



Delivering therapy where it matters[®]

NASDAQ | RNXT

**Roth Healthcare Opportunities Conference
October 6, 2022**

**A Late-Stage Biopharmaceutical Company with an Innovative
Therapy For Targeted Treatment Of Difficult-to-Treat Cancer**

RENOVO | RX

Forward-Looking Statement

This presentation and any accompanying oral presentation contain forward-looking statements that involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this presentation, including statements regarding our future financial condition, results of operations, business strategy and plans, and objectives of management for future operations, as well as statements regarding industry trends, are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as “estimate,” “intend,” “may,” “can be,” “plan,” “potential,” “target,” “will,” “mission” or the negative of these terms or other similar expressions. We have based these forward-looking statements largely on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, business strategy and financial needs. Such statements include, but are not limited to, the potential of, and expectations regarding the potential of, potential benefits of, and expectations regarding RNXT’s therapy platform, RenovoRx Trans-Arterial Micro-Perfusion, or RenovoTAMP™, statements regarding the market potential of RNXT’s product candidates, statements regarding RNXT’s Phase 3 clinical trial for RenovoGem™ and planned clinical trials in extrahepatic cholangiocarcinoma (eCCA), including the timing of such trials, enrollment of such trials, milestones and expectations relating to data readouts from such clinical trials, and RNXT’s ability to leverage its therapy platform to expand our pipeline including our ability to expand our technology platform by developing therapies to treat other diseases. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including, among other things: the timing of the initiation, progress and potential results of our preclinical studies, clinical trials and our research programs; our ability to use and expand our therapy platform to build a pipeline of product candidates; our ability to advance product candidates into, and successfully complete, clinical trials; the timing or likelihood of regulatory filings and approvals; our estimates of the number of patients who suffer from the diseases we are targeting and the number of patients that may enroll in our clinical trials; the commercialization potential of our product candidates, if approved; our ability and the potential to successfully manufacture and supply our product candidates for clinical trials and for commercial use, if approved; future strategic arrangements and/or collaborations and the potential benefits of such arrangements; our estimates regarding expenses, future revenue, capital requirements and needs for additional financing and our ability to obtain additional capital; the sufficiency of our existing cash and cash equivalents to fund our future operating expenses and capital expenditure requirements; our ability to retain the continued service of our key personnel and to identify, hire and retain additional qualified personnel; the implementation of our strategic plans for our business and product candidates; the scope of protection we are able to establish and maintain for intellectual property rights, including our therapy platform, product candidates and research programs; our ability to contract with third-party suppliers and manufacturers and their ability to perform adequately; the pricing, coverage and reimbursement of our product candidates, if approved; developments relating to our competitors and our industry, including competing product candidates and therapies; negative impacts of the COVID-19 pandemic on our operations; and other risks. These risks are not exhaustive. New risk factors emerge from time to time and it is not possible for our management to predict all risk factors. Actual results may differ materially from those in the forward-looking statements as a result of a number of factors, including those described in the company’s filings with the Securities and Exchange Commission. You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. Except as required by law, we undertake no obligation to update publicly any forward-looking statements for any reason after the date of this presentation. This presentation also contains estimates and other statistical data made by independent parties and by us relating to market size and growth and other data about our industry. This data involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. In addition, projections, assumptions, and estimates of our future performance and the future performance of the markets in which we operate are necessarily subject to a high degree of uncertainty and risk. This presentation concerns product candidates that are under clinical investigation and which have not yet been approved for marketing by the U.S. Food and Drug Administration (FDA). Those product candidates are currently limited by federal law to investigational use, and no representation is made as to their safety or effectiveness for the purposes for which they are being investigated.

RenovoTAMP[®]

Trans-Arterial Micro-Perfusion

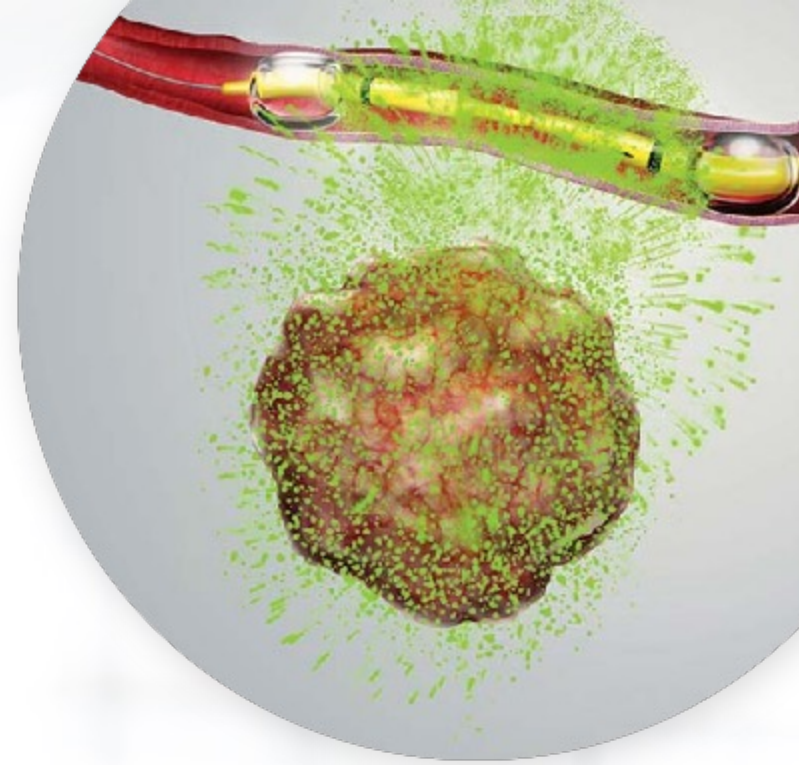
(DRUG/DEVICE COMBINATION) THERAPY PLATFORM

