



# Third Quarter 2022 Results

November 14, 2022

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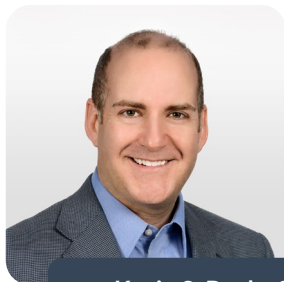
# Forward Looking Statements

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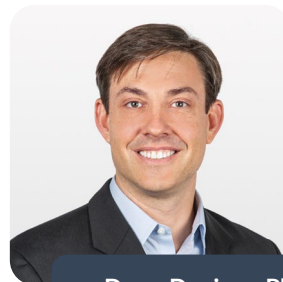
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# Speakers on Today's Call

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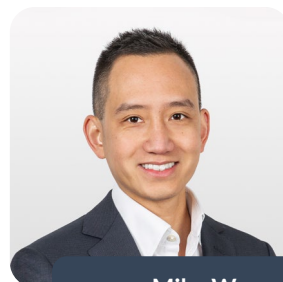
**Kevin S. Boyle, Sr.**  
Chief Executive Officer



**Drew Deniger, Ph.D.**  
VP, Research & Development



**Abhishek Srivastava, Ph.D.**  
VP, Technical Operations



**Mike Wong**  
VP, Finance

# Confirmed Partial Response Following Treatment with *Sleeping Beauty* TCR-T Cells at First Dose Level



TCR-T Library Phase 1/2 Trial Enrolling; Confirmed Partial Response in First Patient (NSCLC); Now Treating at Dose Level 2

- 1 Increasing cGMP Manufacturing Facility Capacity; Consistently Producing High Quality TCR-T Cells at Clinical Scale
- 2 Growing Clinical Library of TCRs (*KRAS*, *TP53*, *EGFR*) Increasing the Addressable Market
- 3 Proprietary TCR Discovery Platform, hunTR™ is Expanding and Advancing the Pipeline
- 4 60% Fewer Employees and 50%+ Reduction in Operating Cash Burn Year-over-Year

# TCR-T Platform Targeting Hotspot Mutations with Multiple Solid Tumor Programs in Pipeline

PROGRAM	TARGETS	INDICATION	DISCOVERY	PRECLINICAL	IND-ENABLING	PHASE 1
<b>Library TCR-T Cell Therapy</b> (Company Sponsored at MDACC - NCT05194735)	<b>KRAS, TP53 &amp; EGFR Hotspot Mutations</b>	Lung	██████████	██████████	██████████	██████████
		Colon/Rectum	██████████	██████████	██████████	██████████
		Endometrium	██████████	██████████	██████████	██████████
		Pancreas	██████████	██████████	██████████	██████████
		Ovary	██████████	██████████	██████████	██████████
		Bile Duct	██████████	██████████	██████████	██████████
<b>mbIL-15 TCR-T Cell Therapy</b>	<b>KRAS &amp; TP53 Hotspot Mutations</b>	Solid Tumors	██████████	██████████	██████████	██████████

# Clinical Update

# Encouraging Early Clinical Data for Non-viral TCR-T Therapy: Safety, Persistence and Efficacy with 1 Confirmed PR

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- First in human confirmed response in solid tumor by TCR-T cell therapy using *Sleeping Beauty*
  - Patients have been treated with *KRAS* and *TP53* mutation specific cells
- Two patients treated; now treating at dose level 2
  - Manageable safety profile with no neurotoxicity
  - Persistence of TCR-T cells observed at six months
  - Confirmed Partial Response in Patient 1 with Non-Small Cell Lung Cancer (NSCLC)
- Early clinical validation highlights potential of TCR-T cell therapy in high value indications with significant unmet medical need

