



RenovoRx, Inc.

Initiating Coverage with BUY and \$8.00 Target

Large market opportunities for its TAMP oncology therapy platform. We believe expected positive clinical data in late-2024 to be strong catalysts for stock.

Initiating with BUY: We are initiating coverage of RenovoRx with a BUY rating and a 12-month price target of \$8.00. RenovoRx is a clinical-stage pharmaceutical company developing novel therapies to treat, cure, and prevent cancer.

Focus on TAMP: The company is developing novel precision oncology therapies based on a local drug delivery platform. The company's proprietary Trans-Arterial Micro-Perfusion (TAMP) therapy platform is designed to ensure precise therapeutic delivery to directly target the tumor while potentially minimizing a therapy's toxicities versus systemic IV therapy. This approach has the goal to improve therapeutic outcomes for cancer patients undergoing treatment by increasing safety, tolerance, and improved efficacy.

RenovoGem: RenovoRx's lead drug therapy candidate RenovoGem is an oncology drug-device combination product. It is currently in a Phase 3 registration trial to treat Locally Advanced Pancreatic Cancer (LAPC). The company also plans to evaluate RenovoGem as a potential therapy in other indications including bile duct cancer (eCCA), non-small cell lung cancer, uterine tumors, glioblastoma, and sarcoma.

LAPC: Pancreatic cancer is one of the deadliest cancers in the U.S. with very poor prognosis and outcomes. According to American Cancer Society, pancreatic cancer has a 5-year combined overall survival rate of 12%, which is the worst of any other cancer types. Locally Advanced Pancreatic Cancer (LAPC) is diagnosed when the disease has not spread far beyond the pancreas, however, has advanced to the point where it cannot be surgically removed.

TIGeR-PaC Trial: The company's Phase 3 registration trial of RenovoGem for the treatment of LAPC is called TIGeR-PaC. This clinical trial is an ongoing randomized multi-center study using TAMP to evaluate RenovoGem. The study is comparing treatment of an FDA-approved cancer drug, gemcitabine, with TAMP versus systemic IV administration of gemcitabine and nab-paclitaxel.

Positive 1st interim analysis: In March 2023, the company announced positive interim analysis results of the study suggesting a 6-month potential improvement in median overall survival with RenovoGem. The Data Monitoring Committee determined the interim data warrants continuation of this pivotal trial without modification and no safety concerns were observed.

Late 2024 2nd interim analysis: The company expects that the 2nd interim data analysis to occur in late 2024.

However, challenges exist: RenovoRx operates in a highly competitive environment and competes against a wide range of other drugs, therapeutics, and treatments. There is the chance that competing therapeutic treatments for LAPC may be developed and launched before the company's drugs/drug therapies are launched.

Positive high risks versus high rewards: Overall, concerns outweighed by growth prospects and valuation. RenovoRx TAMP platform still have long development roads left and the high risks of clinical trials failures, but we believe the ~billion dollars market potential presents high rewards for the risks.

Current valuation attractive: We calculate a 12-month price target for shares of RenovoRx to be \$8.00 based on a NPV analysis, representing significant upside from the current share price. We believe this valuation appropriately balances out the company's high risks with its high growth prospects and large upside opportunities.

Company Description

Based in Los Altos, CA, RenovoRx is a clinical-stage pharmaceutical company developing novel therapies to treat, cure, and prevent cancer.

United States
Healthcare

June 17, 2024

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COVERAGE INITIATION

Rating: BUY

Ticker: RNXT

Price: \$1.18

Target: \$8.00

Stock Data

Exchange:	NasdaqCM
52-week Range:	0.53 – 3.29
Shares Outstanding (million):	24
Market cap (\$million):	\$28
EV (\$million):	\$13
Debt (\$million):	\$0
Cash (\$million):	\$15
Avg. Daily Trading Vol. (\$million):	\$0.1
Float (million shares):	23
Short Interest (million shares):	0.1
Dividend, annual (yield):	\$0 (NA%)

Revenues (US\$ million)

	<u>2023A</u> (Cur.)	<u>2024E</u> (Cur.)	<u>2025E</u> (Cur.)
Q1 Mar	0A	0A	0E
Q2 Jun	0A	0E	0E
Q3 Sep	0A	0E	0E
Q4 Dec	<u>0A</u>	<u>0E</u>	<u>0E</u>
Total	0A	0E	0E
EV/Revs	N/A	N/A	N/A

Earnings per Share (pro forma)

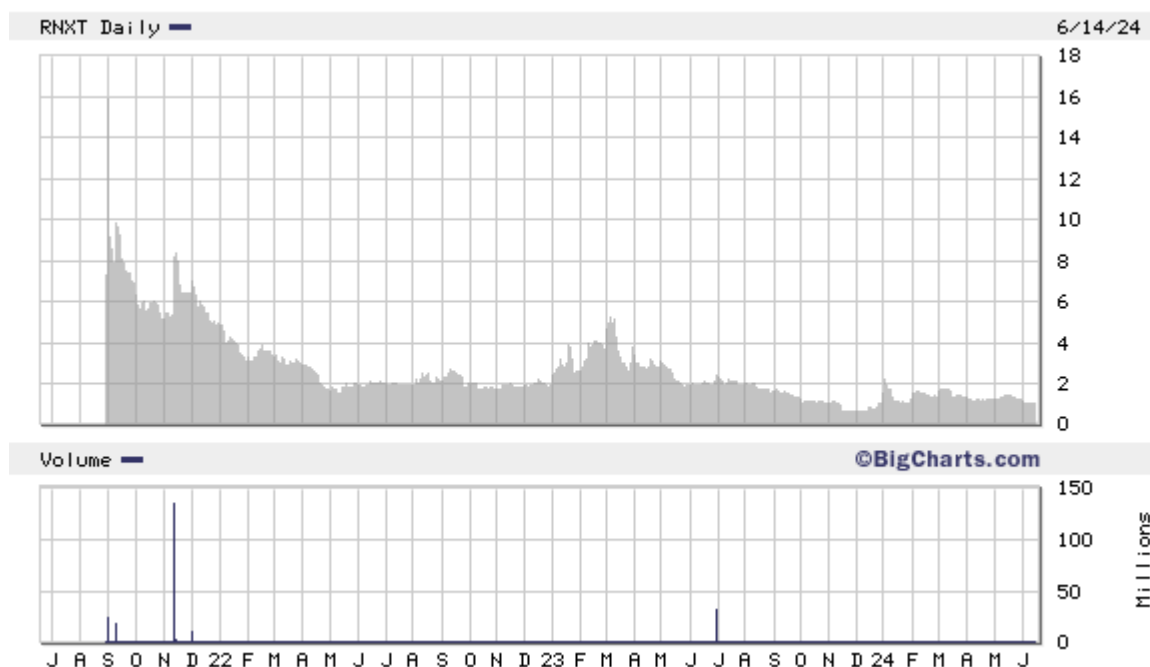
	<u>2023A</u> (Cur.)	<u>2024E</u> (Cur.)	<u>2025E</u> (Cur.)
Q1 Mar	(0.36)A	(0.07)A	(0.10)E
Q2 Jun	(0.22)A	(0.11)E	(0.10)E
Q3 Sep	(0.13)A	(0.11)E	(0.10)E
Q4 Dec	<u>(0.30)A</u>	<u>(0.11)E</u>	<u>(0.10)E</u>
Total	(0.99)A	(0.40)E	(0.41)E
P/E	N/A	N/A	N/A

Important Disclosures

Ascendant Capital Markets LLC seeks to do business with companies covered by its research team. Consequently, investors should be aware that the firm may have a conflict of interest that could affect the objectivity of this report. Investors should consider this report as only a single factor in making an investment decision.

For analyst certification and other important disclosures, refer to the Disclosure Section, located at the end of this report, beginning on page 36.

Exhibit 1: RenovoRx, Inc. Stock Price (3-years since August 2021 IPO)



Source: <https://bigcharts.marketwatch.com/>

INVESTMENT THESIS

We are initiating coverage of RenovoRx with a BUY rating and a 12-month price target of \$8.00.

Based in Los Altos, CA, RenovoRx is a clinical-stage pharmaceutical company developing novel therapies to treat, cure, and prevent cancer. The company is developing novel precision oncology therapies based on a local drug delivery platform. The company's proprietary Trans-Arterial Micro-Perfusion (TAMP) therapy platform is designed to ensure precise therapeutic delivery to directly target the tumor while potentially minimizing a therapy's toxicities versus systemic (intravenous ("IV") therapy). This approach to targeted treatment for high unmet medical need has the goal to improve therapeutic outcomes for cancer patients undergoing treatment by increasing safety, tolerance, and improved efficacy.

RenovoRx's lead drug therapy candidate RenovoGem is an oncology drug-device combination product. It is currently in a Phase 3 registration trial to treat Locally Advanced Pancreatic Cancer (LAPC). The company also plans to evaluate RenovoGem as a potential therapy in other indications including bile duct cancer (eCCA), non-small cell lung cancer, uterine tumors, glioblastoma, and sarcoma.

The company's Phase 3 registration (pivotal) trial of RenovoGem for the treatment of LAPC is called TIGeR-PaC. This clinical trial is an ongoing randomized multi-center study using TAMP to evaluate RenovoGem. The study is evaluating trans-arterial delivery, a form of intra-arterial ("IA") administration, of an FDA-approved chemotherapy, gemcitabine, to treat LAPC following stereotactic body radiation therapy ("SBRT"). The study is comparing treatment of an FDA-approved cancer drug, gemcitabine, with TAMP versus systemic IV administration of gemcitabine and nab-paclitaxel.

The company obtained FDA approval for a Phase 3 IND (Investigational New Drug) study in February 2018 comparing TAMP with IA gemcitabine to standard of care. In the FDA pre-IND meeting, the FDA confirmed the study design and endpoints and indicated that this Phase III study should result in New Drug Application (NDA) approval if successful.

On March 8, 2023, the company announced positive interim analysis results of the study suggesting a 6-month potential improvement in median overall survival with RenovoGem. The TIGeR-PaC Data Monitoring Committee ("DMC") met and determined the interim data warrants continuation of this pivotal trial without modification and no safety concerns were observed.

The company believes this first-of-two interim analyses indicates that the TIGeR-PaC study is on track to demonstrate increased lifespan for patients being treated with RenovoGem for LAPC. Final analysis will be conducted after 86 protocol-specified events have occurred in the SBRT population with two planned interim analyses: this first analysis with 30% of the specified events (26th event/deaths) reported and the second analysis when 60% of the events (52nd event/death) have been reported (expected in late 2024), with the final study readout expected in 2026.

Pancreatic cancer is one of the deadliest cancers in the U.S. with very poor prognosis and outcomes. According to American Cancer Society's Cancer Facts & Figures 2023, pancreatic cancer has a 5-year combined overall survival rate of 12% (Stages I-IV), which is the worst of any other cancer types. It is also on track to be the second leading cause of cancer-related deaths before 2030.

Locally Advanced Pancreatic Cancer (LAPC) is diagnosed when the disease has not spread far beyond the pancreas, however, has advanced to the point where it cannot be surgically removed.

Chemotherapy is at the forefront of systemic therapy treatment for cancer. It can be used in the neoadjuvant (before surgery) setting to attempt to decrease tumor size in resectable or borderline resectable patients, in the adjuvant (after surgery) setting, or first line in the metastatic/advanced setting. RenovoGem utilizes gemcitabine, which is a chemotherapy medication that is a nucleoside metabolic inhibitor that exhibits antitumor activity by blocking the synthesis of new DNA, which results in cell death. Since its introduction in the U.S. as Gemzar (gemcitabine for injection in IV) in 1996 with FDA approval, it remains in the guidelines as standard of care.

Gemcitabine has been demonstrated to provide clinical benefit for subjects (decreased pain and improved performance status) as well as to improve the time to tumor progression and survival for subjects with metastatic pancreatic cancer and LAPC. However, major improvement in the survival curve of all pancreatic cancer subjects has been a clinical challenge, with an average median survival time for LAPC stalled at 12-15 months from time of diagnosis.

Certain cancer tumor types are sufficiently vascularized (i.e., tumors with blood vessels associated with them) to enable use of systemic chemotherapy and standard of care local therapy techniques. Further, visible tumor feeder blood vessels can be reached by simple end-hole catheters to deliver targeted therapy to these tumors. In contrast, pancreatic cancer tumors typically lack tumor feeder blood vessels.


To overcome the limitations resulting from a lack of tumor feeder blood vessels, RenovoRx 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, the company can introduce chemotherapy directly across the arterial wall into the surrounding tissue via pressurized diffusion, which it calls Trans-Arterial Micro-Perfusion (for the acronym TAMP). This blanketing approach of large fluid volume delivery over time may enable the drug to approach these difficult-to-reach tumors.

Exhibit 2: RenovoRx, Inc. Corporate Overview

RENOVO | RX

Delivering Therapy Where it Matters™

Company Overview

-  Founded in 2009 by a physician with first external funding 2012. Last private financing led by Boston Scientific, 2018. IPO, Q3 2021. HQ: Los Altos, CA.
-  Developing **proprietary targeted combination therapies**. **Trans-Arterial Micro-Perfusion (TAMP™)** platform's goal is to improve therapeutic index.
-  Pivotal **Phase III TIGeR-PaC** study interim analysis demonstrated positive 1^o and 2^o endpoint data including **increased Overall Survival and progression-free survival, and 65% reduction in side effects**.
-  **FDA Orphan Drug Designation** granted to **RenovoGem™** in pancreatic and bile duct cancers.
-  **\$1B global market opportunity** in the primary indication. Additional financial opportunity for pipeline platform expansion.