RenovoGem[™]

Intra-Arterial Gemcitabine + RenovoCath[®]

(FIRST PRODUCT CANDIDATE—REGULATED AS A DRUG)

Economics of a Branded Oncology Drug



Targeted Approach: designed to decrease side effects and increase tumor penetration

- Reduced systemic drug exposure (compared to systemic chemotherapy)
- Higher local drug concentration

Phase 3 Lead Drug Product Candidate: RenovoGem

- Drug/Device Combination:
 - Intra-arterial gemcitabine (chemotherapy) delivered through FDA cleared RenovoCath delivery system
- Initial Phase 1/2 and observational registry trial data published/presented
 - Demonstrated efficacy signal (27.9 month vs. 12-15 month historical control OS)
- Registrational Phase 3 TIGeR-PaC interim analysis expected Q4 '22

Broadly applicable to locally advanced solid tumors

- Initial indications: pancreatic cancer (\$1B addressable market) and cholangiocarcinoma
- Potential future indications include non-small cell lung cancer, uterine tumors, glioblastoma

Novel therapy platform: RenovoTAMP

- Trans-Arterial Micro-Perfusion compatible with multiple small molecule chemotherapy drugs

RenovoTAMP platform: layers of market exclusivity (regulatory and IP)

- 7 US patents issued on RenovoTAMP, delivery system, and drug/device combination
- Orphan Drug Designation for Pancreatic Cancer and Cholangiocarcinoma
 - provides 7 years of market exclusivity for RenovoGem upon NDA approval

Locally Advanced Pancreatic Cancer 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

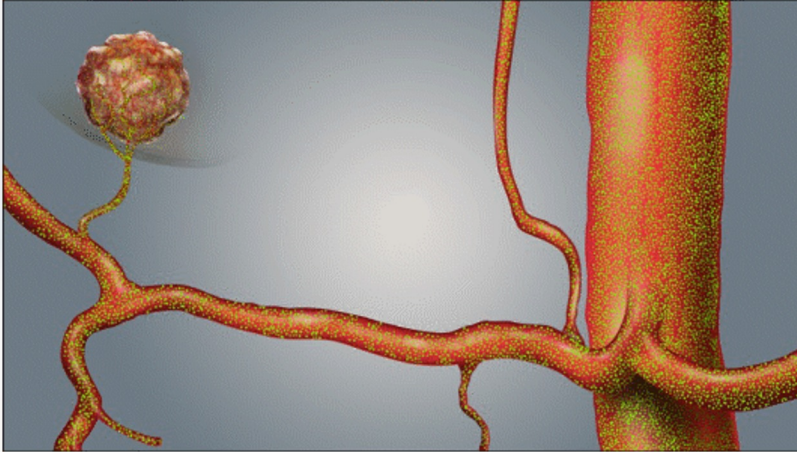
New Oncology Drug Market

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

Prospective/formal pricing analysis to be conducted with Phase 3 data prior to commercial launch of RenovoGem

*Fletcher Spaght, 2019

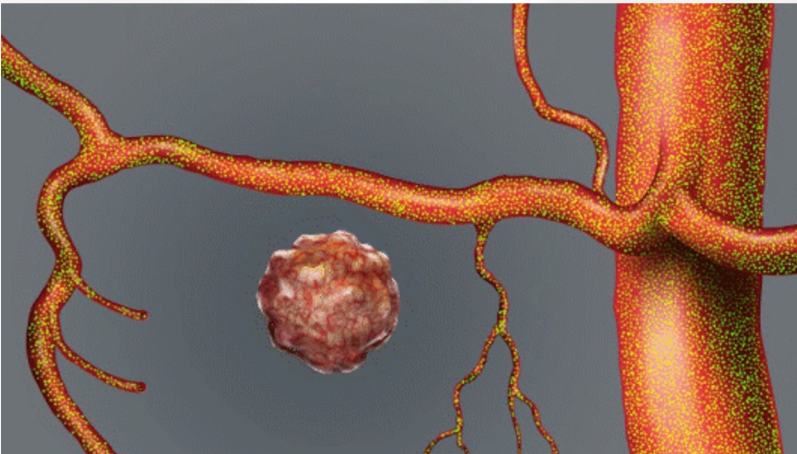
Addressing a Significant Problem in Cancer Treatment