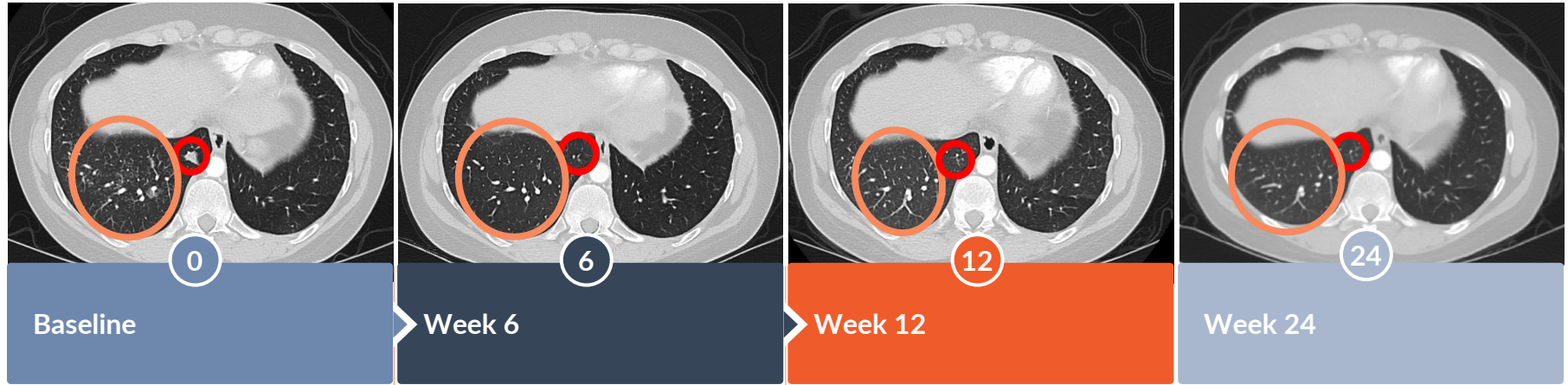
# Patient 1: PR in NSCLC

Six-month imaging

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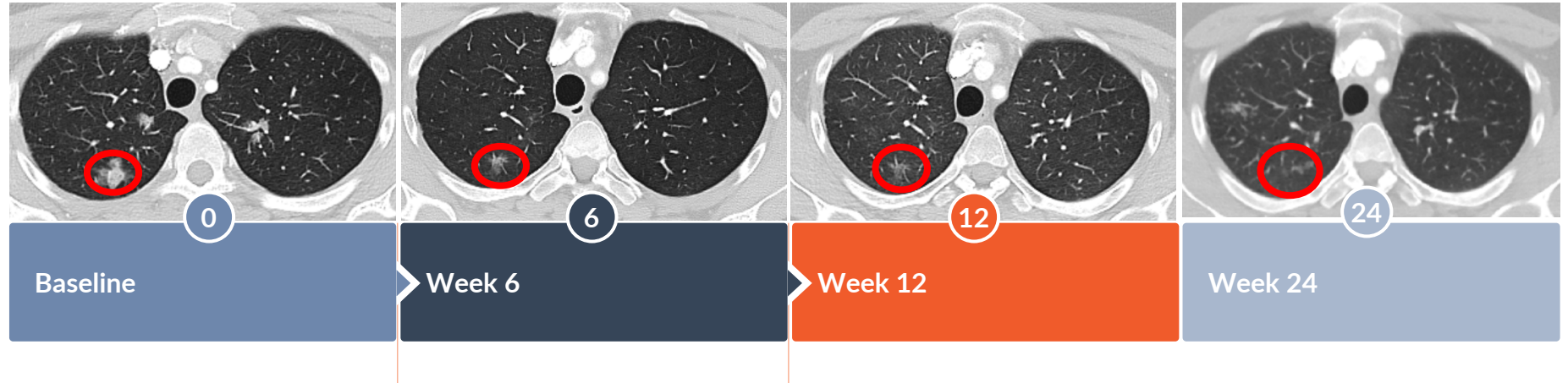