Source: Company reports.

Exhibit 3: RenovoRx Investment Highlights

RenovoRx Highlights

Targeted Trans-arterial Approach: TAMP Designed to Decrease Side Effects and Increase Tumor Penetration

- Reduced systemic drug exposure
- **Higher local drug concentration**

Lead Product Candidate: RenovoGem

Targeted Combination Therapy:

- Trans-arterial (IA) gemcitabine delivered through proprietary FDA-cleared delivery system

Positive interim analysis data from Phase III TIGeR-PaC study:

- **6-month Overall Survival benefit**
- **8-month progression-free survival benefit**
- **65% reduction in side effects**

RenovoGem Targets Locally Advanced Solid Tumors

- Initial indications: pancreatic cancer (**\$1B addressable market**) and bile duct cancer
- Potential **pipeline indications** include non-small cell lung cancer, uterine tumors, glioblastoma, sarcoma

Novel Therapy Platform: TAMP Pipeline

- TAMP **compatible with multiple potential targets**
- Platform expanding pre-clinical studies underway
- **Collaboration with Imugene further validates the TAMP platform** and will **explore expansion of the pipeline** with CF33 oncolytic virus therapy for the treatment of difficult-to-access tumors

TAMP Platform: Layers of Market Exclusivity (Regulatory & IP)

- **9 patents issued** on TAMP and proprietary delivery system for targeted combination therapy
 - 8 US patents issued; 1 EU patent issued
 - 8 additional pending patents in US, EU, Asia
- **Orphan Drug Designation** for pancreatic cancer and bile duct cancer provides **7 years of market exclusivity** for RenovoGem upon NDA approval

Investment Opportunity

- De-risked drug development and validated TAMP platform
- Large first indication market (\$1B) and platform broadly applicable to growing market segment
- Experienced clinical and commercial Leadership Team and Board
- **Positive 1st Phase III interim analysis completed 1H '23:**
 - **6-month Overall Survival benefit**
 - **8-month progression-free survival benefit**
 - **>65% reduction in side effects**

Source: Company reports.

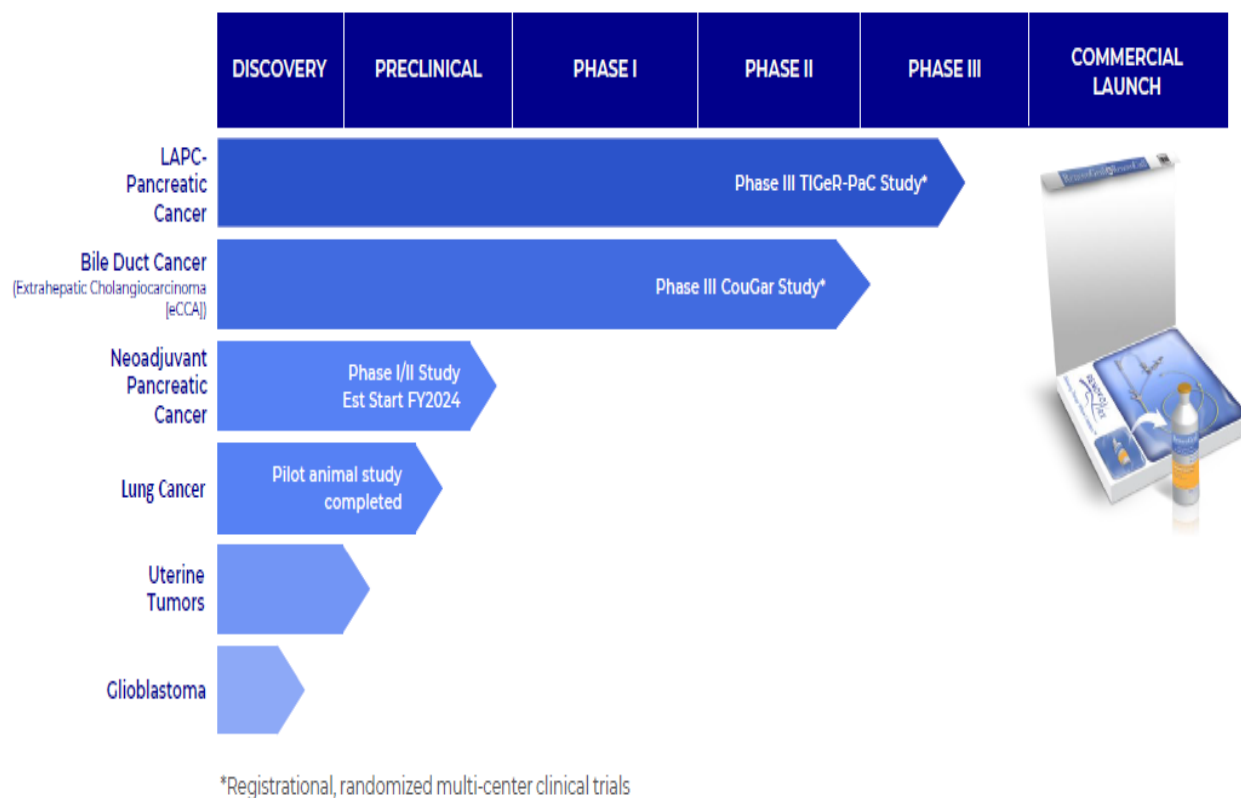
RenovoGem uses the company’s proprietary Trans-Arterial Micro-Perfusion (TAMP) therapy platform which is designed to ensure precise therapeutic delivery to directly target the tumor while potentially minimizing a therapy’s toxicities versus systemic (whole body) (intravenous (“IV”) therapy). This approach to targeted treatment has the goal to improve therapeutic outcomes for cancer patients undergoing treatment by increasing safety, tolerance, and improved efficacy.

RenovoGem delivers gemcitabine (sold under the brand name Gemzar, among others, is a chemotherapy medication used to treat cancers) via its patented pressure-mediated delivery system across the arterial wall to bathe tumor tissue in chemotherapy. RenovoGem’s proprietary delivery system, RenovoCath, is a double balloon catheter designed with the capability to isolate sections of the blood vessel through the adjustment of the distance between the balloons to create the pressure needed to push drug across the blood vessel wall.

RenovoTAMP can be utilized with other approved chemotherapeutics (anti-cancer drugs used in chemotherapy), with the goal of increasing their efficacy, improving their safety, and widening their therapeutic window.

Exhibit 4: RenovoRx Pipeline Overview

RenovoGem Product Development Plan



Source: Company reports.

Exhibit 5: RenovoGem Lead Indication: LAPC (Locally Advanced Pancreatic Cancer)

RenovoGem Lead Indication: LAPC

Pancreatic Cancer Worldwide Incidence:

495,000 new cases/year with
30% locally advanced at presentation



 62,000

 58,007

(diagnosis)

Soon to be second leading cause of cancer-related death in US (48,000 deaths annually)

Current Standard of Care:

12 to 18.8-month median Overall Survival from time of diagnosis

Using chemo-radiation regimens with gemcitabine+nab-paclitaxel OR mFOLFIRINOX as base treatment

Only Three Drugs Approved by FDA to Treat LAPC within Past 10 Years

LAPC Market Opportunity*

\$1B MARKET OPPORTUNITY*

US: \$500M
REST OF WORLD: \$500M

New Orphan Drug Product Regulatory and Reimbursement

- Orphan Drug Protection (2 indications)
- Will submit New Drug Application (NDA) approval for RenovoGem
- National Drug Code (J-Code) reimbursement upon FDA NDA approval

New Oncology Drug Market

Average new oncology drug pricing: \$150,000/year*

Will submit New Drug Application (NDA) approval for RenovoGem

* Fletcher Spaght, 2019

Source: Company reports.

RenovoRx's share price has been volatile and weak in the past year. In the past year, RenovoRx share price was -41% (was \$2.00 on 6/14/23 and to the current share price of \$1.18 on 6/14/24), and so far in 2024 is -48% (was \$2.29 on 12/29/23). While the Russell 2000 Index of small-cap U.S. stocks has been relatively flat in 2024 (~0% YTD and compares to the S&P500 +14% and NASDAQ +18%), it and small and micro-cap companies have remained volatile even as the overall stock market has been strong and positive.

The company's balance sheet has \$4 million in cash and no debt as of March 2024. In April (current Q2), the company raised ~\$11 million selling stock (7.9 million shares at \$ 1.4075 per share). We believe the company has enough cash into 2026. Although it is very likely that the company will have to keep raising capital to achieve its product development goals, we believe that positive progress will make future financings accretive to current shareholders.

The company's near term plans over the next year is to advance RenovoGem in its clinical trials towards a FDA approval for the treatment of for LAPC and eCCA. We believe expected positive milestones and clinical data (particularly for the 2nd interim data analysis expected in late 2024) over the next year to be strong catalysts for stock.

Our investment thesis factors in an uncertain drug development process and very competitive industry which is offset by the very large potential upside opportunities created from a successful drug/drug therapy. We believe that the current valuation for RenovoRx has already factored in many of its risks (principally drug approval and successful commercialization) but is under valuing its overall growth prospects and product portfolio, resulting in a positive risk versus reward scenario for an investment in RenovoRx.

We believe the current valuation is attractive.

Based on our expectations and assumptions and our NPV analysis, we calculate a 12-month price target for shares of RenovoRx to be \$8.00, representing significant upside from current share price. We believe this valuation appropriately balances out the company's high risks with the company's high growth prospects and large upside opportunities. We acknowledge that RenovoRx is still at a very early stage in its drug development and product commercialization, but we believe key milestones over the next year should be positive catalysts for the stock.

INVESTMENT RISKS

Long and Uncertain Drug Development Cycles

RenovoRx is highly dependent upon securing drug approvals for its products in order to sell them (produce revenue). The drug development cycle can be long (average of 12 years), expensive (average of \$350 million), complicated, and uncertain. On average only about 10% of drugs entering clinical trials ever make it to final approval. Because RenovoRx's main drug therapy (RenovoGem for LAPC) is still in clinical development in a Phase 3 trial (along with one other drug candidate (eCCA) preparing for a Phase 2/3 trial), there are still significant risks and a long time horizon to receive FDA approval. We estimate that it likely at least two years before any of its drug therapies can receive FDA approval. With a high likelihood of binary outcomes (either success or failure), the risks are high but the potential rewards can also be very high as well.

Product Commercialization Risks

Even after obtaining drug approvals, there is still a chance that commercial success will not be achieved (due to competition, changes in the market, better or newer drugs or technologies, lack of reasonable reimbursements, or lack of market acceptance). While there are currently no good therapeutics to prevent or treat pancreatic cancer, there is the chance that other potential therapeutic treatments and options may be developed and launched before the company's drugs are launched. In addition, RenovoRx will need to replace existing therapies and treatments being used currently as standards of care. Like most health care drugs, the company will also need to get suitable insurance and government reimbursements for its products.

High Level of Competition

RenovoRx operates in a highly competitive environment and competes against a wide range of other biopharmaceutical companies that are attempting to replicate or already have comparable treatments as the company's drugs. Some of these competitors are much larger or have greater resources, and proprietary technology; which could result in lower projected sales for its drugs and higher costs, reduced margins, and lowered profitability for the company. Even if RenovoRx were to be successful with its drug therapy development, its products will have to compete with existing or new standards of care.

Concentrated Product Pipeline

Although the company is currently developing 4 drug therapeutics, only two are currently in clinical trials (LAPC and eCCA). If RenovoRx were to experience difficulties with development of its drug therapies for LAPC or eCCA, then it may have a material negative impact on its business and financials as there are no meaningful products that are as far along in development which can offset.

Coronavirus and Economic Uncertainties

While healthcare costs tends to be less correlated with economic activity and income levels due to their nondiscretionary nature, major deterioration in economic conditions tends to result in an overall decline in consumer spending. This was demonstrated during the 2008 and 2009 Great Recession and global economic slowdown. While consumer spending levels and economic conditions have rebounded since and have been strong most of the 2010s, the global macroeconomic environment can change significantly quickly as was shown with the start of the COVID-19 pandemic in March 2020. Since then, due to huge government stimulus the U.S. economy has been very strong the past 4 years. However, the pandemic has still negatively impacted many businesses and has been a huge disruption to the U.S. (and global) economy. This includes biotechs as many have seen FDA drug development reviews, feedback, and approvals delayed along with disruptions in clinical trials. We note most of the economy is currently back to normal, but potential economic weakness or volatility may result in depressed government, enterprise, and consumer spending levels; this may have a negative impact on RenovoRx, its business partners, government, and consumers.

Capital Markets Risks

We believe RenovoRx has enough cash to fund its operations into 2026 (Q1 (March) 2026), but we estimate that it will need to raise capital by Q4 2025 (December 2025). We believe that it will be at least several years before the company can be cash flow self-sufficient from operations. Many biopharmaceutical companies fund their operations from the sale of equity or debt capital until

their products reach commercial success or until they sell off the commercial rights to other companies. Biopharmaceuticals (“biotechs”) valuations tend to fluctuate widely, and though they are reasonably strong now (due to a strong M&A market for biotechs and large government funding for healthcare), there is always the chance that market interests and valuations for companies in this industry decline significantly. Share price weakness and volatility for small/micro cap and biotech stocks may make capital raising much more difficult and expensive.

