underwriter has agreed to purchase from us, the respective number of shares of common stock set forth opposite its name below:

Underwriter	Number of Shares
Roth Capital Partners, LLC	
Total	

The underwriting agreement provides that the obligation of the underwriters to purchase the shares of common stock offered by this prospectus is subject to certain conditions. The underwriter is obligated to purchase all of the shares of common stock offered hereby if any of the shares are purchased.

We have granted the underwriters an option to buy up to an additional shares of common stock from us at the initial public offering price, less the underwriting discounts and commissions, to cover over-allotments, if any. The underwriter may exercise this option at any time, in whole or in part, during the 45-day period after the date of this prospectus.

Discounts, Commissions and Expenses

The underwriter proposes to offer to the shares of common stock purchased pursuant to the underwriting agreement to the public at the initial public offering price set forth on the cover page of this prospectus and to certain dealers at that price less a concession not in excess of \$ per share. After this offering, the initial public offering price and concession may be changed by the underwriter. No such change shall change the amount of proceeds to be received by us as set forth on the cover page of this prospectus.

In connection with the sale of the common stock to be purchased by the underwriter, the underwriter will be deemed to have received compensation in the form of underwriting commissions and discounts. The underwriter’s commissions and discounts will be 7.0% of the gross proceeds of this offering, or \$ per share of common stock, based on the public offering price per share set forth on the cover page of this prospectus.

We have also agreed to reimburse Roth Capital Partners at closing for legal expenses incurred by it in connection with the offering up to a maximum of \$150,000.

The following table shows the underwriting discounts and commissions payable to the underwriter by us in connection with this offering (assuming both the exercise and non-exercise of the over-allotment option to purchase additional shares of common stock we have granted to the underwriters):

	Per Share		Total	
	Without Over-allotment	With Over-allotment	Without Over-allotment	With Over-allotment
Initial public offering price	\$	\$		
Underwriting discounts and commissions paid by us	\$	\$		

Representative’s Warrants

We will issue to Roth Capital Partners or its designees warrants to purchase an aggregate number of shares of our common stock equal to 5.0% of the number of shares of common stock issued in this offering, at an exercise price per share equal to 120% of the initial public offering price (the “Representative’s Warrants”). The Representative’s Warrants will be exercisable, in whole or in part, six months after issuance and will expire on the fifth anniversary of the commencement of sales in this offering in accordance with FINRA Rule 5110(g)(8)(A). The Representative’s Warrants will provide for one demand registration right at the Company’s expense and an additional demand registration right at the holder’s expense and unlimited piggyback registration rights at the Company’s expense for a period of five years following the date of commencement of sales of this offering. Pursuant to FINRA Rule 5110(e), the Representative’s Warrants and any shares of common stock issued upon exercise of the Representative’s Warrants shall not be sold, transferred, assigned, pledged, or hypothecated, or be the subject of any hedging, short sale, derivative, put or call transaction that would result in the effective economic disposition of the securities by any person for a period of 180 days immediately following the date of commencement of sales of this offering, except the transfer of any security: (i) by operation of law or by reason of reorganization of the issuer; (ii) to any FINRA member firm participating in the offering and the officers, partners, registered persons or affiliates thereof, if all securities so transferred remain subject to the lock-up restriction set forth above for the remainder of the time period; (iii) if the aggregate amount of our securities held by the Representative or related persons does not exceed 1% of the securities being offered; (iv) that is beneficially owned on a pro-rata basis by all equity owners of an investment fund, provided that no participating member manages or otherwise directs investments by the fund and the participating members in the aggregate do not own more than 10% of the equity in the fund; (v) the exercise or conversion of any security, if all securities remain subject to the lock-up restriction set forth

above for the remainder of the time period; (vi) if we meet the registration requirements of Forms S-3, F-3 or F-10; or (vii) back to us in a transaction exempt from registration with the SEC. The Representative's Warrants and the shares of common stock underlying the Representative's Warrants are registered in the registration statement of which this prospectus is a part.

Right of First Refusal

We have granted the underwriter an 18-month right first refusal to act as the exclusive placement agent or sole book-running manager and sole lead managing underwriter for any private or public offering of equity, equity-linked or debt securities undertaken by us, provided that this offering is consummated.

Indemnification

Pursuant to the underwriting agreement, we have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act, or to contribute to payments that the underwriters or such other indemnified parties may be required to make in respect of those liabilities.

Lock-Up Agreements

We and each of our directors, officers and stockholders have agreed not to offer, sell, agree to sell, directly or indirectly, or otherwise dispose of any shares of common stock or any securities convertible into or exchangeable for shares of common stock for a period of days after the closing date of the offering pursuant to the underwriting agreement without the prior written consent of Roth Capital Partners. These lock-up agreements provide for limited exceptions and their restrictions may be waived at any time by Roth Capital Partners.

Electronic Distribution

This prospectus may be made available in electronic format on websites or through other online services maintained by the underwriters or by their affiliates. In those cases, prospective investors may view offering terms online and prospective investors may be allowed to place orders online. Other than this prospectus and the accompanying prospectus in electronic format, the information on the underwriters' websites or our website and any information contained in any other websites maintained by the underwriters or by us is not part of this prospectus or the registration statement of which this prospectus forms a part, has not been approved and/or endorsed by us or the underwriter in its capacity as underwriter, and should not be relied upon by investors.

Price Stabilization, Short Positions and Penalty Bids

In connection with the offering the underwriters may engage in stabilizing transactions, over-allotment transactions, syndicate covering transactions and penalty bids in accordance with Regulation M under the Exchange Act:

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- Stabilizing transactions permit bids to purchase the underlying security so long as the stabilizing bids do not exceed a specified maximum.
- Over-allotment involves sales by the underwriters of shares in excess of the number of shares the underwriters are obligated to purchase, which creates a syndicate short position. The short position may be either a covered short position or a naked short position. In a covered short position, the number of shares over-allotted by the underwriters is not greater than the number of shares that they may purchase in the over-allotment option. In a naked short position, the number of shares involved is greater than the number of shares in the over-allotment option. The underwriters may close out any covered short position by either exercising their over-allotment option and/or purchasing shares in the open market.
- Syndicate covering transactions involve purchases of the common stock in the open market after the distribution has been completed in order to cover syndicate short positions. In determining the source of shares to close out the short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the over-allotment option. A naked short position occurs if the underwriters sell more shares than could be covered by the over-allotment option. This position can only be closed out by buying shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there could be downward pressure on the price of the shares in the open market after pricing that could adversely affect investors who purchase in the offering.
- Penalty bids permit the underwriters to reclaim a selling concession from a syndicate member when the common stock originally sold by the syndicate member is purchased in a stabilizing or syndicate covering transaction to cover syndicate short positions.

These stabilizing transactions, syndicate covering transactions and penalty bids may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of the common stock. As a result, the price of our common stock may be higher than the price that might otherwise exist in the open market. These transactions may be discontinued at any time

Neither we nor the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of our shares of common stock. In addition, neither we nor the underwriters make any representation that the underwriter will engage in these transactions or that any transaction, if commenced, will not be discontinued without notice.

Offer restrictions outside the United States

Other than in the United States, no action has been taken by us or the underwriter that would permit a public offering of the securities offered by this prospectus in any jurisdiction where action for that purpose is required. The securities offered by this prospectus may not be offered or sold, directly or indirectly, nor may this prospectus or any other offering material or advertisements in connection with the offer and sale of any such securities be distributed or published in any jurisdiction, except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons into whose possession this prospectus comes are advised to inform themselves about and to observe any restrictions relating to this offering and the distribution of this prospectus. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any securities offered by this prospectus in any jurisdiction in which such an offer or a solicitation is unlawful.

Australia

This prospectus is not a disclosure document under Chapter 6D of the Australian Corporations Act, has not been lodged with the Australian Securities and Investments Commission and does not purport to include the information required of a disclosure document under Chapter 6D of the Australian Corporations Act. Accordingly, (i) the offer of the securities under this prospectus is only made to persons to whom it is lawful to offer the securities without disclosure under Chapter 6D of the Australian Corporations Act under one or more exemptions set out in section 708 of the Australian Corporations Act, (ii) this prospectus is made available in Australia only to those persons as set forth in clause (i) above, and (iii) the offeree must be sent a notice stating in substance that by accepting this offer, the offeree represents that the offeree is such a person as set forth in clause (i) above, and, unless permitted under the Australian Corporations Act, agrees not to sell or offer for sale within Australia any of the securities sold to the offeree within 12 months after its transfer to the offeree under this prospectus.

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Canada

The securities may be sold in Canada only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 Prospectus Exemptions or subsection 73.3(1) of the Securities Act (Ontario), and are permitted clients, as defined in National Instrument 31-103 Registration Requirements, Exemptions and Ongoing Registrant Obligations. Any resale of the securities must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws. Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor. Pursuant to section 3A.3 of National Instrument 33-105 Underwriting Conflicts (NI 33-105), the underwriter is not required to comply with the disclosure requirements of NI33-105 regarding underwriter conflicts of interest in connection with this offering.

China

The information in this document does not constitute a public offer of the securities, whether by way of sale or subscription, in the People's Republic of China (excluding, for purposes of this paragraph, Hong Kong Special Administrative Region, Macau Special Administrative Region and Taiwan). The securities may not be offered or sold directly or indirectly in the PRC to legal or natural persons other than directly to "qualified domestic institutional investors."

European Economic Area — Belgium, Germany, Luxembourg and Netherlands

The information in this document has been prepared on the basis that all offers of securities will be made pursuant to an exemption under the Directive 2003/71/EC ("Prospectus Directive"), as implemented in Member States of the European Economic Area (each, a "Relevant Member State"), from the requirement to produce a prospectus for offers of securities.

An offer to the public of securities has not been made, and may not be made, in a Relevant Member State except pursuant to one of the following exemptions under the Prospectus Directive as implemented in that Relevant Member State:

- to legal entities that are authorized or regulated to operate in the financial markets or, if not so authorized or regulated, whose corporate purpose is solely to invest in securities;
- to any legal entity that has two or more of (i) an average of at least 250 employees during its last fiscal year; (ii) a total balance sheet of more than €43,000,000 (as shown on its last annual unconsolidated or consolidated financial statements) and (iii) an annual net turnover of more than €50,000,000 (as shown on its last annual unconsolidated or consolidated financial statements);
- to fewer than 100 natural or legal persons (other than qualified investors within the meaning of Article 2(1)(c) of the Prospectus Directive) subject to obtaining our prior consent or any underwriter for any such offer; or
- in any other circumstances falling within Article 3(2) of the Prospectus Directive, provided that no such offer of securities shall require us to publish a prospectus pursuant to Article 3 of the Prospectus Directive.

France

This document is not being distributed in the context of a public offering of financial securities (*offre au public de titres financiers*) in France within the meaning of Article L.411-1 of the French Monetary and Financial Code (*Code monétaire et financier*) and Articles 211-1 et seq. of the General Regulation of the French *Autorité des marchés financiers* ("AMF"). The securities have not been offered or sold and will not be offered or sold, directly or indirectly, to the public in France.

This document and any other offering material relating to the securities have not been, and will not be, submitted to the AMF for approval in France and, accordingly, may not be distributed or caused to be distributed, directly or indirectly, to the public in France.

Such offers, sales and distributions have been and shall only be made in France to (i) qualified investors (*investisseurs qualifiés*) acting for their own account, as defined in and in accordance with Articles L.411-2-II-2 and D.411-1 to D.411-3, D. 744-1, D.754-1 and D.764-1 of the French Monetary and Financial Code and any implementing regulation and/or (ii) a restricted number of non-qualified investors (*cercle restreint d'investisseurs*) acting for their own account, as defined in and in accordance with Articles L.411-2-II-2° and D.411-4, D.744-1, D.754-1 and D.764-1 of the French Monetary and Financial Code and any implementing regulation.

Pursuant to Article 211-3 of the General Regulation of the AMF, investors in France are informed that the securities cannot be distributed (directly or indirectly) to the public by the investors otherwise than in accordance with Articles L.411-1, L.411-2, L.412-1 and L.621-8 to L.621-8-3 of the French Monetary and Financial Code.

Ireland

The information in this document does not constitute a prospectus under any Irish laws or regulations and this document has not been filed with or approved by any Irish regulatory authority as the information has not been prepared in the context of a public offering of securities in Ireland within the meaning of the Irish Prospectus (Directive 2003/71/EC) Regulations 2005 (the "Prospectus Regulations"). The securities have not been offered or sold, and will not be offered, sold or delivered directly or indirectly in Ireland by way of a public offering, except to (i) qualified investors as defined in Regulation 2(l) of the Prospectus Regulations and (ii) fewer than 100 natural or legal persons who are not qualified investors.

Israel

The securities offered by this prospectus have not been approved or disapproved by the Israeli Securities Authority (the ISA), or ISA, nor have such securities been registered for sale in Israel. The shares may not be offered or sold, directly or indirectly, to the public in Israel, absent the publication of a prospectus. The ISA has not issued permits, approvals or licenses in connection with this offering or publishing the prospectus; nor has it authenticated the details included herein, confirmed their reliability or completeness, or rendered an opinion as to the quality of the securities being offered. Any resale in Israel, directly or indirectly, to the public of the securities offered by this prospectus is subject to restrictions on transferability and must be effected only in compliance with the Israeli securities laws and regulations.

Italy

The offering of the securities in the Republic of Italy has not been authorized by the Italian Securities and Exchange Commission (Commissione Nazionale per le Società e la Borsa, "CONSOB") pursuant to the Italian securities legislation and, accordingly, no offering material relating to the securities may be distributed in Italy and such securities may not be offered or sold in Italy in a public offer within the meaning of Article 1.1(t) of Legislative Decree No. 58 of 24 February 1998 ("Decree No. 58"), other than:

- to Italian qualified investors, as defined in Article 100 of Decree no. 58 by reference to Article 34-ter of CONSOB Regulation no. 11971 of 14 May 1999 (“Regulation no. 11971”) as amended (“Qualified Investors”); and
- in other circumstances that are exempt from the rules on public offer pursuant to Article 100 of Decree No. 58 and Article 34-ter of Regulation No. 11971 as amended.

Any offer, sale or delivery of the securities or distribution of any offer document relating to the securities in Italy (excluding placements where a Qualified Investor solicits an offer from the issuer) under the paragraphs above must be:

- made by investment firms, banks or financial intermediaries permitted to conduct such activities in Italy in accordance with Legislative Decree No. 385 of 1 September 1993 (as amended), Decree No. 58, CONSOB Regulation No. 16190 of 29 October 2007 and any other applicable laws; and
- in compliance with all relevant Italian securities, tax and exchange controls and any other applicable laws.

Any subsequent distribution of the securities in Italy must be made in compliance with the public offer and prospectus requirement rules provided under Decree No. 58 and the Regulation No. 11971 as amended, unless an exception from those rules applies. Failure to comply with such rules may result in the sale of such securities being declared null and void and in the liability of the entity transferring the securities for any damages suffered by the investors.

Japan

The securities have not been and will not be registered under Article 4, paragraph 1 of the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948), as amended (the “FIEL”) pursuant to an exemption from the registration requirements applicable to a private placement of securities to Qualified Institutional Investors (as defined in and in accordance with Article 2, paragraph 3 of the FIEL and the regulations promulgated thereunder). Accordingly, the securities may not be offered or sold, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan other than Qualified Institutional Investors. Any Qualified Institutional Investor who acquires securities may not resell them to any person in Japan that is not a Qualified Institutional Investor, and acquisition by any such person of securities is conditional upon the execution of an agreement to that effect.

New Zealand

The shares of common stock offered hereby have not been offered or sold, and will not be offered or sold, directly or indirectly in New Zealand and no offering materials or advertisements have been or will be distributed in relation to any offer of shares in New Zealand, in each case other than:

- to persons whose principal business is the investment of money or who, in the course of and for the purposes of their business, habitually invest money;
- to persons who in all the circumstances can properly be regarded as having been selected otherwise than as members of the public;
- to persons who are each required to pay a minimum subscription price of at least NZ\$500,000 for the shares before the allotment of those shares (disregarding any amounts payable, or paid, out of money lent by the issuer or any associated person of the issuer); or
- in other circumstances where there is no contravention of the Securities Act 1978 of New Zealand (or any statutory modification or reenactment of, or statutory substitution for, the Securities Act 1978 of New Zealand).

Portugal

This document is not being distributed in the context of a public offer of financial securities (oferta pública de valores mobiliários) in Portugal, within the meaning of Article 109 of the Portuguese Securities Code (Código dos Valores Mobiliários). The securities have not been offered or sold and will not be offered or sold, directly or indirectly, to the public in Portugal. This document and any other offering material relating to the securities have not been, and will not be, submitted to the Portuguese Securities Market Commission (Comissão do Mercado de Valores Mobiliários) for approval in Portugal and, accordingly, may not be distributed or caused to be distributed, directly or indirectly, to the public in Portugal, other than under circumstances that are deemed not to qualify as a public offer under the Portuguese Securities Code. Such offers, sales and distributions of securities in Portugal are limited to persons who are “qualified investors” (as defined in the Portuguese Securities Code). Only such investors may receive this document and they may not distribute it or the information contained in it to any other person.

Sweden

This document has not been, and will not be, registered with or approved by Finansinspektionen (the Swedish Financial Supervisory Authority). Accordingly, this document may not be made available, nor may the securities be offered for sale in Sweden, other than under circumstances that are deemed not to require a prospectus under the Swedish Financial Instruments Trading Act (1991:980) (Sw. lag (1991:980) om handel med finansiella instrument). Any offering of securities in Sweden is limited to persons who are “qualified investors” (as defined in the Financial Instruments Trading Act). Only such investors may receive this document and they may not distribute it or the information contained in it to any other person.

Switzerland

The securities may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange (“SIX”) or on any other stock exchange or regulated trading facility in Switzerland. This document has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this document nor any other offering material relating to the securities may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this document nor any other offering material relating to the securities have been or will be filed with or approved by any Swiss regulatory authority. In particular, this document will not be filed with, and the offer of securities will not be supervised by, the Swiss Financial Market Supervisory Authority (FINMA).

This document is personal to the recipient only and not for general circulation in Switzerland.

United Arab Emirates

Neither this document nor the securities have been approved, disapproved or passed on in any way by the Central Bank of the United Arab Emirates or any other governmental authority in the United Arab Emirates, nor have we received authorization or licensing from the Central Bank of the United Arab Emirates or any other governmental authority in the United Arab Emirates to market or sell the securities within the United Arab Emirates. This document does not constitute and may not be used for

the purpose of an offer or invitation. We may not render services relating to the securities within the United Arab Emirates, including the receipt of applications and/or the allotment or redemption of such shares.

No offer or invitation to subscribe for securities is valid or permitted in the Dubai International Financial Centre.

United Kingdom

Neither the information in this document nor any other document relating to the offer has been delivered for approval to the Financial Services Authority in the United Kingdom and no prospectus (within the meaning of section 85 of the Financial Services and Markets Act 2000, as amended (“FSMA”)) has been published or is intended to be published in respect of the securities. This document is issued on a confidential basis to “qualified investors” (within the meaning of section 86(7) of FSMA) in the United Kingdom, and the securities may not be offered or sold in the United Kingdom by means of this document, any accompanying letter or any other document, except in circumstances which do not require the publication of a prospectus pursuant to section 86(1) FSMA. This document should not be distributed, published or reproduced, in whole or in part, nor may its contents be disclosed by recipients to any other person in the United Kingdom.

Any invitation or inducement to engage in investment activity (within the meaning of section 21 of FSMA) received in connection with the issue or sale of the securities has only been communicated or caused to be communicated and will only be communicated or caused to be communicated in the United Kingdom in circumstances in which section 21(1) of FSMA does not apply us.

In the United Kingdom, this document is being distributed only to, and is directed at, persons (i) who have professional experience in matters relating to investments falling within Article 19(5) (investment professionals) of the Financial Services and Markets Act 2000 (Financial Promotions) Order 2005 (“FPO”), (ii) who fall within the categories of persons referred to in Article 49(2)(a) to (d) (high net worth companies, unincorporated associations, etc.) of the FPO or (iii) to whom it may otherwise be lawfully communicated (together “relevant persons”). The investments to which this document relates are available only to, and any invitation, offer or agreement to purchase will be engaged in only with, relevant persons. Any person who is not a relevant person should not act or rely on this document or any of its contents.

LEGAL MATTERS

The validity of the securities offered hereby will be passed upon by Sheppard Mullin Richter & Hampton LLP, New York, New York. Ellenoff Grossman & Schole LLP, New York, New York, is acting as counsel for the underwriter in connection with this offering.

EXPERTS

The financial statements as of December 31, 2019 and 2020 and for the years then ended included in this prospectus and in the registration statement have been so included in reliance on the report of Frank, Rimerman & Co. LLP, an independent registered public accounting firm, (the report on the financial statements contains an explanatory paragraph regarding the Company’s ability to continue as a going concern) appearing elsewhere herein and in the registration statement, given on the authority of said firm as experts in auditing and accounting.

WHERE TO FIND MORE INFORMATION

This prospectus, which constitutes a part of the registration statement, does not contain all the information set forth in the registration statement, some of which is contained in exhibits to the registration statement as permitted by the rules and regulations of the SEC. For further information with respect to us and our securities, we refer you to the registration statement, including the exhibits filed as a part of the registration statement. Statements contained in this prospectus concerning the contents of any contract or any other document are not necessarily complete. If a contract or document has been filed as an exhibit to the registration statement, please see the copy of the contract or document that has been filed. Each statement in this prospectus relating to a contract or document filed as an exhibit is qualified in all respects by the filed exhibit. You may obtain copies of this information by mail from the Public Reference Section of the SEC, 100 F Street, N.E., Room 1580, Washington, D.C. 20549, at prescribed rates. You may obtain information on the operation of the public reference rooms by calling the SEC at 1-800-SEC-0330. The SEC also maintains an internet website that contains reports and other information about issuers, like us, that file electronically with the SEC. The address of that website is www.sec.gov. You may also request a copy of these filings, at no cost, by writing us at:

RenovoRx, Inc.
4546 El Camino Real, Suite B1
Los Altos, California 94022
Attn: Shaun R. Bagai, Chief Executive Officer
E-Mail: info@renovorx.com
Telephone: (650) 284-4433

We are subject to the information and reporting requirements of the Exchange Act and, in accordance with this law, file periodic reports, proxy statements and other information with the SEC. These periodic reports, proxy statements and other information are available for inspection and copying at the SEC’s public reference facilities and the website of the SEC referred to above. We also maintain a website at www.RenovoRx.com. Information contained in, or accessible through, our website is not a part of this prospectus, and the inclusion of our website address in this prospectus is only as an inactive textual reference. You may access these materials free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC.

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Unaudited Condensed Interim Financial Statements for the Three Months Ended March 31, 2020 and 2021[Condensed Balance Sheets as of December 31, 2020 and March 31, 2021](#)

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[Condensed Statements of Operations for the Three Months Ended March 31, 2020 and 2021 \(unaudited\)](#)

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[Condensed Statements of Convertible Preferred Stock and Stockholders' Deficit for the Three Months Ended March 31, 2020 and 2021 \(unaudited\)](#)

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[Condensed Statements of Cash Flows for the Three Months Ended March 31, 2020 and 2021 \(unaudited\)](#)

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[Notes to Unaudited Condensed Interim Financial Statements](#)

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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 sheets of RenovoRx, Inc. (the "Company") as of December 31, 2019 and 2020 and the related statements of operations, convertible preferred stock and stockholders' deficit, and cash flows for each of the years in the two-year period 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, 2019 and 2020, and the results of its operations and its cash flows for each of the years in the two-year period 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 audits. 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 audits 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 audits, 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 audits 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 audits 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 audits provide a reasonable basis for our opinion.

/s/ Frank, Rimerman + Co. LLP

We have served as the Company's auditor since 2019.

San Francisco, California
May 12, 2021, except for Note 14, as to which the date is June 15, 2021

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

	As of December 31,	
	2019	2020
Assets		
Current assets:		
Cash and cash equivalents	\$ 2,104	\$ 1,795
Restricted cash	20	-
Prepaid expenses and other current assets	142	115
Total current assets	2,266	1,910
Deposits	4	4
Total assets	\$ 2,270	\$ 1,914
Liabilities, Convertible Preferred Stock and Stockholders' Deficit		
Current liabilities:		

Accounts payable	\$	538	\$	162
Accrued expenses		232		311
Promissory note, current portion		-		117
Convertible note		-		2,650
Derivative liability		-		856
Warrant liability		35		-
Total current liabilities		805		4,096
Promissory note, net of current portion		-		23
Total liabilities		805		4,119
Commitments and contingencies (Note 11)				
Convertible preferred stock, \$0.0001 par value; 22,360,455 shares authorized; 17,543,161 and 17,677,353 shares issued and outstanding at December 31, 2019 and 2020, respectively (aggregate liquidation preference of \$12,757 and \$12,782, respectively)		12,391		12,451
Stockholders' deficit:				
Common stock, \$0.0001 par value; 42,000,000 shares authorized; 10,885,936 and 11,165,703 shares issued and outstanding, respectively		1		1
Additional paid-in capital		235		303
Accumulated deficit		(11,162)		(14,960)
Total stockholders' deficit		(10,926)		(14,656)
Total liabilities, convertible preferred stock and stockholders' deficit	\$	2,270	\$	1,914

See accompanying notes to financial statements.