Hypervascular tumors 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

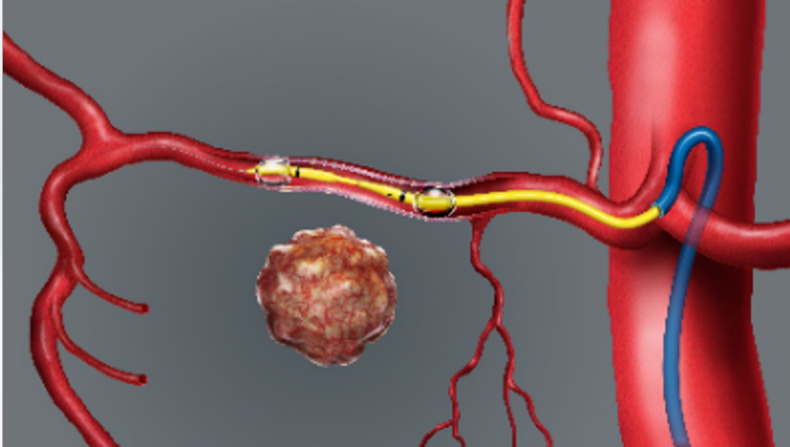


Hypovascular tumors pose major barrier to chemotherapy treatment success

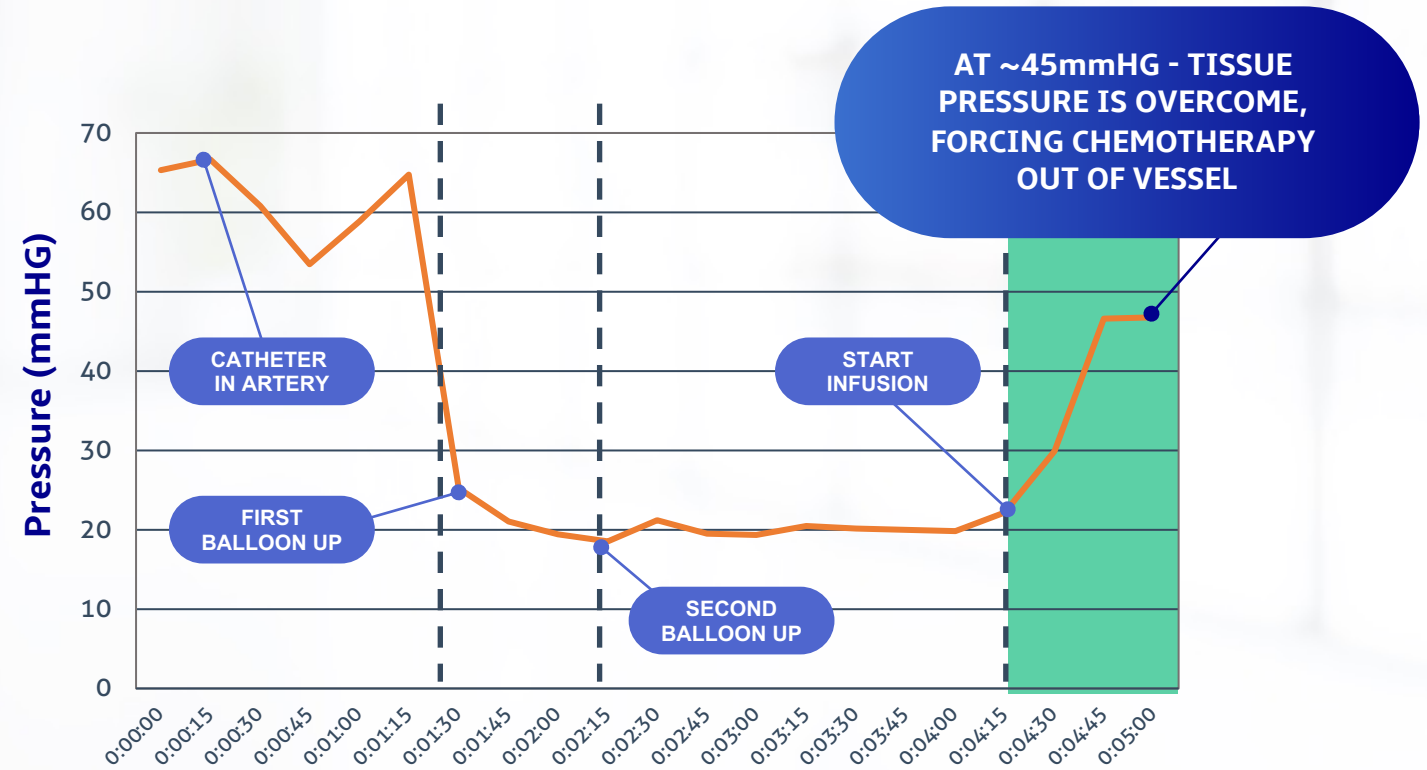
Pancreatic tumors have poor blood supply

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

Our Solution: Trans-Arterial Micro-Perfusion (RenovoTAMP)



Mechanism: after vessel isolation, increase in pressure forces drug into tumor tissue



First and Second Indications:

LOCALLY ADVANCED PANCREATIC CANCER AND EXTRAHEPATIC CHOLANGIOCARCINOMA

First Indication: Pancreatic Cancer (Orphan Designation)

- One of the **deadliest cancers**, with poor outcomes
- Pancreatic cancer is expected to quickly become the **second leading cause of cancer-related deaths**
 - 5-year overall survival rate of 5-10% (Stages I-IV)
- In 2021, it is estimated that
 - **60,000+** Americans were be diagnosed with pancreatic cancer
 - **More than 48,000** died of the disease
 - Approximately **30% of patients** have locally advanced pancreatic cancer (LAPC) and are not candidates for surgery

Current Standard of Care

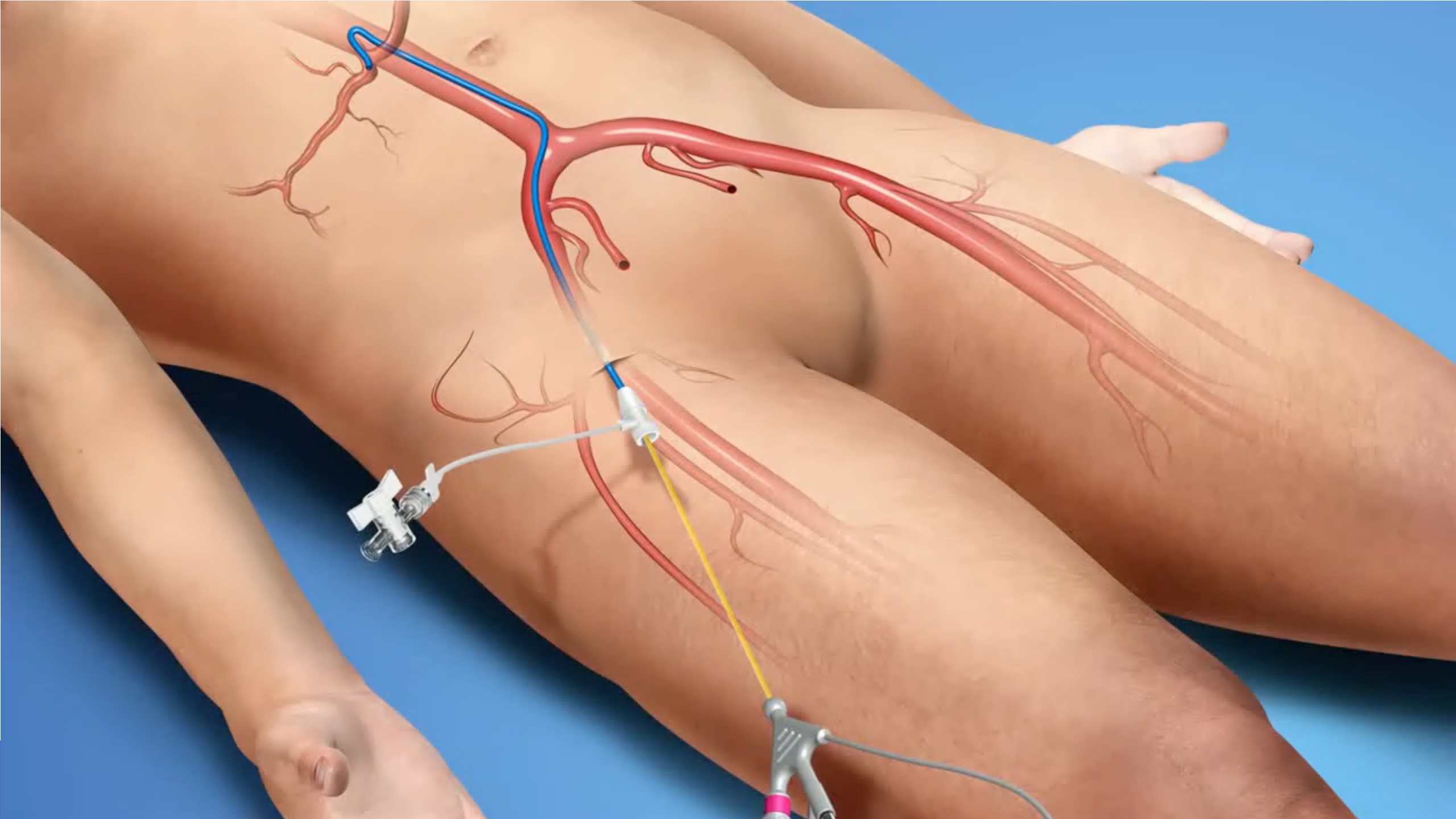
- Gemcitabine with Abraxane was approved in 2013 based on an **8-week survival benefit**
- LAPC has approximately 12-15 month median overall survival

Second Indication: extrahepatic Cholangiocarcinoma (eCCA), Bile Duct Cancer (Orphan Designation)

- Extrahepatic Cholangiocarcinoma (eCCA) is a disease with an **exceptionally poor prognosis**
- 7,000 new cases diagnosed annually in the US.
- Based on the tumor location, eCCA is defined as either intra-hepatic (within the liver) or extra-hepatic (extrahepatic Cholangiocarcinoma, or eCCA)