# Durable, Complete Resolution of Right Lower Lobe NSCLC Lesion Through Week 24

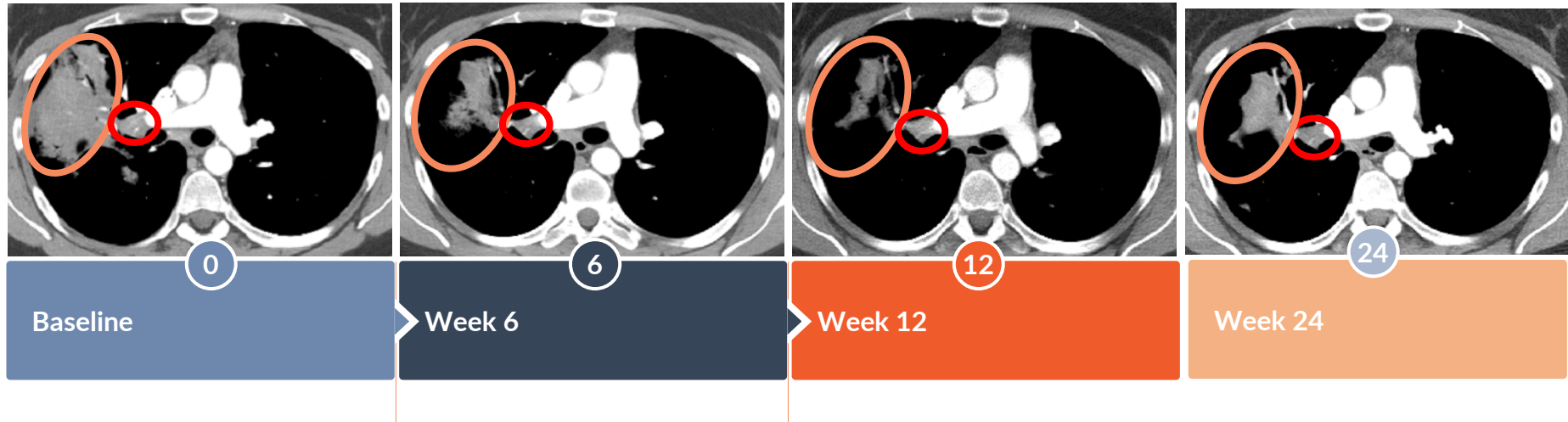


- Patient 1 had multiple lines of prior therapy and was refractory to checkpoint inhibitors
- Treated with  $9 \times 10^9$  TCR-T cells (dose level 1) targeting KRAS-G12D and HLA-A\*11:01 with manageable safety profile
- Red circles represent target lesions, orange circles represent non-measurable disease

# Sustained Reduction in Right Upper Lobe Lesion through Week 24



# Growth of Non-measurable Disease at 24 Weeks Relative to Week 12; Six Month Progression Free Survival



Perceived growth of non-measurable disease in orange circles led investigator to request biopsy of this area and additional scan at 28 weeks

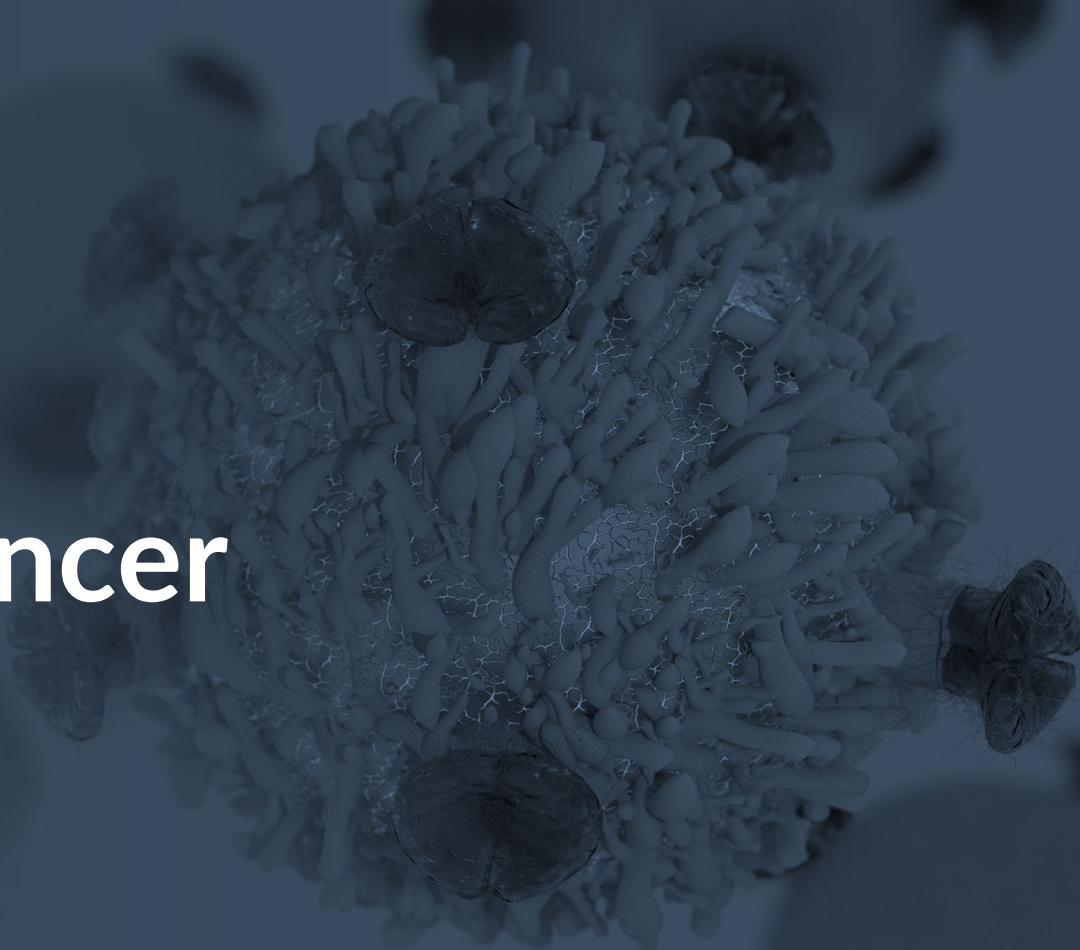
# Best Response is Partial Response, with a Six Month Progression Free Survival