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

	Year Ended December 31,	
	2019	2020
Operating expenses:		
Research and development	\$ 2,997	\$ 2,386
General and administrative	899	818
Total operating expenses	3,896	3,204
Loss from operations	(3,896)	(3,204)
Other income (expenses), net:		
Interest income (expense), net	63	(587)
Other income (expense), net	2	(7)
Loss on change in fair value of warrant liability	(8)	-
Total other income (expense), net	57	(594)
Net loss	\$ (3,839)	\$ (3,798)
Net loss per share - basic and diluted	\$ (0.35)	\$ (0.34)
Weighted average shares of common stock - basic and diluted	10,886	11,072

See accompanying notes to financial statements.

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RenovoRx, Inc.
Statements of Convertible Preferred Stock and Stockholders' Deficit
(in thousands, except share data)

	Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount			
Balance at January 1, 2019	17,543,161	\$ 12,391	10,885,936	\$ 1	\$ 197	\$ (7,323)	\$ (7,125)
Stock-based compensation expense	-	-	-	-	38	-	38
Net loss	-	-	-	-	-	(3,839)	(3,839)
Balance at December 31, 2019	17,543,161	12,391	10,885,936	1	235	(11,162)	(10,926)
Issuance of restricted stock award to nonemployee for service	-	-	122,393	-	17	-	17
Issuance of Series A-1 convertible preferred stock upon exercise of warrant	134,192	25	-	-	-	-	-
Issuance of common stock upon exercise of stock options	-	-	157,374	-	18	-	18
Warrant liability transferred to mezzanine equity	-	35	-	-	-	-	-
Stock-based compensation expense	-	-	-	-	33	-	33
Net loss	-	-	-	-	-	(3,798)	(3,798)
Balance at December 31, 2020	17,677,353	\$ 12,451	11,165,703	\$ 1	\$ 303	\$ (14,960)	\$ (14,656)

See accompanying notes to financial statements.

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

	Years Ended December 31,	
	2019	2020
Cash flows from operating activities:		
Net loss	\$ (3,839)	\$ (3,798)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	38	33
Issuance of restricted stock award to nonemployee	-	17
Loss on change in fair value of warrant liability	8	-
Amortization of debt discount	-	477
Amortization of debt issuance cost	-	12
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(24)	27
Accounts payable	343	(376)
Accrued expenses	124	(21)
Interest accrued on convertible notes	-	101
Net cash used in operating activities	<u>(3,350)</u>	<u>(3,528)</u>
Cash flows from investing activities:		
Change in deposits	(1)	-
Net cash used in investing activities	<u>(1)</u>	<u>-</u>
Cash flows from financing activities:		
Proceeds from convertible notes	-	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	-	18
Net cash provided by financing activities	<u>3,199</u>	<u>3,199</u>
Net decrease in cash, cash equivalents and restricted cash	<u>(3,351)</u>	<u>(329)</u>
Cash, cash equivalents and restricted cash, beginning of year	5,475	2,124
Cash, cash equivalents and restricted cash, end of year	<u>\$ 2,124</u>	<u>\$ 1,795</u>
Supplemental disclosure of non-cash investing and financing activities:		
Derivative liability	\$ -	\$ 856
Warrant liability transferred to equity	\$ -	\$ 35

See accompanying notes to financial statements.

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1. Organization

Description of the Business

RenovoRx, Inc. (“RenovoRx” or the “Company”) was incorporated in 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 registrational 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. RenovoTAMP combines the Company’s 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 the Company anticipates investigating other chemotherapeutic agents for intra-arterial delivery via RenovoTAMP, the Company’s clinical work to date has focused on gemcitabine, which is a generic drug. The Company’s first product candidate, RenovoGem, is a drug and device combination consisting of intra-arterial gemcitabine and RenovoCath. FDA has determined that RenovoGem will be regulated as, and if approved the Company expects will be reimbursed as, a new oncology drug product. The Company has secured FDA Orphan Drug Designation for RenovoGem in its first two indications: pancreatic cancer and cholangiocarcinoma (bile duct cancer, or CCA). The Company has completed its 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 treated with RenovoGem and radiation versus expected survival of 12-15 months in patients receiving only intravenous (IV) systemic chemotherapy dosed at 1,000mg/m² based on historical control data. Unlike the historical controls, the Company’s RR1 and RR2 studies were not randomized or controlled for potential confinement. Based on FDA safety review of the Company’s Phase 1/2 study the FDA allowed the Company to proceed to evaluate RenovoGem within its Phase 3 registration Investigational New Drug, or IND, clinical trial. This Phase 3 trial is 40% enrolled as of April 30, 2021 and the Company expects to report data from a planned interim data readout in the second half of 2022. The Company intends to evaluate RenovoGem in a second indication in a Phase 2/3 trial in hilar CCA (cancer that occurs in the bile ducts that lead out of the liver and join with the gallbladder, also called extrahepatic cholangiocarcinoma, or HCCA). The Company plans to propose the trial to the FDA and potentially launch in the first half of 2022. In addition, the Company 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, the Company has used gemcitabine, but in the future it may develop other chemotherapeutic agents for intra-arterial delivery via RenovoCath.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying financial statements and the related disclosures have been prepared in conformity with accounting principles generally accepted in the United States (“GAAP”), applicable rules and regulations of the U.S. Securities and Exchange Commission (“SEC”) and include all adjustments necessary for the fair presentation of the Company’s financial position for the periods presented.

Liquidity and Going Concern

The financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of

business. In order to continue its operations, the Company must raise additional equity or debt financings and achieve profitable operations. Although management has historically been successful in raising capital, there can be no assurance that the Company will be able to obtain additional equity or debt financing on terms acceptable to the Company, or at all. The failure to obtain sufficient funds on acceptable terms when needed could have a material adverse effect on the Company's business, financial position, results of operations, and future cash flows. The Company is seeking to complete an initial public offering ("IPO") of its common stock. Upon the closing of an IPO, on specified terms, the Company's outstanding convertible preferred stock will automatically convert into shares of common stock (see Note 8). In the event the Company does not complete an IPO, the Company expects to seek additional funding through other capital sources including through the sale of equity, debt financings or other capital sources including collaborations with other companies or other strategic transactions. However, the Company may be unable to raise additional funds or enter into such agreements or arrangements when needed on acceptable terms, or at all.

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As a company with no commercial operating history, the Company is subject to all of the risks and expenses associated with a start-up company. The Company must among other things respond to competitive developments, attract, retain and motivate qualified personnel and support ongoing clinical trials for its product candidate. The Company has generated operating losses and negative cash flows from operations in each year since inception. The Company has not generated any revenue from product sales to date and will continue to incur significant research and development and other expenses related to its ongoing operations. The Company has incurred net losses of \$3.8 million for each of the years ended December 31, 2019 and 2020, and had an accumulated deficit of \$15.0 million at December 31, 2020. The Company has funded its operations primarily through the sale and issuance of convertible preferred stock and convertible notes. 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"), cash requirements for the upcoming year, terms of the Company's current debt arrangements, funding capacity, net working capital, total stockholders' deficit and future access to capital. These factors along with the Company's cash and cash equivalents, raise substantial doubt about the Company's ability to continue as a going concern for at least one year from the date the financial statements are issued. The financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the outcome of this uncertainty. If future financing is not achieved, the Company may be required to curtail spending to reduce cash outflows.

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.

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. The Company has made estimates of the impact of COVID-19 within its financial statements and there may be changes to those estimates in future periods. Actual results could materially differ from those estimates.

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. Significant estimates and assumptions made in the accompanying financial statements include, but are not limited to, the accrual of certain liabilities, the valuation of financial instruments, the valuation allowance related to deferred income tax assets, the fair value of the Company's common stock and the fair value of options granted under the Company's equity incentive plan. Actual results could differ from materially from these estimates.

Concentration of Credit Risk and Significant Suppliers

Financial instruments that potentially subject the Company to concentration of credit risk consist of cash and cash equivalents. At December 31, 2019, the Company maintained approximately \$2.1 million in cash, cash equivalents and restricted cash, and at December 31, 2020, the Company maintained \$1.8 million in cash and cash equivalents, with one financial institution. The Company is exposed to credit risk in the event of default by the financial institutions to the extent that cash and cash equivalent deposits are in excess of the \$250,000 insured by the Federal Deposit Insurance Corporation. These deposits routinely exceed the insurable limit. To date, the Company has not experienced any losses on its cash and cash equivalents.

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The Company is dependent on third-party manufacturers to supply products and services for its research and development activities, including preclinical and clinical development. In particular, the Company relies, and expects to continue 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 the supply of these items.

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. If a planned financing is abandoned, the deferred offering costs are expensed as a charge to operating expenses in the statement of operations.

There were no deferred offering costs on the Company's balance sheets at December 31, 2019 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. For the years ended December 31, 2019 and 2020, the Company's potentially dilutive common stock equivalents are comprised of convertible preferred stock, convertible notes, options outstanding under the Company's stock option plan and the warrant to purchase Series A-1 preferred stock.

Fair Value of Financial Instruments

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. To increase the comparability of fair value measures, the following hierarchy prioritizes the inputs to valuation methodologies used to measure fair value.

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 value of all remaining current assets and current liabilities approximates fair value because of their short-term nature.

Cash and Cash Equivalents and Restricted Cash

The Company considers all highly liquid investments purchased with a remaining maturity date upon acquisition of three months or less to be cash equivalents. Cash and cash equivalents consist primarily of cash held in checking and money market accounts. As of December 31, 2019, the Company had restricted cash of \$20,000, which consisted of reserve funds held at one financial institution to collateralize the Company’s credit cards. The Company held no funds in restricted cash at December 31, 2020.

The following table provides a reconciliation of cash, cash equivalents and restricted cash reported within the balance sheets to the amounts shown in the statements of cash flows (in thousands):

	<u>2019</u>	<u>2020</u>
Cash and cash equivalents	\$ 2,104	\$ 1,795
Restricted cash	20	-
Total cash and cash equivalents and restricted cash shown in the statements of cash flows	<u>\$ 2,124</u>	<u>\$ 1,795</u>

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Convertible Instruments and Embedded Derivatives

The Company evaluates all of its agreements to determine if such instruments have derivatives or contain features that qualify as 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. The Company had no derivative liability as of December 31, 2019. As of December 31, 2020, the Company’s only derivative financial instrument was related to the 2020 Convertible Notes (defined in Note 5), which contained certain redemptive features (see Note 5).

Research and Development Costs

Research and development costs, which include direct and allocated expenses, are expensed in the period incurred. Research and development costs include primarily clinical development-related expenses, pre-clinical research and development expenses, employee compensation and related benefits, regulatory support and related services, clinical consulting, travel-related expenses and allocated expenses for rent, insurance and other general overhead costs. The Company also receives payments from vendors in performing clinical trials on behalf of the Company for the delivery device used by such vendors in performing such clinical trials. These payments are offset against the Company’s research and development expenses.

Clinical Trial Expenses

The Company makes payments in connection with clinical trials 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, 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 or 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 levels 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 the Company is 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. As noted above, the Company receives payments from vendors performing clinical trials on behalf of the Company for the delivery device used by such vendors in performing such clinical trials.

General and Administrative

General and administrative expenses consist primarily of personnel costs, including employee compensation and related benefits and consulting. Additionally, these expenses include professional fees, including audit, legal, recruiting services and allocated expenses for rent, insurance and other general overhead costs. General and administrative expenses are expensed in the period incurred.

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Convertible Preferred Stock

The Company records preferred stock at fair value on the date of issuance, net of issuance costs. The preferred stock is recorded outside of stockholders’ deficit because the shares contain liquidation features that are not solely within the Company’s control. As a result, the preferred stock is classified as mezzanine equity (temporary equity). The Company has elected not to adjust the carrying value of the preferred stock to the liquidation preferences of such shares because it is uncertain whether or when an event would occur that would obligate the Company to pay the liquidation preferences to holders of shares of preferred stock. Subsequent adjustments to the carrying values to the liquidation preferences will be made only when it becomes probable that such a liquidation event will occur.

Stock-Based Compensation

The Company calculates the fair value of stock options using the Black-Scholes option pricing model, which incorporates various assumptions including volatility, expected life

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—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 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.

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. 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 to non-employees, the expected term equals the remaining contractual term of the option from the vesting date.

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 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 grants stock options to its employees for a fixed number of shares with an exercise price equal to the fair value of the underlying shares on the date of 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.

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Preferred Stock Warrant Liability

The Company accounts for its warrants as either equity or liability based upon the characteristics and provisions of each instrument. Warrants classified as derivative liabilities are recorded on the Company's accompanying balance sheets at their fair value on the date of issuance and are revalued at each subsequent balance sheet date, with fair value changes recognized as increases or reductions to other income (expense), net in the statements of operations.

Income Taxes

The Company accounts 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 the Company's deferred income tax assets when their realization is not reasonably assured.

The Company is 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, the Company recognizes 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. The Company's policy is to recognize interest and/or penalties related to income tax matters in income tax expense.

Segment Reporting

Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 280, *Segment Reporting*, requires use of the "management approach" model for segment reporting. The management approach model is based on the way a company's management organizes segments within the company for making operating decisions and assessing performance.

The Company determined it has one reportable segment, the development of a platform technology to deliver de-risked small molecules for localized treatment of solid cancer tumors. The segment is based on financial information that is utilized by the Company's Chief Operating Decision Maker who is the Company's Chief Executive Officer, to assess performance and allocate resources.

Emerging Growth Company Status

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

As an "emerging growth company" ("EGC") under the Jumpstart Our Business Startups Act ("JOBS Act"), the Company may elect to take advantage of certain forms of relief from various reporting requirements that are applicable to public companies. The relief afforded under the JOBS Act includes an extended transition period for the implementation of new or revised accounting standards. The Company has elected to take advantage of this extended transition period and, as a result, the Company's financial statements may not be comparable to those of companies that implement accounting standards as of the effective dates for public companies. The Company may take advantage of the relief afforded under the JOBS Act up until the last day of the fiscal year following the fifth anniversary of an offering or such earlier time that it is no longer an EGC.

Recently Adopted Accounting Pronouncements

In June 2018, the FASB issued ASU No. 2018-07, *Improvements to Nonemployee Share-Based Payment Accounting*. 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.

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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*. 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.

Effective January 1, 2019, the Company adopted FASB ASU 2016-18, *Statement of Cash Flows (Topic 230): Restricted Cash*, 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. The adoption of ASU 2016-18 did not have an impact on the Company's 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)*. 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 deferring the effective date for private entities 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 which further defers the effective date for private entities for fiscal years beginning after December 15, 2021 and interim periods within fiscal years beginning after December 15, 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*, 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*, which included an amendment of the effective date. The standard is effective for the Company for annual reporting periods beginning after December 15, 2022, and for interim periods within those periods. Early adoption is permitted. The Company plans to adopt this new standard on January 1, 2023 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* which simplifies the accounting for income taxes. For the Company, ASU 2019-12 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.

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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): 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. ASU 2020-06 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

A summary of the components of accrued expenses is as follows (in thousands):

	December 31,	
	2019	2020
Accrued clinical trials	\$ 219	\$ 171
Accrued interest	-	101
Accrued personnel	13	39
	<u>\$ 232</u>	<u>\$ 311</u>

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, 2019 and 2020 (in thousands):

	Fair Value Measurements at December 31, 2019 using:			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds	\$ 1,087	\$ -	\$ -	\$ 1,087
	<u>\$ 1,087</u>	<u>\$ -</u>	<u>\$ -</u>	<u>\$ 1,087</u>
Liabilities:				
Series A-1 preferred stock warrant liability	\$ -	\$ -	\$ 35	\$ 35
	<u>\$ -</u>	<u>\$ -</u>	<u>\$ 35</u>	<u>\$ 35</u>

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	Fair Value Measurements at December 31, 2020 using:			
	Level 1	Level 2	Level 3	Total
Assets:				
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 as of January 1, 2019	\$ 27
Change in fair value recorded in other income (expense), net	8
Fair value as of December 31, 2019	\$ 35
Change in fair value upon warrant exercise in January 2020 recorded in other income (expense), net	-
Fair value as of January 2020	\$ 35
Transfer of warrant liability to mezzanine equity upon exercise of warrant	(35)
Fair value as of December 31, 2020	\$ -

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.

There was no derivative liability as of December 31, 2019.

The change in the fair value of the derivative liability for the year ended December 31, 2020 is summarized below (in thousands):

Fair value as of December 31, 2019	\$ -
Derivative liability upon issuance of 2020 Convertible Notes	856
Change in fair value recorded in other income (expense), net	-
Fair value as of December 31, 2020	\$ 856

The derivative liability in the table above related to the 2020 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 is measured at fair value on a recurring basis and is classified as a Level 3 liability. The Company records 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).

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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. The Company entered into a series of convertible note payable agreements (the “2020 Convertible Notes”) for aggregate borrowings of approximately \$3.0 million. Outstanding borrowings under the 2020 Convertible Notes and accrued interest are due in March 2021, if not previously converted. The 2020 Notes bear interest at the rate of 5% per annum. The 2020 Notes cannot be prepaid prior to the maturity date unless approved in writing by the Company and requisite holders.

Pursuant to the 2020 Convertible Notes, the outstanding principal and accrued interest are automatically convertible 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 mean the Company’s preferred stock or any securities providing for rights to purchase the Company’s preferred stock or securities convertible into or exchangeable for the Company’s preferred stock issued in the Qualified Financing. If the Company consummates a Change of Control prior to a Qualified Financing, the Company will 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 (\$1.1030, adjusted for any stock dividends, combinations, splits, and recapitalizations).

The Company evaluated whether the 2020 Convertible Notes contain embedded features that meet the definition of derivatives under FASB ASC Topic 815, *Derivatives and Hedging*. The Company determined that these redemption features 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. The derivative liability had a fair value of approximately \$856,000 on the issuance date with the offsetting amount being recorded as a debt discount. The Company also incurred \$22,000 of debt issuance costs. The derivative liability is subject to fair value remeasurement at the end of each reporting period. The discount and debt issuance costs are being amortized to interest expense using the effective interest method over the expected term of the 2020 Convertible Notes. The Company recognized approximately \$477,000 of amortization of debt discount and \$12,000 of amortization of debt issuance costs as interest expense in the statement of operations for the year ended December 31, 2020. The effective interest rate on the 2020 Convertible Notes was 30.8%. During the year ended December 31, 2020, the Company also recognized interest expense in the statement of operations of approximately \$101,000 related to the 2020 Convertible Notes. The Company incurred no interest expense during the year ended December 31, 2019.

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”) 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 are forgivable, if the loan proceeds are 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. As of December 31, 2020, payments were deferred for 10 months. The PPP Loan matures on April 22, 2022 and bears interest at a rate of 1.0% per annum. The PPP Loan contains events of default and other provisions customary for a loan of this type. The Company has recorded the PPP Loan as a promissory note in the December 31, 2020 balance sheet as both a current and non-current liability.

7. Warrant Liability

In conjunction with the January 2013 Series A-1 convertible preferred stock financing, the Company issued a warrant to purchase 134,192 shares of the Company's Series A-1 convertible preferred stock at \$0.1863 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 is exercisable for shares of Series A-1 preferred stock that are puttable upon a deemed liquidation event. In 2019, the fair value of the warrant liability of \$35,000 was included in current liabilities as the seven-year expiration date was January 23, 2020. 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 (expense), net in the statement of operations as of December 31, 2020.

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8. Convertible Preferred Stock and Stockholders' Deficit

Common Stock

Pursuant to the December 2019 fifth amended and restated certificate of incorporation, the Company is authorized to issue 42,000,000 shares of common stock with a par value of \$0.0001 per share. Each holder of common stock is entitled to one vote per share of common stock held. The Company's common stock reserved for future issuance related to the convertible preferred stock and common stock options as of December 31, 2019 and 2020 are as follows:

	As of December 31,	
	2019	2020
Series A-1 convertible preferred stock	3,542,669	3,542,669
Series A-2 convertible preferred stock	3,546,095	3,546,095
Series A-3 convertible preferred stock	2,660,230	2,660,230
Series B convertible preferred stock	12,611,461	12,611,461
Common stock options outstanding	5,016,875	4,986,334
Common stock options reserved for issuance	313,693	64,467
Total	27,691,023	27,411,256

The shares that would be issued upon a conversion of the 2020 Convertible Notes have been excluded from the table above as the number of common shares that would be issued is contingent upon the occurrence of a future Qualified Financing and the conversion price per share would be equal to 80% of the price per share paid by the investors in the future Qualified Financing.

Convertible Preferred Stock

As of December 31, 2020, the Company was authorized to issue two classes of stock consisting of common stock and preferred stock.

In December 2019, the Company filed an amendment to its Certificate of Incorporation to re-designate its issuable convertible preferred stock. Series D convertible preferred stock was re-designated as Series B, Series C convertible preferred stock was re-designated as Series A-3 convertible preferred stock (Series A-3), Series B convertible preferred stock was re-designated as Series A-2 convertible preferred stock (Series A-2) and Series A convertible preferred stock was re-designated as Series A-1 convertible preferred stock (Series A-1). The re-designation did not change any of the rights, privileges or preferences of any series of preferred stock. The accompanying financial statements and notes to the financial statements have been updated to reflect these re-designations.

The total number of shares the Company is authorized to issue is 64,360,455 of which 42,000,000 shares shall be common stock and 22,360,455 shares shall be preferred stock with both the common stock and preferred stock having a par value of \$0.0001 per share. As of December 31, 2019 and 2020, the Board of Directors designated the convertible preferred stock as follows (in thousands, except shares):

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Preferred Series	December 31, 2019			
	Shares Authorized	Shares Issued and Outstanding	Net Carrying Value	Liquidation Value
Series A-1	3,542,669	3,408,477	\$ 579	\$ 635
Series A-2	3,546,095	3,546,095	1,099	1,150
Series A-3	2,660,230	2,660,230	2,166	2,227
Series B	12,611,461	7,928,359	8,547	8,745
	22,360,455	17,543,161	\$ 12,391	\$ 12,757

Preferred Series	December 31, 2020			
	Shares Authorized	Shares Issued and Outstanding	Net Carrying Value	Liquidation Value
Series A-1	3,542,669	3,542,669	\$ 639	\$ 660
Series A-2	3,546,095	3,546,095	1,099	1,150
Series A-3	2,660,230	2,660,230	2,166	2,227
Series B	12,611,461	7,928,359	8,547	8,745
	22,360,455	17,677,353	\$ 12,451	\$ 12,782

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.

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 remain 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.

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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. As of December 31, 2020, 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: \$0.1863 for Series A-1, \$0.3243 for Series A-2, \$0.8370 for Series A-3, and \$1.1030 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, 2019 and 2020.

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: \$0.1863, \$0.3243, \$0.8370 and \$1.1030 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, 2019 and 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.

Mezzanine Equity

The convertible preferred stock does not have a mandatory redemption date. However, while it is not mandatorily redeemable, the convertible preferred stock was reclassified into mezzanine equity because it will become redeemable at the option of the stockholders upon the occurrence of certain deemed liquidation events that are considered not solely within the Company's control. That is, unless a majority of the then outstanding convertible preferred stock, on an as-if-converted to common stock basis, elect otherwise, deemed liquidation events include a sale of all or substantially all of the Company's assets or a sale of at least fifty percent (50%) of the issued and outstanding voting securities, capital stock, or other comparable equity or ownership interest in the Company.

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Upon issuance of the convertible preferred stock, the Company assessed the embedded conversion and liquidation features of the securities. The Company determined that the convertible preferred stock did not require the Company to separately account for the liquidation features. The Company also concluded that no beneficial conversion feature existed upon the issuance date of the convertible preferred stock.

9. Stock-Based Compensation

In January 2013, the Board of Directors of the Company adopted the 2013 Equity Incentive Plan (the "2013 Plan"). The 2013 Plan provides for the grant of incentive and nonqualified stock options, stock appreciation rights, restricted stock awards and restricted stock units to employees, directors and consultants. The 2013 Plan allows for up to 6,346,504 shares of the Company's common stock to be issued with respect to awards granted. The exercise price of incentive stock options and nonqualified stock options will be no less than 100% of the fair value per share of the Company's common stock on the grant date. If an individual owns capital stock representing more than 10% of the voting shares, the exercise price of each share will be at least 110% of the fair market value on the date of grant. Fair value is determined by the Board of Directors. The Company's

stock options generally have 10-year contractual terms (five years for stockholders owning greater than 10% of all classes of stock) and generally vest over a four-year period from the date of grant. The Board of Directors determines the period over which options vest and become exercisable. The Company has a repurchase option for shares issued under unvested options exercisable upon the voluntary or involuntary termination of the purchaser's employment with, or service to, the Company for any reason.

Activity under the 2013 Plan for the years ended December 31, 2019 and December 31, 2020 is set forth below (in thousands except shares, per share amounts and years):

	Shares Available for Grant	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value
Outstanding at January 1, 2019	53,019	4,927,549	\$ 0.08	6.75	\$ 232
Authorized	350,000	-	-		
Options granted	(283,500)	283,500	0.13		
Options cancelled	194,174	(194,174)	0.10		
Outstanding at December 31, 2019	313,693	5,016,875	\$ 0.08	6.75	\$ 232
Options granted	(243,500)	243,500	0.14		
Options exercised	-	(157,374)	0.11		
Options cancelled	116,667	(116,667)	0.13		
Restricted stock award granted	(122,393)	-	-		
Outstanding at December 31, 2020	64,467	4,986,334	\$ 0.08	5.84	\$ 276
Vested and exercisable at December 31, 2020		4,238,068	\$ 0.08	5.47	\$ 269
Vested and expected to vest at December 31, 2020		4,984,459	\$ 0.08	5.84	\$ 276

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 estimated fair value of the Company's common stock, as determined by the Board of Directors, as of December 31, 2020.