Current Standard of Care

- Due to **toxicity of the standard of care**, a practice standard of care has not been established for eCCA
- **Gemcitabine** with cisplatin used in ABC-2 clinical trial



How Patients and Physicians Experience RenovoTAMP Therapy

- **Interventional Radiology** Lab-based procedure
- Patient under **local anesthetic/conscious sedation**
- RenovoCath inserted through femoral artery
- Using contrast agent under x-ray fluoroscopy, blood vessel segment adjacent to tumor is isolated by adjusting balloon placement
 - 120mL of gemcitabine/saline delivered over 20 minutes
- RenovoTAMP Procedure takes **approximately 90 minutes**
 - Catheter placement
 - Drug infusion
 - Catheter removal and access site hemostasis
- Patient moved to recovery room and **discharged same day**
- RenovoTAMP Procedure repeated every 2 weeks over 4 months (**8 treatments**)
- Procedure **easy to learn**: physicians are proctored for first 2-3 procedures



We Employ De-risked Small Molecule Chemotherapy

Drugs First Drug Candidate: Intra-Arterial Gemcitabine

Gemcitabine

- IV (systemic) gemcitabine marketed in US since 1996
- Established as part of current standard of care for pancreatic cancer and other solid tumors
- Potent anti-tumor agent: cell phase specificity primarily killing cells undergoing DNA synthesis (S-phase)
- Preclinical studies: inhibits 80-100% of tumor growth with subsequent increases in lifespan
- Limitations of IV/systemic delivery of gemcitabine include poor tumor tissue penetration and high systemic toxicity

RenovoGem

(Intra-arterial Gemcitabine + RenovoCath)

- Intra-arterial gemcitabine for treatment of solid tumors
- FDA Orphan Drug Designation (7 years marketing exclusivity post-approval) for pancreatic cancer and CCA
- Phase 1/2 and observational registry trial data demonstrated an increase in overall survival time in patients with LAPC
 - Median survival of 27.9 months (including radiation pre-treatment) vs. 12-15 months historical control
- Phase 3 TIGeR-PaC interim analysis expected in Q4 '22

