

A joint venture between Resilience + MD Anderson Cancer Center

# **Drug Development Resources in Texas**

- Jason Bock, Co-Founder + CEO, CTMC
- Tom Luby, Director, TMC Innovation, Texas Medical Center
- Kieron Jones, Co-founder, CEO + President, K2 Biolabs
- Joe McDonough, Vice-President, Southwest Research Institute

# ACCELERATOR FOR CANCER THERAPEUTICS (ACT)









#### 

# THROUGH CPRIT, ACT HAS UNITED TRANSLATIONAL ONCOLOGY THROUGHOUT TEXAS





## **OUR GUIDE STAR**

 Access to key talent, advisor, and strategic consultant resources to build credible plans

 To support product development through computational chemistry and CPRIT core network access

 To support fundraising efforts through both non-dilutive grant applications and venture capital raises



## **Accelerator Structure and Benefits**

### 2024 Accelerator Schedule

**January** 

Bootcamp (1 week)

**February – July** Bimonthly in-person curriculum (2 days each)

September

Grant submission TMCi ACT SUMMIT event

#### **Benefits**

- Expert consultant access
- Executive mentor advisory sessions
- Grant writing support for SBIR and CPRIT applications
- Investor introductions
- GCC CPRIT core access
- Computation Chemistry Support





TMC/CPRIT Can Take Credit For Enabling Entrepreneurs To Reach Commercialization Milestones

19

companies formed

\$90M

in dilutive funding

\$10M

in non-dilutive funding

2

**CPRIT Product Development Awardees** 

4 of 4

CPRIT Product Development
Awardees Advancing to Final
Diligence Phase of Current Cycle

4

Hit to lead programs thru Comp Chem; 2 new grants awarded



# Applications Open! (Close on Oct 13th)

- Apply on TMC ACT website <a href="https://www.tmc.edu/innovation/accelerator-cancer/">https://www.tmc.edu/innovation/accelerator-cancer/</a>
- Office hours available year-round to get project feedback or find out additional program information
- Questions? Email <u>act@tmc.edu</u>



# Where Discovery Begins

K2bio is a hybrid Contract Research Organization (CRO) enabling early-stage life science companies to develop the next generation of innovative therapies.





# Welcome To K2 BIOLABS!

- Less than 10 minutes to TMC
- Decades of collective industry experience
- 28,345 sq ft state-of-the-art laboratory
- AAALAC accredited Vivarium
- OLAW Assurance Approved
- Phase appropriate Regulatory environment
- Drug discovery & pharmacology services
- Process Development
- Pre-IND, CMC Support



## Giving you more control...

## **Community of Industry Scientists**

- Reduce the need for FTE by leveraging our experts
- On-demand support for scientific & regulatory hurdles

### **Onsite Vivarium**

- Experts to provide custom support or training
- IACUC support for efficient and fast reviews
- Surgical and breeding capabilities

## **Technical Equipment**

- Flow cytometers
- HPLC
- LCMS
- Xenium, chromium and visium
- ddPCR
- Cell sorter
- Prodigy
- And much more...

Lab Features	Standard Labs	Advanced Labs	K2bio
BSL2 lab space	$\overline{\checkmark}$	$\overline{\checkmark}$	$\overline{\checkmark}$
Standard Equipment	$\overline{\checkmark}$	$\overline{\checkmark}$	$\checkmark$
Advanced Equipment		$\overline{\checkmark}$	$\overline{\checkmark}$
Experienced Scientists		$\overline{\checkmark}$	$\checkmark$
Vendor relationships		$\overline{\checkmark}$	$\overline{\checkmark}$
Onsite Vivarium Access			$\checkmark$
Scientific/equipment training			$\overline{\checkmark}$
Contract Services			$\checkmark$
Consulting Services			$\checkmark$
Equipment dev/launch involvement			$\checkmark$





Office Area
BSL2 Labs
Vivarium



## **CRO Service Matrix**

Service Offerings	Tenants	Non-tenant Clients
Analytical Development (AD)	$\checkmark$	$\overline{\checkmark}$
Process Development (PD)	$\checkmark$	$\overline{\checkmark}$
Shared lab space	$\overline{\checkmark}$	
In vivo & In vitro	$\checkmark$	$\checkmark$
Access to vivarium	$\overline{\checkmark}$	Coming soon
Rentable office space	$\checkmark$	
CMC support	$\overline{\checkmark}$	$\overline{\checkmark}$
Regulatory Oversight	$\checkmark$	
Procurement & logistics	$\overline{\checkmark}$	