VALUATION

We are initiating coverage of RenovoRx with a BUY rating and a 12-month price target of \$8.00, which is based on a NPV analysis. As the company is a clinical stage drug therapy development company, it currently generates minimal revenue and significant losses so traditional valuation metrics are not useful. We believe a more accurate valuation should take into consideration the potential value of its drug therapy product pipeline. We do acknowledge that this valuation is complex and requires a large number of forward assumptions that we have to estimate that may be imprecise and may vary significantly from actual results. This is particularly so for a company like RenovoRx which is still in early Phase III clinical trials with one drug therapy and even earlier stage with its other potential therapies.

However, we believe our assumptions are fair and provide a reasonable basis for our valuation analysis. Our analysis considers future estimated revenue from each of its major drug product pipelines (based on estimated future sales, a probability rate of success, and discounted this back to a current value), mainly focused on its 2 later stage drug therapies (LAPC-pancreatic cancer and eCCA-bile duct cancer). We apply a high discount rate and a low probability of success to capture the high uncertainties associated generally with drugs in development. We then added up the values, made an assumption about future investments required and allocated the value based on current share count. Based on our NPV analysis, we arrived at our 12-month price target of \$8.00, which we believe appropriately balances out the company’s risks with its high growth prospects.

Exhibit 6: Company Valuation (DCF) (in \$ millions)

Valuation of Business Segments (in millions)

Drug Products	Estimated NPV	% of Success	Calculated NPV	Discount Rate	Estimated Annual Sales	% of Market Share	Market Potential per year
Locally Advanced Pancreatic Cancer (LAPC)	\$ 163	30%	\$ 542	30%	\$ 163	33%	\$ 500
Bile Duct Cancer (eCCA)	\$ 31	15%	\$ 208	30%	\$ 63	25%	\$ 250
Trans-Arterial Micro-Perfusion (TAMP) Platform	\$ 13	10%	\$ 133	30%	\$ 40	20%	\$ 200
Total	\$ 207						
Net cash	\$ 15						
Estimated additional investments (& debt) required	\$ 30						
Current Value for existing shareholders	\$ 192						
Shares Outstanding (mils)	24						
Estimated Value per share	\$ 8.00						

Source: Ascendant Capital Markets estimates.

RenovoRx's share price has been volatile and weak in the past year. In the past year, RenovoRx share price was -41% (was \$2.00 on 6/14/23 and to the current share price of \$1.18 on 6/14/24), and so far in 2024 is -48% (was \$2.29 on 12/29/23). This is in contrast with general stock price weakness and volatility with small/microcap tech stocks in 2022 and then a sharp rebound in 2023 (Russell 2000 Index of small-cap U.S. stocks was -20% in 2022 and +19% in 2023). While the Russell 2000 Index has been relatively flat in 2024 (~0% YTD and compares to the S&P500 +14% and NASDAQ +18%), it and small and micro-cap companies have remained volatile even as the overall stock market has been strong and positive.

We believe that there are near term catalysts that can drive the stock (particularly for key milestones expected in late 2024). As the company is likely to make significant progress (and milestones) in its drug therapy development and product commercialization over the next several years, we believe this will result in much improved visibility into future cash flows and higher share price. Although it is very likely that the company will have to keep raising capital to achieve its product development goals, we believe that positive progress will make future financings accretive to current shareholders.

We expect valuations for RenovoRx to improve as visibility into cash flow generation becomes clearer (though we acknowledge that product commercialization is likely at least 2 years away), resulting in significant upside to the current share price. We also want to note that investor's interest in drugs development to treat and prevent cancer (oncology) are very high with many companies in this area attributed high valuations due to the large market opportunities given lack of good treatment options and the high incidence rate.

COMPANY

Based in Los Altos, CA, RenovoRx is a clinical-stage pharmaceutical company developing novel therapies to treat, cure, and prevent cancer. The company is developing novel precision oncology therapies based on a local drug delivery platform. The company's proprietary Trans-Arterial Micro-Perfusion (TAMP) therapy platform is designed to ensure precise therapeutic delivery to directly target the tumor while potentially minimizing a therapy's toxicities versus systemic (intravenous ("IV") therapy). This approach to targeted treatment for high unmet medical need has the goal to improve therapeutic outcomes for cancer patients undergoing treatment by increasing safety, tolerance, and improved efficacy.

RenovoRx's lead drug therapy candidate RenovoGem is an oncology drug-device combination product. It is currently in a Phase 3 registration trial to treat Locally Advanced Pancreatic Cancer (LAPC). The company also plans to evaluate RenovoGem as a potential therapy in other indications including bile duct cancer (eCCA), non-small cell lung cancer, uterine tumors, glioblastoma, and sarcoma.

In 2009, the company's founder Dr. Ramtin Agah, an experienced interventional cardiologist with a degree in biomedical engineering, developed the concept for RenovoTAMP as a way to deliver chemotherapy locally to treat poorly vascularized tumors. He founded RenovoRx with Kamran Najmabadi, who brought significant medical device engineering experience. RenovoRx was incorporated in Delaware in December 2012. The company received its first FDA 510(k) clearance for RenovoCath in 2014 and a second clearance to use the RenovoCath for infusion of chemotherapy agents in 2017. In August 2021, the company completed its IPO (initial public offering) raising \$17 million. Since inception, the company has raised ~\$60 million in funding to advance its business. As of March 2024, RenovoRx had ~8 employees.

Exhibit 7: RenovoRx Management and Advisors

Experienced Management Team Supported by World Class Board of Directors



Shaun R. Bagai
 Chief Executive Officer & Board Member
 • HeartFlow (\$1B+ raised) Ardian (acq for > \$900M)
 • Medtronic Vascular
 • TransVascular



Ramtin Agah, MD
 Chief Medical Officer, Founder & Chairman of the Board
 • Interventional Cardiology, Sutter Health
 • Consultant Abbott Vascular



Leesa Gentry
 Chief Clinical Officer
 • Evotec
 • Otsuka America Pharmaceuticals
 • Omnicare Clinical Research



Ronald B. Kocak, CPA
 Vice President, Controller & Principal Financial Officer
 • Sensei Biotherapeutics, Inc.
 • Member of the American Institute of Certified Public Accountants
 • Member of Chartered Global Management Accountant



Una S. Ryan, PhD, OBE
 Board Member
 • Board: Cortxyme, Elemental Machines



Laurence J. Marton, MD
 Board Member
 • Board: Cellsonics, TOMA Biosciences, xCures



Angela Macfarlane
 Board Member
 • CEO, Perceive Biotherapeutics (\$78M raised led by JJDC)
 • CEO Foresight Labs



Robert J. Spiegel, MD
 Board Member
 • CMO, PTC Therapeutics
 • CMO, Schering-Plough (\$4.1B merger with Merck)

Led or Contributed to the Development of:



- >200 years of combined development / commercial experience
- Contributed to 30+ successful New Drug Application filings with the Food and Drug Administration
- Launched multiple blockbuster drugs
- Served as executives or board members in companies acquired by Medtronic, Roche, Merck, and Allergan

Scientific Advisory Board



Mike Pishvaian, MD, PhD
 • Associate Professor, 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



Karyn A. Goodman, MD, MS
 • Professor and Vice Chair of Clinical Research, Department of Radiation Oncology, Icahn School of Medicine at Mount Sinai
 • Associate Director of Clinical Research, The Tisch Cancer Institute at Mount Sinai



Margaret A. Tempero, M.D.
 • Professor of Medicine and Director of the UCSF Pancreas Center
 • Editor-in-Chief of JNCCN
 • Former ASCO President



Michel Ducreux, M.D., Ph.D.
 • Head of the Gastrointestinal Oncology Unit and Gastrointestinal Oncology Tumor Board at Gustave Roussy
 • Professor of Oncology at Paris-Saclay University in France
 • Vice-Chair of ESMO GI

Source: Company reports.

Management Team

Shaun Bagai (age 47) Chief Executive Officer - Mr. Bagai has served as CEO since June 2014. Prior to joining the company, 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 (KOL) development to create value resulting in a company investment to form HeartFlow-Japan. In addition, Mr. Bagai has launched innovative technologies into regional and global marketplaces in both large corporations and growth-phase novel technology companies. Mr. Bagai is a graduate from the University of California, Santa Barbara with a BSc. in Biology/Pre-Med.

Ramtin Agah, M.D. (age 58) Chief Medical Officer and Chairman of the Board - Dr. Agah has served as Chief Medical Officer and Co-Founder since December 2009, and as Chairman of the Board since May 2018. Dr. Agah is currently an Interventional Cardiologist at El Camino Hospital in Mountain View, CA a role he began in September 2005. He also has acted as a physician consultant for Abbott Vascular since July 2012. Previously, Dr. Agah was an Assistant Professor of Internal Medicine with the Division of Cardiology, University of Utah. Dr. Agah completed a fellowship in Interventional Cardiology with Cleveland Clinic Foundation, a residency in Internal Medicine with Baylor College of Medicine and a fellowship in Cardiology with University of California, San Francisco (“UCSF”). He received his M.D. from the University of Texas Southwestern Medical School.

DRUG PIPELINE

RenovoRx’s lead drug therapy candidate RenovoGem is an oncology drug-device combination product. It is currently in a Phase 3 registration trial to treat Locally Advanced Pancreatic Cancer (LAPC). The company also plans to evaluate RenovoGem as a potential therapy in other oncology indications including bile duct cancer (eCCA), non-small cell lung cancer, uterine tumors, glioblastoma, and sarcoma.

RenovoGem uses the company’s proprietary Trans-Arterial Micro-Perfusion (TAMP) therapy platform which is designed to ensure precise therapeutic delivery to directly target the tumor while potentially minimizing a therapy’s toxicities versus systemic (whole body) (intravenous (“IV”) therapy). This approach to targeted treatment has the goal to improve therapeutic outcomes for cancer patients undergoing treatment by increasing safety, tolerance, and improved efficacy.

RenovoGem delivers gemcitabine (sold under the brand name Gemzar, among others, is a chemotherapy medication used to treat cancers) via its patented pressure-mediated delivery system across the arterial wall to bathe tumor tissue in chemotherapy. Gemcitabine is considered a standard of care drug for several solid tumors and its anti-cancer tumor effects are well documented.

RenovoGem’s proprietary delivery system, RenovoCath, is a double balloon catheter designed with the capability to isolate sections of the blood vessel through the adjustment of the distance between the balloons to create the pressure needed to push drug across the blood vessel wall.

RenovoTAMP can be utilized with other approved chemotherapeutics (anti-cancer drugs used in chemotherapy), with the goal of increasing their efficacy, improving their safety, and widening their therapeutic window.

Exhibit 8: RenovoGem

RenovoTAMP Therapy Platform and First Product Candidate, RenovoGem

Our Therapy
Platform

RenovoTAMP
RenovoRx® Trans-Arterial Micro-Perfusion
(drug/device combination)

Our First Product
Candidate



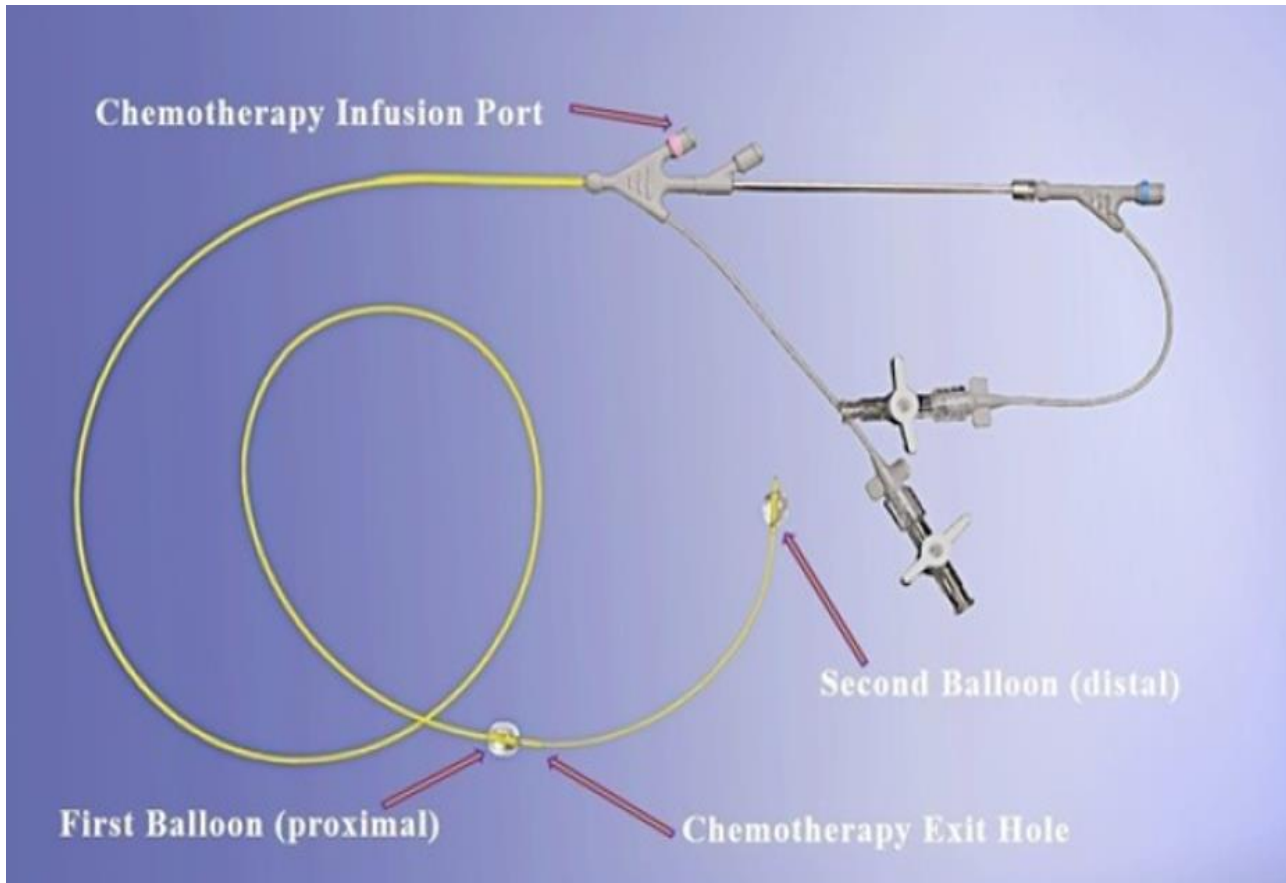
Source: Company reports.