OUR THERAPY PLATFORM

RenovoTAMP: RenovoRx Trans-Arterial Micro-Perfusion

OUR FIRST PRODUCT CANDIDATE

RenovoGem

INTRA-ARTERIAL GEMCITABINE
+ RENOVOCATH®



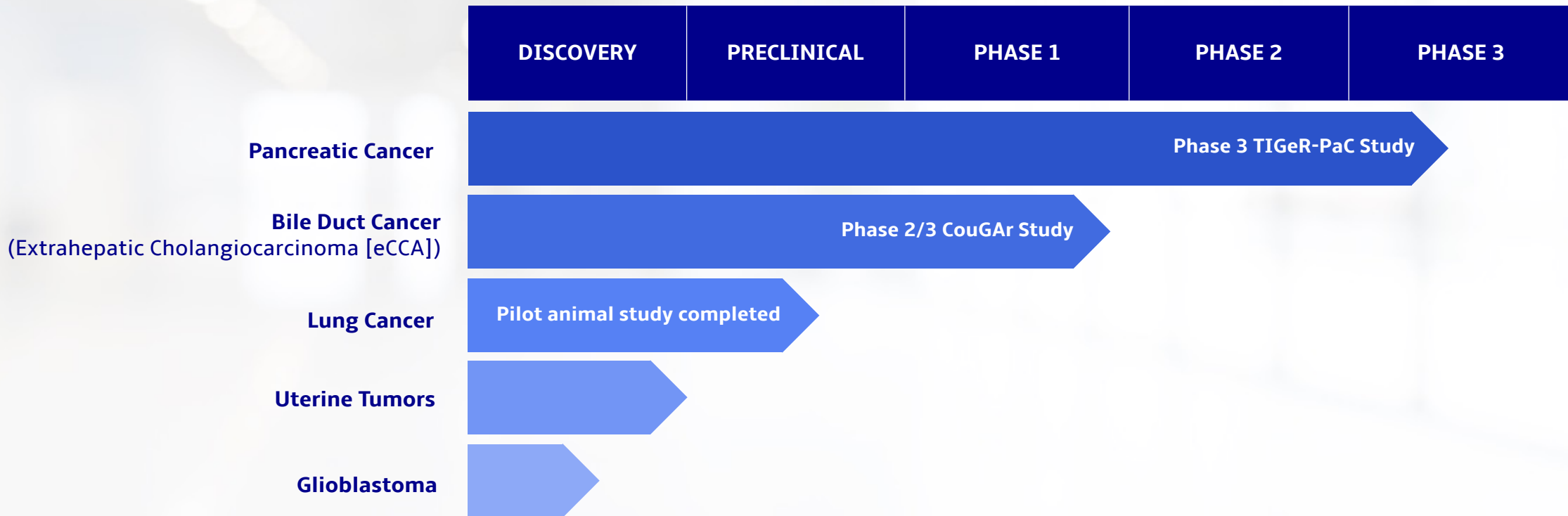
DRUG/DEVICE COMBINATION

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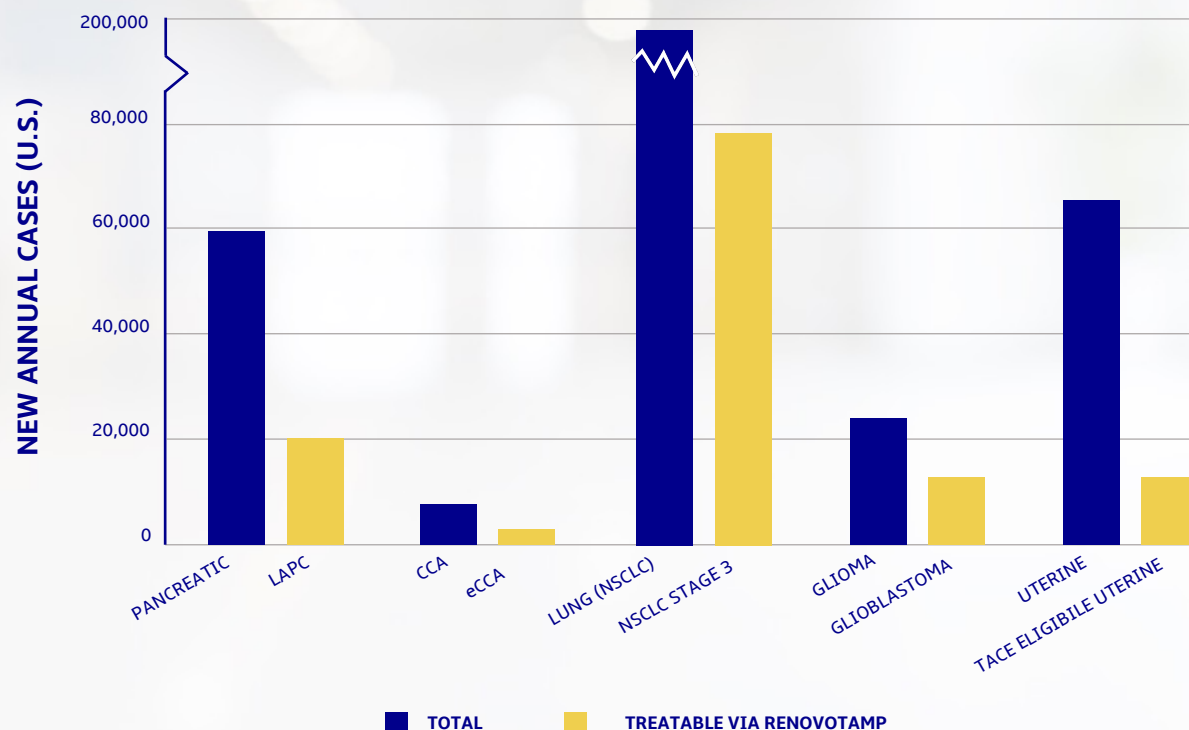
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Pipeline Overview



RenovoGem Broad Market Opportunity in Target Cancers



US Annual Incidence of Initial RenovoGem Target Tumor Types

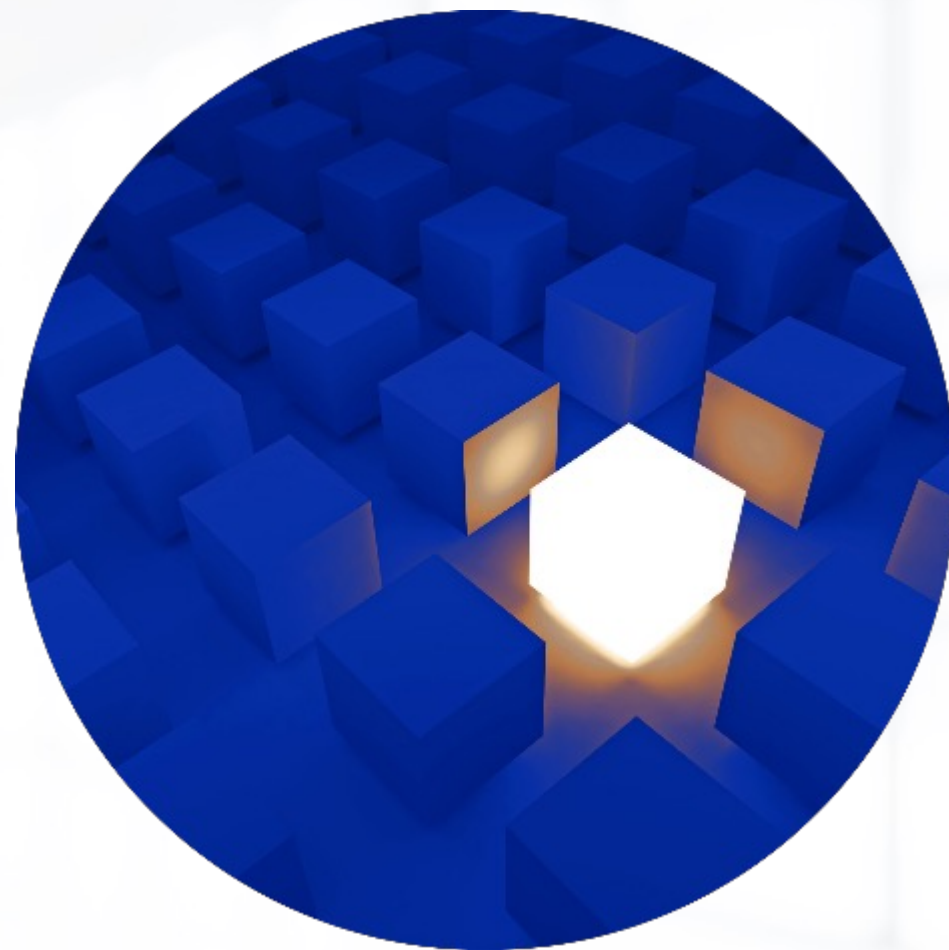
- 350,000 total patients diagnosed/year
- ~125,000 all locally advanced (stage 3) potentially addressable via RenovoGem

