

**SunnyBay Biotech**

# First-in-Class ADC Targeting HERV-K in Solid Tumors

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# The Unmet Need: Targeted Oncology Still Fails the Majority of Solid Tumor Patients

Despite the success of targeted therapies and ADCs, most solid tumor patients continue to have limited treatment options.

- FDA-approved ADCs primarily target HER2, TROP2, and B7-H3
- These targets are:
  - Expressed in limited patient subsets
  - Present in normal tissues, limiting dosing
  - Increasingly crowded and competitive
- Resistance and lack of durable responses are common, particularly in later-line disease

**Conclusion:** The field needs **new, tumor-associated targets** to expand the reach and durability of targeted oncology.

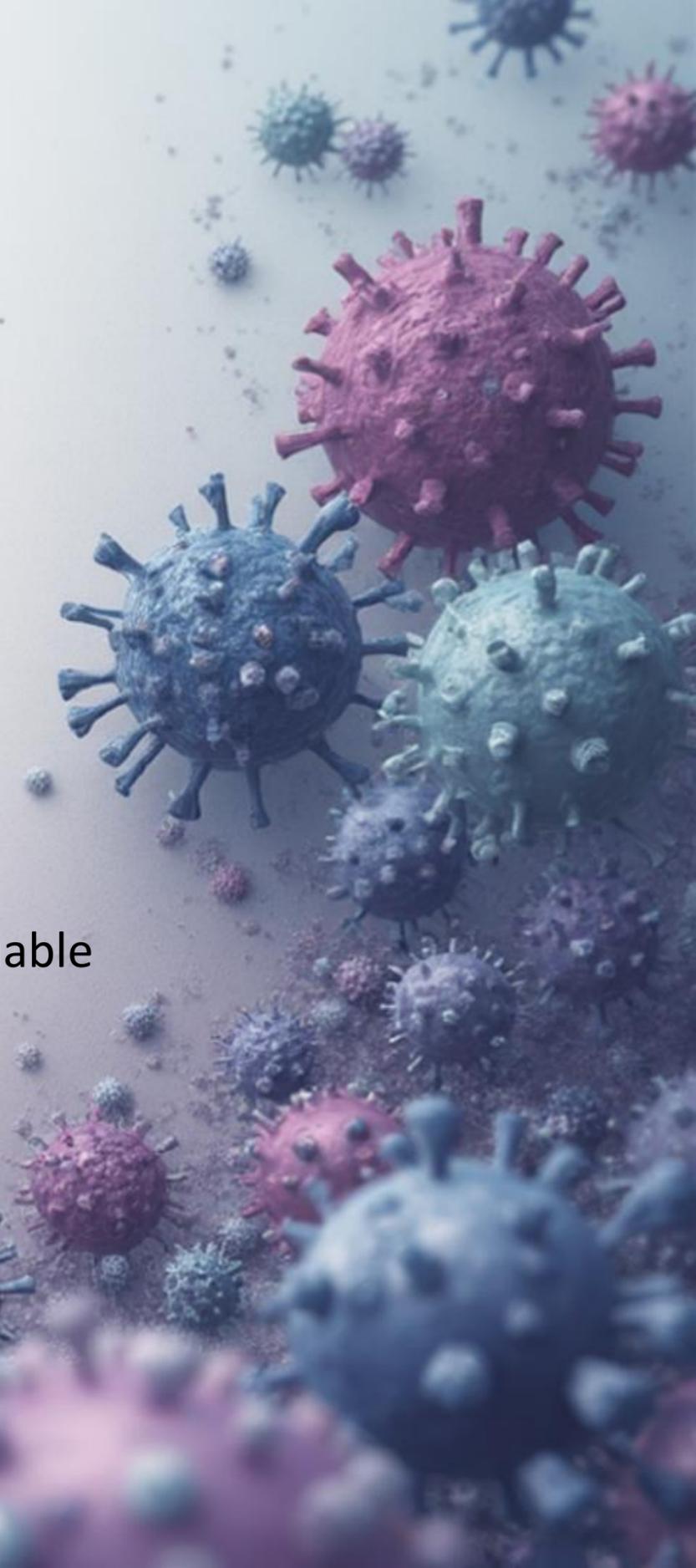


# Why HERV-K: A Tumor-Associated Antigen with Broad Relevance

Human Endogenous Retrovirus-K (HERV-K) represents a differentiated oncology target.

- Expressed in approximately **70–80% of multiple solid tumor types**, including:
  - Breast, lung, ovarian, pancreatic, colon, melanoma
- Minimal or absent expression in normal adult tissues
- Expression increases with disease progression and metastasis
- Cell-surface localization enables antibody binding and internalization

**Key Insight:** HERV-K combines **broad prevalence with tumor specificity**, a rare and valuable profile for ADC development.