Exhibit 9: RenovoTAMP and RenovoGem



Source: Company reports.

Exhibit 10: RenovoCath

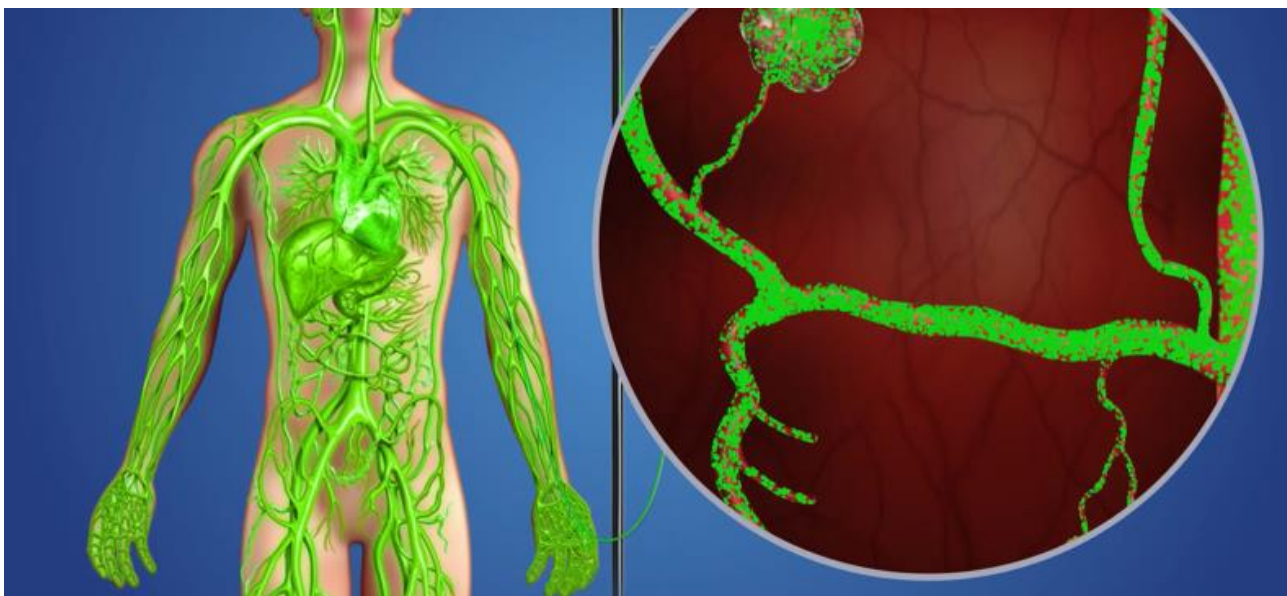


Source: Company reports.

Certain cancer tumor types are sufficiently vascularized (i.e., tumors with blood vessels associated with them) to enable use of systemic chemotherapy and standard of care local therapy techniques. Further, visible tumor feeder blood vessels can be reached by simple end-hole catheters to deliver targeted therapy to these tumors. In contrast, pancreatic cancer tumors typically lack tumor feeder blood vessels.

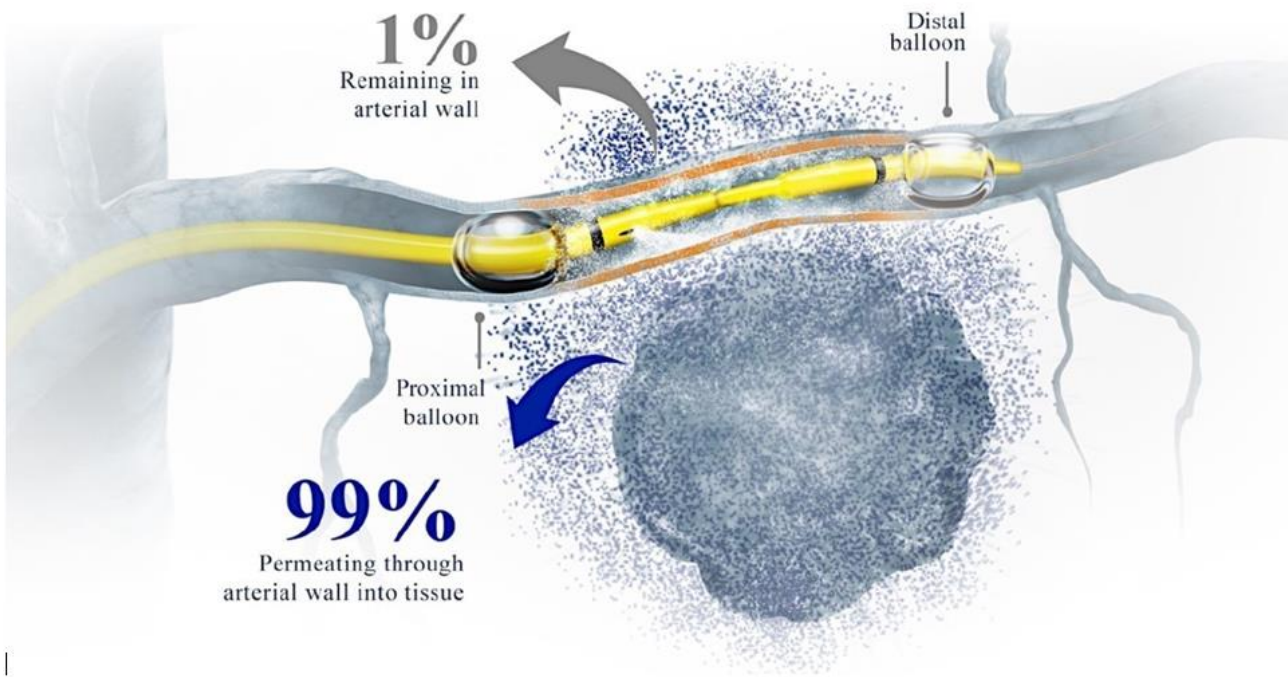
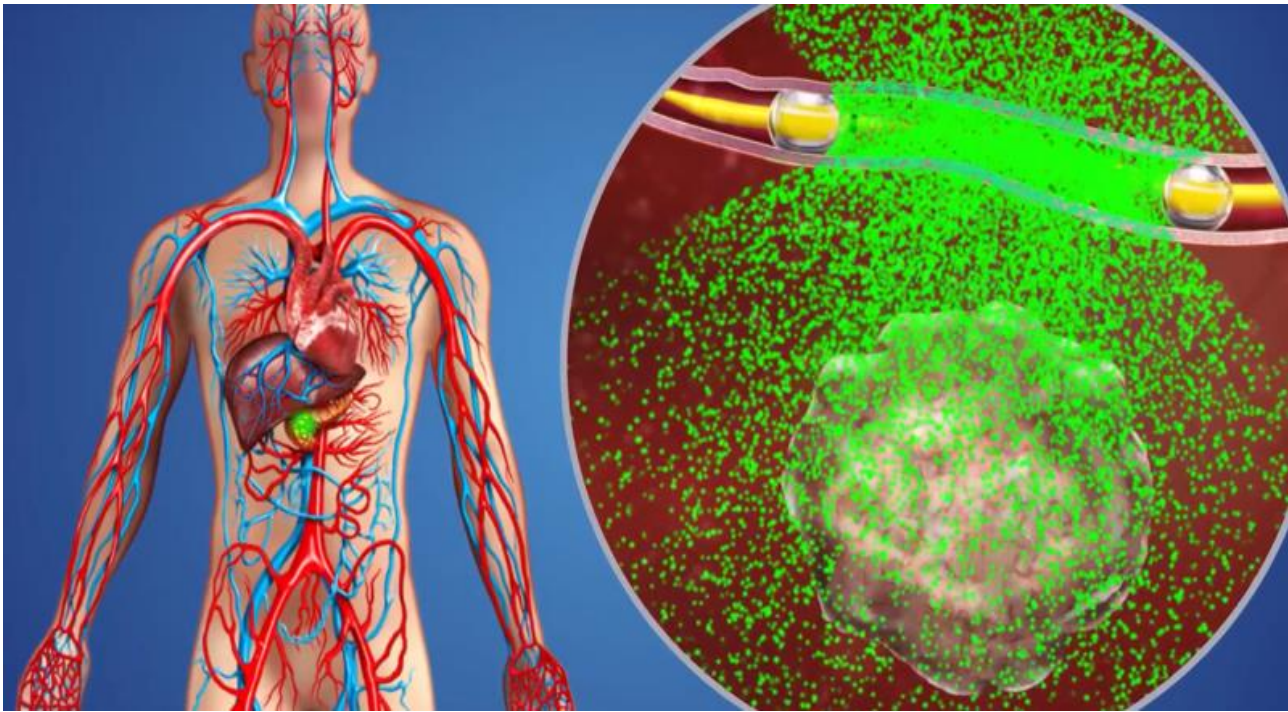
To overcome the limitations resulting from a lack of tumor feeder blood vessels, RenovoRx explored a different approach to locally deliver anti-cancer drugs. By isolating a section of the blood vessel and then increasing the intravascular pressure in the isolated segment, the company can introduce chemotherapy directly across the arterial wall into the surrounding tissue via pressurized diffusion, which it calls Trans-Arterial Micro-Perfusion (for the acronym TAMP). This blanketing approach of large fluid volume delivery over time may enable the drug to approach these difficult-to-reach tumors.

Exhibit 11: Systemic Intravenous (IV) Therapy (affecting the entire body, rather than localized or single area)



Source: Company report.

Exhibit 12: Trans-Arterial Micro-Perfusion (TAMP) Therapy (affecting a localized or single area)



Source: Company report.

The key advantages of TAMP (Trans-Arterial Micro-Perfusion) include:

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

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, RenovoTAMP is able to force the small molecule chemotherapy across the vessel directly into surrounding tissue or tumor. RenovoTAMP accomplishes this with the company’s patented RenovoCath delivery system. RenovoCath is a double balloon catheter designed with the capability to isolate the proximal and distal sections of the vessel through the adjustment of the distance between the balloons.

Using standard interventional techniques, an interventional radiologist inserts the RenovoCath delivery system into the body through the femoral artery and positions it in the artery closest to the tumor. Once the balloons are inflated and the position is confirmed, chemotherapy is delivered through the handle, exiting the device between the balloons. It is forced through the vessel wall into the tissue over a 20-minute period. After the procedure is complete, the RenovoCath is discarded, and the patient is generally discharged the same day. On average, the entire procedure takes approximately 90 minutes.

Exhibit 13: Improved Drug’s Therapeutic Index

TAMP Improves a Drug’s Therapeutic Index

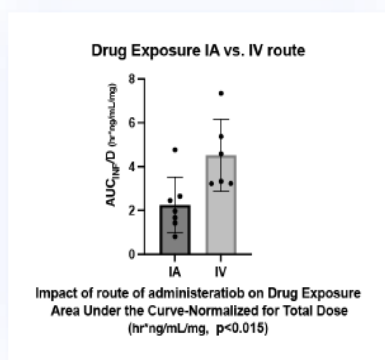
Higher Amounts of Drug to Pathological Site (↑ Efficacy) & Less Systemic Exposure (↑ Safety)

Increases Drug Concentration to Target Pathological Site by ~100X* Compared to IV Administration*



*As demonstrated in animal studies presented at SIR 2019

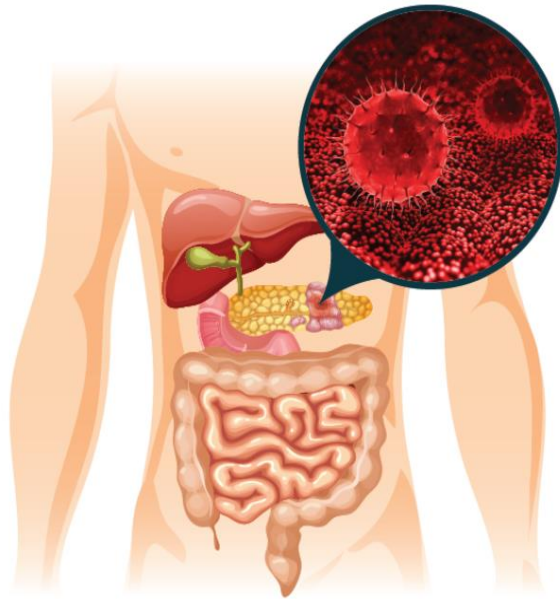
Reduces Drug AUC by >50% Compared to IV Administration+



*As demonstrated in Sub-study performed in Phase III TIGeR-PaC study presented at ASCO-GI 2023

Source: Company reports.