During the year ended December 31, 2019, the Company recognized \$38,000 in stock-based compensation expense. During the year ended December 31, 2020, the Company recognized \$50,000 in stock-based compensation expense comprised of \$33,000 from stock option grants and \$17,000 from the issuance of a restricted stock award to a consultant for services rendered. 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 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 during the years ended December 31, 2019 and 2020:

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	Years Ended December 31,	
	2019	2020
Expected term (years)	6.98	5.24
Risk-free interest rate	1.88%	1.29%
Volatility factor	37%	38%
Dividend yield	-	-

Expected volatility is based on historical volatilities of public companies operating in the Company's industry. The expected term of the options represents the period of time options are expected to be outstanding and is estimated considering vesting terms and historical exercise and post-vesting employment termination behavior. The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the time of grant. The weighted-average fair value of options granted was \$0.05 per share in both 2019 and 2020.

Future stock-based compensation for unvested employee options granted and outstanding as of December 31, 2020 is \$38,000, to be recognized over a weighted-average remaining requisite service period of 1.56 years.

As of December 31, 2020, options outstanding had a weighted-average remaining contractual life of 5.8 years. As of December 31, 2020, 4,238,068 options were vested and exercisable with a weighted-average exercise price of \$0.08 and a weighted-average remaining contractual life of 5.5 years.

In February 2020, the Company granted 122,393 shares of restricted common stock under the 2013 Plan to a consultant as partial consideration for services rendered, with a deemed fair value of \$0.14 per share or \$17,000. The fair value of this restricted stock award was expensed on the date of grant as they were fully vested on that date.

Stock-based compensation is included in the statements of operations in general and administrative and research and development, depending on the nature of the services provided. Stock-based compensation expense recorded to operations for stock options was as follows (in thousands):

	Years ended December 31,	
	2019	2020
General and administrative	\$ 23	\$ 25
Research and development	15	8
Total	\$ 38	\$ 33

The Company also issued a restricted stock award to a consultant during the year ended December 31, 2020 for which \$17,000 in stock-based compensation was included in general and administrative in the statement of operations.

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10. Income Taxes

For the years ended December 31, 2019 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):

	<u>2019</u>	<u>2020</u>
Statutory federal income tax rate	\$ (806)	\$ (799)
Increase (decrease) resulting from:		
Change in valuation allowance	999	844
Permanent Items	8	107
Prior year true ups	(12)	-
Tax credits	(184)	(125)
State	(5)	(28)
Other	-	1
Income tax provision/(benefit)	<u>\$ -</u>	<u>\$ -</u>

The components of our deferred tax assets and liabilities consist of (in thousands):

	<u>2019</u>	<u>2020</u>
Deferred tax assets:		
Net operating loss carryforwards	\$ 2,516	\$ 3,146
Tax credit carryforwards	405	607
Stock based compensation	18	24
Fixed assets/intangible assets	65	74
Charitable contributions	1	1
Accruals and other	3	-
	<u>3,008</u>	<u>3,852</u>
Valuation allowance	<u>(3,008)</u>	<u>(3,852)</u>
Total deferred tax assets	<u>\$ -</u>	<u>\$ -</u>

We have established a valuation allowance to offset net deferred tax assets as of December 31, 2019 and 2020 due to the uncertainty of realizing future tax benefits from such assets.

As of December 31, 2020, the Company had U.S. federal and state net operating loss (“NOL”) carryforward amounts of \$12.9 million and \$6.4 million. The federal NOL carryforward consists of \$4.7 million that has a carryforward of 20 years and begin to expire in 2030 and can and can be used to offset 100% of taxable income while \$8.2 million 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 for the Coronavirus Aid, Relief, and Economic Security Act (P.L. 116-136), otherwise known as the CARES Act. The state NOL carryforward will begin to expire in 2033.

As of December 31, 2020, we had federal and state tax credit carryforwards of \$0.7 million and \$0.2 million, respectively. The federal tax credit carryforwards will begin to expire in 2033. The state tax credit carryforwards 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, 2020, the Company recorded unrecognized tax benefits related to federal and state tax credits of \$0.2 million. The Company’s policy is to recognize interest and penalties related to income tax matters in income tax expense. The Company did not have tax-related interest and penalties at December 31, 2020. 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:

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The following summarizes the activity related to the Company’s unrecognized tax benefits for the years ended December 31, 2019 and December 31, 2020 (in thousands):

Balance at January 1, 2019	\$ -
Tax positions related to the current year:	
Additions	77
Reductions	-
Tax positions related to the prior year:	
Additions	65
Reductions	-
Settlements	-
Lapses in statute	-
Balance at December 31, 2019	<u>142</u>
Tax positions related to the current year:	
Additions	70
Reductions	-
Tax positions related to the prior year:	
Additions	-
Reductions	-
Settlements	-
Lapses in Statute	-
Balance at December 31, 2020	<u>\$ 212</u>

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 Coronavirus Aid, Relief and Economic Security Act (“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, 2020.

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,	
	2019	2020
Numerator:		
Net loss	\$ (3,839)	\$ (3,798)
Denominator:		
Weighted average shares used in computing net loss per share – basic and diluted	10,886	11,072
Net loss per share – basic and diluted	\$ (0.35)	\$ (0.34)

For the years ended December 31, 2019 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,	
	2019	2020
Convertible preferred stock	17,543,161	17,677,353
Options to purchase common stock	5,016,875	4,986,334
Series A-1 preferred stock warrant	134,192	-
	<u>22,694,228</u>	<u>22,663,687</u>

The table above omits the potentially dilutive shares into which the 2020 Convertible Notes would convert.

12. Commitments and Contingencies

Operating Lease

The Company leases its headquarters in Los Altos, California under a non-cancelable operating lease agreement which expired and became month-to-month on July 31, 2019. As a result, there are no future minimum lease payments for 2020. Rent expense under the operating lease was \$42,000 and \$44,000 in 2019 and 2020, respectively.

Legal Proceedings

From time to time, the Company may become involved in legal proceedings arising in the ordinary course of business. Management is not currently aware of any matters that will have a material adverse effect on the financial position, results of operations or cash flows of the Company.

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, 2020, 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 2013, the Company entered into a consulting agreement (the “Agreement”) with one of the Company’s co-founders whereby the co-founder provides consulting services as the Company’s Chief Medical Officer (“CMO”) by overseeing Company-sponsored clinical trials. The Agreement is for a term of 15 years with automatic one-year renewals. The sole compensation payable to the CMO is the continued vesting of shares of common stock of the Company held by the CMO. In July 2018, the CMO was awarded options for the purchase of 200,000 shares of the Company’s common stock with 25% vested after one year and the remaining 75% vesting ratably over 36 months. The Company and the CMO entered into an amendment to the Agreement in 2019 providing cash compensation to the CMO of \$10,000 per month for additional services. Consulting fees paid to the CMO were \$78,000 and \$120,000 for the years ended December 31, 2019 and 2020, respectively.

In July 2019, the Company entered into a consulting agreement (the “CFO Agreement”) with the Company’s Chief Financial Officer (“CFO”). In February 2020, the Company granted the CFO an option to purchase 140,000 shares of the Company’s common stock, of which 25% were vested at the grant date and the remaining 75% vested ratably over 18 months. The Company entered into an amendment to the Agreement in December 2020 increasing the cash compensation to \$150 per hour. Consulting fees paid to the CFO were \$19,000 and \$37,000 for the years ended December 31, 2019 and 2020, respectively.

Mr. Najmabadi, another co-founder of the Company has served as our consulting technical engineering advisor on manufacturing and intellectual property matters since January 2020. Previously he was CEO of the Company from 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 quarterly compensation of \$3,000.

14. Subsequent Events

For the financial statements as of December 31, 2020 and for the year then ended, the Company evaluated subsequent events through May 12, 2021, the date on which those financial statements were issued. The Company has concluded that no events or transactions have occurred that require disclosure in the accompanying financial statements, other than the following:

On February 6, 2021, the Company received notification and confirmation from Silicon Valley Bank that its PPP loan and related accrued interest has been forgiven in its entirety by the U.S. Small Business Administration and automatically cancelled.

On March 1, 2021, the Company entered into an amendment to the 2020 Convertible Notes which provides for the extension of the maturity date of the 2020 Convertible Notes from March 2021 to October 30, 2021 and 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.

In April 2021, the Company entered into a note purchase agreement and a series of convertible note payable agreements (the “2021 Convertible Notes”) for aggregate borrowings of approximately \$2.0 million. Outstanding borrowings under the 2021 Convertible Notes and accrued interest are due in April 2022, if not previously converted. The 2021 Notes bear 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 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.

In June 2021, the Company amended the 2013 Plan to increase the number of shares of common stock reserved for issuance by 260,000 and also granted 287,000 stock options with a weighted average exercise price of \$0.49 per share and a grant fair value of approximately \$56,000.

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RenovoRx, Inc.

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

	December 31, 2020 (Note 2)	March 31, 2021 (Unaudited)
Assets		
Current assets:		
Cash and cash equivalents	\$ 1,795	\$ 837
Prepaid expenses and other current assets	115	116
Total current assets	1,910	953
Other assets	4	325
Total assets	\$ 1,914	\$ 1,278
Liabilities, Convertible Preferred Stock and Stockholders’ Deficit		
Current liabilities:		
Accounts payable	\$ 162	\$ 472
Accrued expenses	311	413
Promissory note, current	117	-
Convertible note	2,650	2,843
Derivative liability	856	861
Total current liabilities	4,096	4,589
Promissory note, net of current portion	23	-
Total liabilities	4,119	4,589
Commitments and contingencies		
Convertible preferred stock, \$0.0001 par value; 22,360,455 shares authorized; 17,677,353 shares issued and outstanding at December 31, 2020 and March 31, 2021 (aggregate liquidation preference of \$12,782 at December 31, 2020 and March 31, 2021)	12,451	12,451
Stockholders’ deficit:		
Common stock, \$0.0001 par value; 42,000,000 shares authorized; 11,165,703 and 11,415,994 shares issued and outstanding at December 31, 2020 and March 31, 2021, respectively	1	1
Additional paid-in capital	303	345
Accumulated deficit	(14,960)	(16,108)
Total stockholders’ deficit	(14,656)	(15,762)
Total liabilities, convertible preferred stock and stockholders’ deficit	\$ 1,914	\$ 1,278

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

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

	Three Months Ended March 31,	
	2020	2021
Operating expenses:		
Research and development	\$ 805	\$ 635
General and administrative	248	418
Total operating expenses	<u>1,053</u>	<u>1,053</u>
Loss from operations	<u>(1,053)</u>	<u>(1,053)</u>
Other income (expense), net:		
Interest income (expense), net	2	(230)
Other expense, net	-	(5)
Gain on loan extinguishment	-	140
Total other income (expense), net	<u>2</u>	<u>(95)</u>
Net loss	<u>\$ (1,051)</u>	<u>\$ (1,148)</u>
Net loss per share - basic and diluted	<u>\$ (0.10)</u>	<u>\$ (0.10)</u>
Weighted average shares of common stock - basic and diluted	<u>10,974</u>	<u>11,209</u>

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

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

	Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount	Capital	Deficit	Deficit
Balance at December 31, 2019	17,543,161	\$ 12,391	10,885,936	\$ 1	\$ 235	\$ (11,162)	\$ (10,926)
Issuance of restricted stock award to nonemployee for service	-	-	122,393	-	17	-	17
Issuance of common stock upon exercise of stock options	-	-	83,333	-	11	-	11
Issuance of Series A-1 convertible preferred stock upon exercise of warrant	134,192	25	-	-	-	-	-
Warrant liability transferred to mezzanine equity	-	35	-	-	-	-	-
Stock-based compensation expense	-	-	-	-	10	-	10
Net loss	-	-	-	-	-	(1,051)	(1,051)
Balance at March 31, 2020	<u>17,677,353</u>	<u>\$ 12,451</u>	<u>11,091,662</u>	<u>\$ 1</u>	<u>\$ 273</u>	<u>\$ (12,213)</u>	<u>\$ (11,939)</u>
Balance at December 31, 2020	17,677,353	\$ 12,451	11,165,703	\$ 1	\$ 303	\$ (14,960)	\$ (14,656)
Issuance of common stock upon exercise of stock options	-	-	250,291	-	34	-	34
Stock-based compensation expense	-	-	-	-	8	-	8
Net loss	-	-	-	-	-	(1,148)	(1,148)
Balance at March 31, 2021	<u>17,677,353</u>	<u>\$ 12,451</u>	<u>11,415,994</u>	<u>\$ 1</u>	<u>\$ 345</u>	<u>\$ (16,108)</u>	<u>\$ (15,762)</u>

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

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

	Three Months Ended March 31,	
	2020	2021
Cash flows from operating activities:		

Net loss	\$	(1,051)	\$	(1,148)
Adjustments to reconcile net loss to net cash used in operating activities:				
Stock-based compensation expense		10		8
Loss on change in fair value of derivative liability		-		5
Gain on loan extinguishment		-		(140)
Amortization of debt discount		-		188
Amortization of debt issuance cost		-		5
Changes in operating assets and liabilities:				
Prepaid expenses and other current assets		(66)		(1)
Other assets		-		(321)
Accounts payable		(132)		310
Accrued expenses		200		102
Net cash used in operating activities		<u>(1,039)</u>		<u>(992)</u>
Cash flows from financing activities:				
Proceeds from convertible notes		1,290		-
Payment of debt issuance costs		(14)		-
Proceeds from exercise of Series A-1 warrant		25		-
Proceeds from exercise of stock options		11		34
Net cash provided by financing activities		<u>1,312</u>		<u>34</u>
Increase (decrease) in cash, cash equivalents and restricted cash		273		(958)
Cash, cash equivalents and restricted cash, beginning of period		2,124		1,795
Cash, cash equivalents and restricted cash, end of period	\$	<u>2,397</u>	\$	<u>837</u>
Supplemental disclosure of non-cash investing and financing activities:				
Derivative liability	\$	<u>363</u>	\$	<u>861</u>
Supplemental disclosure of non-cash activity:				
Debt issuance costs - 2021 Convertible Notes	\$	<u>-</u>	\$	<u>6</u>

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

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1. Organization

Description of the Business

RenovoRx, Inc. (“RenovoRx” or the “Company”) was incorporated in 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 registrational 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. RenovoTAMP combines the Company’s 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 the Company anticipates investigating other chemotherapeutic agents for intra-arterial delivery via RenovoTAMP, to date the Company’s clinical work has focused on gemcitabine, which is a generic drug. The Company’s first product candidate, RenovoGem, is a drug and device combination consisting of intra-arterial gemcitabine and RenovoCath. FDA has determined that RenovoGem will be regulated as, and if approved the Company expects will be reimbursed as, a new oncology drug product. The Company has secured FDA Orphan Drug Designation for RenovoGem in its first two indications: pancreatic cancer and cholangiocarcinoma (bile duct cancer, or CCA). The Company has completed its 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 treated with RenovoGem and radiation versus expected survival of 12-15 months in patients receiving only intravenous (IV) systemic chemotherapy dosed at 1,000mg/m² based on historical control data. Unlike the historical controls, the Company’s RR1 and RR2 studies were not randomized or controlled for potential confinement. Based on FDA safety review of the Company’s Phase 1/2 study the FDA allowed the Company to proceed to evaluate RenovoGem within its Phase 3 registration Investigational New Drug, or IND, clinical trial. This Phase 3 trial is 40% enrolled as of April 30, 2021 and the Company expects to report data from a planned interim data readout in the second half of 2022. The Company intends to evaluate RenovoGem in a second indication in a Phase 2/3 trial in hilar CCA (cancer that occurs in the bile ducts that lead out of the liver and join with the gallbladder, also called extrahepatic cholangiocarcinoma, or HCCA). The Company plans to propose the trial to the FDA and potentially launch in the first half of 2022. In addition, the Company 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, the Company has used gemcitabine, but in the future it may develop other chemotherapeutic agents for intra-arterial delivery via RenovoCath.

2. Summary of Significant Accounting Policies

Unaudited Financial Statements

The accompanying unaudited condensed interim financial statements should be read in conjunction with the audited financial statements and notes thereto included elsewhere in this prospectus. The unaudited condensed interim balance sheet as of December 31, 2020 included herein was derived from the audited financial statements as of that date. The results of operations for the three months ended March 31, 2021 are not necessarily indicative of the results for the fiscal year ending December 31, 2021 or any future interim period. The financial statement data and the other financial information contained in these notes to the unaudited condensed interim financial statements related to the three-month periods are also unaudited. Certain disclosures have been condensed or omitted from the unaudited condensed interim financial statements.

Basis of Presentation

The accompanying unaudited condensed interim 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 U.S. Securities and Exchange Commission (“SEC”) for interim 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”).

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In the opinion of management, the accompanying unaudited condensed interim financial statements include all normal and recurring adjustments (which consist primarily of

accruals, estimates and assumptions that impact the financial statements) considered necessary to present fairly the Company's financial position as of March 31, 2021 and its results of operations and changes in convertible preferred stock and stockholders' deficit for the three months ended March 31, 2020 and 2021 and cash flows for the three months ended March 31, 2020 and 2021. Operating results for the three months ended March 31, 2021 are not necessarily indicative of the results that may be expected for the year ending December 31, 2021.

Liquidity and Going Concern

The financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. In order to continue its operations, the Company must raise additional equity or debt financings and achieve profitable operations. Although management has historically been successful in raising capital, there can be no assurance that the Company will be able to obtain additional equity or debt financing on terms acceptable to the Company, or at all. The failure to obtain sufficient funds on acceptable terms when needed could have a material adverse effect on the Company's business, financial position, results of operations, and future cash flows. The Company is seeking to complete an initial public offering ("IPO") of its common stock. Upon the closing of an IPO, on specified terms, the Company's outstanding convertible preferred stock will automatically convert into shares of common stock (see Note 8). In the event the Company does not complete an IPO, the Company expects to seek additional funding through other capital sources including through the sale of equity, debt financings or other capital sources including collaborations with other companies or other strategic transactions. However, the Company may be unable to raise additional funds or enter into such agreements or arrangements when needed on acceptable terms, or at all.

As a company with no commercial operating history, the Company is subject to all of the risks and expenses associated with a start-up company. The Company must among other things respond to competitive developments, attract, retain and motivate qualified personnel and support ongoing clinical trials for its product candidate. The Company has generated operating losses and negative cash flows from operations in each year since inception and anticipates that it will continue to incur net losses into the foreseeable future. The Company has not generated any revenue from product sales to date and will continue to incur significant research and development and other expenses related to its ongoing operations. As of March 31, 2021, the Company had cash and cash equivalents of \$837,000 and had an accumulated deficit of \$16.1 million. In April 2021, the Company entered into a series of convertible note agreements with several lenders including current investors to provide an aggregate \$2.0 million in cash proceeds. The Company has funded its operations primarily through the sale and issuance of convertible preferred stock and convertible notes. 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"), cash requirements for the upcoming year, terms of the Company's current debt arrangements, funding capacity, net working capital, total stockholders' deficit and future access to capital. These factors along with the Company's cash and cash equivalents raise substantial doubt about the Company's ability to continue as a going concern for at least one year from the date the financial statements are issued. The financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the outcome of this uncertainty. If future financing is not achieved, the Company may be required to curtail spending to reduce cash outflows.

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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.

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. The Company has made estimates of the impact of COVID-19 within its financial statements and there may be changes to those estimates in future periods. Actual results could materially differ from those estimates.

Use of Estimates

The preparation of unaudited condensed interim 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. Significant estimates and assumptions made in the accompanying unaudited condensed interim financial statements include, but are not limited to, the accrual of certain liabilities, 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. Actual results could differ from materially from these estimates.

Recent Accounting Pronouncements

From time to time, new accounting pronouncements, or Accounting Standard Updates ("ASU") 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.

Concentration of Credit Risk and Significant Suppliers

Financial instruments that potentially subject the Company to concentration of credit risk consist of cash and cash equivalents. At December 31, 2020 and March 31, 2021, the Company maintained \$1.8 million and \$837,000 in cash and cash equivalents, respectively, with one financial institution. The Company is exposed to credit risk in the event of default by the financial institutions to the extent that cash and cash equivalent deposits are in excess of the \$250,000 insured by the Federal Deposit Insurance Corporation. These deposits routinely exceed the insurable limit. To date, the Company has not experienced any losses on its cash and cash equivalents.

The Company is dependent on third-party manufacturers to supply products and services for its research and development activities, including preclinical and clinical development. In particular, the Company relies, and expects to continue 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 the supply of these items.

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. If a planned financing is abandoned, the deferred offering costs are expensed as a charge to operating expenses in the statements of operations.

There were zero and \$321,000 in deferred offering costs included in other assets in the Company's condensed balance sheets at December 31, 2020 and March 31, 2021, respectively.

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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 options outstanding under the Company's stock option plan. For the three months ended March 31, 2020 and 2021, 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 price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. To increase the comparability of fair value measures, the following hierarchy prioritizes the inputs to valuation methodologies used to measure fair value.

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 value of all remaining current assets and current liabilities approximates fair value because of their short-term nature.

Cash and Cash Equivalents

The Company considers all highly liquid investments purchased with a remaining maturity date upon acquisition of three months or less to be cash equivalents. Cash and cash equivalents consist primarily of cash held in checking and money market accounts. As of March 31, 2020, the Company had restricted cash of \$20,000, which consisted of reserve funds held at one financial institution to collateralize the Company's credit cards. The Company held no funds in restricted cash at December 31, 2020 or March 31, 2021.

Convertible Instruments and Embedded Derivatives

The Company evaluates all of its agreements to determine if such instruments have derivatives or contain features that qualify as 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 condensed statements of operations. Derivative instrument liabilities are classified in the condensed 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 and March 31, 2021, the Company's only derivative financial instrument was related to the 2020 Convertible Notes (defined in Note 5), which contained certain redemptive features (see Note 5).

Research and Development Costs

Research and development costs, which include direct and allocated expenses, are expensed in the period incurred. Research and development costs include primarily clinical development-related expenses, pre-clinical research and development expenses, employee compensation and related benefits, regulatory support and related services, clinical consulting, travel-related expenses and allocated expenses for rent, insurance and other general overhead costs. The Company also receives payments from vendors in performing clinical trials on behalf of the Company for the delivery device used by such vendors in performing such clinical trials. These payments are offset against the Company's research and development expenses.

Clinical Trial Expenses

The Company makes payments in connection with clinical trials 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, 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 or 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 levels 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 the Company is 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. As noted above, the Company receives payments from vendors performing clinical trials on behalf of the Company for the delivery device used by such vendors in performing such clinical trials.

General and Administrative

General and administrative expenses consist primarily of personnel costs, including employee compensation and related benefits and consulting. Additionally, these expenses include professional fees, including audit, legal, recruiting services and allocated expenses for rent, insurance and other general overhead costs. 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. The preferred stock is recorded outside of stockholders' deficit because the shares contain liquidation features that are not solely within the Company's control. As a result, the preferred stock is classified as mezzanine equity (temporary equity). The Company has elected not to adjust the carrying value of the preferred stock to the liquidation preferences of such shares because it is uncertain whether or when an event would occur that would obligate the Company to pay the liquidation preferences to holders of shares of preferred stock. Subsequent adjustments to the carrying values to the

liquidation preferences will be made only when it becomes probable that such a liquidation event will occur.

Stock-Based Compensation

The Company calculates the fair value of stock options using the Black-Scholes option pricing model, which incorporates various assumptions including volatility, expected life 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.

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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—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 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.

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. 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 to non-employees, the expected term equals the remaining contractual term of the option from the vesting date.

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 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 grants stock options to its employees for a fixed number of shares with an exercise price equal to the fair value of the underlying shares at date of 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

In determining quarterly provisions for income taxes, the Company uses the annual estimated effective tax rate applied to the actual year-to-date profit or loss, adjusted for discrete items arising in that quarter. The Company's annual estimated effective tax rate differs from the U.S. federal statutory rate primarily as a result of state taxes, foreign taxes, and changes in the Company's valuation allowance against its deferred tax assets. For the three months ended March 31, 2020 and 2021, the Company recorded an immaterial provision for income taxes.

Segment Reporting

Financial Accounting Standards Board ("FASB") ASC Topic 280, *Segment Reporting*, requires use of the "management approach" model for segment reporting. The management approach model is based on the way a Company's management organizes segments within the company for making operating decisions and assessing performance.

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The Company determined it has one reportable segment, the development of a platform technology to deliver de-risked small molecules for localized treatment of solid cancer tumors. The segment is based on financial information that is utilized by the Company's Chief Operating Decision Maker who is the Company's Chief Executive Officer, to assess performance and allocate resources.

Emerging Growth Company Status

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

As an "emerging growth company" ("EGC") under the Jumpstart Our Business Startups Act ("JOBS Act"), the Company may elect to take advantage of certain forms of relief from various reporting requirements that are applicable to public companies. The relief afforded under the JOBS Act includes an extended transition period for the implementation of new or revised accounting standards. The Company has elected to take advantage of this extended transition period and, as a result, the Company's financial statements may not be comparable to those of companies that implement accounting standards as of the effective dates for public companies. The Company may take advantage of the relief afforded under the JOBS Act up until the last day of the fiscal year following the fifth anniversary of an offering or such earlier time that it is no longer an EGC.