- Patient 1 had an observed clinical benefit from our TCR-T cell therapy
- Persistence of TCR-T cells was observed in the blood at approximately 30% of T-cells at 24 weeks
- Elective tumor core biopsy showed continued presence of some tumor cells at six months
- Progression was corroborated by seven month scan; patient is now off study

	Baseline	Week 6	Week 12	Week 24
<b>Target Lesions</b>				
#1: Right lower lobe (mm)	13	0	0	0
#2: Right upper lobe (mm)	13	11	10	10
#3: Right hilar lymph node (mm)	15	11	10	12
<b>Sum of Diameters (mm)</b>	41	22	20	22
<b>Percent Change</b>		(46.3%)	(51.2%)	(46.3%)
<b>Non-measurable Disease</b>		Decreased	Decreased	Increased
<b>Overall Response</b>		Partial Response	Partial Response	Progressive Disease

# Patient 2: Colorectal Cancer

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# Patient 2: Previously Treated Advanced Colorectal Cancer Achieved Best Overall Response of Stable Disease

- Patient 2 received one prior line of therapy and was treated with  $64 \times 10^9$  TCR-T cells (dose level 2) targeting TP53-R175H and HLA-A\*02:01
- Treatment was well tolerated with manageable safety events; patient received one dose of tocilizumab with no neurotoxicity
- Some evidence of efficacy at six weeks with reduction of pelvic mass and overall decrease in target lesions combined
- Persistence of TCR-T cells was observed in the blood at approximately 20% of T-cells at 12 weeks
- Patient off study due to disease progression at Week 12 due to new lesions in the liver and lung

	Baseline	Week 6	Week 12
<b>Target Lesions</b>			
#1: Pelvic Mass (mm)	65	49	67
#2: Retroperitoneal Lymph Node (mm)	27	30	28
<b>Sum of Diameters (mm)</b>	92	79	95
<b>Percent Change</b>		(15.2%)	21.9%
<b>New Lesion</b>		No	Liver/Lung
<b>Overall Response</b>		Stable Disease	Progressive Disease



# Clinical Summary to Date

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# Encouraging Clinical Activity from *Sleeping Beauty* TCR-T Therapy Demonstrating Safety, Persistence and Efficacy

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- Treatment was well tolerated with no DLTs or ICANS in either patient
- Persistence of TCR-T cells was noted in both patients to last follow-up
- Indications of efficacy observed in both patients
  - Six-month progression free survival in KRAS NSCLC patient, comparable to other therapeutics
- Infiltration of TCR-T cells into the tumor was observed at six months suggesting the cells could home to the tumor microenvironment
- Progressing tumor had both mutation and HLA expressed indicating that the target was intact and still required for the cancer





# Manufacturing Update

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# Successful Manufacturing of High Purity Products at Dose Levels 1 and 2

- Successfully manufactured two clinical products by our own employees at our in-house cGMP facility at dose levels 1 and 2
- Produced both KRAS and TP53 mutation-specific TCR-T cells with expected characteristics

**TCR-T Infusion Product- Patient 1**

	Result
Viability	97.3%
Total TCR-T Cells	$9 \times 10^9$
CD3+ Purity	99.7%
TCR+	95.2%

**TCR-T Infusion Product- Patient 2**

	Result
Viability	92.5%
Total TCR-T Cells	$6.4 \times 10^{10}$
CD3+ Purity	99.7%
TCR+	92.4%