Exhibit 14: Pancreatic Cancer

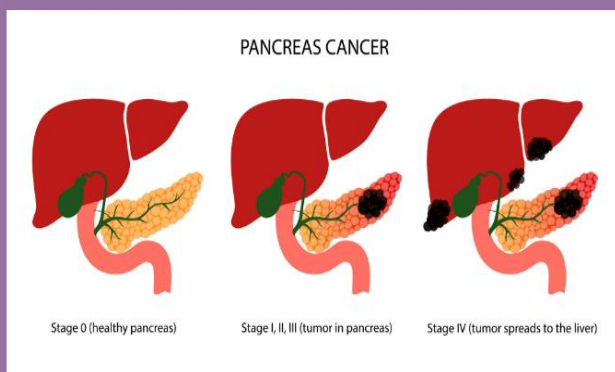


Why Should I learn About Pancreatic Cancer?

Pancreatic Cancer causes 7% of cancer-related deaths in the United States. This type of cancer has one of the lowest five-year survival rates of any major cancer, at only 10% combined. Sadly, many patients receive diagnoses too late. Distant cancer has a 5-year survivability of 3%. This means cancer has spread into other areas of the body.

The American Cancer Society's estimates for pancreatic cancer in the United States for 2023 are:

- ✓ About 64,050 people (33,130 men and 30,920 women) will be diagnosed with pancreatic cancer.
- ✓ About 50,550 people (26,620 men and 23,930 women) will die of pancreatic cancer.



A cancer type is based on the location of the tumor's origin within the pancreas organ. In this case, the origin is the pancreas organ.

Cancer is the name for a disease in which abnormal cells divide without control and can invade nearby tissues. Cancer cells can also spread to other parts of the body through the blood and lymph systems.

If you want to learn more about cancer consider reading the What Is Cancer article published by the NIH National Cancer Institute.

What is Pancreatic Cancer?

Pancreatic cancer is uncontrolled cell growth that starts in the organ of the pancreas.

Types of Pancreatic Cancer

- ✓ Acinar Cell Cancers are cancerous tumors that form on the ends of the pancreatic ducts.
- ✓ Adenocarcinoma is cancer that begins in the cells that line internal organs and have the function to secrete fluids. In the pancreas, this is a cancer of the exocrine cells that line the pancreatic ducts. More than 95% of pancreatic cancers are adenocarcinomas of the exocrine pancreas.
- ✓ Cystic Tumors derive their name from the presence of fluid-filled sacs within the pancreas. The fluid is produced by the lining of abnormal tissues or tumors. These tumors may lead to cancer in some patients; however, most cystic tumors of the pancreas are benign.
- ✓ Sarcomas are tumors that form in the connective tissue that bonds pancreatic cells together and are rare.

Source: The National Pancreatic Cancer Foundation.

Pancreatic cancer is one of the deadliest cancers in the U.S. with very poor prognosis and outcomes. According to American Cancer Society's Cancer Facts & Figures 2023, pancreatic cancer has a 5-year combined overall survival rate of 12% (Stages I-IV), which is the worst of any other cancer types. It is also on track to be the second leading cause of cancer-related deaths before 2030.

Locally Advanced Pancreatic Cancer (LAPC) is diagnosed when the disease has not spread far beyond the pancreas, however, has advanced to the point where it cannot be surgically removed. LAPC is typically associated with patients in stage 3 of the disease as determined by the TNM (tumor, nodes and metastasis) grading system.

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

Chemotherapy is at the forefront of systemic therapy treatment for cancer. It can be used in the neoadjuvant (before surgery) setting to attempt to decrease tumor size in resectable or borderline resectable patients, in the adjuvant (after surgery) setting, or first line in the metastatic/advanced setting. RenovoGem utilizes gemcitabine, which is a chemotherapy medication that is a nucleoside metabolic inhibitor that exhibits antitumor activity by blocking the synthesis of new DNA, which results in cell death. Since its introduction in the U.S. as Gemzar (gemcitabine for injection in IV) in 1996 with FDA approval, it remains in the guidelines as standard of care.

Gemcitabine has been demonstrated to provide clinical benefit for subjects (decreased pain and improved performance status) as well as to improve the time to tumor progression and survival for subjects with metastatic pancreatic cancer and LAPC. However, major improvement in the survival curve of all pancreatic cancer subjects has been a clinical challenge, with an average median survival time for LAPC stalled at 12-15 months from time of diagnosis.

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

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

For the treatment of some localized solid tumors, TACE (transarterial chemoembolization) is an established first line therapy. Many solid tumors have a dedicated blood supply: small blood vessels, called tumor feeder blood vessels, that branch off of larger native arteries and terminate in the tumors to provide nutrition to the tumors. A key aspect of TACE is to identify and isolate these tumor feeder blood vessels during x-ray angiography and then deliver the desired therapy including chemotherapy and embolic agents into the tumors through these feeder blood vessels. In patients with LAPC, no tumor feeder blood vessels are visible due to the avascular (lack of blood vessels) nature of these tumors. This limitation has rendered TACE ineffective in the treatment of patients with LAPC, eCCA, and a subset of other solid tumors.

Exhibit 15: Pancreatic Cancer Five-Year Relative Survival Rates
Table 8. Five-year Relative Survival Rates* (%) by Stage at Diagnosis, US, 2013-2019

	All stages	Local	Regional	Distant		All stages	Local	Regional	Distant
Breast (female)	91	99	86	31	Non-Hodgkin lymphoma	74	86	78	67
Colon & rectum†	64	91	73	14	Oral cavity & pharynx	69	87	69	39
Colon†	63	91	73	13	Ovary	51	92	73	32
Rectum	67	90	74	18	Pancreas	13	44	16	3
Esophagus	22	49	28	6	Prostate	97	>99	>99	34
Kidney & renal pelvis	78	93	74	17	Stomach	36	75	35	7
Larynx	62	79	47	34	Thyroid	99	>99	98	54
Liver‡	22	37	14	4	Urinary bladder§	78	71	39	8
Lung & bronchus	25	63	35	8	Uterine cervix	67	91	60	19
Melanoma of the skin	94	>99	74	35	Uterine corpus	81	95	70	18

*Rates are adjusted for normal life expectancy and are based on cases diagnosed in the SEER 22 areas from 2013-2019; all cases were followed through 2020. †Excludes appendix. ‡Includes intrahepatic bile duct. §Rate for in situ cases is 96%.

Stage classification based on Combined Summary Stage. **Local:** an invasive malignant cancer confined entirely to the organ of origin. **Regional:** a malignant cancer that 1) has extended beyond the limits of the organ of origin directly into surrounding organs or tissues; 2) involves regional lymph nodes; or 3) has both regional extension and involvement of regional lymph nodes. **Distant:** a malignant cancer that has spread to parts of the body remote from the primary tumor either by direct extension or by discontinuous metastasis to distant organs, tissues, or via the lymphatic system to distant lymph nodes.

Source: SEER*Explorer, National Cancer Institute, 2023. Available from <https://seer.cancer.gov/explorer/>. Colon & rectal cancer – SEER*Stat software (version 8.4.0.1), National Cancer Institute, 2022.

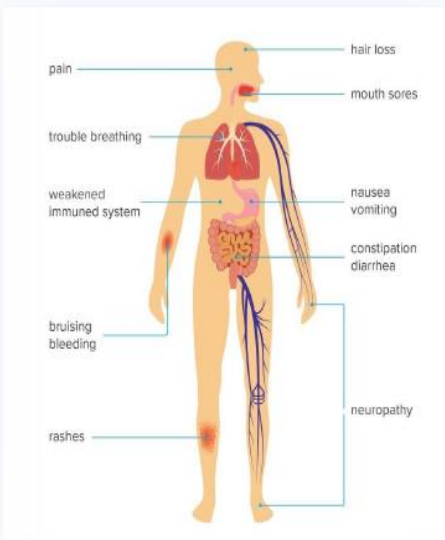
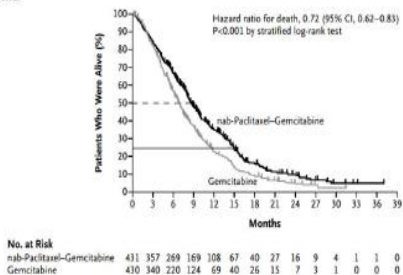
©2024 American Cancer Society, Inc., Surveillance and Health Equity Science

Source: The American Cancer Society, American Cancer Society Inc. Cancer Facts & Figures 2024.

Exhibit 16: Pancreatic Cancer Treatment Options

All Three FDA Approvals (Abraxane, Olaparib, Onivyde) in past 10-years: <2 Months Median Overall Survival Benefits and Increases in Toxicity Rates Highlighting FDA continued concordance of Pancreatic Cancer as High Unmet Need

A Overall Survival



Abraxane obtained FDA approval in 2013 on a 7-week Median Overall Survival benefit

38% Grade 3 or Higher Neutropenia and 17% Neuropathy

Olaparib received full FDA approval in 4Q 2019 with no Median OS Difference (<4-mo PFS benefit); Onivyde received FDA approval on a 1.9-mo Median OS benefit in 2015.

Source: Company report.

The company’s Phase 3 registration (pivotal) trial of RenovoGem for the treatment of LAPC is called TIGeR-PaC. This clinical trial is an ongoing randomized multi-center study using TAMP to evaluate RenovoGem. The study is evaluating trans-arterial delivery, a form of intra-arterial (“IA”) administration, of an FDA-approved chemotherapy, gemcitabine, to treat LAPC following stereotactic body radiation therapy (“SBRT”). The study is comparing treatment of an FDA-approved cancer drug, gemcitabine, with TAMP versus systemic IV administration of gemcitabine and nab-paclitaxel.

The company obtained FDA approval for a Phase 3 IND (Investigational New Drug) study in February 2018 comparing TAMP with IA gemcitabine to standard of care. In the FDA pre-IND meeting, the FDA confirmed the study design and endpoints and indicated that this Phase III study should result in New Drug Application (NDA) approval if successful.

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 U.S.

On March 8, 2023, the company announced positive interim analysis results of the study suggesting a 6-month potential improvement in median overall survival with RenovoGem. The TIGeR-PaC Data Monitoring Committee (“DMC”) met and determined the interim data warrants continuation of this pivotal trial without modification and no safety concerns were observed.

In this first interim analysis, the control and treatment arms demonstrated divergence in median overall survival for patients. The study is designed to randomize 114 patients (57 in each arm) with all patients receiving upfront induction chemotherapy and SBRT.

As of the date of the analysis, 45 patients from U.S. sites had been randomized in this trial and the survival status of all subjects was used for the analysis.

- 23 patients were randomized to IA gemcitabine (RenovoGem investigational treatment) arm and 22 to continuation of IV gemcitabine and nab-paclitaxel (control or standard of care) arm. There were an equal number of primary events, 13 in each arm.
- The median overall survival in the IV gemcitabine and nab-paclitaxel control arm was 10 months, versus 16 months in the IA RenovoGem arm. (NOTE: Both arms' median overall survival calculations do not include 4-5-months of life since diagnosis during the induction chemotherapy and radiation phase of the trial).
- Observed a positive trend in median overall survival by 24-weeks (6-months); in this interim analysis, the statistical significance was not reached to stop the study early ($p=0.051$).

The company believes this first-of-two interim analyses indicates that the TIGeR-PaC study is on track to demonstrate increased lifespan for patients being treated with RenovoGem for LAPC. Final analysis will be conducted after 86 protocol-specified events have occurred in the SBRT population with two planned interim analyses: this first analysis with 30% of the specified events (26th event/deaths) reported and the second analysis when 60% of the events (52nd event/death) have been reported (expected in late 2024), with the final study readout expected in 2026.