3. Accrued Expenses

A summary of the components of accrued expenses is as follows (in thousands):

	<u>December 31, 2020</u>	<u>March 31, 2021</u>
Accrued clinical trials	\$ 171	\$ 254
	101	138
Accrued interest		
Accrued personnel	39	21
	<u>\$ 311</u>	<u>\$ 413</u>

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, 2020 and March 31, 2021 (in thousands):

Fair Value Measurements at December 31, 2020 using:				
Assets:	Level 1	Level 2	Level 3	Total
Money market funds	\$ 1,703	\$ -	\$ -	\$ 1,703
	<u>\$ 1,703</u>	<u>\$ -</u>	<u>\$ -</u>	<u>\$ 1,703</u>
Liabilities:				
Derivative liability – 2020 Convertible Notes		\$ -	\$ 856	\$ 856
		<u>\$ -</u>	<u>\$ 856</u>	<u>\$ 856</u>

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Fair Value Measurements at March 31, 2021 using:				
Assets:	Level 1	Level 2	Level 3	Total
Money market funds	\$ 803	\$ -	\$ -	\$ 803
	<u>\$ 803</u>	<u>\$ -</u>	<u>\$ -</u>	<u>\$ 803</u>
Liabilities:				
Derivative liability – 2020 Convertible Notes	\$ -	\$ -	\$ 861	\$ 861
	<u>\$ -</u>	<u>\$ -</u>	<u>\$ 861</u>	<u>\$ 861</u>

The change in the fair value of the derivative liability is summarized below (in thousands):

	Three Months Ended	
	March 31	
	2020	2021
Fair value at beginning of the period	\$ -	\$ 856
Initial fair value of instruments issued	363	-
Change in fair value of instruments	-	5
Fair value at end of the period	<u>\$ 363</u>	<u>\$ 861</u>

The derivative liability in the table above related to the 2020 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 is measured at fair value on a recurring basis and is classified as a Level 3 liability. The Company records subsequent adjustments to reflect the increase or decrease in estimated fair value at each reporting date in other income (expense), net in the condensed statements of operations (see Note 5).

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. The Company entered into a series of convertible note payable agreements (the "2020 Convertible Notes") for aggregate borrowings of approximately \$3.0 million. Outstanding borrowings under the 2020 Convertible Notes and accrued interest are due in March 2021, if not previously converted. The 2020 Notes bear interest at the rate of 5% per annum. The 2020 Notes cannot be prepaid prior to the maturity date unless approved in writing by the Company and requisite holders.

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The Company evaluated whether the 2020 Convertible Notes contain embedded features that meet the definition of derivatives under FASB ASC 815, *Derivatives and Hedging*. The Company determined that these redemption features 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. The fair value of the derivative liability at December 31, 2020 and March 31, 2021 was \$856,000 and \$861,000, respectively with the offsetting amount being recorded as a debt discount. Debt issuance costs were \$22,000 at December 31, 2020. There were no debt issuance costs during the three months ended March 31, 2021. The derivative liability is subject to fair value remeasurement at the end of each reporting period. The discount and debt issuance costs are being amortized to interest expense using the effective interest method over the expected term of the 2020 Convertible Notes. There was no amortization of debt discount or debt issuance costs for the three months ended March 31, 2020. For the three months ended March 31, 2021, the Company recognized \$193,000 for amortization of the debt discount and debt issuance costs, of which \$188,000 pertains to the debt discount and \$5,000 pertains to debt issuance costs. This amortization expense is recognized as interest expense in the condensed statements of operations for the three months ended March 31, 2021. For the three months ended March 31, 2020 and 2021, the effective interest rate of the 2020 Convertible Notes was 30.8% 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 three months ended March 31, 2020 and 2021, the Company recognized interest expense in the condensed statements of operations of zero and \$37,000, respectively, related to the 2020 Convertible Notes.

On March 1, 2021, the Company entered into an amendment to the 2020 Convertible Notes which extends the maturity date of the 2020 Convertible Notes from March 31, 2021 to October 30, 2021 and provides 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.

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") 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 are forgivable, if the loan proceeds are 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. As of December 31, 2020, payments were deferred for 10 months. The PPP Loan matures on April 22, 2022 and bears interest at a rate of 1.0% per annum. The PPP Loan contains events of default and other provisions customary for a loan of this type. The Company has 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 have been forgiven in their entirety by the U.S. Small Business Administration and automatically cancelled. During the three-months ended March 31, 2021, a gain on loan extinguishment of \$140,000 was recognized and included in other income (expense), net in the condensed 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 134,192 shares of the Company's Series A-1 convertible preferred stock at \$0.1863 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 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 and the fair value was subsequently transferred to mezzanine equity as of the date of exercise.

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8. Common Stock

The Company's common stock reserved for future issuance related to the convertible preferred stock and common stock options as of March 31, 2020 and 2021 are as follows:

	<u>As of March 31,</u>	
	<u>2020</u>	<u>2021</u>
Series A-1 convertible preferred stock	3,542,669	3,542,669
Series A-2 convertible preferred stock	3,546,095	3,546,095
Series A-3 convertible preferred stock	2,660,230	2,660,230
Series B convertible preferred stock	12,611,461	12,611,461
Common stock options outstanding	5,012,875	4,755,668
Common stock options reserved for issuance	111,967	44,842
	<u>27,485,297</u>	<u>27,160,965</u>
Total		

The shares that would be issued upon a conversion of the 2020 Convertible Notes have been excluded from the table above as the number of common shares that would be issued is contingent upon the occurrence of a future Qualified Financing and the conversion price per share would be equal to 80% of the price per share paid by the investors in the future Qualified Financing.

9. Stock-Based Compensation

Activity under the 2013 Plan for the three-month period ended March 31, 2021 is set forth below (in thousands except shares, per share amounts and years):

	<u>Shares Available for Grant</u>	<u>Number of Shares</u>	<u>Weighted Average Exercise Price</u>	<u>Weighted Average Remaining Contractual Life (Years)</u>	<u>Aggregate Intrinsic Value</u>
Outstanding at December 31, 2020	64,467	4,986,334	\$ 0.08	5.84	\$ 276
Options granted	(54,000)	54,000	0.16		
Options exercised	-	(250,291)	0.14		
Options forfeited	34,375	(34,375)	0.13		
Outstanding at March 31, 2021	<u>44,842</u>	<u>4,755,668</u>	\$ 0.08	5.41	\$ 369
Vested and exercisable at March 31, 2021		<u>4,150,142</u>	\$ 0.08	5.05	\$ 352
Vested and expected to vest at March 31, 2021		<u>4,755,668</u>	\$ 0.08	5.41	\$ 369

During the three-month period ended March 31, 2020, the Company recognized \$10,000 in stock-based compensation expense from stock option grants. During the three-month period ended March 31, 2021, the Company recognized \$8,000 in stock-based compensation expense. The compensation expense is allocated on a departmental basis, based on the classification of the option holder. No income tax benefits have been recognized in the condensed statements of operations for stock-based compensation arrangements.

The following sets forth the weighted average assumptions used to determine the fair value of stock options for the three months ended March 31, 2020 and 2021:

	<u>Three Months Ended March 31,</u>	
	<u>2020</u>	<u>2021</u>
Expected term (years)	4.64	5.51
Risk-free interest rate	1.60%	0.72%
Volatility factor	37%	42%
Dividend yield	-	-

The weighted-average fair value of options granted was \$0.05 per share and \$0.06 per share in the three-months ended March 31, 2020 and 2021, respectively.

Future stock-based compensation for unvested employee options granted and outstanding as of March 31, 2021 is \$30,000, to be recognized over a weighted-average remaining requisite service period of 1.46 years.

10. Income Tax

The Company had no income tax expense for the three months ended March 31, 2020 and 2021. During the three months ended March 31, 2020 and 2021, the Company had a net operating loss (“NOL”) for each period that generated deferred tax assets for NOL carryforwards. Deferred income tax assets and liabilities are recognized for temporary differences between the financial statements and income tax carrying values using tax rates in effect for the years such differences are expected to reverse. Due to uncertainties surrounding our ability to generate future taxable income and consequently realize such deferred income tax assets, the Company has determined that it is more-likely-than-not that these deferred tax assets will not be realized. Accordingly, the Company has established a full valuation allowance against its deferred tax assets as of March 31, 2021.

The Company’s policy is to recognize any interest and penalties related to unrecognized tax benefits as a component of income tax expense. As of the three months ended March 31, 2020 and 2021, the Company had no accrued interest or penalties related to uncertain tax positions.

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11. Net Loss per Share

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

	Three Months Ended March 31,	
	2020	2021
Numerator:		
Net loss	\$ (1,051)	\$ (1,148)
Denominator:		
Weighted average shares used in computing net loss per share – basic and diluted	10,974	11,209
Net loss per share – basic and diluted	\$ (0.10)	\$ (0.10)

For the three-month periods ended March 31, 2020 and 2021, 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):

	Three Months Ended March 31,	
	2020	2021
Convertible preferred stock	17,677,353	17,677,353
Options to purchase common stock	5,012,875	4,755,668
	22,690,228	22,433,021

The table above omits the potentially dilutive shares into which the 2020 Convertible Notes would convert.

12. Related Party Transactions

In January 2013, the Company entered into a consulting agreement (the “Agreement”) with one of the Company’s co-founders whereby the co-founder provides consulting services as the Company’s Chief Medical Officer (“CMO”) by overseeing Company-sponsored clinical trials. An amendment to the Agreement was signed in 2019 providing cash compensation to the CMO of \$10,000 per month for additional services. Consulting fees paid to the CMO were \$30,000 for each of the three-month periods ended March 31, 2020 and 2021.

In July 2019, the Company entered into a consulting agreement (the “CFO Agreement”) with the Company’s Chief Financial Officer (“CFO”) providing for compensation of \$50 per hour. In February 2020, the Company granted the CFO an option to purchase 140,000 shares of the Company’s common stock, of which 25% were vested at the grant date and the remaining 75% vested ratably over 18 months. The Company entered into an amendment to the Agreement in December 2020 increasing the cash compensation to \$150 per hour. Consulting fees paid to the CFO were \$12,000 and \$54,000 for the three months ended March 31, 2020 and 2021, respectively.

Another co-founder of the Company has served as our consulting technical engineering advisor on manufacturing and intellectual property matters since January 2020. Previously he was CEO of the Company from 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 quarterly compensation of \$3,000.

13. Subsequent Events

The Company has evaluated all events occurring through May 12, 2021, the date on which the unaudited condensed interim financial statements were issued.

In April 2021, the Company entered into a note purchase agreement and a series of convertible note payable agreements (the “2021 Convertible Notes”) for aggregate borrowings of approximately \$2.0 million. Outstanding borrowings under the 2021 Convertible Notes and accrued interest are due in April 2022, if not previously converted. The 2021 Notes bear 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 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.

In June 2021, the Company amended the 2013 Plan to increase the number of shares of common stock reserved for issuance by 260,000 and also granted 287,000 stock options with a weighted average exercise price of \$0.49 per share and a grant fair value of approximately \$56,000.

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[] Shares of Common Stock

PROSPECTUS

Roth Capital Partners

The date of this prospectus is , 2021

PART II
INFORMATION NOT REQUIRED IN PROSPECTUS

Item 13. Other Expenses of Issuance and Distribution.

The following table sets forth the costs and expenses, other than underwriter fees to be paid by us in connection with the sale of the shares of our common stock being registered hereby. All amounts are estimates except for the SEC registration fee, the FINRA filing fee and the NASDAQ listing fee. All such expenses will be borne by the Company.

Table with 2 columns: Expense Category, Amount. Rows include SEC registration fee, FINRA filing fee, NASDAQ listing fee, Legal fees and expenses, Accounting fees and expenses, Printing and engraving expenses, Transfer agent and registrar fees and expenses, Other expenses, and Total.

Item 14. Indemnification of Directors and Officers.

Section 102(b)(7) of Delaware’s General Corporation Law (“DGCL”) allows a corporation to provide in its certificate of incorporation that a director of the corporation will not be personally liable to the corporation or its stockholders for monetary damages for breach of fiduciary duty as a director, except where the director breached the duty of loyalty, failed to act in good faith, engaged in intentional misconduct or knowingly violated a law, authorized the payment of a dividend or approved a stock repurchase in violation of Delaware corporate law or obtained an improper personal benefit. Our amended and restated certificate of incorporation provides for this limitation of liability.

Section 145 of the DGCL, or Section 145, provides that a Delaware corporation may indemnify any person who was, is or is threatened to be made, party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of such corporation), by reason of the fact that such person is or was an officer, director, employee or agent of such corporation or is or was serving at the request of such corporation as a director, officer, employee or agent of another corporation or enterprise. The indemnity may include expenses (including attorneys’ fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by such person in connection with such action, suit or proceeding, provided such person acted in good faith and in a manner he reasonably believed to be in or not opposed to the corporation’s best interests and, with respect to any criminal action or proceeding, had no reasonable cause to believe that his or her conduct was illegal. A Delaware corporation may indemnify any persons who are, were or are a party to any threatened, pending or completed action or suit by or in the right of the corporation by reason of the fact that such person is or was a director, officer, employee or agent of another corporation or enterprise. The indemnity may include expenses (including attorneys’ fees) actually and reasonably incurred by such person in connection with the defense or settlement of such action or suit, provided such person acted in good faith and in a manner he reasonably believed to be in or not opposed to the corporation’s best interests, provided that no indemnification is permitted without judicial approval if the officer, director, employee or agent is adjudged to be liable to the corporation. Where an officer or director is successful on the merits or otherwise in the defense of any action referred to above, the corporation must indemnify him against the expenses which such officer or director has actually and reasonably incurred.

Section 145 further authorizes a corporation to purchase and maintain insurance on behalf of any person who is or was a director, officer, employee or agent of the corporation or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation or enterprise, against any liability asserted against him and incurred by him in any such capacity, or arising out of his or her status as such, whether or not the corporation would otherwise have the power to indemnify him under Section 145.

Our amended and restated bylaws provide that we must indemnify our directors and officers to the fullest extent permitted by the DGCL and must also pay expenses incurred in defending any such proceeding in advance of its final disposition upon delivery of an undertaking, by or on behalf of an indemnified person, to repay all amounts so advanced if it should be determined ultimately that such person is not entitled to be indemnified.

We will enter into indemnification agreements with certain of our executive officers and directors pursuant to which we will agree to indemnify such persons against all expenses and liabilities incurred or paid by such person in connection with any proceeding arising from the fact that such person is or was an officer or director of our company, and to advance expenses as incurred by or on behalf of such person in connection therewith.

The indemnification rights set forth above shall not be exclusive of any other right which an indemnified person may have or hereafter acquire under any statute, provision of our certificate of incorporation, our bylaws, agreement, vote of stockholders or disinterested directors or otherwise.

We maintain standard policies of insurance that provide coverage (1) to our directors and officers against loss rising from claims made by reason of breach of duty or other wrongful act and (2) to us with respect to indemnification payments that we may make to such directors and officers.

Item 15. Recent Sales of Unregistered Securities

During the past three years, we issued the following securities, which were not registered under the Securities Act.

In March 2020, the Company entered into a note purchase agreement for the issuance of up to \$4.0 million of convertible promissory notes. The Company entered into a series of convertible note payable agreements (the “2020 Convertible Notes”) for aggregate borrowings of approximately \$3.0 million. Outstanding borrowings under the 2020 Convertible Notes and accrued interest are due in March 2021, if not previously converted. The 2020 Notes bear interest at the rate of 5% per annum. The 2020 Notes cannot be prepaid prior to the maturity date unless approved in writing by the Company and requisite holders.

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”) 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 are forgivable, if the loan proceeds are 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. As of December 31, 2020, payments were deferred for 10 months. The PPP Loan matures on April 22, 2022 and bears interest at a rate of 1.0% per annum.

In April 2021, the Company entered into a note purchase agreement and a series of convertible note payable agreements (the “2021 Convertible Notes”) for aggregate borrowings of approximately \$2.0 million. Outstanding borrowings under the 2021 Convertible Notes and accrued interest are due in April 2022, if not previously converted. The 2021 Notes bear 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.

We deemed the offers, sales and issuances of the securities described above to be exempt from registration under the Securities Act in reliance on Section 4(2) of the Securities Act, including Regulation D and Rule 506 promulgated thereunder, relative to transactions by an issuer not involving a public offering.

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Item 16. Exhibits and Financial Statement Schedules

<u>Exhibit</u>	<u>Description</u>
1.1**	Form of Underwriting Agreement.
3.1*	Fifth Amended and Restated Certificate of Incorporation of Company
3.2	Certificate of Amendment of Fifth Amended and Restated Certificate of Incorporation of the Company
3.3*	Form of Sixth Amended and Restated Certificate of Incorporation, to be effective immediately prior to the closing of the offering
3.4*	By-Laws of the Company
3.5*	Form of Amended and Restated By-Laws of the Company, to be effective immediately prior to the closing of the offering
4.1	Form of Representative’s Warrant
5.1**	Opinion of Sheppard, Mullin, Richter & Hampton, LLP
10.1	2013 Stock Incentive Plan
10.2*	Consulting Agreement with Ramtin Agah, MD
10.3*	Amended Consulting Agreement with Ramtin Agah, MD
10.4*	Consulting Agreement with Paul Manners
10.5*	Amended Consulting Agreement with Paul Manners
10.6**	Form of 2021 Equity Incentive Plan
10.7**	Form of Indemnification Agreement
10.8*	Form of April 2021 Convertible Promissory Note
10.9*	Form of March 2020 Convertible Promissory Note
10.10*	Form of Amendment to 2020 Convertible Promissory Note
10.11+*	Master Supply Agreement dated October 28, 2019 by and between Medical Murray, Inc. and RenovoRx, Inc.
23.1**	Consent of Sheppard Mullin Richter & Hampton, LLP (included in Exhibit 5.1)
23.2**	Consent of Frank, Rimerman & Co. LLP, independent registered public accounting firm.
24.1**	Power of Attorney (included on the signature page)

* Previously filed

** To be filed by amendment

+ Portions of this exhibit (indicated by asterisks) have been redacted in compliance with Regulation S-K Item 601(b)(10)(iv).

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Item 17. Undertakings

(a) The undersigned registrant hereby undertakes as follows:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) To include any prospectus required by Section 10(a)(3) of the Securities Act of 1933;

(ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than 20 percent change in the maximum aggregate offering price set forth in the “Calculation of Registration Fee” table in the effective registration statement;

(iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement.

(2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(4) That, for the purpose of determining liability under the Securities Act of 1933 to any purchaser, each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A, shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use.

(5) That, for the purpose of determining any liability under the Securities Act of 1933 to any purchaser in the initial distribution of the securities, the undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:

(i) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;

(ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;

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(iii) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or our securities provided by or on behalf of the undersigned registrant; and

(iv) Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.

(b) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the undersigned pursuant to the foregoing provisions, or otherwise, the undersigned has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the undersigned of expenses incurred or paid by a director, officer or controlling person of the undersigned in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the undersigned will, unless in the opinion of our counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

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SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, RenovoRx, Inc., a Delaware corporation, has duly caused this Registration Statement on Form S-1 to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Los Altos, state of California, on June [], 2021.

RENOVORX, INC.

By: _____

Name: Shaun R. Bagai

Title: Chief Executive Officer

POWER OF ATTORNEY

Each person whose signature appears below constitutes and appoints each of Shaun R. Bagai and Paul Manners as his or her true and lawful attorneys-in-fact and agents with full power of substitution and resubstitution, for him and his name, place and stead, in any and all capacities, to sign any or all amendments (including post-effective amendments) to this registration statement and to file a new registration statement under Rule 461, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the foregoing, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or their substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, this Amendment to Registration Statement on Form S-1 has been signed by the following persons in the capacities indicated.

<u>SIGNATURE</u>	<u>TITLE</u>	<u>DATE</u>
_____ Shaun R. Bagai	Chief Executive Officer and Director (Principal Executive Officer)	June [], 2021
_____ Paul Manners	Chief Financial Officer (Principal Financial Officer)	June [], 2021
_____ Ramtin Agah	Director	June [], 2021
_____ Laurence J. Marton	Director	June [], 2021
_____ Una S. Ryan	Director	June [], 2021

Maky Zanganeh

Director

June [], 2021

Kristen Angela Macfarlane

Director

June [], 2021

David Diamond

Director

June [], 2021

**CERTIFICATE OF AMENDMENT OF
FIFTH AMENDED AND RESTATED CERTIFICATE OF INCORPORATION OF
RENOVORX, INC.**

RenovoRx, Inc., a corporation organized and existing under the laws of the State of Delaware (the “**Company**”), certifies that:

1. The name of the Company is RenovoRx, Inc. The Company’s original Certificate of Incorporation was filed with the Secretary of State of the State of Delaware on December 17, 2012.

2. This Certificate of Amendment of Fifth Amended and Restated Certificate of Incorporation was duly adopted in accordance with Section 242 of the Delaware General Corporation Law, with the approval of such amendment by the Company’s stockholders having been given by written consent without a meeting in accordance with Sections 228 and 242 of the Delaware General Corporation Law, and amends the provisions of the Company’s Fifth Amended and Restated Certificate of Incorporation, as currently in effect, as set forth below.

3. Article Fourth, Part E, Section 2(c)(i) of the Company’s Fifth Amended and Restated Certificate of Incorporation is hereby amended and restated in its entirety as follows:

“The size of the Board shall be no more than eight (8) directors; provided, however, that upon a Board Restructuring Event (as defined in that certain Amended and Restated Voting Agreement dated on or about the date hereof), the size of the Board of Directors shall be reduced to seven (7) directors.”

4. Article Fourth, Part E, Section 2(c)(vii) of the Company’s Fifth Amended and Restated Certificate of Incorporation is hereby amended and restated in its entirety as follows:

“If the holders of shares of Series Preferred or Common Stock, as the case may be, fail to elect a sufficient number of directors to fill all directorships for which they are entitled to elect directors, voting exclusively and as a separate class, pursuant to this Section IV.E.2(c), then any directorship not so filled shall remain vacant until such time as the holders of the Series Preferred (or any particular series of Preferred Stock) or Common Stock, as the case may be, elect a person to fill such directorship by vote or written consent in lieu of a meeting; and no such directorship may be filled by stockholders of the Company other than by the stockholders of the Company that are entitled to elect a person to fill such directorship, voting exclusively and as a separate class. The holders of record of the shares of Common Stock and of any other class or series of voting stock (including the Preferred Stock), exclusively and voting together as a single class, shall be entitled to elect the balance of the total number of directors of the Company. Any director may be removed during his or her term of office without cause, by, and only by, the affirmative vote of the holders of the shares of the class or series of stock entitled to elect such director or directors, given either at a meeting of such stockholders or pursuant to a written consent of stockholders, and any vacancy thereby created may be filled by the holders of that class or series of stock represented at the meeting or pursuant to written consent; provided that such director shall be deemed removed immediately upon the termination of the right of the appointing stockholders to elect such director. At any meeting held for the purpose of electing a director, the presence in person or by proxy of the holders of a majority of the outstanding shares of the class or series entitled to elect such director shall constitute a quorum for the purpose of electing such director.”

[Signature Page Follows]

IN WITNESS WHEREOF, this Certificate of Amendment has been signed this ____ day of _____, 2021.

RENOVORX, INC.

By: _____
Shaun R. Bagai
Chief Executive Officer

**Signature Page to
the Certificate of Amendment of Fifth Amended and Restated Certificate of Incorporation of
RenovoRx, Inc.**

UNDERWRITER COMMON STOCK PURCHASE WARRANT

RENOVORX, INC.

Warrant Shares: _____

Initial Exercise Date: _____

Issue Date: _____

THIS UNDERWRITER COMMON STOCK PURCHASE WARRANT (the "Warrant") certifies that, for value received, _____ or its assigns (the "Holder") is entitled, upon the terms and subject to the limitations on exercise and the conditions hereinafter set forth, at any time on or after _____¹ (the "Initial Exercise Date") and on or prior to 5:00 p.m. (New York City time) on _____² (the "Termination Date") but not thereafter, to subscribe for and purchase from RenovorX, Inc., a Delaware corporation (the "Company"), up to _____ shares (as subject to adjustment hereunder, the "Warrant Shares") of Common Stock. The purchase price of one share of Common Stock under this Warrant shall be equal to the Exercise Price, as defined in Section 2(b). This Warrant is issued pursuant to the Underwriting Agreement.

Section 1. Definitions. In addition to the terms defined elsewhere in this Warrant, the following terms have the meanings indicated in this Section 1:

"Affiliate" means any Person that, directly or indirectly through one or more intermediaries, controls or is controlled by or is under common control with a Person, as such terms are used in and construed under Rule 405 under the Securities Act.

"Bid Price" means, for any date, the price determined by the first of the following clauses that applies: (a) if the Common Stock is then listed or quoted on a Trading Market, the bid price of the Common Stock for the time in question (or the nearest preceding date) on the Trading Market on which the Common Stock is then listed or quoted as reported by Bloomberg L.P. (based on a Trading Day from 9:30 a.m. (New York City time) to 4:02 p.m. (New York City time)), (b) if OTCQB or OTCQX is not a Trading Market, the volume weighted average price of the Common Stock for such date (or the nearest preceding date) on OTCQB or OTCQX as applicable, (c) if the Common Stock is not then listed or quoted for trading on OTCQB or OTCQX and if prices for the Common Stock are then reported on the Pink Open Market (or a similar organization or agency succeeding to its functions of reporting prices), the most recent bid price per share of the Common Stock so reported, or (d) in all other cases, the fair market value of a share of Common Stock as determined by an independent appraiser selected in good faith by the Holders of a majority in interest of the Warrants then outstanding and reasonably acceptable to the Company, the fees and expenses of which shall be paid by the Company.

¹ Insert the date that is the 6 month anniversary of the effective date of the Registration Statement.