RenovoTAMP is broadly applicable to locally advanced tumors:

Platform may be used with multiple small molecule chemotherapeutic agents in multiple solid tumor indications

Exclusivity: Orphan Drug Designation + Intellectual Property Portfolio

- FDA Orphan Drug Designation for RenovoGem provides for **7 years of market exclusivity** post NDA approval for:
 - Pancreatic cancer
 - Cholangiocarcinoma
- **7 US method and device patents issued** around Trans-Arterial Micro-Perfusion (RenovoTAMP), radiation + RenovoTAMP, RenovoCath delivery system, and drug/device combination
- **1 EU patent** issued on delivery system
- 9 additional patents pending in **US, EU, and Asia**
- *Sourcing gemcitabine commercially from one of several FDA ANDA holders*



Clinical Development Pathway to Commercialization:

Pivotal Phase 3 TIGeR-PaC Trial Designed to Support NDA Submission

FDA Alignment During Pre-Phase 3 IND Study Meeting:

- FDA confirmed study design and proposed endpoints
- One Phase 3 study could support New Drug Application approval if significant overall survival benefit is demonstrated

TIGeR-PaC Phase 3 trial is a multi-center, open-label, randomized, active-controlled study

Study design:

- Includes “induction phase” with up front systemic chemo and radiation therapy (Stereotactic Body Radiation Therapy – SBRT)
- Patients still locally advanced after induction phase proceed to randomization: systemic chemo vs. RenovoTAMP

Primary endpoint: hard endpoint of overall survival

- From time of randomization until death

Secondary endpoints include:

- Systemic toxicities including peripheral neuropathy and neutropenia
- Quality of life questionnaire results

3rd party KOL interviews: 4-month survival benefit is threshold for deep market adoption

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Phase 3 TIGeR-PaC Primary Endpoint Analysis and Enrollment Considerations

Endpoint Analysis:

TIGeR-PaC is based on Overall Survival difference between control and treatment arms

- From time of randomization
- Final analysis : 86 deaths

Enrollment Update:

- As of 10/1/22, 43 patients randomized with SBRT induction*
- Forecasted enrollment and randomization completion (114 patients): 2024

Interim analyses (1st - estimated Q4 '22):

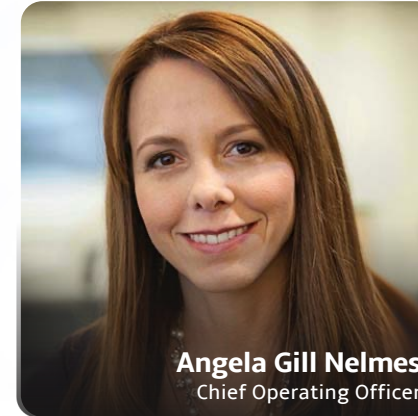
Event based: (deaths)

- 1st interim analysis: 30% (26 of 86) of the total number of deaths
- 2nd interim analysis: 60% (52 of 86) of the total number of deaths
- Final analysis: 86 total deaths

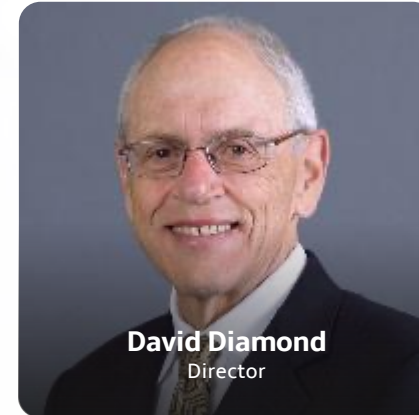
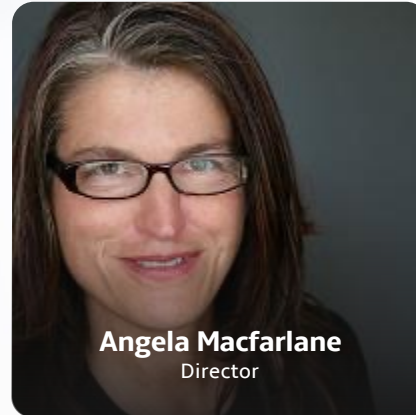
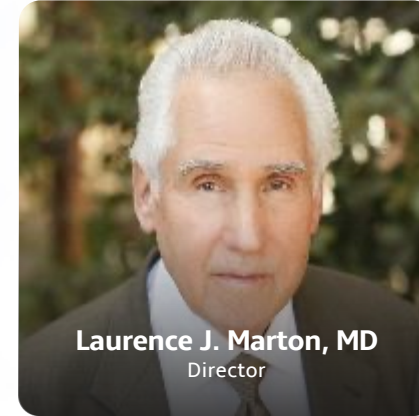
Data Monitoring Committee can stop study based on efficacy or futility