Exhibit 17: Pancreatic Tumors Have Poor Blood Supply

A Paradigm Shift: We Are Addressing a Significant Problem in Cancer Treatment



Hypervascular tumors are adequately treated with current therapies

Liver tumors are highly vascularized

- Large tumor feeders – excellent targets for systemic therapy
- Can be accessed and treated with current local therapy techniques



Hypovascular tumors = major barrier to chemotherapy treatment success

Pancreatic tumors have poor blood supply

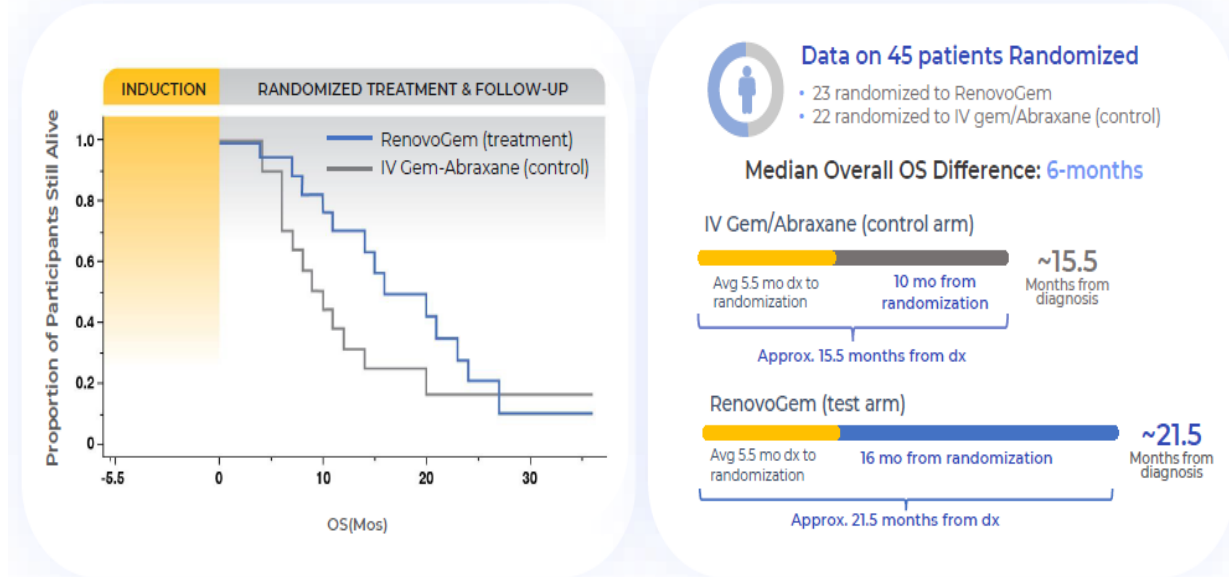
- No visible tumor feeder vessels
- Systemic therapy does not reach tumor tissue
- Inability to identify or engage tumor feeder vessels: local therapy is ineffective

Source: Company reports.

Exhibit 18: TIGeR-PaC Phase 3 Interim Data Update (March and June 2023)

TIGeR-PaC Phase III Data Update (1st Interim Analysis):

RenovoGem Arm Observes 6-month Median Overall Survival (OS) Benefit Over IV Gem-Abraxane (Control)



Data Presented at AACR 2023

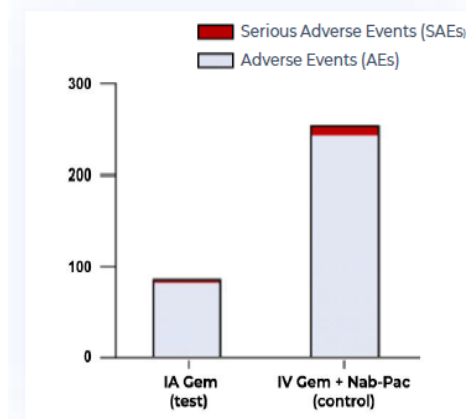
Statistical significance was not reached to stop the study early

TIGeR-PaC Phase III Data Update (1st Interim Analysis)

RenovoGem (Treatment) Arm Observes **>65% Fewer AEs and SAEs** Compared to Standard of Care Systemic/IV Gem/Abraxane (Control)

65% fewer total AEs and SAEs in IA vs. IV arm

Fewer AEs in 11/13 categories with greater than 10% frequency in each arm (All Grades)



Data Presented at AACR 2023 and ESMO GI 2023

Adverse Events	IV Gem + Pac	IA Gem
Neutropenia	81%	21%
Anemia	48%	8%
Thrombocytopenia	38%	4%
Elevated AST	33%	4%
Elevated ALT	29%	13%
Fatigue	19%	8%
Neuropathy	19%	0%
Dehydration	19%	8%
Hypertension	14%	4%
Hypokalemia	14%	4%
Hypoalbuminemia	14%	4%
Abdominal Pain	0%	21%
Nausea	10%	17%

Source: Company reports.

Exhibit 19: TIGeR-PaC Phase 3 Interim Data Update (March and June 2023)

RenovoRx Phase III Open Label TIGeR-PaC Interim Analysis Shows Promising Data That Support Continued Clinical Investigation of RenovoGem™ as a Treatment Option for Locally Advanced Pancreatic Cancer

March 08, 2023 8:30am EST

[Download as PDF](#)

Positive Trend in Median Overall Survival Versus Standard of Care, Warrants Continuation of the Pivotal Trial

Full Data Presentation, April 17, 2023, at the 2023 American Association of Cancer Research (AACR) Annual Meeting

LOS ALTOS, Calif.--(BUSINESS WIRE)-- RenovoRx, Inc. ("RenovoRx" or the "Company") (Nasdaq: RNXT), a biopharmaceutical company focused on the localized treatment of solid tumors, today announced promising interim data in the Phase III open label TIGeR-PaC clinical trial. The study is investigating the Company's first product candidate, RenovoGem, as a potential treatment option in locally advanced pancreatic cancer ("LAPC").

The interim analysis suggests a 6-month potential improvement in median overall survival with RenovoGem, pending ongoing clinical investigation. TIGeR-PaC is a randomized multi-center Phase III open label clinical trial designed to investigate the Company's first product candidate, RenovoGem, which utilizes RenovoRx's proprietary therapy platform, RenovoTAMP®, to provide targeted intra-arterial delivery of FDA-approved chemotherapy, gemcitabine, to treat LAPC following stereotactic body radiation therapy ("SBRT"). The study compares treatment with RenovoTAMP versus standard of care systemic intravenous ("IV") administration of gemcitabine and nab-paclitaxel, which has a seven-week survival benefit and \$1 billion addressable market.

RenovoRx Announces New Positive Interim Phase III Data Demonstrating RenovoGem™ Delays Cancer Progression by Eight Months in Locally Advanced Pancreatic Cancer

June 29, 2023 8:00am EDT

[Download as PDF](#)

Six-Month Overall Survival Benefit with RenovoGem Versus Systemic Chemotherapy, and 65% reduction in adverse effects and clinically meaningful overall survival trend

Results highlight RenovoGem's potential to change treatment paradigm for Locally Advanced Pancreatic Cancer

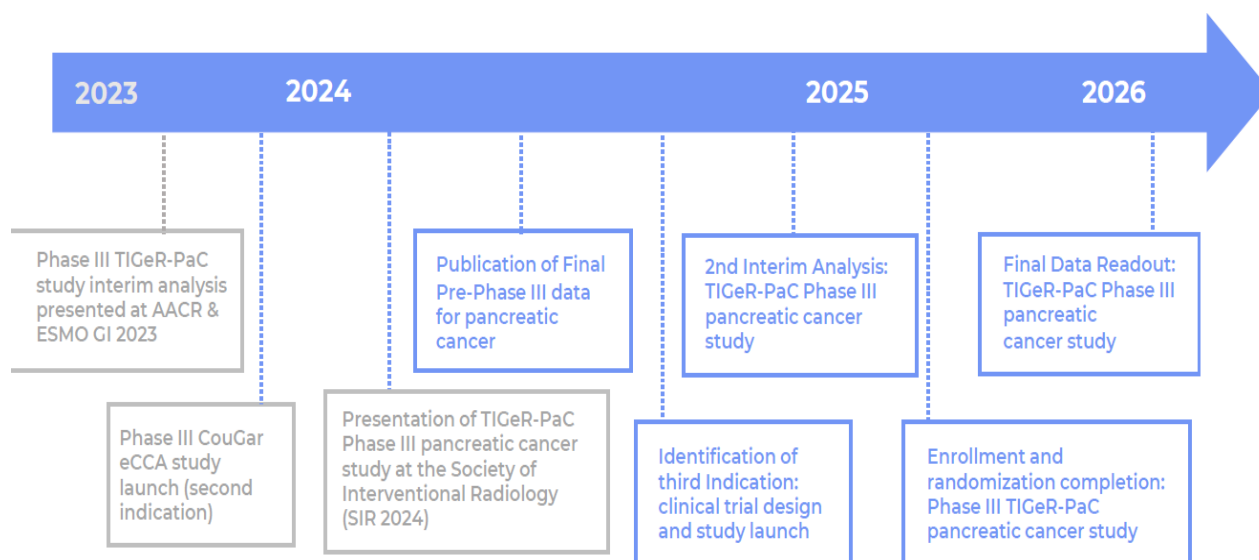
LOS ALTOS, Calif.--(BUSINESS WIRE)-- [RenovoRx, Inc.](#) ("RenovoRx" or the "Company") (Nasdaq: RNXT), a clinical-stage biopharmaceutical company developing targeted combination therapies, today presented new positive data on progression-free survival (PFS) from the pivotal Phase III open label TIGeR-PaC study of RenovoGem (intra-arterial administration of gemcitabine) in locally advanced pancreatic cancer (LAPC). The interim data was featured as a late-breaking oral presentation at the 2023 ESMO World Congress on Gastrointestinal Cancer, and presented by Michael J. Pishvaian, M.D., Ph.D., Johns Hopkins Medicine and Principal Investigator (PI) of the TIGeR-PaC study.

The interim analysis demonstrated an eight-month median PFS benefit, 15 versus 7 months, in delaying the progression of cancer for patients receiving treatment with RenovoGem versus standard-of-care. PFS is the measure of the length of time from study randomization to either death or progression of disease.

Source: Company reports.

Exhibit 20: TIGeR-PaC Phase 3 Trial Upcoming Milestones

Upcoming Milestones



Source: Company reports.

Cholangiocarcinoma (bile duct cancer) is the second most common primary malignant tumor of the liver with over 7,000 new cases diagnosed annually in the U.S. Cholangiocarcinoma or (“CCA”) is a type of liver cancer that develops after malignant transformation of the biliary tract mucosa. Bile ducts are slender tubes that carry the digestive fluid bile. Bile ducts connect your liver to your gallbladder and to your small intestine. According to Cholangiocarcinoma (CCA) - Market Insight, Epidemiology And Market Forecast, the global market of CCA was estimated to be \$786 million in 2021 with the U.S. accounting for \$237 million.

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

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

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

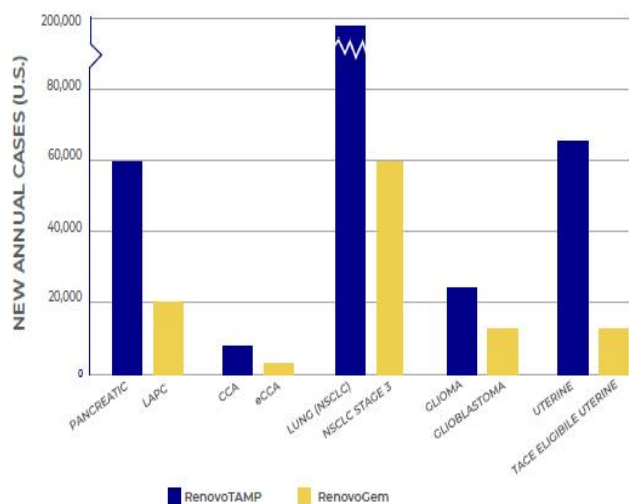
These characteristics include:

- Local disease with possible extension of disease to local vasculature;
- Avascular nature of the tumor lends itself to its TAMP 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 its approach to this vasculature and organ; and
- The bile duct around the hilum is usually within 1-14 mm (mean of 3.8 mm) of the hepatic artery: a reasonable target for TAMP therapy given the potential 4 cm tissue penetration of drug.

The company is planning to evaluate RenovoGem in a second indication in a Phase II/III trial in extrahepatic (or outside the liver) cholangiocarcinoma (or eCCA), cancer that occurs in the bile ducts that leads out of the liver and join with the gallbladder. The company has submitted the study protocol for a Phase II/III eCCA clinical trial to the FDA, and after receiving feedback, are finalizing the clinical trial protocol. The clinical trial study is expected to launch in mid-2024.

Exhibit 21: TAMP Broad Market Opportunities

TAMP Broad Market Opportunity in Target Cancers



US Annual Incidence of Initial RenovoGem Target Tumor Types

- ~125,000 all locally advanced (Stage 3) potentially addressable via RenovoGem

NEXT:

TAMP platform is broadly applicable to solid tumors:

Platform may be used with additional agents in multiple solid tumor indications

COMPANY NEWS

RenovoRx and Imugene Announce Collaboration to Deliver Oncolytic Virus Therapy Using Proprietary Trans-Arterial Micro-Perfusion (TAMP™) Platform

Source: Company reports.

The company believes TAMP is broadly applicable to locally advanced tumors and its platform may be used with multiple small molecule chemotherapeutic agents in multiple solid tumor indications. The company is currently primarily focused on developing

RenovoGem for LAPC, but is also developing it for eCCA which is currently in process with its clinical trials. The company is also in preclinical work to develop it for locally advanced lung cancer, locally advanced uterine cancer, and glioblastoma. In addition, the company may explore a strategy where it sells RenovoCath as a standalone catheter (i.e., without any specific cancer therapeutic) for use by oncology surgeons.