² Insert the date that is the 5 year anniversary of the effective date of the Registration Statement, provided that, if such date is not a Trading Day, insert the immediately preceding Trading Day.

"Business Day" means any day other than Saturday, Sunday or other day on which commercial banks in The City of New York are authorized or required by law to remain closed; provided, however, for clarification, commercial banks shall not be deemed to be authorized or required by law to remain closed due to "stay at home", "shelter-in-place", "non-essential employee" or any other similar orders or restrictions or the closure of any physical branch locations at the direction of any governmental authority so long as the electronic funds transfer systems (including for wire transfers) of commercial banks in The City of New York generally are open for use by customers on such day.

"Commission" means the United States Securities and Exchange Commission.

"Common Stock" means the common stock of the Company, par value \$0.0001 per share, and any other class of securities into which such securities may hereafter be reclassified or changed.

"Common Stock Equivalents" means any securities of the Company or the Subsidiaries which would entitle the holder thereof to acquire at any time Common Stock, including, without limitation, any debt, preferred stock, right, option, warrant or other instrument that is at any time convertible into or exercisable or exchangeable for, or otherwise entitles the holder thereof to receive, Common Stock.

"Exchange Act" means the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.

"Person" means an individual or corporation, partnership, trust, incorporated or unincorporated association, joint venture, limited liability company, joint stock company, government (or an agency or subdivision thereof) or other entity of any kind.

"Registration Statement" means the Company's registration statement on Form S-1 (File No. _____).

"Securities Act" means the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder.

"Subsidiary" means any subsidiary of the Company and shall, where applicable, also include any direct or indirect subsidiary of the Company formed or acquired after the date hereof.

"Trading Day" means a day on which the Common Stock is traded on a Trading Market.

"Trading Market" means any of the following markets or exchanges on which the Common Stock is listed or quoted for trading on the date in question: the NYSE American, the Nasdaq Capital Market, the Nasdaq Global Market, the Nasdaq Global Select Market or the New York Stock Exchange (or any successors to any of the foregoing).

"Transfer Agent" means _____, the current transfer agent of the Company, with a mailing address of _____ and a facsimile number of _____, and any successor transfer agent of the Company.

"Underwriting Agreement" means the underwriting agreement, dated as of _____, between the Company and Roth Capital Partners, LLC as representative of the underwriters named therein, as amended, modified or supplemented from time to time in accordance with its terms.

"VWAP" means, for any date, the price determined by the first of the following clauses that applies: (a) if the Common Stock is then listed or quoted on a Trading Market, the daily volume weighted average price of the Common Stock for such date (or the nearest preceding date) on the Trading Market on which the Common Stock is then listed or quoted as reported by Bloomberg L.P. (based on a Trading Day from 9:30 a.m. (New York City time) to 4:02 p.m. (New York City

time)), (b) if OTCQB or OTCQX is not a Trading Market, the volume weighted average price of the Common Stock for such date (or the nearest preceding date) on OTCQB or OTCQX as applicable, (c) if the Common Stock is not then listed or quoted for trading on OTCQB or OTCQX and if prices for the Common Stock are then reported on the Pink Open Market (or a similar organization or agency succeeding to its functions of reporting prices), the most recent bid price per share of the Common Stock so reported, or (d) in all other cases, the fair market value of a share of Common Stock as determined by an independent appraiser selected in good faith by the holders of a majority in interest of the Warrants then outstanding and reasonably acceptable to the Company, the fees and expenses of which shall be paid by the Company.

“Warrants” means this Warrant and other Common Stock purchase warrants issued by the Company pursuant to the Registration Statement.

Section 2. Exercise.

a) **Exercise of Warrant.** Exercise of the purchase rights represented by this Warrant may be made, in whole or in part, at any time or times on or after the Initial Exercise Date and on or before the Termination Date by delivery to the Company of a duly executed facsimile copy or PDF copy submitted by e-mail (or e-mail attachment) of the Notice of Exercise in the form annexed hereto (the “Notice of Exercise”). Within the earlier of (i) two (2) Trading Days and (ii) the number of Trading Days comprising the Standard Settlement Period (as defined in Section 2(d)(i) herein) following the date of exercise as aforesaid, the Holder shall deliver the aggregate Exercise Price for the shares specified in the applicable Notice of Exercise by wire transfer or cashier’s check drawn on a United States bank unless the cashless exercise procedure specified in Section 2(c) below is specified in the applicable Notice of Exercise. No ink-original Notice of Exercise shall be required, nor shall any medallion guarantee (or other type of guarantee or notarization) of any Notice of Exercise be required. Notwithstanding anything herein to the contrary, the Holder shall not be required to physically surrender this Warrant to the Company until the Holder has purchased all of the Warrant Shares available hereunder and the Warrant has been exercised in full, in which case, the Holder shall surrender this Warrant to the Company for cancellation within three (3) Trading Days of the date on which the final Notice of Exercise is delivered to the Company. Partial exercises of this Warrant resulting in purchases of a portion of the total number of Warrant Shares available hereunder shall have the effect of lowering the outstanding number of Warrant Shares purchasable hereunder in an amount equal to the applicable number of Warrant Shares purchased. The Holder and the Company shall maintain records showing the number of Warrant Shares purchased and the date of such purchases. The Company shall deliver any objection to any Notice of Exercise within one (1) Business Day of receipt of such notice. **The Holder and any assignee, by acceptance of this Warrant, acknowledge and agree that, by reason of the provisions of this paragraph, following the purchase of a portion of the Warrant Shares hereunder, the number of Warrant Shares available for purchase hereunder at any given time may be less than the amount stated on the face hereof.**

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b) **Exercise Price.** The exercise price per share of Common Stock under this Warrant shall be \$_____, subject to adjustment hereunder (the “Exercise Price”).

c) **Cashless Exercise.** If at the time of exercise hereof there is no effective registration statement registering, or the prospectus contained therein is not available for the issuance of the Warrant Shares to the Holder, then this Warrant may also be exercised, in whole or in part, at such time by means of a “cashless exercise” in which the Holder shall be entitled to receive a number of Warrant Shares equal to the quotient obtained by dividing [(A-B) (X)] by (A), where:

(A) = as applicable: (i) the VWAP on the Trading Day immediately preceding the date of the applicable Notice of Exercise if such Notice of Exercise is (1) both executed and delivered pursuant to Section 2(a) hereof on a day that is not a Trading Day or (2) both executed and delivered pursuant to Section 2(a) hereof on a Trading Day prior to the opening of “regular trading hours” (as defined in Rule 600(b)(68) of Regulation NMS promulgated under the federal securities laws) on such Trading Day, (ii) at the option of the Holder, either (y) the VWAP on the Trading Day immediately preceding the date of the applicable Notice of Exercise or (z) the Bid Price of the Common Stock on the principal Trading Market as reported by Bloomberg L.P. as of the time of the Holder’s execution of the applicable Notice of Exercise if such Notice of Exercise is executed during “regular trading hours” on a Trading Day and is delivered within two (2) hours thereafter (including until two (2) hours after the close of “regular trading hours” on a Trading Day) pursuant to Section 2(a) hereof or (iii) the VWAP on the date of the applicable Notice of Exercise if the date of such Notice of Exercise is a Trading Day and such Notice of Exercise is both executed and delivered pursuant to Section 2(a) hereof after the close of “regular trading hours” on such Trading Day;

(B) = the Exercise Price of this Warrant, as adjusted hereunder; and

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(X) = the number of Warrant Shares that would be issuable upon exercise of this Warrant in accordance with the terms of this Warrant if such exercise were by means of a cash exercise rather than a cashless exercise.

If Warrant Shares are issued in such a cashless exercise, the parties acknowledge and agree that in accordance with Section 3(a)(9) of the Securities Act, the Warrant Shares shall take on the registered characteristics of the Warrants being exercised. The Company agrees not to take any position contrary to this Section 2(c).

Notwithstanding anything herein to the contrary, on the Termination Date, this Warrant shall be automatically exercised via cashless exercise pursuant to this Section 2(c).

d) Mechanics of Exercise.

i. **Delivery of Warrant Shares Upon Exercise.** The Company shall cause the Warrant Shares purchased hereunder to be transmitted by the Transfer Agent to the Holder by crediting the account of the Holder’s or its designee’s balance account with The Depository Trust Company through its Deposit or Withdrawal at Custodian system (“DWAC”) if the Company is then a participant in such system and either (A) there is an effective registration statement permitting the issuance of the Warrant Shares to or resale of the Warrant Shares by Holder or (B) this Warrant is being exercised via cashless exercise, and otherwise by physical delivery of a certificate, registered in the Company’s share register in the name of the Holder or its designee, for the number of Warrant Shares to which the Holder is entitled pursuant to such exercise to the address specified by the Holder in the Notice of Exercise by the date that is the earliest of (i) two (2) Trading Days after the delivery to the Company of the Notice of Exercise, (ii) one (1) Trading Day after delivery of the aggregate Exercise Price to the Company and (iii) the number of Trading Days comprising the Standard Settlement Period after the delivery to the Company of the Notice of Exercise (such date, the “Warrant Share Delivery Date”). Upon delivery of the Notice of Exercise, the Holder shall be deemed for all corporate purposes to have become the holder of record of the Warrant Shares with respect to which this Warrant has been exercised, irrespective of the date of delivery of the Warrant Shares, provided that payment of the aggregate Exercise Price (other than in the case of a cashless exercise) is received within the earlier of (i) two (2) Trading Days and (ii) the number of Trading Days comprising the Standard Settlement Period following delivery of the Notice of Exercise. If the Company fails for any reason to deliver to the Holder the Warrant Shares subject to a Notice of Exercise by the Warrant Share Delivery Date, the Company shall pay to the Holder, in cash, as liquidated damages and not as a penalty, for each \$1,000 of Warrant Shares subject to such exercise (based on the VWAP of the Common Stock on the date of the applicable Notice of Exercise), \$10 per Trading Day (increasing to \$20 per Trading Day on the fifth Trading Day after such liquidated damages begin to accrue) for each Trading Day after such Warrant Share Delivery Date until such Warrant Shares are delivered or Holder rescinds such exercise. The Company agrees to maintain a transfer agent that is a participant in the FAST program so long as this Warrant remains outstanding and exercisable. As used herein, “Standard Settlement Period” means the standard settlement period, expressed in a number of Trading Days, on the Company’s primary Trading Market with respect to the Common Stock as in effect on the date of delivery of the Notice of Exercise.

ii. Delivery of New Warrants Upon Exercise. If this Warrant shall have been exercised in part, the Company shall, at the request of a Holder and upon surrender of this Warrant certificate, at the time of delivery of the Warrant Shares, deliver to the Holder a new Warrant evidencing the rights of the Holder to purchase the unpurchased Warrant Shares called for by this Warrant, which new Warrant shall in all other respects be identical with this Warrant.

iii. Rescission Rights. If the Company fails to cause the Transfer Agent to transmit to the Holder the Warrant Shares pursuant to Section 2(d)(i) by the Warrant Share Delivery Date, then the Holder will have the right to rescind such exercise.

iv. Compensation for Buy-In on Failure to Timely Deliver Warrant Shares Upon Exercise. In addition to any other rights available to the Holder, if the Company fails to cause the Transfer Agent to transmit to the Holder the Warrant Shares in accordance with the provisions of Section 2(d)(i) above pursuant to an exercise on or before the Warrant Share Delivery Date, and if after such date the Holder is required by its broker to purchase (in an open market transaction or otherwise) or the Holder's brokerage firm otherwise purchases, shares of Common Stock to deliver in satisfaction of a sale by the Holder of the Warrant Shares which the Holder anticipated receiving upon such exercise (a "Buy-In"), then the Company shall (A) pay in cash to the Holder the amount, if any, by which (x) the Holder's total purchase price (including brokerage commissions, if any) for the shares of Common Stock so purchased exceeds (y) the amount obtained by multiplying (1) the number of Warrant Shares that the Company was required to deliver to the Holder in connection with the exercise at issue times (2) the price at which the sell order giving rise to such purchase obligation was executed, and (B) at the option of the Holder, either reinstate the portion of the Warrant and equivalent number of Warrant Shares for which such exercise was not honored (in which case such exercise shall be deemed rescinded) or deliver to the Holder the number of shares of Common Stock that would have been issued had the Company timely complied with its exercise and delivery obligations hereunder. For example, if the Holder purchases Common Stock having a total purchase price of \$11,000 to cover a Buy-In with respect to an attempted exercise of shares of Common Stock with an aggregate sale price giving rise to such purchase obligation of \$10,000, under clause (A) of the immediately preceding sentence the Company shall be required to pay the Holder \$1,000. The Holder shall provide the Company written notice indicating the amounts payable to the Holder in respect of the Buy-In and, upon request of the Company, evidence of the amount of such loss. Nothing herein shall limit a Holder's right to pursue any other remedies available to it hereunder, at law or in equity including, without limitation, a decree of specific performance and/or injunctive relief with respect to the Company's failure to timely deliver shares of Common Stock upon exercise of the Warrant as required pursuant to the terms hereof.

v. No Fractional Shares or Scrip. No fractional shares or scrip representing fractional shares shall be issued upon the exercise of this Warrant. As to any fraction of a share which the Holder would otherwise be entitled to purchase upon such exercise, the Company shall, at its election, either pay a cash adjustment in respect of such final fraction in an amount equal to such fraction multiplied by the Exercise Price or round up to the next whole share.

vi. Charges, Taxes and Expenses. Issuance of Warrant Shares shall be made without charge to the Holder for any issue or transfer tax or other incidental expense in respect of the issuance of such Warrant Shares, all of which taxes and expenses shall be paid by the Company, and such Warrant Shares shall be issued in the name of the Holder or in such name or names as may be directed by the Holder; provided, however, that, in the event that Warrant Shares are to be issued in a name other than the name of the Holder, this Warrant when surrendered for exercise shall be accompanied by the Assignment Form attached hereto duly executed by the Holder and the Company may require, as a condition thereto, the payment of a sum sufficient to reimburse it for any transfer tax incidental thereto. The Company shall pay all Transfer Agent fees required for same-day processing of any Notice of Exercise and all fees to the Depository Trust Company (or another established clearing corporation performing similar functions) required for same-day electronic delivery of the Warrant Shares.

vii. Closing of Books. The Company will not close its stockholder books or records in any manner which prevents the timely exercise of this Warrant, pursuant to the terms hereof.

e) Holder's Exercise Limitations. The Company shall not effect any exercise of this Warrant, and a Holder shall not have the right to exercise any portion of this Warrant, pursuant to Section 2 or otherwise, to the extent that after giving effect to such issuance after exercise as set forth on the applicable Notice of Exercise, the Holder (together with the Holder's Affiliates, and any other Persons acting as a group together with the Holder or any of the Holder's Affiliates (such Persons, "Attribution Parties")), would beneficially own in excess of the Beneficial Ownership Limitation (as defined below). For purposes of the foregoing sentence, the number of shares of Common Stock beneficially owned by the Holder and its Affiliates and Attribution Parties shall include the number of shares of Common Stock issuable upon exercise of this Warrant with respect to which such determination is being made, but shall exclude the number of shares of Common Stock which would be issuable upon (i) exercise of the remaining, nonexercised portion of this Warrant beneficially owned by the Holder or any of its Affiliates or Attribution Parties and (ii) exercise or conversion of the unexercised or nonconverted portion of any other securities of the Company (including, without limitation, any other Common Stock Equivalents) subject to a limitation on conversion or exercise analogous to the limitation contained herein beneficially owned by the Holder or any of its Affiliates or Attribution Parties. Except as set forth in the preceding sentence, for purposes of this Section 2(e), beneficial ownership shall be calculated in accordance with Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder, it being acknowledged by the Holder that the Company is not representing to the Holder that such calculation is in compliance with Section 13(d) of the Exchange Act and the Holder is solely responsible for any schedules required to be filed in accordance therewith. To the extent that the limitation contained in this Section 2(e) applies, the determination of whether this Warrant is exercisable (in relation to other securities owned by the Holder together with any Affiliates and Attribution Parties) and of which portion of this Warrant is exercisable shall be in the sole discretion of the Holder, and the submission of a Notice of Exercise shall be deemed to be the Holder's determination of whether this Warrant is exercisable (in relation to other securities owned by the Holder together with any Affiliates and Attribution Parties) and of which portion of this Warrant is exercisable, in each case subject to the Beneficial Ownership Limitation, and the Company shall have no obligation to verify or confirm the accuracy of such determination. In addition, a determination as to any group status as contemplated above shall be determined in accordance with Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder. For purposes of this Section 2(e), in determining the number of outstanding shares of Common Stock, a Holder may rely on the number of outstanding shares of Common Stock as reflected in (A) the Company's most recent periodic or annual report filed with the Commission, as the case may be, (B) a more recent public announcement by the Company or (C) a more recent written notice by the Company or the Transfer Agent setting forth the number of shares of Common Stock outstanding. Upon the written or oral request of a Holder, the Company shall within one Trading Day confirm orally and in writing to the Holder the number of shares of Common Stock then outstanding. In any case, the number of outstanding shares of Common Stock shall be determined after giving effect to the conversion or exercise of securities of the Company, including this Warrant, by the Holder or its Affiliates or Attribution Parties since the date as of which such number of outstanding shares of Common Stock was reported. The "Beneficial Ownership Limitation" shall be 4.99% of the number of shares of the Common Stock outstanding immediately after giving effect to the issuance of shares of Common Stock issuable upon exercise of this Warrant. The Holder, upon notice to the Company, may increase or decrease the Beneficial Ownership Limitation provisions of this Section 2(e), provided that the Beneficial Ownership Limitation in no event exceeds 9.99% of the number of shares of the Common Stock outstanding immediately after giving effect to the issuance of shares of Common Stock upon exercise of this Warrant held by the Holder and the

provisions of this Section 2(e) shall continue to apply. Any increase in the Beneficial Ownership Limitation will not be effective until the 61st day after such notice is delivered to the Company. The provisions of this paragraph shall be construed and implemented in a manner otherwise than in strict conformity with the terms of this Section 2(e) to correct this paragraph (or any portion hereof) which may be defective or inconsistent with the intended Beneficial Ownership Limitation herein contained or to make changes or supplements necessary or desirable to properly give effect to such limitation. The limitations contained in this paragraph shall apply to a successor holder of this Warrant.

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Section 3. Certain Adjustments.

a) Stock Dividends and Splits. If the Company, at any time while this Warrant is outstanding: (i) pays a stock dividend or otherwise makes a distribution or distributions on shares of its Common Stock or any other equity or equity equivalent securities payable in shares of Common Stock (which, for avoidance of doubt, shall not include any shares of Common Stock issued by the Company upon exercise of this Warrant), (ii) subdivides outstanding shares of Common Stock into a larger number of shares, (iii) combines (including by way of reverse stock split) outstanding shares of Common Stock into a smaller number of shares, or (iv) issues by reclassification of shares of the Common Stock any shares of capital stock of the Company, then in each case the Exercise Price shall be multiplied by a fraction of which the numerator shall be the number of shares of Common Stock (excluding treasury shares, if any) outstanding immediately before such event and of which the denominator shall be the number of shares of Common Stock outstanding immediately after such event, and the number of shares issuable upon exercise of this Warrant shall be proportionately adjusted such that the aggregate Exercise Price of this Warrant shall remain unchanged. Any adjustment made pursuant to this Section 3(a) shall become effective immediately after the record date for the determination of stockholders entitled to receive such dividend or distribution and shall become effective immediately after the effective date in the case of a subdivision, combination or re-classification.

b) Subsequent Rights Offerings. In addition to any adjustments pursuant to Section 3(a) above, if at any time the Company grants, issues or sells any Common Stock Equivalents or rights to purchase stock, warrants, securities or other property pro rata to the record holders of any class of shares of Common Stock (the "Purchase Rights"), then the Holder will be entitled to acquire, upon the terms applicable to such Purchase Rights, the aggregate Purchase Rights which the Holder could have acquired if the Holder had held the number of shares of Common Stock acquirable upon complete exercise of this Warrant (without regard to any limitations on exercise hereof, including without limitation, the Beneficial Ownership Limitation) immediately before the date on which a record is taken for the grant, issuance or sale of such Purchase Rights, or, if no such record is taken, the date as of which the record holders of shares of Common Stock are to be determined for the grant, issue or sale of such Purchase Rights (provided, however, that, to the extent that the Holder's right to participate in any such Purchase Right would result in the Holder exceeding the Beneficial Ownership Limitation, then the Holder shall not be entitled to participate in such Purchase Right to such extent (or beneficial ownership of such shares of Common Stock as a result of such Purchase Right to such extent) and such Purchase Right to such extent shall be held in abeyance for the Holder until such time, if ever, as its right thereto would not result in the Holder exceeding the Beneficial Ownership Limitation).

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c) Pro Rata Distributions. During such time as this Warrant is outstanding, if the Company shall declare or make any dividend or other distribution of its assets (or rights to acquire its assets) to holders of shares of Common Stock, by way of return of capital or otherwise, other than cash (including, without limitation, any distribution of stock or other securities, property or options by way of a dividend, spin off, reclassification, corporate rearrangement, scheme of arrangement or other similar transaction) (a "Distribution"), at any time after the issuance of this Warrant, then, in each such case, the Holder shall be entitled to participate in such Distribution to the same extent that the Holder would have participated therein if the Holder had held the number of shares of Common Stock acquirable upon complete exercise of this Warrant (without regard to any limitations on exercise hereof, including without limitation, the Beneficial Ownership Limitation) immediately before the date of which a record is taken for such Distribution, or, if no such record is taken, the date as of which the record holders of shares of Common Stock are to be determined for the participation in such Distribution (provided, however, that, to the extent that the Holder's right to participate in any such Distribution would result in the Holder exceeding the Beneficial Ownership Limitation, then the Holder shall not be entitled to participate in such Distribution to such extent (or in the beneficial ownership of any shares of Common Stock as a result of such Distribution to such extent) and the portion of such Distribution shall be held in abeyance for the benefit of the Holder until such time, if ever, as its right thereto would not result in the Holder exceeding the Beneficial Ownership Limitation).

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d) Fundamental Transaction. If, at any time while this Warrant is outstanding, (i) the Company, directly or indirectly, in one or more related transactions effects any merger or consolidation of the Company with or into another Person, (ii) the Company or any Subsidiary, directly or indirectly, effects any sale, lease, license, assignment, transfer, conveyance or other disposition of all or substantially all of its assets in one or a series of related transactions, (iii) any, direct or indirect, purchase offer, tender offer or exchange offer (whether by the Company or another Person) is completed pursuant to which holders of Common Stock are permitted to sell, tender or exchange their shares for other securities, cash or property and has been accepted by the holders of 50% or more of the outstanding Common Stock, (iv) the Company, directly or indirectly, in one or more related transactions effects any reclassification, reorganization or recapitalization of the Common Stock or any compulsory share exchange pursuant to which the Common Stock is effectively converted into or exchanged for other securities, cash or property, or (v) the Company, directly or indirectly, in one or more related transactions consummates a stock or share purchase agreement or other business combination (including, without limitation, a reorganization, recapitalization, spin-off, merger or scheme of arrangement) with another Person or group of Persons whereby such other Person or group acquires more than 50% of the outstanding shares of Common Stock (not including any shares of Common Stock held by the other Person or other Persons making or party to, or associated or affiliated with the other Persons making or party to, such stock or share purchase agreement or other business combination) (each a "Fundamental Transaction"), then, upon any subsequent exercise of this Warrant, the Holder shall have the right to receive, for each Warrant Share that would have been issuable upon such exercise immediately prior to the occurrence of such Fundamental Transaction, at the option of the Holder (without regard to any limitation in Section 2(e) on the exercise of this Warrant), the number of shares of Common Stock of the successor or acquiring corporation or of the Company, if it is the surviving corporation, and any additional consideration (the "Alternate Consideration") receivable as a result of such Fundamental Transaction by a holder of the number of shares of Common Stock for which this Warrant is exercisable immediately prior to such Fundamental Transaction (without regard to any limitation in Section 2(e) on the exercise of this Warrant). For purposes of any such exercise, the determination of the Exercise Price shall be appropriately adjusted to apply to such Alternate Consideration based on the amount of Alternate Consideration issuable in respect of one share of Common Stock in such Fundamental Transaction, and the Company shall apportion the Exercise Price among the Alternate Consideration in a reasonable manner reflecting the relative value of any different components of the Alternate Consideration. If holders of Common Stock are given any choice as to the securities, cash or property to be received in a Fundamental Transaction, then the Holder shall be given the same choice as to the Alternate Consideration it receives upon any exercise of this Warrant following such Fundamental Transaction. The Company shall cause any successor entity in a Fundamental Transaction in which the Company is not the survivor (the "Successor Entity") to assume in writing all of the obligations of the Company under this Warrant in accordance with the provisions of this Section 3(e) pursuant to written agreements in form and substance reasonably satisfactory to the Holder and approved by the Holder (without unreasonable delay) prior to such Fundamental Transaction and shall, at the option of the Holder, deliver to the Holder in exchange for this Warrant a security of the Successor Entity evidenced by a written instrument substantially similar in form and substance to this Warrant which is exercisable for a corresponding number of shares of capital stock of such Successor Entity (or its parent entity) equivalent to the shares of Common Stock acquirable and receivable upon exercise of this Warrant (without regard to any limitations on the exercise of this Warrant) prior to such Fundamental Transaction, and with an exercise price which applies the exercise price hereunder to such shares of capital stock (but taking into account the relative value of the shares of Common Stock pursuant to such Fundamental Transaction and the value of such shares of capital stock, such number of shares of capital stock and such exercise price being for the purpose of protecting the economic value of this Warrant immediately prior to the consummation of such Fundamental Transaction), and which is reasonably satisfactory in form and substance to the Holder. Upon the occurrence of any such Fundamental Transaction, the Successor Entity shall succeed to, and be substituted for (so that from and

after the date of such Fundamental Transaction, the provisions of this Warrant referring to the “Company” shall refer instead to the Successor Entity), and may exercise every right and power of the Company and shall assume all of the obligations of the Company under this Warrant with the same effect as if such Successor Entity had been named as the Company herein.

e) Calculations. All calculations under this Section 3 shall be made to the nearest cent or the nearest 1/100th of a share, as the case may be. For purposes of this Section 3, the number of shares of Common Stock deemed to be issued and outstanding as of a given date shall be the sum of the number of shares of Common Stock (excluding treasury shares, if any) issued and outstanding.

f) Notice to Holder.

i. Adjustment to Exercise Price. Whenever the Exercise Price is adjusted pursuant to any provision of this Section 3, the Company shall promptly deliver to the Holder by facsimile or email a notice setting forth the Exercise Price after such adjustment and any resulting adjustment to the number of Warrant Shares and setting forth a brief statement of the facts requiring such adjustment.

ii. Notice to Allow Exercise by Holder. If (A) the Company shall declare a dividend (or any other distribution in whatever form) on the Common Stock, (B) the Company shall declare a special nonrecurring cash dividend on or a redemption of the Common Stock, (C) the Company shall authorize the granting to all holders of the Common Stock rights or warrants to subscribe for or purchase any shares of capital stock of any class or of any rights, (D) the approval of any stockholders of the Company shall be required in connection with any reclassification of the Common Stock, any consolidation or merger to which the Company (or any of its Subsidiaries) is a party, any sale or transfer of all or substantially all of its assets, or any compulsory share exchange whereby the Common Stock is converted into other securities, cash or property, or (E) the Company shall authorize the voluntary or involuntary dissolution, liquidation or winding up of the affairs of the Company, then, in each case, the Company shall cause to be delivered by facsimile or email to the Holder at its last facsimile number or email address as it shall appear upon the Warrant Register of the Company, at least 20 calendar days prior to the applicable record or effective date hereinafter specified, a notice stating (x) the date on which a record is to be taken for the purpose of such dividend, distribution, redemption, rights or warrants, or if a record is not to be taken, the date as of which the holders of the Common Stock of record to be entitled to such dividend, distributions, redemption, rights or warrants are to be determined or (y) the date on which such reclassification, consolidation, merger, sale, transfer or share exchange is expected to become effective or close, and the date as of which it is expected that holders of the Common Stock of record shall be entitled to exchange their shares of the Common Stock for securities, cash or other property deliverable upon such reclassification, consolidation, merger, sale, transfer or share exchange; provided that the failure to deliver such notice or any defect therein or in the delivery thereof shall not affect the validity of the corporate action required to be specified in such notice. To the extent that any notice provided in this Warrant constitutes, or contains, material, non-public information regarding the Company or any of the Subsidiaries, the Company shall simultaneously file such notice with the Commission pursuant to a Current Report on Form 8-K. The Holder shall remain entitled to exercise this Warrant during the period commencing on the date of such notice to the effective date of the event triggering such notice except as may otherwise be expressly set forth herein.

g) Voluntary Adjustment By Company. Subject to the rules and regulations of the Trading Market, the Company may at any time during the term of this Warrant, subject to the prior written consent of the Holder, reduce the then current Exercise Price to any amount and for any period of time deemed appropriate by the board of directors of the Company.