*Modified study protocol in Dec 2021 to only allow for pre-treatment with SBRT radiation (vs. long course, IMRT radiation)
Updated Statistical Analysis Plan Q2 2022

Highly Experienced Leadership Team



Board of Directors



Capital Structure/Financial Highlights

\$2.00

RNXT/SHARE
(AS OF 9/28/22)

\$18.1M

MARKET CAPITALIZATION
(AS OF 9/28/22)

19%

Officer & Director
OWNERSHIP
(AS OF 6/30/22)

15.5K

3 MONTH AVERAGE
DAILY VOLUME
(AS OF 8/22/22)

\$10.8M

CASH & INVESTMENTS*
(AS OF 6/30/22)

9.0M

SHARES OUTSTANDING
(AS OF 8/8/22)

Analyst Coverage

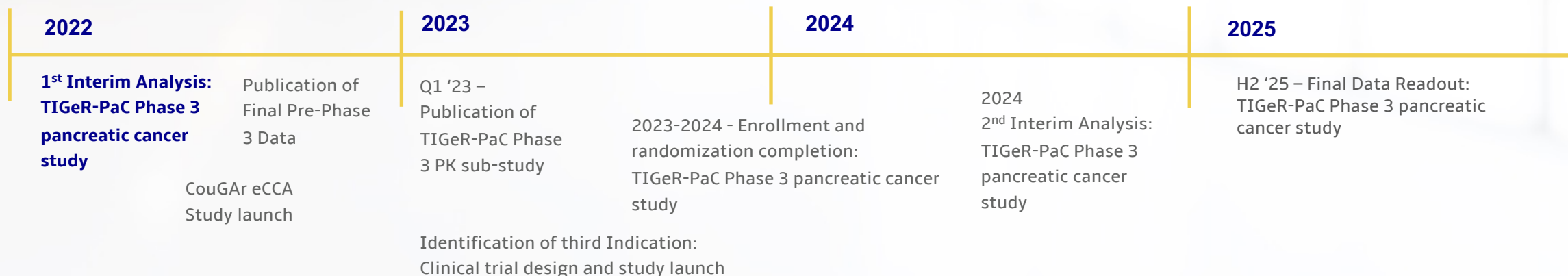
ROTH Capital Partners: Scott R. Henry, CFA

MAXIM Group: Jason McCarthy, Ph.D.

Investment Highlights

- De-risked drug development and validated RenovoTAMP approach
- Large first indication market (\$1B) and platform broadly applicable to locally advanced solid tumors
- Capital efficient: <\$750,000 average monthly burn
- Talented and experienced Leadership Team and Board of Directors
- **RenovoGem Phase 3 interim analysis expected Q4 '22**

Significant Upcoming Catalysts:



Delivering therapy where it matters[®]

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Phase 3 TIGeR-PaC Study Schema

INDUCTION

IV Gemcitabine +
Abraxane
2 months

SBRT

IV Gemcitabine +
Abraxane
1 month

~190 Patients

Randomize

Control
77 patients

1:1 RANDOMIZATION

IV Gemcitabine
+ Abraxane
4 months

Test
77 Patients

Intra Arterial
Gemcitabine
4 months
8 bi-weekly
treatments

Continuation Therapy
Until disease progression

1° Endpoint

SURVIVAL
OUTCOME

Phase 3 TIGeR-PaC Statistical Analysis Plan (SAP)

December 2021:

- Original protocol design allowed for Stereotactic Body Radiation Therapy (SBRT) & Intensity-modulated Radiation Therapy (IMRT) – modified to only allow for SBRT
- IMRT
 - 25 radiation treatments in combination with oral chemo
 - 35 to 56 days to complete
 - Higher patient drop out rate due to:
 - High frequency of hospital visits
 - Side-effects from chemo
- SBRT
 - 5 treatments over five consecutive days, no oral chemo
 - 35 to 56 days to complete

June 2022:

- Submitted modified SAP to FDA*
 - Enrollment and analysis focused on SBRT patients
 - Added second interim analysis
 - Repower from 90% to commonly used 80%
 - Changed total number of randomized patients to 114 (reduced from 200), with total of 86 deaths for final analysis
- Benefits
 - Shortens timeframe to complete study
 - Decreases costs
- Anticipate that all patients will be enrolled and randomized in 2024, with the final study readout in 2025

Plan to submit a protocol amendment to FDA in Q3'22 to reflect the changes in the Modified SAP