

(NASDAQ: RNXT)

Maxim Growth Conference March 2022

Late-Stage Clinical Biopharmaceutical Company with Novel Therapy Platform to Treat Locally Advanced Solid Tumors

### **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<sup>TM</sup>, statements regarding the market potential of RNXT's product candidates, statements regarding RNXT's Phase 3 clinical trial for RenovoGem<sup>TM</sup> and planned clinical trials in hilar cholangiocarcinoma (HCCA), 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 product candidates; the scope of protection we are able to establish and maintain for intellectual property rights, including our therapy platform, 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 c

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.

Delivering therapy Where it matters

RenovoTAMP<sup>™</sup>: Trans-Arterial Micro-Perfusion (drug/device combination) Therapy Platform

RenovoGem<sup>™</sup>: Intra-Arterial Gemcitabine + RenovoCath® (first product candidate - regulated as a drug)

**Economics of a Branded Oncology Drug** 

### **Company Overview**



#### Phase 3 Lead Drug Product Candidate: RenovoGem

- Intra-arterial gemcitabine (chemotherapy) delivered through FDA cleared RenovoCath delivery system
- Phase 1/2 and observational registry trial data demonstrated efficacy signals
- Phase 3 interim analysis based on patient deaths estimated Q4 '22/Q1 '23

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

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

#### Novel therapy platform: RenovoTAMP

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

#### 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

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

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

### Locally Advanced Pancreatic Cancer Market Opportunity\*





### US: \$500M Rest of World: \$500M

#### New Orphan Drug Product Regulatory and Reimbursement

**Orphan Drug Protection +** 

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

### 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)



Blood vessel segment is isolated to deliver drug across blood vessel wall into tumor tissue





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



### First and Second Indications: Locally Advanced Pancreatic Cancer and Hilar 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 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 survival

#### **Second Indication:**

#### Hilar Cholangiocarcinoma (HCCA), Bile Duct Cancer (Orphan Designation)

- Cholangiocarcinoma (CCA) is a disease with an exceptionally poor prognosis
- CCA is the second most common primary malignant tumor of the liver with over 7,000 new cases diagnosed annually in the US.
- Based on the tumor location, CCA is defined as either intra-hepatic (within the liver) or extra-hepatic (hilar cholangiocarcinoma, or HCCA)

#### **Current Standard of Care**

- Due to toxicity of the standard of care, a practice standard of care has not been established for HCCA
- 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
- 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)
- Pre-clinical studies: inhibits 80-100% of tumor growth with subsequent increases in lifespan
- Limitations of IV/systemic delivery 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 interim analysis expected in Q1 '22/Q3 '23



### **RenovoTAMP**

Our Therapy Platform

**Our First Product** 

Candidate

RenovoRx<sup>®</sup> Trans-Arterial Micro-Perfusion (drug/device combination)

### RenovoGem

### intra-arterial gemcitabine + RenovoCath<sup>®</sup>





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### **RenovoGem Clinical Pipeline**





### **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), 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



### Pre-Phase 3 IND Study Meeting with FDA: Guidance Received

- 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 Population: 340 subjects with LAPC

Primary endpoint: hard endpoint of overall survival

• From time of randomization until death

### Secondary endpoints include:

- Quality of life (QoL) questionnaire results
- Progression free survival

### 3<sup>rd</sup> party KOL interviews: 4-month survival benefit is threshold for deep market adoption



### **TIGeR-PaC Primary Endpoint Analysis and Enrollment Considerations**

#### **Endpoint Analysis:**

#### TIGeR-PaC designed to detect a 6-month difference between control and treatment arms

• From time of randomization

#### Interim analysis (estimated Q4 '22/Q1 '23):

- Timing dependent on study participant deaths (events): 65
- Designed to detect an 8-month difference
- Data Monitoring Committee can stop study based on efficacy or futility
- Data Monitoring Committee has ability to increase sample size if needed

#### **Enrollment Considerations:**

- Strong enrollment: past 3 years roughly same annual enrollment despite COVID
- Anticipating 50% enrollment completion Q1 '22
- Forecasted enrollment completion 2023

### **Highly Experienced Management Team and Board of Directors**



#### Ramtin Agah, MD, MS Chairman, Founder and CMO

Biomedical Engineer and Interventional Cardiologist, El Camino Hospital, Mountain View CA.



#### David Diamond Director

National Life Sciences and Technology Practice Lead at Mayer Hoffman McCann P.C. 30+ years in both public accounting and industry.

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#### Shaun R. Bagai Director, CEO

20+ years of clinical research, sales & marketing, and market development leadership experience at TransVascular, Ardian, Medtronic, and HeartFlow.



#### Angela Macfarlane Director

CEO Voyant Bio, ForSight Labs Managing Partner, former CEO of Forsight Vision 4 and Forsight Vision 5, former Technology Counsel for Thomas J. Fogarty, M.D.



#### Laurence Marton, MD Director

Progen, Cellgate, SLIL Biomedical - former CSO, Dean of UWM Med. School. Board Member AACR Foundation, Cancer Commons, CHCF.

## Una Ryan, PhD, OBE Director

Diagnostics for All and AVANT Immunotherapeutics former CEO, MassBio Chair. Golden Seeds Director.



#### Christopher J. Lehman CFO

25+ years of experience with venture backed private and public industry leaders in areas of therapeutics, biosimilars, diagnostics, contract research and industrial biotech.



### **Capital Structure/ Financial Highlights**





#### **Analyst Coverage**

ROTH Capital Partners: Scott R. Henry, CFA MAXIM Group: Jason McCarthy, Ph.D.



### **Investment Highlights**

- De-risked and validated RenovoTAMP approach
- Large market (\$1B): platform broadly applicable to locally advanced solid tumors
- Phase 3 interim data based on patient deaths estimated Q3 '22/Q1 '23
- \$17.7M or ~\$1.98/share in cash, sufficient to get to data read out
- Talented and experienced Board of Directors and Scientific Advisory Board

### Significant Upcoming Catalysts:

2022	2023	2024	2025
Q2/3 '22 – FDA Q3/4 '22 – Q4 '22 Pre-IND CCA Study Interin Meeting for launch TIGeF CCA 3 pane study	2 – Q1 '23 2023 n Analysis: Enrollment Comple R-PaC Phase TIGeR-PaC Phase creatic cancer pancreatic cancer	Identification of Third Indication: etion: Clinical trial design and study 3 launch study	H2 '25 – Final Data Readout: TIGeR-PaC Phase 3 pancreatic cancer study



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