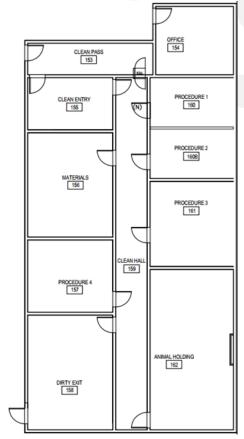


## Vivarium and In Vivo Services



# Your research. Our expertise, Your way.

- <u>Vivarium and in vivo services:</u> ~3000 sq ft with dedicated air handler, BSL2, AAALAC accredited, OLAW Assurance for NIH funded studies and internal IACUC Committee for quick review and approval
- <u>Capacity:</u> capable of housing up to 6000 mice/rats in isolator cages to support both immune competent, immunodeficient models and genetically modified
- <u>Preconditioning services:</u> Irradiation (whole body and targeted), IV, SubQ, oral gavage, intraperitoneal & retro-orbital, catheterization, device implantation, surgical, & timed mating
- <u>In-life Assessments:</u> whole blood & plasma collection, body weight, tumor size, behavioral, gross motor function, wound healing & IVIS bioluminescence and fluorescence imaging
- <u>Post-mortem Assessments:</u> necropsy, tissue fixation, paraffin embedding, fresh frozen, tumor removal, ex vivo tissue imaging (IVIS), & blood collection
- *Models:* I/O, efficacy, adoptive transfer and bone marrow transplant, PK, MTD, AMDE, immunization, UV damage and skin repair, diabetic and EAE model of Multiple Sclerosis









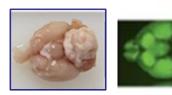
## Histology and Image Analysis Services

Your research.
Our expertise,
Your way.

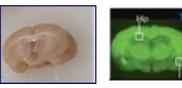
- K2's histology and imaging group works closely with our vivarium team on tissue recovery and preservation
- <u>Services:</u> Tissue harvesting and processing for Paraffin Embedding, Fresh Frozen and OCT Embedding, wax and cryo-sectioning, IHC and Immunofluorescent staining
- Image Analysis: Leica DM1000 Light Microscope, Biotek Cytation 5, IVIS for ex vivo tissue imaging

# Luminescence Luminescence Intravenous injection (7/7/23) Step Hurrescence Intravenous injection (7/7/23) Step Hurrescence Intravenous injection (7/7/23) M1-1 M1-2 M1-3 M2-2 M2-3 M2-3 M2-3 M2-3 M2-3

#### **Ex Vivo**

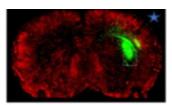


Whole Brain



**Brain Slice** 







# Xenium In Situ Spatial Gene Expression – 10x Genomics

Your research.
Our expertise,
Your way.

Xenium in situ platform uses a proprietary padlock probe rolling circle amplification chemistry Providing high sensitivity across broad range of gene expression using dual target recognition and hybridization

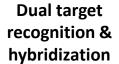
Tunable sensitivity and custom adaptable to distinguish between transcripts isoforms

On-instrument detection & decoding

Works on both FFPE and fresh tissue sections

Detection of transcripts at single cell resolution within spatial context







**Probe ligation** 



Rolling circle amplification



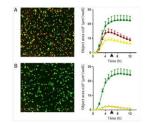




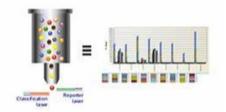
## **Analytical Development Capability**

- > Cell-based In-Vitro Mechanism of Action and Potency Assay Development
- High Throughput Live Cell Imaging
  - IncuCyte S3 Dual-fluorescence and phase contrast
  - Cytation 5
- Comprehensive immune profiling
  - Cell Surface and Intracellular
  - Immunoassays
  - Single and multiplexed bead arrays (ELISA & Luminex)
- Molecular Assay Development
  - ddPCR
  - 10x Chromium Single Cell RNA Seq
  - 10x Visium Spatial RNA Seq
- Reporter cell line development
  - Transfection/transduction
  - Selection and Isolation
    - Miltenyi Bead-based
    - FACS based Sterile Cell Sorting