Section 4. Transfer of Warrant.

a) Transferability. Pursuant to FINRA Rule 5110(e), neither this Warrant nor any Warrant Shares issued upon exercise of this Warrant shall be sold, transferred, assigned, pledged or hypothecated, or be the subject of any hedging, short sale, derivative, put or call transaction that would result in the effective economic disposition of the securities by any person for a period of 180 days immediately following the date of commencement of sales of the offering pursuant to which this Warrant is being issued, except the transfer of any security:

- (i) by operation of law or by reason of reorganization of the Company;
- (ii) to any FINRA member firm participating in the offering and the officers, partners, registered persons or affiliates thereof, if all securities so transferred remain subject to the lock-up restriction in this Section 4(a) for the remainder of the time period;
- (iii) if the aggregate amount of securities of the Company held by the Holder or related person does not exceed 1% of the securities being offered;
- (iv) that is beneficially owned on a pro-rata basis by all equity owners of an investment fund, provided that no participating member manages or otherwise directs investments by the fund, and participating members in the aggregate do not own more than 10% of the equity in the fund; or
- (v) the exercise or conversion of any security, if all securities received remain subject to the lock-up restriction in this Section 4(a) for the remainder of the time period;
- (vi) if the Company meets the registration requirements of Forms S-3, F-3 or F-10; or
- (vii) back to the Company in a transaction exempt from registration with the Commission.

Subject to the foregoing restriction, this Warrant and all rights hereunder (including, without limitation, any registration rights) are transferable, in whole or in part, upon surrender of this Warrant at the principal office of the Company or its designated agent, together with a written assignment of this Warrant substantially in the form attached hereto duly executed by the Holder or its agent or attorney and funds sufficient to pay any transfer taxes payable upon the making of such transfer. Upon such surrender and, if required, such payment, the Company shall execute and deliver a new Warrant or Warrants in the name of the assignee or assignees, as applicable, and in the denomination or denominations specified in such instrument of assignment, and shall issue to the assignor a new Warrant evidencing the portion of this Warrant not so assigned, and this Warrant shall promptly be cancelled. Notwithstanding anything herein to the contrary, the Holder shall not be required to physically surrender this Warrant to the Company unless the Holder has assigned this Warrant in full, in which case, the Holder shall surrender this Warrant to the Company within three (3) Trading Days of the date on which the Holder delivers an assignment form to the Company assigning this Warrant in full. The Warrant, if properly assigned in accordance herewith, may be exercised by a new holder for the purchase of Warrant Shares without having a new Warrant issued.

b) New Warrants. This Warrant may be divided or combined with other Warrants upon presentation hereof at the aforesaid office of the Company, together with a written notice specifying the names and denominations in which new Warrants are to be issued, signed by the Holder or its agent or attorney. Subject to

compliance with Section 4(a), as to any transfer which may be involved in such division or combination, the Company shall execute and deliver a new Warrant or Warrants in exchange for the Warrant or Warrants to be divided or combined in accordance with such notice. All Warrants issued on transfers or exchanges shall be dated the initial issuance date of this Warrant and shall be identical with this Warrant except as to the number of Warrant Shares issuable pursuant thereto.

c) Warrant Register. The Company shall register this Warrant, upon records to be maintained by the Company for that purpose (the "Warrant Register"), in the name of the record Holder hereof from time to time. The Company may deem and treat the registered Holder of this Warrant as the absolute owner hereof for the purpose of any exercise hereof or any distribution to the Holder, and for all other purposes, absent actual notice to the contrary.

Section 5. Demand Registrations. To the extent the Company does not maintain an effective registration statement for the Warrant Shares, then for a period commencing on the Initial Exercise Date and terminating on the Termination Date, the Holder is entitled to one "demand" registration right at the Company's expense and one "demand" registration right at the Holder's expense, each such right to be exercised not later than the Termination Date. Upon receipt of a demand registration request from the registered Holder, the Company shall file a registration statement on Form S-3 ("Form S-3") or, if Form S-3 is not available, on any other appropriate form, including Form S-1, within 60 days of demand thereof and cause such registration statement to become effective within 120 days thereof. A registration requested pursuant to this Section 4 shall not be deemed to have been effected: (i) unless a registration statement with respect thereto has become effective or (ii) if, after it has become effective, such registration is interfered with by any stop order, injunction or other order or requirement of the Commission or other governmental agency or court of competent jurisdiction for any reason, other than by reason of some act or omission by the Holder. The Company shall use its commercially reasonable efforts to cause any registration statement filed pursuant to the demand rights granted under this Section 5 to remain effective for a period of at least nine (9) consecutive months.

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Section 6. Piggy-Back Registrations. If, at any time while this Warrant is outstanding, there is not an effective registration statement covering all of the Warrant Shares and the Company shall determine to prepare and file with the Commission a registration statement relating to an offering for its own account or the account of others under the Securities Act of any of its equity securities, other than on Form S-4 or Form S-8 (each as promulgated under the Securities Act) or their then equivalents relating to equity securities to be issued solely in connection with any acquisition of any entity or business or equity securities issuable in connection with the Company's stock option or other employee benefit plans, then the Company shall deliver to each Holder a written notice of such determination and, if within fifteen days after the date of the delivery of such notice, any such Holder shall so request in writing, the Company shall include in such registration statement all or any part of such Warrant Shares such Holder requests to be registered; provided, however, that the Company shall not be required to register any Warrant Shares pursuant to this Section 6 that are eligible for resale pursuant to Rule 144 (without volume restrictions or current public information requirements) or that are the subject of a then effective registration statement that is available for resales or other dispositions by such Holder.

Section 7. Miscellaneous.

a) No Rights as Stockholder Until Exercise; No Settlement in Cash. This Warrant does not entitle the Holder to any voting rights, dividends or other rights as a stockholder of the Company prior to the exercise hereof as set forth in Section 2(d)(i), except as expressly set forth in Section 3. Without limiting any rights of a Holder to receive Warrant Shares on a "cashless exercise" pursuant to Section 2(c) or to receive cash payments pursuant to Section 2(d)(i) and Section 2(d)(iv) herein, in no event shall the Company be required to net cash settle an exercise of this Warrant.

b) Loss, Theft, Destruction or Mutilation of Warrant. The Company covenants that upon receipt by the Company of evidence reasonably satisfactory to it of the loss, theft, destruction or mutilation of this Warrant or any stock certificate relating to the Warrant Shares, and in case of loss, theft or destruction, of indemnity or security reasonably satisfactory to it (which, in the case of the Warrant, shall not include the posting of any bond), and upon surrender and cancellation of such Warrant or stock certificate, if mutilated, the Company will make and deliver a new Warrant or stock certificate of like tenor and dated as of such cancellation, in lieu of such Warrant or stock certificate.

c) Saturdays, Sundays, Holidays, etc. If the last or appointed day for the taking of any action or the expiration of any right required or granted herein shall not be a Business Day, then such action may be taken or such right may be exercised on the next succeeding Business Day.

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d) Authorized Shares.

The Company covenants that, during the period the Warrant is outstanding, it will reserve from its authorized and unissued Common Stock a sufficient number of shares to provide for the issuance of the Warrant Shares upon the exercise of any purchase rights under this Warrant. The Company further covenants that its issuance of this Warrant shall constitute full authority to its officers who are charged with the duty of issuing the necessary Warrant Shares upon the exercise of the purchase rights under this Warrant. The Company will take all such reasonable action as may be necessary to assure that such Warrant Shares may be issued as provided herein without violation of any applicable law or regulation, or of any requirements of the Trading Market upon which the Common Stock may be listed. The Company covenants that all Warrant Shares which may be issued upon the exercise of the purchase rights represented by this Warrant will, upon exercise of the purchase rights represented by this Warrant and payment for such Warrant Shares in accordance herewith, be duly authorized, validly issued, fully paid and nonassessable and free from all taxes, liens and charges created by the Company in respect of the issue thereof (other than taxes in respect of any transfer occurring contemporaneously with such issue).

Except and to the extent as waived or consented to by the Holder, the Company shall not by any action, including, without limitation, amending its certificate of incorporation or through any reorganization, transfer of assets, consolidation, merger, dissolution, issue or sale of securities or any other voluntary action, avoid or seek to avoid the observance or performance of any of the terms of this Warrant, but will at all times in good faith assist in the carrying out of all such terms and in the taking of all such actions as may be necessary or appropriate to protect the rights of Holder as set forth in this Warrant against impairment. Without limiting the generality of the foregoing, the Company will (i) not increase the par value of any Warrant Shares above the amount payable therefor upon such exercise immediately prior to such increase in par value, (ii) take all such action as may be necessary or appropriate in order that the Company may validly and legally issue fully paid and nonassessable Warrant Shares upon the exercise of this Warrant and (iii) use commercially reasonable efforts to obtain all such authorizations, exemptions or consents from any public regulatory body having jurisdiction thereof, as may be, necessary to enable the Company to perform its obligations under this Warrant.

Before taking any action which would result in an adjustment in the number of Warrant Shares for which this Warrant is exercisable or in the Exercise Price, the Company shall obtain all such authorizations or exemptions thereof, or consents thereto, as may be necessary from any public regulatory body or bodies having jurisdiction thereof.

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e) Governing Law. All questions concerning the construction, validity, enforcement and interpretation of this Warrant shall be governed by and construed and enforced in accordance with the internal laws of the State of New York, without regard to the principles of conflicts of law thereof. Each party agrees that all legal proceedings concerning the interpretations, enforcement and defense of the transactions contemplated by this Warrant (whether brought against a party hereto or their respective affiliates, directors, officers, shareholders, partners, members, employees or agents) shall be commenced exclusively in the state and federal courts sitting in the City of New York. Each party hereby irrevocably submits to the exclusive jurisdiction of the state and federal courts sitting in the City of New York, Borough of

Manhattan for the adjudication of any dispute hereunder or in connection herewith or with any transaction contemplated hereby or discussed herein, and hereby irrevocably waives, and agrees not to assert in any suit, action or proceeding, any claim that it is not personally subject to the jurisdiction of any such court, that such suit, action or proceeding is improper or is an inconvenient venue for such proceeding. Each party hereby irrevocably waives personal service of process and consents to process being served in any such suit, action or proceeding by mailing a copy thereof via registered or certified mail or overnight delivery (with evidence of delivery) to such party at the address in effect for notices to it under this Warrant and agrees that such service shall constitute good and sufficient service of process and notice thereof. Nothing contained herein shall be deemed to limit in any way any right to serve process in any other manner permitted by law. If either party shall commence an action, suit or proceeding to enforce any provisions of this Warrant, the prevailing party in such action, suit or proceeding shall be reimbursed by the other party for their reasonable attorneys' fees and other costs and expenses incurred with the investigation, preparation and prosecution of such action or proceeding.

f) Restrictions. The Holder acknowledges that the Warrant Shares acquired upon the exercise of this Warrant, if not registered, and the Holder does not utilize cashless exercise, will have restrictions upon resale imposed by state and federal securities laws.

g) Nonwaiver and Expenses. No course of dealing or any delay or failure to exercise any right hereunder on the part of Holder shall operate as a waiver of such right or otherwise prejudice the Holder's rights, powers or remedies. Without limiting any other provision of this Warrant, if the Company willfully and knowingly fails to comply with any provision of this Warrant, which results in any material damages to the Holder, the Company shall pay to the Holder such amounts as shall be sufficient to cover any costs and expenses including, but not limited to, reasonable attorneys' fees, including those of appellate proceedings, incurred by the Holder in collecting any amounts due pursuant hereto or in otherwise enforcing any of its rights, powers or remedies hereunder.

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h) Notices. Any and all notices or other communications or deliveries to be provided by the Holders hereunder including, without limitation, any Notice of Exercise, shall be in writing and delivered personally, by facsimile or e-mail, or sent by a nationally recognized overnight courier service, addressed to the Company, at _____, Attention: _____, facsimile number: _____, email address: _____, or such other facsimile number, email address or address as the Company may specify for such purposes by notice to the Holders. Any and all notices or other communications or deliveries to be provided by the Company hereunder shall be in writing and delivered personally, by facsimile or e-mail, or sent by a nationally recognized overnight courier service addressed to each Holder at the facsimile number, e-mail address or address of such Holder appearing on the books of the Company. Any notice or other communication or deliveries hereunder shall be deemed given and effective on the earliest of (i) the time of transmission, if such notice or communication is delivered via facsimile at the facsimile number or via e-mail at the e-mail address set forth in this Section prior to 5:30 p.m. (New York City time) on any date, (ii) the next Trading Day after the time of transmission, if such notice or communication is delivered via facsimile at the facsimile number or via e-mail at the e-mail address set forth in this Section on a day that is not a Trading Day or later than 5:30 p.m. (New York City time) on any Trading Day, (iii) the second Trading Day following the date of mailing, if sent by U.S. nationally recognized overnight courier service, or (iv) upon actual receipt by the party to whom such notice is required to be given. To the extent that any notice provided hereunder constitutes, or contains, material, non-public information regarding the Company or any Subsidiaries, the Company shall simultaneously file such notice with the Commission pursuant to a Current Report on Form 8-K.

i) Limitation of Liability. No provision hereof, in the absence of any affirmative action by the Holder to exercise this Warrant to purchase Warrant Shares, and no enumeration herein of the rights or privileges of the Holder, shall give rise to any liability of the Holder for the purchase price of any Common Stock or as a stockholder of the Company, whether such liability is asserted by the Company or by creditors of the Company.

j) Remedies. The Holder, in addition to being entitled to exercise all rights granted by law, including recovery of damages, will be entitled to specific performance of its rights under this Warrant. The Company agrees that monetary damages would not be adequate compensation for any loss incurred by reason of a breach by it of the provisions of this Warrant and hereby agrees to waive and not to assert the defense in any action for specific performance that a remedy at law would be adequate.

k) Successors and Assigns. Subject to applicable securities laws, this Warrant and the rights and obligations evidenced hereby shall inure to the benefit of and be binding upon the successors and permitted assigns of the Company and the successors and permitted assigns of Holder. The provisions of this Warrant are intended to be for the benefit of any Holder from time to time of this Warrant and shall be enforceable by the Holder or holder of Warrant Shares.

l) Amendment. This Warrant may be modified or amended or the provisions hereof waived with the written consent of the Company, on the one hand, and the Holder, on the other hand.

m) Severability. Wherever possible, each provision of this Warrant shall be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Warrant shall be prohibited by or invalid under applicable law, such provision shall be ineffective to the extent of such prohibition or invalidity, without invalidating the remainder of such provisions or the remaining provisions of this Warrant.

n) Headings. The headings used in this Warrant are for the convenience of reference only and shall not, for any purpose, be deemed a part of this Warrant.

(Signature Page Follows)

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IN WITNESS WHEREOF, the Company has caused this Warrant to be executed by its officer thereunto duly authorized as of the date first above indicated.

RENOVORX, INC.

By: _____

Name: _____

Title: _____

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NOTICE OF EXERCISE

TO: RENOVORX, INC.

(1) The undersigned hereby elects to purchase _____ Warrant Shares of the Company pursuant to the terms of the attached Warrant (only if exercised in full), and tenders herewith payment of the exercise price in full, together with all applicable transfer taxes, if any.

(2) Payment shall take the form of (check applicable box):

in lawful money of the United States; or

if permitted the cancellation of such number of Warrant Shares as is necessary, in accordance with the formula set forth in subsection 2(c), to exercise this Warrant with respect to the maximum number of Warrant Shares purchasable pursuant to the cashless exercise procedure set forth in subsection 2(c).

(3) Please issue said Warrant Shares in the name of the undersigned or in such other name as is specified below:

The Warrant Shares shall be delivered to the following DWAC Account Number:

[SIGNATURE OF HOLDER]

Name of Investing Entity: _____

Signature of Authorized Signatory of Investing Entity: _____

Name of Authorized Signatory: _____

Title of Authorized Signatory: _____

Date: _____

ASSIGNMENT FORM

(To assign the foregoing Warrant, execute this form and supply required information. Do not use this form to purchase shares.)

FOR VALUE RECEIVED, the foregoing Warrant and all rights evidenced thereby are hereby assigned to

Name: _____
(Please Print)

Address: _____
(Please Print)

Phone Number: _____

Email Address: _____

Dated: _____, _____, _____

Holder's Signature: _____

Holder's Address: _____

RenovoRx, Inc.

Amended and Restated 2013 Equity Incentive Plan

Termination Date: January 22, 2023

1. General.

(a) **Eligible Stock Award Recipients.** The persons eligible to receive Stock Awards are Employees, Directors and Consultants.

(b) **Available Stock Awards.** The Plan provides for the grant of the following Stock Awards: (i) Incentive Stock Options, (ii) Nonstatutory Stock Options, (iii) Stock Appreciation Rights, (iv) Restricted Stock Awards, and (v) Restricted Stock Unit Awards.

(c) **Purpose.** The Company, by means of the Plan, seeks to secure and retain the services of the group of persons eligible to receive Stock Awards as set forth in Section 1(a), to provide incentives for such persons to exert maximum efforts for the success of the Company and any Affiliate, and to provide a means by which such eligible recipients may be given an opportunity to benefit from increases in value of the Common Stock through the granting of Stock Awards.

2. Administration.

(a) **Administration by Board.** The Board shall administer the Plan unless and until the Board delegates administration of the Plan to a Committee or Committees, as provided in Section 2(c).

(b) **Powers of Board.** The Board shall have the power, subject to, and within the limitations of, the express provisions of the Plan:

(i) To determine from time to time (A) which of the persons eligible under the Plan shall be granted Stock Awards; (B) when and how each Stock Award shall be granted; (C) what type or combination of types of Stock Award shall be granted; (D) the provisions of each Stock Award granted (which need not be identical), including the time or times when a person shall be permitted to receive cash or Common Stock pursuant to a Stock Award; (E) the number of shares of Common Stock with respect to which a Stock Award shall be granted to each such person; and (F) the Fair Market Value applicable to a Stock Award.

(ii) To construe and interpret the Plan and Stock Awards granted under it, and to establish, amend and revoke rules and regulations for administration of the Plan. The Board, in the exercise of this power, may correct any defect, omission or inconsistency in the Plan or in any Stock Award Agreement, in a manner and to the extent it shall deem necessary or expedient to make the Plan or Stock Award fully effective.

(iii) To settle all controversies regarding the Plan and Stock Awards granted under it.

(iv) To accelerate the time at which a Stock Award may first be exercised or the time during which a Stock Award or any part thereof will vest in accordance with the Plan, notwithstanding the provisions in the Stock Award stating the time at which it may first be exercised or the time during which it will vest.

(v) To suspend or terminate the Plan at any time. Suspension or termination of the Plan shall not impair rights and obligations under any Stock Award granted while the Plan is in effect except with the written consent of the affected Participant.

(vi) To amend the Plan in any respect the Board deems necessary or advisable, including, without limitation, amendments relating to Incentive Stock Options and certain nonqualified deferred compensation under Section 409A of the Code and/or to bring the Plan or Stock Awards granted under the Plan into compliance therewith, subject to the limitations, if any, of applicable law. However, except as provided in Section 9(a) relating to Capitalization Adjustments, to the extent required by applicable law, stockholder approval shall be required for any amendment of the Plan that either (A) materially increases the number of shares of Common Stock available for issuance under the Plan, (B) materially expands the class of individuals eligible to receive Stock Awards under the Plan, (C) materially increases the benefits accruing to Participants under the Plan or materially reduces the price at which shares of Common Stock may be issued or purchased under the Plan, (D) materially extends the term of the Plan, or (E) expands the types of Stock Awards available for issuance under the Plan. Except as provided above, rights under any Stock Award granted before amendment of the Plan shall not be impaired by any amendment of the Plan unless (1) the Company requests the consent of the affected Participant, and (2) such Participant consents in writing.

(vii) To submit any amendment to the Plan for stockholder approval, including, but not limited to, amendments to the Plan intended to satisfy the requirements of Section 422 of the Code regarding Incentive Stock Options.

(viii) To approve forms of Stock Award Agreements for use under the Plan and to amend the terms of any one or more Stock Awards, including, but not limited to, amendments to provide terms more favorable to the Participant than previously provided in the Stock Award Agreement, subject to any specified limits in the Plan that are not subject to Board discretion; *provided however*, that, the rights under any Stock Award shall not be impaired by any such amendment unless (i) the Company requests the consent of the affected Participant, and (ii) such Participant consents in writing. Notwithstanding the foregoing, subject to the limitations of applicable law, if any, and without the affected Participant's consent, the Board may amend the terms of any one or more Stock Awards if necessary to maintain the qualified status of the Stock Award as an Incentive Stock Option or to bring the Stock Award into compliance with Section 409A of the Code.

(ix) Generally, to exercise such powers and to perform such acts as the Board deems necessary or expedient to promote the best interests of the Company and that are not in conflict with the provisions of the Plan or Stock Awards.

(x) To adopt such procedures and sub-plans as are necessary or appropriate to permit participation in the Plan by Employees, Directors or Consultants who are foreign nationals or employed outside the United States.

(xi) To effect, at any time and from time to time, with the consent of any adversely affected Participant, (A) the reduction of the exercise price (or strike price) of any outstanding Option or SAR under the Plan, (B) the cancellation of any outstanding Option or SAR under the Plan and the grant in substitution therefore of (1) a new Option or SAR under the Plan or another equity plan of the Company covering the same or a different number of shares of Common Stock, (2) a Restricted Stock Award, (3) a Restricted Stock Unit Award, (4) cash and/or (5) other valuable consideration (as determined by the Board, in its sole discretion), or (C) any other action that is treated as a repricing under generally accepted accounting principles; *provided, however*, that no such reduction or cancellation may be effected if it is determined, in the Company's sole discretion, that such reduction or cancellation would result in any such outstanding Option becoming subject to the requirements of Section 409A of the Code.