# Execution Against Multipronged Expansion Strategy Has Doubled Manufacturing Capacity

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- Changes in Process & Procedures
  - Updated SOPs to allow for simultaneous manufacture of multiple products in the cGMP suite
  - Expect to file IND amendment to move from fresh to cryopreserved product in 4Q 2022 and implement change in 1H 2023
- Reduced Manufacturing Time by 13%
  - Implementation of cryopreservation anticipated to shorten manufacturing time from 30 to 26 days, increasing cGMP suite throughput potential
- Expanded Manufacturing Team
  - Hired and trained additional staff to enable manufacture of simultaneous products



# R&D Update

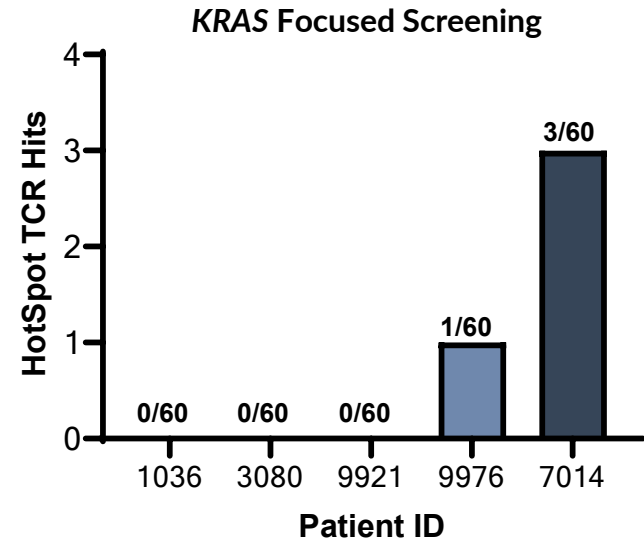
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# hunTR™ Is Differentiated from Competing TCR Discovery Platforms

Differentiator	Alaunos	Competition
Starting material	TILs from patient with target	Blood from healthy donors without target
TCR screening	Reporter cell line (fast, universal)	Virally transduced donor T cells (donor-to-donor variability, labor intensive and time consuming)
HLA and mutation screening	All mutations and HLAs	Limited and commonly dependent on peptide prediction algorithms

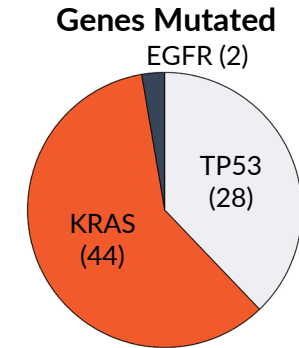
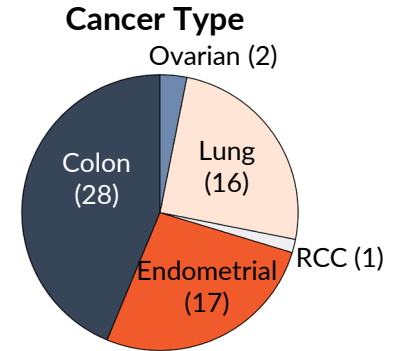
# hunTR™ Platform for TCR Discovery Expected to Expand Addressable Market with Exclusive TCRs

- Established end-to-end platform from TCR discovery to clinical translation
- Focused on key mutations in *KRAS*, *TP53* and *EGFR* genes
- Goal to add more mutations and HLAs to the existing mutations in the TCR library
- In *KRAS*-G12D and *KRAS*-G12V focused screening, two patients have had hotspot mutation-reactive TCRs



# Throughput of hunTR™ Increased to Expand the Number of Patients Who May Benefit from TCR-T Cell Therapy

- Pre-screened over 250 commercially-sourced tumors for mutation and HLA and 64 are entering hunTR™ queue
- Evaluating diverse group of cancer types that are representative of potential treatment populations
- Two EGFR mutations are targeted (L858R and 19del)
- Focused on four KRAS mutations based on their prevalence in solid tumors (G12C, G12D, G12V, G13D)
- *TP53* is among the most frequently mutated genes; we are targeting eight hotspots





# Financial Update

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# Selected Financial Data for the Third Quarter; Over a 50% Reduction in Operating Cash Burn Year-Over-Year

## Revenue

- **Collaboration revenue of \$2.9 million:** primarily related to the first commercial sale of darinaparsin by Solasia Pharma K.K.