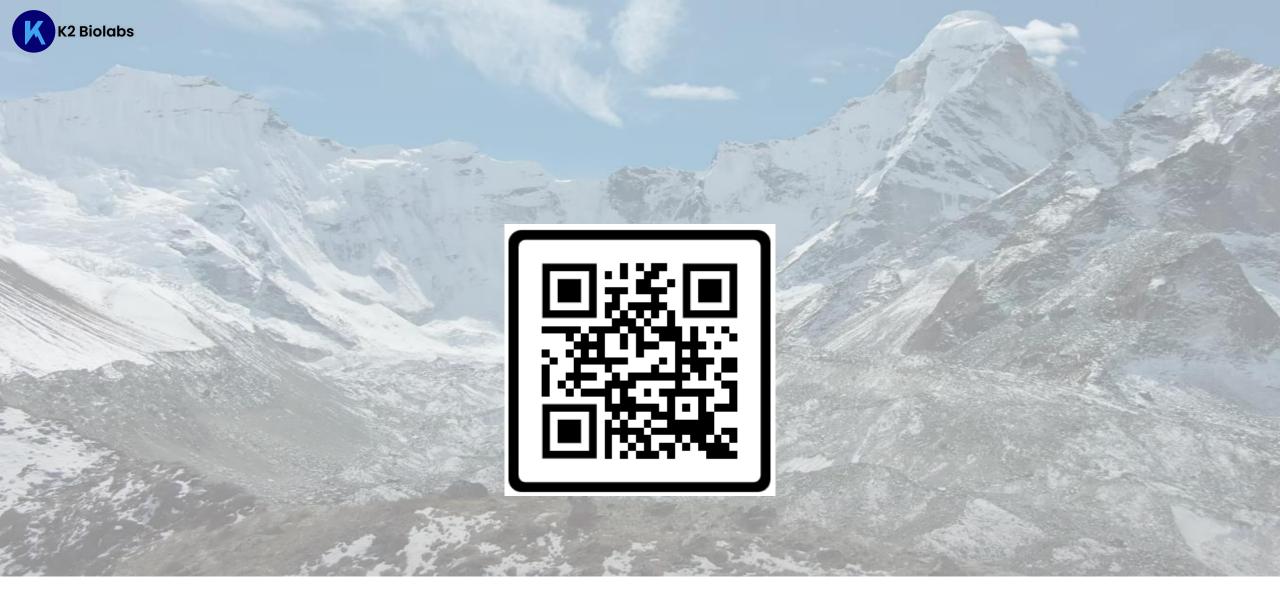
Providing
Better Service,
Better Science.



Satorius IncuCyte Live -cell Imaging



Protein Arrays; BioRad



2710 REED RD SUITE 160 HOUSTON, TX 77051 www.k2-biolabs.com



Schedule a tour today! Info@K2-BIOLABS.COM 832.390.0947

## Southwest Research Institute

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pharmdev.swri.org

**CHEMISTRY & CHEMICAL ENGINEERING** 



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## Southwest Research Institute



- cGMP compliant
- FDA Inspected
- 20+ years Pharmaceuticals and Medical Device History
- Synthesis, Scale-up, and Clinical Supply
- Formulation for all routes of administration
- Domestic supplier, San Antonio, Texas



CHEMISTRY & CHEMICAL ENGINEERING

## Medical and Pharmaceutical Development

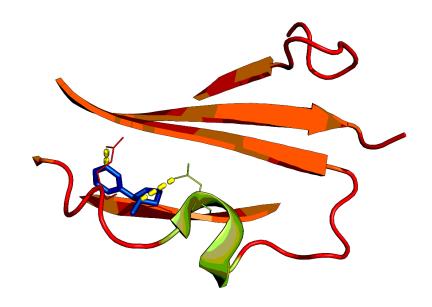
**DISCOVERY** 

REGULATORY
STRATEGY & FILING

PRODUCT DEVELOPMENT

SCALE-UP & cGMP MANUFACTURING

- Small Molecule Development
- Machine Learning—Enabled Drug Discovery
- Medical Device and Bioengineering
- Regulatory Strategy, Support, and Filing
- Drug Product Development
  - Small Molecule Synthesis
  - Clinical Supply Manufacturing
  - Formulation for Any Route of Administration
- Biological cGMP Clinical Supply

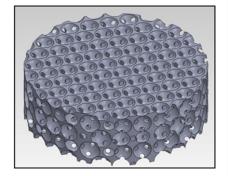




## Recent Examples at SwRI

#### **Bioreactor for CAR T Cell Manufacturing**

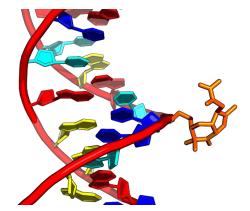
- Perfusion flow
- Automation in progress
- T Cell Purification, Activation and Transduction in one continuous flow system



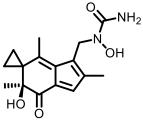
Bioreactor Scaffold US 11,149,244

### *In silico* Modeling with Rhodium<sup>™</sup>

- Reveal mechanisms
- Unbiased docking
- Uses ML and project-specific data
- Predict acute oral tox & in vitro pharmacology
- Predict biological activity, EC50, & perform drug design
- High-throughput virtual screening for accelerated drug discovery



## **Cancer Chemotherapy API**

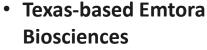


- LP-184
- Lantern Pharma.

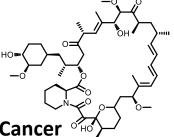
- Texas-based biotech Lantern Pharma
- Novel acylfulvene derivative
- Synthetically lethal in DNA damage repair deficient cancers
- Currently in clinical trials
- SwRI: de novo total synthesis and cGMP manufacturing clinical batch







- Rapamycin: eRapa™
- CPRIT grant
- Colorectal & Prostate Cancer
- Enteric microspheres (US 11,110,067) in filled capsules



**Formulation** 







**CHEMISTRY & CHEMICAL ENGINEERING** 

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## **Thank You**



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**CHEMISTRY & CHEMICAL ENGINEERING** 



And now, we would love to take questions from the audience...