(c) **Delegation to Committee.** The Board may delegate some or all of the administration of the Plan to a Committee or Committees. If administration of the Plan is

delegated to a Committee, the Committee shall have, in connection with the administration of the Plan, the powers theretofore possessed by the Board that have been delegated to the Committee, including the power to delegate to a subcommittee of the Committee any of the administrative powers the Committee is authorized to exercise (and references in this Plan to the Board shall thereafter be to the Committee or subcommittee), subject, however, to such resolutions, not inconsistent with the provisions of the Plan, as may be adopted from time to time by the Board. The Board may retain the authority to concurrently administer the Plan with the Committee and may, at any time, revert in the Board some or all of the powers previously delegated.

(d) Delegation to an Officer. The Board may delegate to one or more Officers of the Company the authority to do one or both of the following: (i) designate Officers and Employees of the Company or any of its Subsidiaries to be recipients of Options and Stock Appreciation Rights (and, to the extent permitted by applicable law, other Stock Awards) and the terms thereof, and (ii) determine the number of shares of Common Stock to be subject to such Stock Awards granted to such Officers and Employees; *provided, however*, that the Board resolutions regarding such delegation shall specify the total number of shares of Common Stock that may be subject to the Stock Awards granted by such Officer and that such Officer may not grant a Stock Award to himself or herself. Notwithstanding the foregoing, the Board may not delegate authority to an Officer to determine the Fair Market Value pursuant to Section 13(t) below.

(e) Effect of Board's Decision. All determinations, interpretations and constructions made by the Board in good faith shall not be subject to review by any person and shall be final, binding and conclusive on all persons.

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3. Shares Subject to the Plan.

(a) Share Reserve. Subject to the provisions of Section 9(a) relating to Capitalization Adjustments, the aggregate number of shares of Common Stock that may be issued pursuant to Stock Awards beginning on the Effective Date shall not exceed six million six hundred six thousand four (6,606,504) shares (the "**Share Reserve**"). Furthermore, if a Stock Award (i) expires or otherwise terminates without having been exercised in full or (ii) is settled in cash (*i.e.*, the holder of the Stock Award receives cash rather than stock), such expiration, termination or settlement shall not reduce (or otherwise offset) the number of shares of Common Stock that may be issued pursuant to the Plan. For clarity, the limitation in this Section 3(a) is a limitation in the number of shares of Common Stock that may be issued pursuant to the Plan. Accordingly, this Section 3(a) does not limit the granting of Stock Awards except as provided in Section 7(a).

(b) Reversion of Shares to the Share Reserve. If any shares of Common Stock issued pursuant to a Stock Award are forfeited back to the Company because of the failure to meet a contingency or condition required to vest such shares in the Participant, then the shares which are forfeited shall revert to and again become available for issuance under the Plan. Also, any shares reacquired by the Company pursuant to Section 8(g) or as consideration for the exercise of an Option shall again become available for issuance under the Plan. Notwithstanding the provisions of this Section 3(b), any such shares shall not be subsequently issued pursuant to the exercise of Incentive Stock Options.

(c) Incentive Stock Option Limit. Notwithstanding anything to the contrary in this Section 3(c), subject to the provisions of Section 9(a) relating to Capitalization Adjustments, the aggregate maximum number of shares of Common Stock that may be issued pursuant to the exercise of Incentive Stock Options shall be two times the Share Reserve.

(d) Source of Shares. The stock issuable under the Plan shall be shares of authorized but unissued or reacquired Common Stock, including shares repurchased by the Company on the open market or otherwise.

4. Eligibility.

(a) Eligibility for Specific Stock Awards. Incentive Stock Options may be granted only to employees of the Company or a "parent corporation" or "subsidiary corporation" thereof (as such terms are defined in Sections 424(e) and (f) of the Code). Stock Awards other than Incentive Stock Options may be granted to Employees, Directors and Consultants; *provided, however*, Nonstatutory Stock Options and SARs may not be granted to Employees, Directors and Consultants who are providing Continuous Service only to any "parent" of the Company, as such term is defined in Rule 405, unless the stock underlying such Stock Awards is treated as "service recipient stock" under Section 409A of the Code because the Stock Awards are granted pursuant to a corporate transaction (such as a spin off transaction) or unless such Stock Awards comply with the distribution requirements of Section 409A of the Code.

(b) Ten Percent Stockholders. A Ten Percent Stockholder shall not be granted an Incentive Stock Option unless the exercise price of such Option is at least one hundred ten percent (110%) of the Fair Market Value on the date of grant and the Option is not exercisable after the expiration of five (5) years from the date of grant.

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(c) Consultants. A Consultant shall not be eligible for the grant of a Stock Award if, at the time of grant, either the offer or the sale of the Company's securities to such Consultant is not exempt under Rule 701 because of the nature of the services that the Consultant is providing to the Company, because the Consultant is not a natural person, or because of any other provision of Rule 701, unless the Company determines that such grant need not comply with the requirements of Rule 701 and will satisfy another exemption under the Securities Act as well as comply with the securities laws of all other relevant jurisdictions.

5. Provisions Relating to Options and Stock Appreciation Rights.

Each Option or SAR shall be in such form and shall contain such terms and conditions as the Board shall deem appropriate. All Options shall be separately designated Incentive Stock Options or Nonstatutory Stock Options at the time of grant, and, if certificates are issued, a separate certificate or certificates shall be issued for shares of Common Stock purchased on exercise of each type of Option. If an Option is not specifically designated as an Incentive Stock Option, then the Option shall be a Nonstatutory Stock Option. The provisions of separate Options or SARs need not be identical; *provided, however*, that each Option Agreement or Stock Appreciation Right Agreement shall conform to (through incorporation of provisions hereof by reference in the applicable Stock Award Agreement or otherwise) the substance of each of the following provisions:

(a) Term. Subject to the provisions of Section 4(b) regarding Ten Percent Stockholders, no Option or SAR shall be exercisable after the expiration of ten (10) years from the date of its grant or such shorter period specified in the Stock Award Agreement.

(b) Exercise Price. Subject to the provisions of Section 4(b) regarding Incentive Stock Options granted to Ten Percent Stockholders, the exercise price (or strike price) of each Option or SAR shall be not less than one hundred percent (100%) of the Fair Market Value of the Common Stock subject to the Option or SAR on the date the Option or SAR is granted. Notwithstanding the foregoing, an Option or SAR may be granted with an exercise price (or strike price) lower than one hundred percent (100%) of the Fair Market Value of the Common Stock subject to the Option or SAR if such Option or SAR is granted pursuant to an assumption of or substitution for another option or stock appreciation right pursuant to a Corporate Transaction and in a manner consistent with the provisions of Sections 409A and 424(a) of the Code (whether or not such Stock Awards are Incentive Stock Options). Each SAR will be denominated in shares of Common Stock equivalents.

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(c) Consideration for Options. The purchase price of Common Stock acquired pursuant to the exercise of an Option shall be paid, to the extent permitted by

applicable law and as determined by the Board in its sole discretion, by any combination of the methods of payment set forth below. The Board shall have the authority to grant Options that do not permit all of the following methods of payment (or otherwise restrict the ability to use certain methods) and to grant Options that require the consent of the Company to utilize a particular method of payment. The permitted methods of payment are as follows:

(i) by cash, check, bank draft or money order payable to the Company;

(ii) pursuant to a program developed under Regulation T as promulgated by the Federal Reserve Board that, prior to the issuance of the stock subject to the Option, results in either the receipt of cash (or check) by the Company or the receipt of irrevocable instructions to pay the aggregate exercise price to the Company from the sales proceeds;

(iii) by delivery to the Company (either by actual delivery or attestation) of shares of Common Stock;

(iv) if the Option is a Nonstatutory Stock Option, by a "net exercise" arrangement pursuant to which the Company will reduce the number of shares of Common Stock issuable upon exercise by the largest whole number of shares with a Fair Market Value that does not exceed the aggregate exercise price; *provided, however*, that the Company shall accept a cash or other payment from the Participant to the extent of any remaining balance of the aggregate exercise price not satisfied by such reduction in the number of whole shares to be issued; *provided, further*, that shares of Common Stock will no longer be subject to an Option and will not be exercisable thereafter to the extent that (A) shares issuable upon exercise are reduced to pay the exercise price pursuant to the "net exercise," (B) shares are delivered to the Participant as a result of such exercise, and (C) shares are withheld to satisfy tax withholding obligations;

(v) according to a deferred payment or similar arrangement with the Optionholder; *provided, however*, that interest shall compound at least annually and shall be charged at the minimum rate of interest necessary to avoid (A) the imputation of interest income to the Company and compensation income to the Optionholder under any applicable provisions of the Code, and (B) the classification of the Option as a liability for financial accounting purposes; or

(vi) in any other form of legal consideration that may be acceptable to the Board.

(d) Exercise and Payment of a SAR. To exercise any outstanding Stock Appreciation Right, the Participant must provide written notice of exercise to the Company in compliance with the provisions of the Stock Appreciation Right Agreement evidencing such Stock Appreciation Right. The appreciation distribution payable on the exercise of a Stock Appreciation Right will be not greater than an amount equal to the excess of (A) the aggregate Fair Market Value (on the date of the exercise of the Stock Appreciation Right) of a number of shares of Common Stock equal to the number of Common Stock equivalents in which the Participant is vested under such Stock Appreciation Right, and with respect to which the Participant is exercising the Stock Appreciation Right on such date, over (B) the strike price that will be determined by the Board at the time of grant of the Stock Appreciation Right. The appreciation distribution in respect to a Stock Appreciation Right may be paid in Common Stock, in cash, in any combination of the two or in any other form of consideration, as determined by the Board and contained in the Stock Appreciation Right Agreement evidencing such Stock Appreciation Right.

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(e) Transferability of Options and SARs. The Board may, in its sole discretion, impose such limitations on the transferability of Options and SARs as the Board shall determine. In the absence of such a determination by the Board to the contrary, the following restrictions on the transferability of Options and SARs shall apply:

(i) **Restrictions on Transfer.** An Option or SAR shall not be transferable except by will or by the laws of descent and distribution and shall be exercisable during the lifetime of the Participant only by the Participant; *provided, however*, that the Board may, in its sole discretion, permit transfer of the Option or SAR to such extent as permitted by Rule 701 and in a manner consistent with applicable tax and securities laws upon the Participant's request.

(ii) **Domestic Relations Orders.** Notwithstanding the foregoing, an Option or SAR may be transferred pursuant to a domestic relations order; *provided, however*, that if an Option is an Incentive Stock Option, such Option may be deemed to be a Nonstatutory Stock Option as a result of such transfer.

(iii) **Beneficiary Designation.** Notwithstanding the foregoing, the Participant may, by delivering written notice to the Company, in a form provided by or otherwise satisfactory to the Company and any broker designated by the Company to effect Option exercises, designate a third party who, in the event of the death of the Participant, shall thereafter be entitled to exercise the Option or SAR and receive the Common Stock or other consideration resulting from such exercise. In the absence of such a designation, the executor or administrator of the Participant's estate shall be entitled to exercise the Option or SAR and receive the Common Stock or other consideration resulting from such exercise.

(f) **Vesting Generally.** The total number of shares of Common Stock subject to an Option or SAR may vest and therefore become exercisable in periodic installments that may or may not be equal. The Option or SAR may be subject to such other terms and conditions on the time or times when it may or may not be exercised (which may be based on the satisfaction of performance goals or other criteria) as the Board may deem appropriate. The vesting provisions of individual Options or SARs may vary. The provisions of this Section 5(f) are subject to any Option or SAR provisions governing the minimum number of shares of Common Stock as to which an Option or SAR may be exercised.

(g) **Termination of Continuous Service.** Except as otherwise provided in the applicable Stock Award Agreement or other agreement between the Participant and the Company, in the event that a Participant's Continuous Service terminates (other than upon the Participant's death or Disability), the Participant may exercise his or her Option or SAR (to the extent that the Participant was entitled to exercise such Stock Award as of the date of termination of Continuous Service) but only within such period of time ending on the earlier of (i) the date three (3) months following the termination of the Participant's Continuous Service (or such longer or shorter period specified in the Stock Award Agreement, which period shall not be less than thirty (30) days if necessary to comply with applicable state laws or (ii) the expiration of the term of the Option or SAR as set forth in the Stock Award Agreement. If, after termination of Continuous Service, the Participant does not exercise his or her Option or SAR within the time specified herein or in the Stock Award Agreement (as applicable), the Option or SAR shall terminate.

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(h) **Extension of Termination Date.** Except as otherwise provided in the applicable Stock Award Agreement or other agreement between the Participant and the Company, if the exercise of an Option or SAR following the termination of the Participant's Continuous Service (other than upon the Participant's death or Disability) would be prohibited at any time solely because the issuance of shares of Common Stock would violate the registration requirements under the Securities Act, then the Option or SAR shall terminate on the earlier of (i) the expiration of a period of three (3) months after the termination of the Participant's Continuous Service during which the exercise of the Option or SAR would not be in violation of such registration requirements, or (ii) the expiration of the term of the Option or SAR as set forth in the Stock Award Agreement. In addition, unless otherwise provided in a Participant's Award Agreement, if the sale of any Common Stock received upon exercise of an Option or SAR following the termination of the Participant's Continuous Service would violate the Company's insider trading policy, then the Option or SAR shall terminate on the earlier of (i) the expiration of a period equal to the applicable post-termination exercise period after the termination of the Participant's Continuous Service during which the exercise of the Option or SAR would not be in violation of the Company's insider trading policy, or (ii) the expiration of the term of the Option or SAR as set forth in the applicable Stock Award Agreement.

(i) **Disability of Participant.** Except as otherwise provided in the applicable Stock Award Agreement or other agreement between the Participant and the Company, in the event that a Participant's Continuous Service terminates as a result of the Participant's Disability, the Participant may exercise his or her Option or SAR (to the extent that

the Participant was entitled to exercise such Option or SAR as of the date of termination of Continuous Service), but only within such period of time ending on the earlier of (i) the date twelve (12) months following such termination of Continuous Service (or such longer or shorter period specified in the Stock Award Agreement, which period shall not be less than six (6) months if necessary to comply with applicable state laws), or (ii) the expiration of the term of the Option or SAR as set forth in the Stock Award Agreement. If, after termination of Continuous Service, the Participant does not exercise his or her Option or SAR within the time specified herein or in the Stock Award Agreement (as applicable), the Option or SAR shall terminate.

(j) Death of Participant. Except as otherwise provided in the applicable Stock Award Agreement or other agreement between the Participant and the Company, in the event that (i) a Participant's Continuous Service terminates as a result of the Participant's death, or (ii) the Participant dies within the period (if any) specified in the Stock Award Agreement after the termination of the Participant's Continuous Service for a reason other than death, then the Option or SAR may be exercised (to the extent the Participant was entitled to exercise such Option or SAR as of the date of death) by the Participant's estate, by a person who acquired the right to exercise the Option or SAR by bequest or inheritance or by a person designated to exercise the Option or SAR upon the Participant's death, but only within the period ending on the earlier of (i) the date eighteen (18) months following the date of death (or such longer or shorter period specified in the Stock Award Agreement, which period shall not be less than six (6) months if necessary to comply with applicable state laws), or (ii) the expiration of the term of such Option or SAR as set forth in the Stock Award Agreement. If, after the Participant's death, the Option or SAR is not exercised within the time specified herein or in the Stock Award Agreement (as applicable), the Option or SAR shall terminate.

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(k) Termination for Cause. Except as explicitly provided otherwise in a Participant's Stock Award Agreement, if a Participant's Continuous Service is terminated for Cause, the Option or SAR shall terminate upon the termination date of such Participant's Continuous Service, and the Participant shall be prohibited from exercising his or her Option or SAR from and after the time of such termination of Continuous Service.

(l) Non-Exempt Employees. No Option or SAR granted to an Employee who is a non-exempt employee for purposes of the Fair Labor Standards Act of 1938, as amended, shall be first exercisable for any shares of Common Stock until at least six months following the date of grant of the Option or SAR. Notwithstanding the foregoing, consistent with the provisions of the Worker Economic Opportunity Act, in the event of the Participant's death or Disability, upon a Corporate Transaction or a Change in Control in which the vesting of such Options or SARs accelerates, or upon the Participant's retirement (as such term may be defined in the Participant's Stock Award Agreement or in another applicable agreement or in accordance with the Company's then current employment policies and guidelines) any such vested Options and SARs may be exercised earlier than six months following the date of grant. The foregoing provision is intended to operate so that any income derived by a non-exempt employee in connection with the exercise or vesting of an Option or SAR will be exempt from his or her regular rate of pay.

(m) Early Exercise of Options. An Option may, but need not, include a provision whereby the Optionholder may elect at any time before the Optionholder's Continuous Service terminates to exercise the Option as to any part or all of the shares of Common Stock subject to the Option prior to the full vesting of the Option. Subject to the "Repurchase Limitation" in Section 8(l), any unvested shares of Common Stock so purchased may be subject to a repurchase right in favor of the Company or to any other restriction the Board determines to be appropriate. Provided that the "Repurchase Limitation" in Section 8(l) is not violated, the Company shall not be required to exercise its repurchase right until at least six (6) months (or such longer or shorter period of time required to avoid classification of the Option as a liability for financial accounting purposes) have elapsed following exercise of the Option unless the Board otherwise specifically provides in the Option Agreement.

(n) Right of Repurchase. Subject to the "Repurchase Limitation" in Section 8(l), the Option or SAR may include a provision whereby the Company may elect to repurchase all or any part of the vested shares of Common Stock acquired by the Participant pursuant to the exercise of the Option or SAR.

(o) Right of First Refusal. The Option or SAR may include a provision whereby the Company may elect to exercise a right of first refusal following receipt of notice from the Participant of the intent to transfer all or any part of the shares of Common Stock received upon the exercise of the Option or SAR. Such right of first refusal shall be subject to the "Repurchase Limitation" in Section 8(l). Except as expressly provided in this Section 5(o) or in the Stock Award Agreement, such right of first refusal shall otherwise comply with any applicable provisions of the Bylaws of the Company.

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6. Provisions of Restricted Stock Awards and Restricted Stock Units.

(a) Restricted Stock Awards. Each Restricted Stock Award Agreement shall be in such form and shall contain such terms and conditions as the Board shall deem appropriate. To the extent consistent with the Company's Bylaws, at the Board's election, shares of Common Stock may be (x) held in book entry form subject to the Company's instructions until any restrictions relating to the Restricted Stock Award lapse; or (y) evidenced by a certificate, which certificate shall be held in such form and manner as determined by the Board. The terms and conditions of Restricted Stock Award Agreements may change from time to time, and the terms and conditions of separate Restricted Stock Award Agreements need not be identical; *provided, however*, that each Restricted Stock Award Agreement shall conform to (through incorporation of the provisions hereof by reference in the agreement or otherwise) the substance of each of the following provisions:

(i) Consideration. A Restricted Stock Award may be awarded in consideration for (A) cash or cash equivalents, (B) past or future services actually or to be rendered to the Company or an Affiliate, or (C) any other form of legal consideration that may be acceptable to the Board in its sole discretion and permissible under applicable law.

(ii) Vesting. Subject to the "Repurchase Limitation" in Section 8(l), shares of Common Stock awarded under the Restricted Stock Award Agreement may be subject to forfeiture to the Company in accordance with a vesting schedule to be determined by the Board.

(iii) Termination of Participant's Continuous Service. If a Participant's Continuous Service terminates, the Company may receive through a forfeiture condition or a repurchase right, any or all of the shares of Common Stock held by the Participant that have not vested as of the date of termination of Continuous Service under the terms of the Restricted Stock Award Agreement.

(iv) Transferability. Rights to acquire shares of Common Stock under the Restricted Stock Award Agreement shall be transferable by the Participant only upon such terms and conditions as are set forth in the Restricted Stock Award Agreement, as the Board shall determine in its sole discretion, so long as Common Stock awarded under the Restricted Stock Award Agreement remains subject to the terms of the Restricted Stock Award Agreement.

(v) Dividends. A Restricted Stock Award Agreement may provide that any dividends paid on Restricted Stock will be subject to the same vesting and forfeiture restrictions as apply to the shares subject to the Restricted Stock Award to which they relate.

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(b) Restricted Stock Unit Awards. Each Restricted Stock Unit Award Agreement shall be in such form and shall contain such terms and conditions as the Board shall deem appropriate. The terms and conditions of Restricted Stock Unit Award Agreements may change from time to time, and the terms and conditions of separate Restricted Stock Unit Award Agreements need not be identical, *provided, however*, that each Restricted Stock Unit Award Agreement shall conform to (through incorporation of the provisions hereof by reference in the Agreement or otherwise) the substance of each of the following provisions:

(i) **Consideration.** At the time of grant of a Restricted Stock Unit Award, the Board will determine the consideration, if any, to be paid by the Participant upon delivery of each share of Common Stock subject to the Restricted Stock Unit Award. The consideration to be paid (if any) by the Participant for each share of Common Stock subject to a Restricted Stock Unit Award may be paid in any form of legal consideration that may be acceptable to the Board in its sole discretion and permissible under applicable law.

(ii) **Vesting.** At the time of the grant of a Restricted Stock Unit Award, the Board may impose such restrictions or conditions to the vesting of the Restricted Stock Unit Award as it, in its sole discretion, deems appropriate.

(iii) **Payment.** A Restricted Stock Unit Award may be settled by the delivery of shares of Common Stock, their cash equivalent, any combination thereof or in any other form of consideration, as determined by the Board and contained in the Restricted Stock Unit Award Agreement.

(iv) **Additional Restrictions.** At the time of the grant of a Restricted Stock Unit Award, the Board, as it deems appropriate, may impose such restrictions or conditions that delay the delivery of the shares of Common Stock (or their cash equivalent) subject to a Restricted Stock Unit Award to a time after the vesting of such Restricted Stock Unit Award.

(v) **Dividend Equivalents.** Dividend equivalents may be credited in respect of shares of Common Stock covered by a Restricted Stock Unit Award, as determined by the Board and contained in the Restricted Stock Unit Award Agreement. At the sole discretion of the Board, such dividend equivalents may be converted into additional shares of Common Stock covered by the Restricted Stock Unit Award in such manner as determined by the Board. Any additional shares covered by the Restricted Stock Unit Award credited by reason of such dividend equivalents will be subject to all the terms and conditions of the underlying Restricted Stock Unit Award Agreement to which they relate.

(vi) **Termination of Participant's Continuous Service.** Except as otherwise provided in the applicable Restricted Stock Unit Award Agreement, such portion of the Restricted Stock Unit Award that has not vested will be forfeited upon the Participant's termination of Continuous Service.

(vii) **Compliance with Section 409A of the Code.** Notwithstanding anything to the contrary set forth herein, any Restricted Stock Unit Award granted under the Plan that is not exempt from the requirements of Section 409A of the Code shall contain such provisions so that such Restricted Stock Unit Award will comply with the requirements of Section 409A of the Code. Such restrictions, if any, shall be determined by the Board and contained in the Restricted Stock Unit Award Agreement evidencing such Restricted Stock Unit Award. For example, such restrictions may include, without limitation, a requirement that any Common Stock that is to be issued in a year following the year in which the Restricted Stock Unit Award vests must be issued in accordance with a fixed pre-determined schedule.

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7. Covenants of the Company.

(a) **Availability of Shares.** During the terms of the Stock Awards, the Company shall keep available at all times the number of shares of Common Stock reasonably required to satisfy such Stock Awards.

(b) **Securities Law Compliance.** The Company shall seek to obtain from each regulatory commission or agency having jurisdiction over the Plan such authority as may be required to grant Stock Awards and to issue and sell shares of Common Stock upon exercise of the Stock Awards; *provided, however,* that this undertaking shall not require the Company to register under the Securities Act the Plan, any Stock Award or any Common Stock issued or issuable pursuant to any such Stock Award. If, after reasonable efforts, the Company is unable to obtain from any such regulatory commission or agency the authority that counsel for the Company deems necessary for the lawful issuance and sale of Common Stock under the Plan, the Company shall be relieved from any liability for failure to issue and sell Common Stock upon exercise of such Stock Awards unless and until such authority is obtained. A Participant shall not be eligible for the grant of a Stock Award or the subsequent issuance of Common Stock pursuant to the Stock Award if such grant or issuance would be in violation of any applicable securities law.

(c) **No Obligation to Notify.** The Company shall have no duty or obligation to any Participant to advise such holder as to the time or manner of exercising such Stock Award. Furthermore, the Company shall have no duty or obligation to warn or otherwise advise such holder of a pending termination or expiration of a Stock Award or a possible period in which the Stock Award may not be exercised. The Company has no duty or obligation to minimize the tax consequences of a Stock Award to the holder of such Stock Award.

8. Miscellaneous.

(a) **Use of Proceeds from Sales of Common Stock.** Proceeds from the sale of shares of Common Stock pursuant to Stock Awards shall constitute general funds of the Company.

(b) **Corporate Action Constituting Grant of Stock Awards.** Corporate action constituting a grant by the Company of a Stock Award to any Participant shall be deemed completed as of the date of such corporate action, unless otherwise determined by the Board, regardless of when the instrument, certificate, or letter evidencing the Stock Award is communicated to, or actually received or accepted by, the Participant.

(c) **Stockholder Rights.** No Participant shall be deemed to be the holder of, or to have any of the rights of a holder with respect to, any shares of Common Stock subject to such Stock Award unless and until (i) such Participant has satisfied all requirements for exercise of the Stock Award pursuant to its terms, if applicable, and (ii) the issuance of the Common Stock subject to such Stock Award has been entered into the books and records of the Company.