## Operating Expense

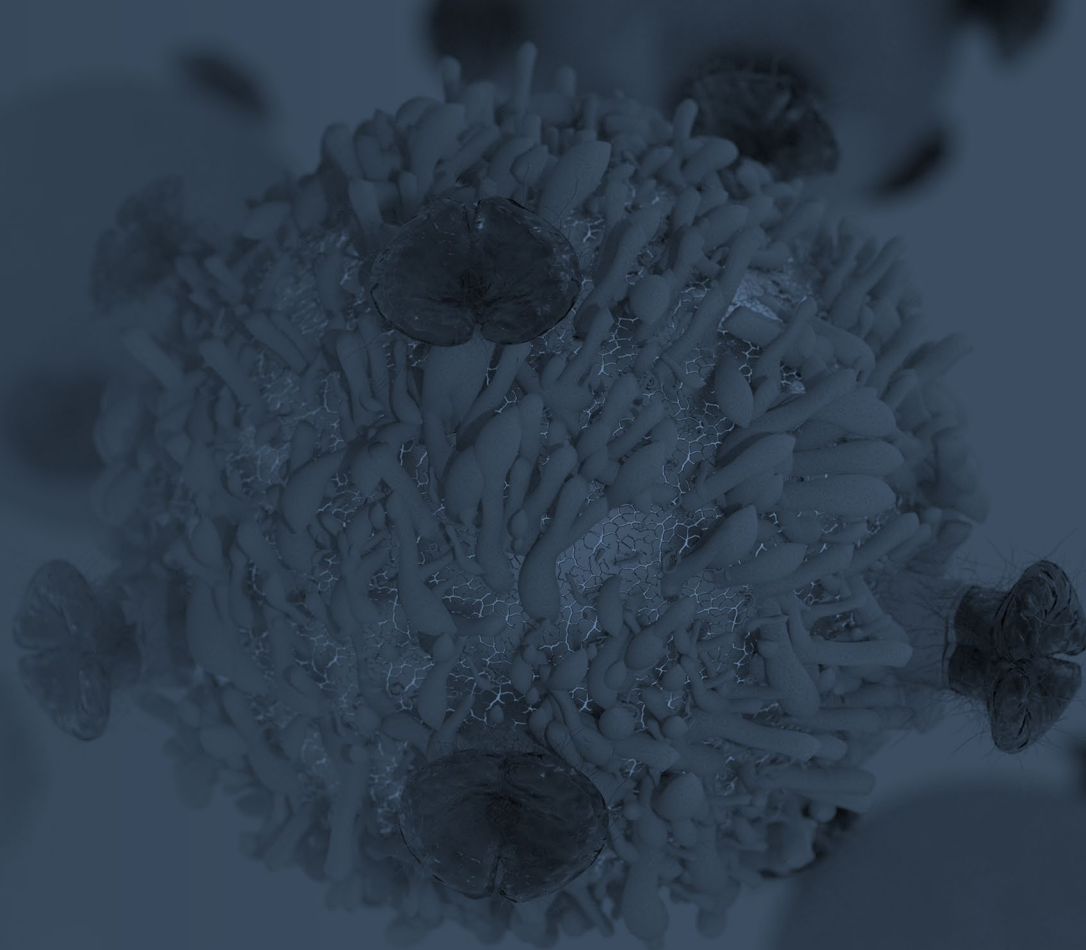
- **R&D costs decreased 46%:** as a result of focused efforts on our TCR-T platform and lower employee related costs; includes one-time milestone expense of \$2.5 million associated with the Solasia collaboration revenue.
- **G&A decreased 60%:** a result of reduced headcount and implemented efficiencies

## Cash & Net Cash

- **Cash:** \$37.8 million
- **Restricted Cash:** \$13.9 million
- **Debt Outstanding:** \$22.7 million
- **Operating Cash Burn:** \$6.1 million in third quarter of 2022, compared to \$9.6 million in third quarter of 2021 a decrease of 36%; Year-to-date of \$22.1 million in 2022, compared to \$46.3 in 2021, a decrease of 52%



# Upcoming Milestones



# Continue to Grow Platform to Expand Number of Patients Who May Benefit from *Sleeping Beauty* TCR-T

## Poised for Continued Progress Generating Additional Clinical Data and Building Pipeline

- 1 Treating Additional Patients on Library TCR-T Cell Clinical Trial
- 2 Amending IND to Include Two New TCRs and Reducing Manufacturing Process Time with Cryopreserved Product
- 3 Planning to File IND for mBL-15 TCR-T Cell Therapy in 2H 2023
- 4 Collaboration with NCI for Personalized *Sleeping Beauty* TCR-T Approach