The company estimate that the total annualized addressable market opportunity for RenovoGem for LAPC in the U.S. is approximately \$0.5 billion and globally could exceed \$1 billion. The total cost of care for a patient on the standard of care treatment of gemcitabine plus 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.

The company plans 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 cancer receiving neoadjuvant (pre-surgery) as well as in subpopulations of patients with metastases (the development of secondary malignant growths away from a primary site of cancer) who also have locally advanced disease. The company estimates that approximately 125,000 patients (across 5 cancer indications) in the U.S. could be potentially addressable with RenovoGem.

FINANCIALS

RenovoRx's fiscal year ends on December 31. We expect its next earnings report (for Q2 2024 ending June 2024) to be in mid-August. Because the company is a clinical stage drug development company, it currently generates minimal revenue and significant losses as it funds its drug therapy development.

Exhibit 22: RenovoRx Historical and Projected Financials

FYE Dec 31					
(in millions except EPS)	2021A	2022A	2023A	2024E	2025E
Total Revenue	-	-	-	-	-
Research & development costs	3.0	4.3	5.7	5.2	5.2
Operating income (loss)	(5.7)	(10.0)	(11.4)	(10.3)	(10.4)
Net income (pro forma)	(6.3)	(9.9)	(10.2)	(8.9)	(10.4)
EPS	\$ (1.21)	\$ (1.09)	\$ (0.99)	\$ (0.40)	\$ (0.41)

Source: Company reports and Ascendant Capital Markets estimates.

Recent Results (fiscal Q1 2024 ending March 2024)

RenovoRx's recent financial performance is reflective of its developmental stage. In its Q1 2024 report (on May 10, 2024), the company reported no revenue and net loss was \$1.1 million. Operating expenses were \$2.5 million (up from \$1.8 million in Q4 2023), consisting mainly of drug development costs and general and administrative expenses. Q1 EPS was \$(0.07).

Exhibit 23: CEO Update Letter to Shareholders (as of May 30, 2024)

RenovoRx CEO Issues Update Letter to Shareholders

With \$17.2 million in gross proceeds raised since the beginning of 2024, RenovoRx is well positioned to advance its pivotal Phase III clinical trial, expand development pipeline into additional cancer indications and explore new commercial business development opportunities with its therapeutic technologies

LOS ALTOS, Calif.--(BUSINESS WIRE)-- RenovoRx, Inc. ("RenovoRx" or the "Company") (Nasdaq: RNXT), a clinical-stage biopharmaceutical company developing novel precision oncology therapies based on a local drug-delivery platform, today provided a letter to shareholders from Chief Executive Officer, Shaun Bagai.

Dear Fellow RenovoRx Shareholders,

The first quarter of 2024 marked a significant period in our company's evolution, and we have set the stage for significant milestones in the foreseeable future. Our team is steadfast in RenovoRx's mission to continue on a clinical pathway towards improving patients' lives by using our patented products to deliver precision therapies that have the potential to transform the standard of care in difficult-to-treat cancers.

With \$17.2 million in gross proceeds raised since the beginning of 2024, and with a proven history of prudent stewardship of our capital resources, RenovoRx has sufficient funding to advance our pivotal Phase III TIGeR-PaC clinical trial and expand the development pipeline into additional cancer indications. Our priority remains on TIGeR-PaC in Locally Advanced Pancreatic Cancer (LAPC) first and foremost, and its progress towards a second interim readout triggered by the 52nd event (death) in the trial estimated late 2024, and ultimate completion thereafter. Additionally, we intend to pursue the expansion of our proprietary Trans-Arterial Micro-Perfusion (TAMP™) therapy platform and the clinical development of our pipeline into additional cancer indications. Lastly, we will continue to investigate our ongoing exploration of new commercial business development opportunities with our therapeutic technologies.

The first interim analysis in the Phase III clinical trial was completed in March 2023, with the Data Monitoring Committee recommending a continuation of the study. The TIGeR-PaC study is investigating TAMP in LAPC. The study's primary endpoint is a 6-month Overall Survival benefit with secondary endpoints including reduced side effects versus standard of care. We are expecting the clinical events necessary for a second interim analysis should take place by the end of this year, and we are eagerly anticipating the outcome of this analysis.

During the first quarter, we continued to progress the TIGeR-PaC clinical trial, an ongoing randomized multi-center study in LAPC using RenovoRx's TAMP therapy platform to evaluate its first product candidate, RenovoGem™, a novel oncology drug-device combination product. The study is comparing treatment with TAMP to the current standard of care (systemic intravenous chemotherapy).

Source: Company reports.

We note that in late 2024 the company is expected to announce its 2nd interim data analysis for its Phase 3 TIGeR-PaC study for LAPC. Over the next 2 years, the company plans to finish its TIGeR-PaC trial and potentially file and receive approval for its NDA (new drug application). The company also plans to start its Phase 2/3 trial for eCCA and to finish pre-clinical development and IND (Investigational New Drug) application filings for its other drugs therapies in development (neoadjuvant (pre-surgery) pancreatic cancer and lung cancer).

The company does not provide specific quarterly financial guidance, but we believe that R&D expenses should remain relatively stable until the company expands clinical trial activities. Going forward, we believe operating expenses of \$2 - 3 million is a reasonable near term quarterly cash burn rate. The company expects continued progress on its drug development milestones in 2024. We do not expect the company to experience revenue until its drugs make significant progress towards FDA approval (either from product sales or from the sales of drug marketing rights to new partners), which is likely at least two years away. We have modeled relatively steady operating costs over the next year, primarily driven by its expected drug clinical trials expenses.

For 2024 (ending December 2024), we expect no revenues and a net loss of \$9 million and EPS of \$(0.40). For 2025 (ending December 2025), we expect no revenues and a net loss of \$10 million and EPS of \$(0.41).

We believe investors should be focused on its progress on its drug therapy development, which will likely take at least two years before a potential FDA approval. Within this year (expected late 2024), the company should release its 2nd interim data analysis for its Phase 3 TIGeR-PaC study for LAPC.

We believe that the biggest potential variable in our financial model is the ability of the company to get FDA (or equivalent) approval for its RenovoGem for LAPC drug therapy under development. It is these approvals that are ultimately how RenovoRx will be able to finally be able to generate revenue. If the company can make significant progress towards these goals, then revenue and earnings will likely be able to grow significantly. However, if the company has difficulties in making progress towards getting drug approvals, then revenue and profitability may not be achieved or will likely grow at a moderate rate or even not at all. Even after drug approvals, RenovoRx faces a big challenge to successfully commercialize its products. However, given the lack of good treatment options for pancreatic cancer and its poor prognosis, we believe RenovoGem commercial prospects are very positive if it obtains FDA approval.

The company's balance sheet has \$4 million in cash and no debt as of March 2024. In Q1, the company raised ~\$6 million selling stock (6.1 million shares at \$0.99 and \$1.22 per share). In April (current Q2), the company raised ~\$11 million selling stock (7.9 million shares at \$ 1.4075 per share). We believe the company has enough cash into 2026 (Q1 2026 (March 2026)), but we estimate that it will need to raise capital by Q4 2025 (December 2025).

Exhibit 24: RenovoRx Financial Metrics

Recent Share Price (6/14/24)	\$ 1.18
52-Weeks Share Price (Low - High)	\$0.53 - 3.29
Shares Outstanding	24 million
Market Capitalization	\$28 million
Enterprise Value	\$13 million
Cash (3/31/24) estimated Pro Forma	\$15 million
Debt (3/31/24)	\$0
2023A Revenue	\$0
2023A Net loss	\$10.2 million
2023A EPS	\$ (0.99)
2024E Revenue	\$0
2024E Net loss	\$8.9 million
2024E EPS	\$ (0.40)
2025E Revenue	\$0
2025E Net loss	\$10.4 million
2025E EPS	\$ (0.41)

Source: Company reports and Ascendant Capital Markets estimates.

FINANCIAL MODEL

RenovoRx, Inc.

Income Statement (\$ mils)	2021	Mar-22	Jun-22	Sep-22	Dec-22	2022	Mar-23	Jun-23	Sep-23	Dec-23	2023	Mar-24	Jun-24	Sep-24	Dec-24	2024	Mar-25	Jun-25	Sep-25	Dec-25	2025		
Fiscal Year End: December 31	FY-A	Q1A	Q2A	Q3A	Q4A	FY-A	Q1A	Q2A	Q3A	Q4A	FY-A	Q1A	Q2E	Q3E	Q4E	FY-E	Q1E	Q2E	Q3E	Q4E	FY-E		
Total Revenue	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	
<u>Cost of Revenues</u>	<u>0.000</u>	<u>0.000</u>	<u>0.000</u>	<u>0.000</u>	<u>0.000</u>	<u>0.000</u>	<u>0.000</u>	<u>0.000</u>	<u>0.000</u>	<u>0.000</u>	<u>0.000</u>	<u>0.000</u>	<u>0.000</u>	<u>0.000</u>	<u>0.000</u>	<u>0.000</u>	<u>0.000</u>	<u>0.000</u>	<u>0.000</u>	<u>0.000</u>	<u>0.000</u>	<u>0.000</u>	<u>0.000</u>
Gross Profit	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
Research & development	3.039	1.289	1.390	0.846	0.776	4.301	1.338	1.925	1.629	0.775	5.667	1.257	1.300	1.300	1.300	5.157	1.300	1.300	1.300	1.300	1.300	5.200	5.200
General & administrative	2.632	1.716	1.224	1.315	1.394	5.649	1.923	1.450	1.354	1.002	5.729	1.219	1.300	1.300	1.300	5.119	1.300	1.300	1.300	1.300	1.300	5.200	5.200
Restructuring and other						0.000					0.000					0.000						0.000	0.000
Total operating expenses	5.671	3.005	2.614	2.161	2.170	9.950	3.261	3.375	2.983	1.777	11.396	2.476	2.600	2.600	2.600	10.276	2.600	2.600	2.600	2.600	2.600	10.400	10.400
Operating income (loss)	(5.671)	(3.005)	(2.614)	(2.161)	(2.170)	(9.950)	(3.261)	(3.375)	(2.983)	(1.777)	(11.396)	(2.476)	(2.600)	(2.600)	(2.600)	(10.276)	(2.600)	(2.600)	(2.600)	(2.600)	(2.600)	(10.400)	(10.400)
Interest income (expense)	(0.834)	0.001	0.020	0.022	0.014	0.057	0.004	0.050	0.043	0.011	0.108	0.037	0.000	0.000	0.000	0.037	0.000	0.000	0.000	0.000	0.000	0.000	0.000
Other income (expense)	0.181	0.001		0.003	0.000	0.004		0.998	1.519	(1.461)	1.056	1.363	0.000	0.000	0.000	1.363	0.000	0.000	0.000	0.000	0.000	0.000	0.000
Income before income taxes	(6.324)	(3.003)	(2.594)	(2.136)	(2.156)	(9.889)	(3.257)	(2.327)	(1.421)	(3.227)	(10.232)	(1.076)	(2.600)	(2.600)	(2.600)	(8.876)	(2.600)	(2.600)	(2.600)	(2.600)	(2.600)	(10.400)	(10.400)
Income taxes						0.000					0.000					0.000						0.000	0.000
Net income (loss)	(6.324)	(3.003)	(2.594)	(2.136)	(2.156)	(9.889)	(3.257)	(2.327)	(1.421)	(3.227)	(10.232)	(1.076)	(2.600)	(2.600)	(2.600)	(8.876)	(2.600)	(2.600)	(2.600)	(2.600)	(2.600)	(10.400)	(10.400)
Nonrecurring/noncash adjustments						0.000					0.000					0.000						0.000	0.000
Net income (pro forma)	(6.324)	(3.003)	(2.594)	(2.136)	(2.156)	(9.889)	(3.257)	(2.327)	(1.421)	(3.227)	(10.232)	(1.076)	(2.600)	(2.600)	(2.600)	(8.876)	(2.600)	(2.600)	(2.600)	(2.600)	(2.600)	(10.400)	(10.400)
EBITDA																							
Shares, Basic	5.217	8.992	9.057	9.068	9.090	9.052	9.090	10.655	10.693	10.725	10.291	14.948	24.000	24.500	24.700	22.037	24.900	25.100	25.300	25.500	25.500	25.200	25.200
Shares, Diluted	5.217	8.992	9.057	9.068	9.090	9.052	9.090	10.655	10.693	10.725	10.291	14.948	24.000	24.500	24.700	22.037	24.900	25.100	25.300	25.500	25.500	25.200	25.200
EPS Basic (pro forma)	(\$1.21)	(\$0.33)	(\$0.29)	(\$0.24)	(\$0.24)	(\$1.09)	(\$0.36)	(\$0.22)	(\$0.13)	(\$0.30)	(\$0.99)	(\$0.07)	(\$0.11)	(\$0.11)	(\$0.11)	(\$0.40)	(\$0.10)	(\$0.10)	(\$0.10)	(\$0.10)	(\$0.10)	(\$0.41)	(\$0.41)
EPS Diluted (pro forma)	(\$1.21)	(\$0.33)	(\$0.29)	(\$0.24)	(\$0.24)	(\$1.09)	(\$0.36)	(\$0.22)	(\$0.13)	(\$0.30)	(\$0.99)	(\$0.07)	(\$0.11)	(\$0.11)	(\$0.11)	(\$0.40)	(\$0.10)	(\$0.10)	(\$0.10)	(\$0.10)	(\$0.10)	(\$0.41)	(\$0.41)
Margins																							
Gross margin																							
Research & development																							
General & administrative																							
Operating margin																							
Tax rate, GAAP																							
Net margin																							
Y/Y % change																							
Total Revenue																							
Gross margin						42%	4%	38%	93%	0%	32%	-6%	-32%	-20%	68%	-9%	3%	0%	0%	0%	0%	1%	1%
Research & development						115%	12%	18%	3%	-28%	1%	-37%	-10%	-4%	30%	-11%	7%	0%	0%	0%	0%	2%	2%
General & administrative						75%	9%	29%	38%	-18%	15%	-24%	-23%	-13%	46%	-10%	5%	0%	0%	0%	0%	1%	1%
Operating income (loss)						56%	8%	-10%	-33%	50%	3%	-67%	12%	83%	-19%	-13%	142%	0%	0%	0%	0%	17%	17%
Net income (loss)						-10%	7%	-24%	-44%	27%	-9%	-80%	-50%	-20%	-65%	-59%	45%	-4%	-3%	-3%	2%	2%	2%
EPS Diluted (pro forma)																							

Source: Company reports and Ascendant Capital Markets estimates.