(d) **No Employment or Other Service Rights.** Nothing in the Plan, any Stock Award Agreement or any other instrument executed thereunder or in connection with any Stock Award granted pursuant thereto shall confer upon any Participant any right to continue to serve the Company or an Affiliate in the capacity in effect at the time the Stock Award was granted or shall affect the right of the Company or an Affiliate to terminate (i) the employment of an Employee with or without notice and with or without cause, (ii) the service of a Consultant pursuant to the terms of such Consultant's agreement with the Company or an Affiliate, or (iii) the service of a Director pursuant to the Bylaws of the Company or an Affiliate, and any applicable provisions of the corporate law of the state in which the Company or the Affiliate is incorporated, as the case may be.

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(e) **Incentive Stock Option \$100,000 Limitation.** To the extent that the aggregate Fair Market Value (determined at the time of grant) of Common Stock with respect to which Incentive Stock Options are exercisable for the first time by any Optionholder during any calendar year (under all plans of the Company and any Affiliates) exceeds one hundred thousand dollars (\$100,000), the Options or portions thereof that exceed such limit (according to the order in which they were granted) shall be treated as Nonstatutory Stock Options, notwithstanding any contrary provision of the applicable Option Agreement(s).

(f) **Investment Assurances.** The Company may require a Participant, as a condition of exercising or acquiring Common Stock under any Stock Award, (i) to give written assurances satisfactory to the Company as to the Participant's knowledge and experience in financial and business matters and/or to employ a purchaser representative reasonably satisfactory to the Company who is knowledgeable and experienced in financial and business matters and that he or she is capable of evaluating, alone or together with the purchaser representative, the merits and risks of exercising the Stock Award; and (ii) to give written assurances satisfactory to the Company stating that the Participant

is acquiring Common Stock subject to the Stock Award for the Participant's own account and not with any present intention of selling or otherwise distributing the Common Stock. The foregoing requirements, and any assurances given pursuant to such requirements, shall be inoperative if (x) the issuance of the shares upon the exercise or acquisition of Common Stock under the Stock Award has been registered under a then currently effective registration statement under the Securities Act, or (y) as to any particular requirement, a determination is made by counsel for the Company that such requirement need not be met in the circumstances under the then applicable securities laws. The Company may, upon advice of counsel to the Company, place legends on stock certificates issued under the Plan as such counsel deems necessary or appropriate in order to comply with applicable securities laws, including, but not limited to, legends restricting the transfer of the Common Stock.

(g) Withholding Obligations. Unless prohibited by the terms of a Stock Award Agreement, the Company may, in its sole discretion, satisfy any federal, state or local tax withholding obligation relating to a Stock Award by any of the following means or by a combination of such means: (i) causing the Participant to tender a cash payment; (ii) withholding shares of Common Stock from the shares of Common Stock issued or otherwise issuable to the Participant in connection with the Stock Award; *provided, however*, that no shares of Common Stock are withheld with a value exceeding the minimum amount of tax required to be withheld by law (or such lesser amount as may be necessary to avoid classification of the Stock Award as a liability for financial accounting purposes); (iii) withholding payment from any amounts otherwise payable to the Participant; (iv) withholding cash from a Stock Award settled in cash; or (v) by such other method as may be set forth in the Stock Award Agreement.

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(h) Electronic Delivery. Any reference herein to a "written" agreement or document shall include any agreement or document delivered electronically or posted on the Company's intranet.

(i) Deferrals. To the extent permitted by applicable law, the Board, in its sole discretion, may determine that the delivery of Common Stock or the payment of cash, upon the exercise, vesting or settlement of all or a portion of any Stock Award may be deferred and may establish programs and procedures for deferral elections to be made by Participants. Deferrals by Participants will be made in accordance with Section 409A of the Code. Consistent with Section 409A of the Code, the Board may provide for distributions while a Participant is still an employee or otherwise providing services to the Company. The Board is authorized to make deferrals of Stock Awards and determine when, and in what annual percentages, Participants may receive payments, including lump sum payments, following the Participant's termination of Continuous Service, and implement such other terms and conditions consistent with the provisions of the Plan and in accordance with applicable law.

(j) Compliance with Section 409A. To the extent that the Board determines that any Stock Award granted hereunder is subject to Section 409A of the Code, the Stock Award Agreement evidencing such Stock Award shall incorporate the terms and conditions necessary to avoid the consequences specified in Section 409A(a)(1) of the Code. To the extent applicable, the Plan and Stock Award Agreements shall be interpreted in accordance with Section 409A of the Code.

(k) Compliance with Exemption Provided by Rule 12h-1(f). If: (i) the aggregate of the number of Optionholders and the number of holders of all other outstanding compensatory employee stock options to purchase shares of Common Stock equals or exceeds five hundred (500), and (ii) the assets of the Company at the end of the Company's most recently completed fiscal year exceed \$10 million, then the following restrictions shall apply during any period during which the Company does not have a class of its securities registered under Section 12 of the Exchange Act and is not required to file reports under Section 15(d) of the Exchange Act: (A) the Options and, prior to exercise, the shares of Common Stock acquired upon exercise of the Options may not be transferred until the Company is no longer relying on the exemption provided by Rule 12h-1(f) promulgated under the Exchange Act ("**Rule 12h-1(f)**"), except: (1) as permitted by Rule 701(c) promulgated under the Securities Act, (2) to a guardian upon the disability of the Optionholder, or (3) to an executor upon the death of the Optionholder (collectively, the "**Permitted Transferees**"); *provided, however*, the following transfers are permitted: (i) transfers by the Optionholder to the Company, and (ii) transfers in connection with a change of control or other acquisition involving the Company, if following such transaction, the Options no longer remain outstanding and the Company is no longer relying on the exemption provided by Rule 12h-1(f); *provided further*, that any Permitted Transferees may not further transfer the Options; (B) except as otherwise provided in (A) above, the Options and shares of Common Stock acquired upon exercise of the Options are restricted as to any pledge, hypothecation, or other transfer, including any short position, any "put equivalent position" as defined by Rule 16a-1(h) promulgated under the Exchange Act, or any "call equivalent position" as defined by Rule 16a-1(b) promulgated under the Exchange Act by the Optionholder prior to exercise of an Option until the Company is no longer relying on the exemption provided by Rule 12h-1(f); and (C) at any time that the Company is relying on the exemption provided by Rule 12h-1(f), the Company shall deliver to Optionholders (whether by physical or electronic delivery or written notice of the availability of the information on an internet site) the information required by Rule 701(e)(3), (4), and (5) promulgated under the Securities Act every six (6) months, including financial statements that are not more than one hundred eighty (180) days old; *provided, however*, that the Company may condition the delivery of such information upon the Optionholder's agreement to maintain its confidentiality.

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(l) Repurchase Limitation. The terms of any repurchase right shall be specified in the Stock Award Agreement. The repurchase price for vested shares of Common Stock shall be the Fair Market Value of the shares of Common Stock on the date of repurchase. The repurchase price for unvested shares of Common Stock shall be the lower of (i) the Fair Market Value of the shares of Common Stock on the date of repurchase or (ii) their original purchase price. However, the Company shall not exercise its repurchase right until at least six (6) months (or such longer or shorter period of time necessary to avoid classification of the Stock Award as a liability for financial accounting purposes) have elapsed following delivery of shares of Common Stock subject to the Stock Award, unless otherwise specifically provided by the Board.

9. Adjustments upon Changes in Common Stock; Other Corporate Events.

(a) Capitalization Adjustments. In the event of a Capitalization Adjustment, the Board shall appropriately and proportionately adjust: (i) the class(es) and maximum number of securities subject to the Plan pursuant to Section 3(a), (ii) the class(es) and maximum number of securities that may be issued pursuant to the exercise of Incentive Stock Options pursuant to Section 3(c), and (iii) the class(es) and number of securities and price per share of stock subject to outstanding Stock Awards. The Board shall make such adjustments, and its determination shall be final, binding and conclusive.

(b) Dissolution or Liquidation. Except as otherwise provided in the Stock Award Agreement, in the event of a dissolution or liquidation of the Company, all outstanding Stock Awards (other than Stock Awards consisting of vested and outstanding shares of Common Stock not subject to a forfeiture condition or the Company's right of repurchase) shall terminate immediately prior to the completion of such dissolution or liquidation, and the shares of Common Stock subject to the Company's repurchase rights or subject to a forfeiture condition may be repurchased or reacquired by the Company notwithstanding the fact that the holder of such Stock Award is providing Continuous Service, *provided, however*, that the Board may, in its sole discretion, cause some or all Stock Awards to become fully vested, exercisable and/or no longer subject to repurchase or forfeiture (to the extent such Stock Awards have not previously expired or terminated) before the dissolution or liquidation is completed but contingent on its completion.

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(c) Corporate Transaction. The following provisions shall apply to Stock Awards in the event of a Corporate Transaction unless otherwise provided in the instrument evidencing the Stock Award or any other written agreement between the Company or any Affiliate and the holder of the Stock Award or unless otherwise expressly provided by the Board at the time of grant of a Stock Award. Except as otherwise stated in the Stock Award Agreement, in the event of a Corporate Transaction, then, notwithstanding any other provision of the Plan, the Board shall take one or more of the following actions with respect to Stock Awards, contingent upon the closing or completion of the Corporate Transaction:

(i) arrange for the surviving corporation or acquiring corporation (or the surviving or acquiring corporation's parent company) to assume or continue the

Stock Award or to substitute a similar stock award for the Stock Award (including, but not limited to, an award to acquire the same consideration paid to the stockholders of the Company pursuant to the Corporate Transaction);

(ii) arrange for the assignment of any reacquisition or repurchase rights held by the Company in respect of Common Stock issued pursuant to the Stock Award to the surviving corporation or acquiring corporation (or the surviving or acquiring corporation's parent company);

(iii) accelerate the vesting, in whole or in part, of the Stock Award (and, if applicable, the time at which the Stock Award may be exercised) to a date prior to the effective time of such Corporate Transaction as the Board shall determine (or, if the Board shall not determine such a date, to the date that is five (5) days prior to the effective date of the Corporate Transaction), with such Stock Award terminating if not exercised (if applicable) at or prior to the effective time of the Corporate Transaction;

(iv) arrange for the lapse of any reacquisition or repurchase rights held by the Company with respect to the Stock Award;

(v) cancel or arrange for the cancellation of the Stock Award, to the extent not vested or not exercised prior to the effective time of the Corporate Transaction, in exchange for such cash consideration, if any, as the Board, in its sole discretion, may consider appropriate; and

(vi) make a payment, in such form as may be determined by the Board equal to the excess, if any, of (A) the value of the property the holder of the Stock Award would have received upon the exercise of the Stock Award, over (B) any exercise price payable by such holder in connection with such exercise. The Board need not take the same action with respect to all Stock Awards or with respect to all Participants.

(d) **Change in Control.** A Stock Award may be subject to additional acceleration of vesting and exercisability upon or after a Change in Control as may be provided in the Stock Award Agreement for such Stock Award or as may be provided in any other written agreement between the Company or any Affiliate and the Participant, but in the absence of such provision, no such acceleration shall occur.

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10. Termination or Suspension of the Plan.

(a) **Plan Term.** The Board may suspend or terminate the Plan at any time. Unless sooner terminated by the Board pursuant to Section 2, the Plan shall automatically terminate on the day before the tenth (10th) anniversary of the earlier of (i) the date the Plan is adopted by the Board, or (ii) the date the Plan is approved by the stockholders of the Company. No Stock Awards may be granted under the Plan while the Plan is suspended or after it is terminated.

(b) **No Impairment of Rights.** Suspension or termination of the Plan shall not impair rights and obligations under any Stock Award granted while the Plan is in effect except with the written consent of the affected Participant.

11. Effective Date of Plan.

This Plan shall become effective on the Effective Date.

12. Choice of Law.

The law of the State of Delaware shall govern all questions concerning the construction, validity and interpretation of this Plan, without regard to that state's conflict of laws rules.

13. Definitions.

As used in the Plan, the following definitions shall apply to the capitalized terms indicated below:

(a) **"Affiliate"** means, at the time of determination, any "parent" or "majority-owned subsidiary" of the Company, as such terms are defined in Rule 405 of the Securities Act. The Board shall have the authority to determine the time or times at which "parent" or "majority-owned subsidiary" status is determined within the foregoing definition.

(b) **"Board"** means the Board of Directors of the Company.

(c) **"Capitalization Adjustment"** means any change that is made in, or other events that occur with respect to, the Common Stock subject to the Plan or subject to any Stock Award after the Effective Date without the receipt of consideration by the Company (through merger, consolidation, reorganization, recapitalization, reincorporation, stock dividend, dividend in property other than cash, stock split, liquidating dividend, combination of shares, exchange of shares, change in corporate structure, or any similar equity restructuring transaction, as that term is used in Statement of Financial Accounting Standards No. 123 (revised). Notwithstanding the foregoing, the conversion of any convertible securities of the Company shall not be treated as a Capitalization Adjustment.

(d) **"Cause"** shall have the meaning ascribed to such term in any written agreement between the Participant and the Company defining such term and, in the absence of such agreement, such term means with respect to a Participant, the occurrence of any of the following events: (i) such Participant's commission of any felony or any crime involving fraud, dishonesty or moral turpitude under the laws of the United States or any state thereof; (ii) such Participant's attempted commission of, or participation in, a fraud or act of dishonesty against the Company; (iii) such Participant's intentional, material violation of any contract or agreement between the Participant and the Company or of any statutory duty owed to the Company; (iv) such Participant's unauthorized use or disclosure of the Company's confidential information or trade secrets; or (v) such Participant's gross misconduct. The determination that a termination of the Participant's Continuous Service is either for Cause or without Cause shall be made by the Company in its sole discretion. Any determination by the Company that the Continuous Service of a Participant was terminated with or without Cause for the purposes of outstanding Stock Awards held by such Participant shall have no effect upon any determination of the rights or obligations of the Company or such Participant for any other purpose.

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(e) **"Change in Control"** means the occurrence, in a single transaction or in a series of related transactions, of any one or more of the following events:

(i) any Exchange Act Person becomes the Owner, directly or indirectly, of securities of the Company representing more than fifty percent (50%) of the combined voting power of the Company's then outstanding securities other than by virtue of a merger, consolidation or similar transaction. Notwithstanding the foregoing, a Change in Control shall not be deemed to occur (A) on account of the acquisition of securities of the Company directly from the Company, (B) on account of the acquisition of securities of the Company by an investor, any affiliate thereof or any other Exchange Act Person that acquires the Company's securities in a transaction or series of related transactions the primary purpose of which is to obtain financing for the Company through the issuance of equity securities or (C) solely because the level of Ownership held by any Exchange Act Person (the **"Subject Person"**) exceeds the designated percentage threshold of the outstanding voting securities as a result of a repurchase or other acquisition of voting securities by the Company reducing the number of shares outstanding, provided that if a Change in Control would occur (but for the operation of this sentence) as a result of the acquisition of voting securities by the Company, and after such share acquisition, the Subject Person becomes the Owner of any additional voting securities that, assuming the repurchase or other acquisition had not occurred, increases the percentage of the then outstanding voting securities Owned by the Subject Person over the designated percentage threshold, then a Change in Control shall be deemed to occur;

(ii) there is consummated a merger, consolidation or similar transaction involving (directly or indirectly) the Company and, immediately after the consummation of such merger, consolidation or similar transaction, the stockholders of the Company immediately prior thereto do not Own, directly or indirectly, either (A) outstanding voting securities representing more than fifty percent (50%) of the combined outstanding voting power of the surviving Entity in such merger, consolidation or similar transaction or (B) more than fifty percent (50%) of the combined outstanding voting power of the parent of the surviving Entity in such merger, consolidation or similar transaction, in each case in substantially the same proportions as their Ownership of the outstanding voting securities of the Company immediately prior to such transaction;

(iii) there is consummated a sale, lease, exclusive license or other disposition of all or substantially all of the consolidated assets of the Company and its Subsidiaries, other than a sale, lease, license or other disposition of all or substantially all of the consolidated assets of the Company and its Subsidiaries 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 in substantially the same proportions as their Ownership of the outstanding voting securities of the Company immediately prior to such sale, lease, license or other disposition; or

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(iv) individuals who, on the date this Plan is adopted by the Board, are members of the Board (the "**Incumbent Board**") cease for any reason to constitute at least a majority of the members of the Board; *provided, however*, that if the appointment or election (or nomination for election) of any new Board member was approved or recommended by a majority vote of the members of the Incumbent Board then still in office, such new member shall, for purposes of this Plan, be considered as a member of the Incumbent Board.

Notwithstanding the foregoing definition or any other provision of this Plan, (A) the term Change in Control shall not include a sale of assets, merger or other transaction effected exclusively for the purpose of changing the domicile of the Company, and (B) the definition of Change in Control (or any analogous term) in an individual written agreement between the Company or any Affiliate and the Participant shall supersede the foregoing definition with respect to Stock Awards subject to such agreement; *provided, however*, that if no definition of Change in Control or any analogous term is set forth in such an individual written agreement, the foregoing definition shall apply.

(f) "**Code**" means the Internal Revenue Code of 1986, as amended, as well as any applicable regulations and guidance thereunder.

(g) "**Committee**" means a committee of one (1) or more Directors to whom authority has been delegated by the Board in accordance with Section 2(c).

(h) "**Common Stock**" means the common stock of the Company.

(i) "**Company**" means RenovoRx, Inc., a Delaware corporation.

(j) "**Consultant**" means any person, including an advisor, who is (i) engaged by the Company or an Affiliate to render consulting or advisory services and is compensated for such services, or (ii) serving as a member of the board of directors of an Affiliate and is compensated for such services. However, service solely as a Director, or payment of a fee for such service, shall not cause a Director to be considered a "Consultant" for purposes of the Plan.

(k) "**Continuous Service**" means that the Participant's service with the Company or an Affiliate, whether as an Employee, Director or Consultant, is not interrupted or terminated. A change in the capacity in which the Participant renders service to the Company or an Affiliate as an Employee, Director, or Consultant or a change in the Entity for which the Participant renders such service, provided that there is no interruption or termination of the Participant's service with the Company or an Affiliate, shall not terminate a Participant's Continuous Service; *provided, however*, if the Entity for which a Participant is rendering service ceases to qualify as an Affiliate, as determined by the Board in its sole discretion, such Participant's Continuous Service shall be considered to have terminated on the date such Entity ceases to qualify as an Affiliate. For example, a change in status from an employee of the Company to a consultant of an Affiliate or to a Director shall not constitute an interruption of Continuous Service. To the extent permitted by law, the Board or the chief executive officer of the Company, in that party's sole discretion, may determine whether Continuous Service shall be considered interrupted in the case of (i) any leave of absence approved by the Board or chief executive officer, including sick leave, military leave or any other personal leave, or (ii) transfers between the Company, an Affiliate, or their successors. Notwithstanding the foregoing, a leave of absence shall be treated as Continuous Service for purposes of vesting in a Stock Award only to such extent as may be provided in the Company's leave of absence policy, in the written terms of any leave of absence agreement or policy applicable to the Participant, or as otherwise required by law.

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(l) "**Corporate Transaction**" means the occurrence, in a single transaction or in a series of related transactions, of any one or more of the following events:

(i) the consummation of a sale or other disposition of all or substantially all, as determined by the Board in its sole discretion, of the consolidated assets of the Company and its Subsidiaries;

(ii) the consummation of a sale or other disposition of at least ninety percent (90%) of the outstanding securities of the Company;

(iii) the consummation of a merger, consolidation or similar transaction following which the Company is not the surviving corporation; or

(iv) the consummation of a merger, consolidation or similar transaction following which the Company is the surviving corporation but the shares of Common Stock outstanding immediately preceding the merger, consolidation or similar transaction are converted or exchanged by virtue of the merger, consolidation or similar transaction into other property, whether in the form of securities, cash or otherwise.

(m) "**Director**" means a member of the Board.

(n) "**Disability**" means the inability of a Participant to engage in any substantially gainful activity by reason of any medically determinable physical or mental impairment which can be expected to result in death or which has lasted or can be expected to last for a continuous period of not less than twelve (12) months as provided in Sections 22(e)(3) and 409A(a)(2)(c)(i) of the Code and shall be determined by the Board on the basis of such medical evidence as the Board deems warranted under the circumstances.

(o) "**Effective Date**" means the effective date of this Plan, which is the earlier of (i) the date that this Plan is first approved by the Company's stockholders, or (ii) the date this Plan is adopted by the Board.

(p) "**Employee**" means any person employed by the Company or an Affiliate. However, service solely as a Director, or payment of a fee for such services, shall not cause a Director to be considered an "Employee" for purposes of the Plan.

(q) "**Entity**" means a corporation, partnership, limited liability company or other entity.

(r) "**Exchange Act**" means the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.

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(s) “**Exchange Act Person**” means any natural person, Entity or “group” (within the meaning of Section 13(d) or 14(d) of the Exchange Act), except that “Exchange Act Person” shall not include (i) the Company or any Subsidiary of the Company, (ii) any employee benefit plan of the Company or any Subsidiary of the Company or any trustee or other fiduciary holding securities under an employee benefit plan of the Company or any Subsidiary of the Company, (iii) an underwriter temporarily holding securities pursuant to a registered public offering of such securities, (iv) an Entity Owned, directly or indirectly, by the stockholders of the Company in substantially the same proportions as their Ownership of stock of the Company; or (v) any natural person, Entity or “group” (within the meaning of Section 13(d) or 14(d) of the Exchange Act) that, as of the Effective Date, is the Owner, directly or indirectly, of securities of the Company representing more than fifty percent (50%) of the combined voting power of the Company’s then outstanding securities.

(t) “**Fair Market Value**” means, as of any date, the value of the Common Stock determined by the Board in compliance with Section 409A of the Code or, in the case of an Incentive Stock Option, in compliance with Section 422 of the Code.

(u) “**Incentive Stock Option**” means an option that qualifies as an “incentive stock option” within the meaning of Section 422 of the Code and the regulations promulgated thereunder.

(v) “**Nonstatutory Stock Option**” means an Option that does not qualify as an Incentive Stock Option.

(w) “**Officer**” means any person designated by the Company as an officer.

(x) “**Option**” means an Incentive Stock Option or a Nonstatutory Stock Option to purchase shares of Common Stock granted pursuant to the Plan.

(y) “**Option Agreement**” means a written agreement between the Company and an Optionholder evidencing the terms and conditions of an Option grant. Each Option Agreement shall be subject to the terms and conditions of the Plan.

(z) “**Optionholder**” means a person to whom an Option is granted pursuant to the Plan or, if applicable, such other person who holds an outstanding Option.

(aa) “**Own,**” “**Owned,**” “**Owner,**” “**Ownership**” A person or Entity shall be deemed to “Own,” to have “Owned,” to be the “Owner” of, or to have acquired “Ownership” of securities if such person or Entity, directly or indirectly, through any contract, arrangement, understanding, relationship or otherwise, has or shares voting power, which includes the power to vote or to direct the voting, with respect to such securities.

(bb) “**Participant**” means a person to whom a Stock Award is granted pursuant to the Plan or, if applicable, such other person who holds an outstanding Stock Award.

(cc) “**Plan**” means this RenovoRx, Inc. 2013 Equity Incentive Plan.

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(dd) “**Restricted Stock Award**” means an award of shares of Common Stock which is granted pursuant to the terms and conditions of Section 6(a).

(ee) “**Restricted Stock Award Agreement**” means a written agreement between the Company and a holder of a Restricted Stock Award evidencing the terms and conditions of a Restricted Stock Award. Each Restricted Stock Award Agreement shall be subject to the terms and conditions of the Plan.

(ff) “**Restricted Stock Unit Award**” means a right to receive shares of Common Stock which is granted pursuant to the terms and conditions of Section 6(b).

(gg) “**Restricted Stock Unit Award Agreement**” means a written agreement between the Company and a holder of a Restricted Stock Unit Award evidencing the terms and conditions of a Restricted Stock Unit Award grant. Each Restricted Stock Unit Award Agreement shall be subject to the terms and conditions of the Plan.

(hh) “**Rule 405**” means Rule 405 promulgated under the Securities Act.

(ii) “**Rule 701**” means Rule 701 promulgated under the Securities Act.

(jj) “**Securities Act**” means the Securities Act of 1933, as amended.

(kk) “**Stock Appreciation Right**” or “**SAR**” means a right to receive the appreciation on Common Stock that is granted pursuant to the terms and conditions of Section 5.

(ll) “**Stock Appreciation Right Agreement**” means a written agreement between the Company and a holder of a Stock Appreciation Right evidencing the terms and conditions of a Stock Appreciation Right grant. Each Stock Appreciation Right Agreement shall be subject to the terms and conditions of the Plan.

(mm) “**Stock Award**” means any right to receive Common Stock granted under the Plan, including an Incentive Stock Option, a Nonstatutory Stock Option, a Restricted Stock Award, a Restricted Stock Unit Award, or a Stock Appreciation Right.

(nn) “**Stock Award Agreement**” means a written agreement between the Company and a Participant evidencing the terms and conditions of a Stock Award grant. Each Stock Award Agreement shall be subject to the terms and conditions of the Plan.

(oo) “**Subsidiary**” means, with respect to the Company, (i) any corporation of which more than fifty percent (50%) of the outstanding capital stock having ordinary voting power to elect a majority of the board of directors of such corporation (irrespective of whether, at the time, stock of any other class or classes of such corporation shall have or might have voting power by reason of the happening of any contingency) is at the time, directly or indirectly, Owned by the Company, and (ii) any partnership, limited liability company or other entity in which the Company has a direct or indirect interest (whether in the form of voting or participation in profits or capital contribution) of more than fifty percent (50%) .

(pp) “**Ten Percent Stockholder**” means a person who Owns (or is deemed to Own pursuant to Section 424(d) of the Code) stock possessing more than ten percent (10%) of the total combined voting power of all classes of stock of the Company or any Affiliate.

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