RenovoRx, Inc.

Balance Sheet (\$ mils)	Dec-21	Mar-22	Jun-22	Sep-22	Dec-22	Mar-23	Jun-23	Sep-23	Dec-23	Mar-24	Jun-24	Sep-24	Dec-24	Mar-25	Jun-25	Sep-25	Dec-25
Fiscal Year End: December 31	Q4A	Q1A	Q2A	Q3A	Q4A	Q1A	Q2A	Q3A	Q4A	Q1A	Q2E	Q3E	Q4E	Q1E	Q2E	Q3E	Q4E
Assets																	
Cash and cash equivalents	15.192	13.121	2.769	3.093	4.391	3.723	5.954	3.226	1.173	4.389	12.989	10.589	8.189	5.789	3.389	0.989	0.052
Short term investments			7.996	5.021	2.049						0.000	0.000	0.000	0.000	0.000	0.000	0.000
Deferred income taxes											0.000	0.000	0.000	0.000	0.000	0.000	0.000
Prepaid expenses and other	1.089	0.822	0.478	1.136	0.825	0.838	0.360	0.293	0.293	0.399	0.399	0.399	0.399	0.399	0.399	0.399	0.399
Total current assets	16.281	13.943	11.243	9.250	7.265	4.561	6.314	3.519	1.466	4.788	13.388	10.988	8.588	6.188	3.788	1.388	0.451
Property and equipment, net	0.006	0.003									0.000	0.000	0.000	0.000	0.000	0.000	0.000
Intangibles, net											0.000	0.000	0.000	0.000	0.000	0.000	0.000
Deferred income tax											0.000	0.000	0.000	0.000	0.000	0.000	0.000
Other											0.000	0.000	0.000	0.000	0.000	0.000	0.000
Total assets	16.287	13.946	11.243	9.250	7.265	4.561	6.314	3.519	1.466	4.788	13.388	10.988	8.588	6.188	3.788	1.388	0.451
Liabilities and stockholders' equity																	
Accounts payable	0.525	0.729	0.473	0.538	0.534	0.828	0.872	0.350	0.561	0.356	0.356	0.356	0.356	0.356	0.356	0.356	0.356
Accrued expenses	0.413	0.677	0.650	0.564	0.568	0.477	0.827	1.255	0.614	0.737	0.737	0.737	0.737	0.737	0.737	0.737	2.200
Deferred income tax											0.000	0.000	0.000	0.000	0.000	0.000	0.000
Warrant liabilities									3.291	1.928	1.928	1.928	1.928	1.928	1.928	1.928	1.928
Other											0.000	0.000	0.000	0.000	0.000	0.000	0.000
Short term debt											0.000	0.000	0.000	0.000	0.000	0.000	0.000
Total current liabilities	0.938	1.406	1.123	1.102	1.102	1.305	1.699	1.605	4.466	3.021	3.021	3.021	3.021	3.021	3.021	3.021	4.484
Deferred income taxes											0.000	0.000	0.000	0.000	0.000	0.000	0.000
Warrant liabilities							3.427	1.908			0.000	0.000	0.000	0.000	0.000	0.000	0.000
Other long term liabilities											0.000	0.000	0.000	0.000	0.000	0.000	0.000
Long term debt											0.000	0.000	0.000	0.000	0.000	0.000	0.000
Total other liabilities	0.000	0.000	0.000	0.000	0.000	0.000	3.427	1.908	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
Preferred stock											0.000	0.000	0.000	0.000	0.000	0.000	0.000
Common stock	0.001	0.001	0.001	0.001	0.001	0.001	0.001	0.001	0.001	0.002	0.202	0.402	0.602	0.802	1.002	1.202	1.402
Additional paid-in capital	36.632	36.826	37.004	37.151	37.318	37.685	37.944	38.183	38.404	44.246	44.246	44.246	44.246	44.246	44.246	44.246	44.246
Retained earnings	(21.284)	(24.287)	(26.881)	(29.017)	(31.173)	(34.430)	(36.757)	(38.178)	(41.405)	(42.481)	(45.081)	(47.681)	(50.281)	(52.881)	(55.481)	(58.081)	(60.681)
Other											11.000	11.000	11.000	11.000	11.000	11.000	11.000
Accumulated other comprehensive income			(0.004)	0.013	0.017						0.000	0.000	0.000	0.000	0.000	0.000	0.000
Total stockholders' equity	15.349	12.540	10.120	8.148	6.163	3.256	1.188	0.006	(3.000)	1.767	10.367	7.967	5.567	3.167	0.767	(1.633)	(4.033)
Total stockholders' equity and liabil	16.287	13.946	11.243	9.250	7.265	4.561	6.314	3.519	1.466	4.788	13.388	10.988	8.588	6.188	3.788	1.388	0.451

Balance Sheet Drivers

	Dec-21	Mar-22	Jun-22	Sep-22	Dec-22	Mar-23	Jun-23	Sep-23	Dec-23	Mar-24	Jun-24	Sep-24	Dec-24	Mar-25	Jun-25	Sep-25	Dec-25
Book & Cash Value (per share)	Q4A	Q1A	Q2A	Q3A	Q4A	Q1A	Q2A	Q3A	Q4A	Q1A	Q2E	Q3E	Q4E	Q1E	Q2E	Q3E	Q4E
Book Value per Share (diluted)	\$2.94	\$1.39	\$1.12	\$0.90	\$0.68	\$0.36	\$0.11	\$0.00	-\$0.28	\$0.12	\$0.43	\$0.33	\$0.23	\$0.13	\$0.03	-\$0.06	-\$0.16
Cash per Share (diluted)	\$2.91	\$1.46	\$1.19	\$0.89	\$0.71	\$0.41	\$0.56	\$0.30	\$0.11	\$0.29	\$0.54	\$0.43	\$0.33	\$0.23	\$0.14	\$0.04	\$0.00
Net cash per Share (diluted)	\$2.91	\$1.46	\$1.19	\$0.89	\$0.71	\$0.41	\$0.56	\$0.30	\$0.11	\$0.29	\$0.54	\$0.43	\$0.33	\$0.23	\$0.14	\$0.04	\$0.00

Source: Company reports and Ascendant Capital Markets estimates

RenovoRx, Inc.

Cash Flow Statement (\$ mils)	2021	Mar-22	Jun-22	Sep-22	Dec-22	2022	Mar-23	Jun-23	Sep-23	Dec-23	2023	Mar-24	Jun-24	Sep-24	Dec-24	2024	Mar-25	Jun-25	Sep-25	Dec-25	2025	
Fiscal Year End: December 31	FY-A	Q1A	Q2A	Q3A	Q4A	FY-A	Q1A	Q2A	Q3A	Q4A	FY-A	Q1A	Q2E	Q3E	Q4E	FY-E	Q1E	Q2E	Q3E	Q4E	FY-E	
Cash flow from operating activities																						
Net income	(6.324)	(3.003)	(2.594)	(2.136)	(2.156)	(9.889)	(3.257)	(2.327)	(1.421)	(3.227)	(10.232)	(1.076)	(2.600)	(2.600)	(2.600)	(8.876)	(2.600)	(2.600)	(2.600)	(2.600)	(10.400)	
Depreciation						0.000					0.000					0.000					0.000	
Amortization	0.009	0.003	0.003			0.006					0.000					0.000					0.000	
Non-cash lease expense						0.000					0.000					0.000					0.000	
Debt related amortization exper	0.697					0.000					0.000					0.000					0.000	
Stock comp	0.147	0.168	0.169	0.143	0.164	0.644	0.361	0.257	0.239	0.221	1.078	0.423	0.200	0.200	0.200	1.023	0.200	0.200	0.200	0.200	0.800	
Deferred income taxes						0.000					0.000					0.000					0.000	
Change in fair value of warrant	(0.118)					0.000		(1.966)	(1.519)	1.776	(1.709)	(1.362)				(1.362)					0.000	
Lease						0.000					0.000					0.000					0.000	
Inventory reserve						0.000					0.000					0.000					0.000	
Accrued interest						0.000					0.000					0.000					0.000	
Writedowns and impairments	0.078					0.000					0.000					0.000					0.000	
Other gains/losses	(0.140)					0.000		0.393		(0.393)	0.000					0.000					0.000	
Other						0.000					0.000					0.000					0.000	
Changes in operating assets and liabilities:																						
Prepaid expenses & other curre	(0.970)	0.267	0.344	(0.658)	0.311	0.264	0.233	0.268	0.072	0.060	0.633	(0.079)	0.000	0.000	0.000	(0.079)	0.000	0.000	0.000	0.000	0.000	
Income tax						0.000					0.000					0.000					0.000	
Other assets					0.009	0.009	(0.246)	0.210	(0.005)	(0.060)	(0.101)	(0.027)	0.000	0.000	0.000	(0.027)	0.000	0.000	0.000	0.000	0.000	
Accounts payable	0.363	0.204	(0.256)	0.065	(0.013)	(0.000)	0.294	0.044	(0.522)	0.211	0.027	(0.206)	0.000	0.000	0.000	(0.206)	0.000	0.000	0.000	0.000	0.000	
Accrued expenses	0.342	0.264	(0.027)	(0.086)	0.004	0.155	(0.091)	0.350	0.428	(0.641)	0.046	0.123	0.000	0.000	0.000	0.123	0.000	0.000	0.000	1.463	1.463	
Deferred revenue						0.000					0.000					0.000					0.000	
Other liabilities						0.000					0.000		0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	
Net cash (used in) provided by	(5.916)	(2.097)	(2.361)	(2.672)	(1.681)	(8.811)	(2.706)	(2.771)	(2.728)	(2.053)	(10.258)	(2.204)	(2.400)	(2.400)	(2.400)	(9.404)	(2.400)	(2.400)	(2.400)	(0.937)	(8.137)	
Cash flow from investing activities																						
Purchases of property and equi	(0.015)					0.000					0.000		0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	
Purchases of short-term investments			(8.000)	2.992	2.976	(2.032)	2.032				2.032					0.000					0.000	
Acquisitions						0.000					0.000					0.000					0.000	
Other						0.000					0.000					0.000					0.000	
Net cash used in investing activ	(0.015)	0.000	(8.000)	2.992	2.976	(2.032)	2.032	0.000	0.000	0.000	2.032	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	
Cash flow from financing activities																						
Issuance of debt	1.977					0.000					0.000		0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	
Repayment of debt						0.000					0.000					0.000					0.000	
Issuance of stock	14.563					0.000		5.000			5.000	5.378	0.000	0.000	0.000	5.378	0.000	0.000	0.000	0.000	0.000	
Proceeds from stock option exe	2.788	0.026	0.009	0.004	0.003	0.042	0.006	0.002			0.008	0.042	11.000			11.042					0.000	
Other						0.000					0.000					0.000					0.000	
Dividends and distributions						0.000					0.000					0.000					0.000	
Cash provided by (used in) fina	19.328	0.026	0.009	0.004	0.003	0.042	0.006	5.002	0.000	0.000	5.008	5.420	11.000	0.000	0.000	16.420	0.000	0.000	0.000	0.000	0.000	
Effect of exchange rate on cash						0.000					0.000					0.000					0.000	
Net increase (decrease) in cash	13.397	(2.071)	(10.352)	0.324	1.298	(10.801)	(0.668)	2.231	(2.728)	(2.053)	(3.218)	3.216	8.600	(2.400)	(2.400)	7.016	(2.400)	(2.400)	(2.400)	(0.937)	(8.137)	
Beginning cash and equivalents	1.795	15.192	13.121	2.769	3.093	15.192	4.391	3.723	5.954	3.226	4.391	1.173	4.389	12.989	10.589	1.173	8.189	5.789	3.389	0.989	8.189	
Ending cash and equivalents	15.192	13.121	2.769	3.093	4.391	4.391	3.723	5.954	3.226	1.173	1.173	4.389	12.989	10.589	8.189	8.189	5.789	3.389	0.989	0.052	0.052	

Source: Company reports and Ascendant Capital Markets estimates

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			Count	Percent
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