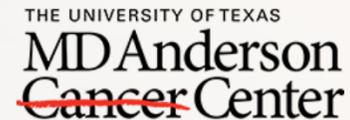


# Leadership Team



**Dr. Feng Wang-Johanning, Founder and CEO**

**Dr. Gary Johanning, Founder and CSO**



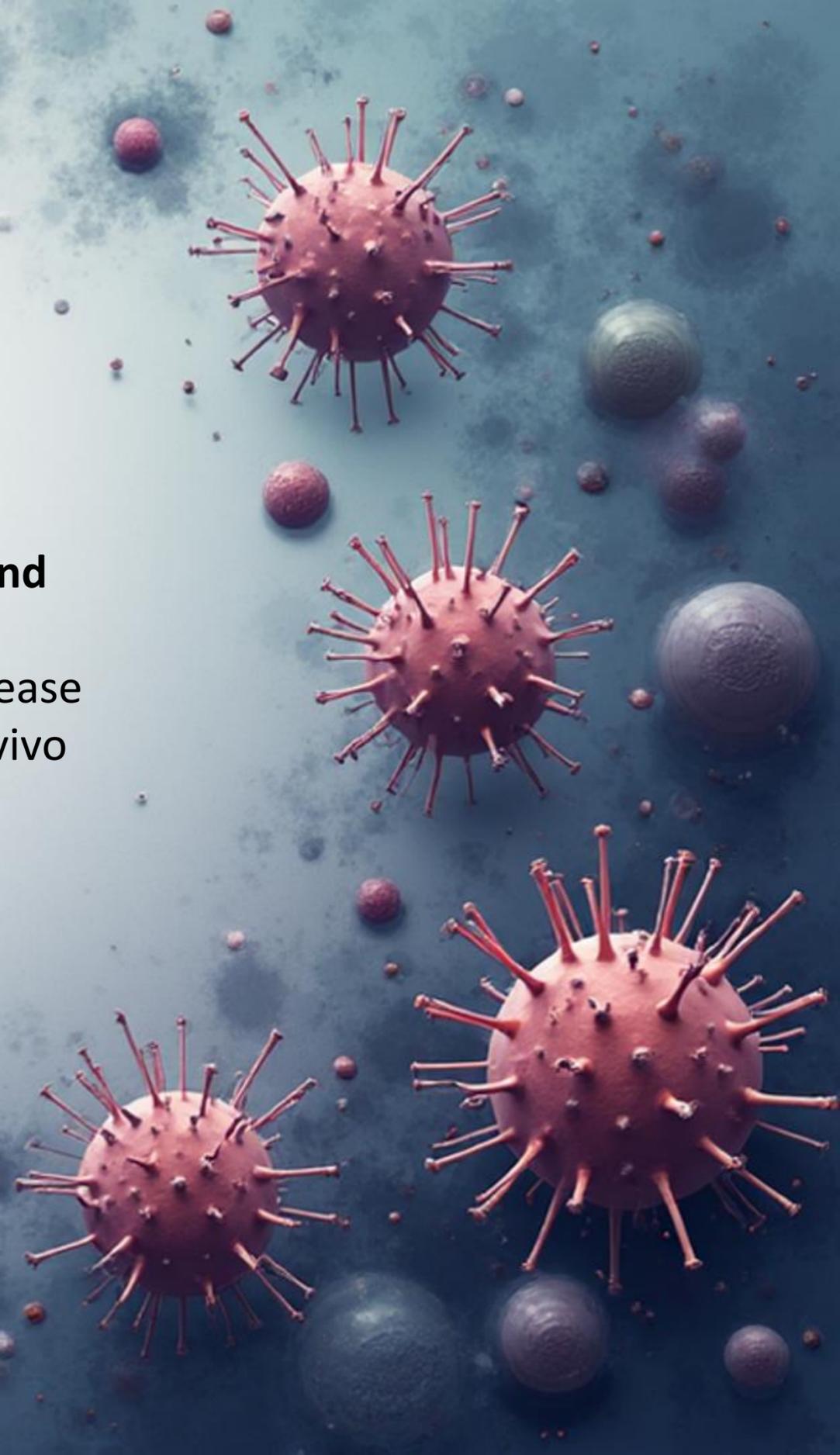
- SunnyBay's CEO and CSO are pioneers in HERV biology with 25+ years of research and extensive publications across solid tumors
- Feng Wang-Johanning has secured >\$15M in non-dilutive NIH and DoD funding
- Analysis of >6,000 tumor and normal biopsies shows HERV-K is tumor-restricted and expressed in ~70–80% of major solid tumors, with higher expression in advanced and metastatic disease
- HERV-K functions as an upstream oncogenic driver, promoting tumorigenesis and metastatic spread
- Targeting HERV-K has demonstrated anti-tumor and anti-metastatic activity across antibodies, ADCs, CAR-T, BiTEs, and cancer vaccines
- SunnyBay holds four international PCT patents covering antibodies, ADCs, cellular therapies, and vaccines

# Lead Program: SBB001 ADC

SBB001 is SunnyBay's lead antibody-drug conjugate targeting HERV-K.

- Fully humanized monoclonal antibody with high specificity for HERV-K
- Multiple clinically validated payloads evaluated, including **MMAE, SN38, and DXd**
- Linker-payload design optimized for stability, potency, and intracellular release
- Efficient tumor targeting and internalization demonstrated in vitro and in vivo

**Status:** Lead optimization complete; IND-enabling studies planned.

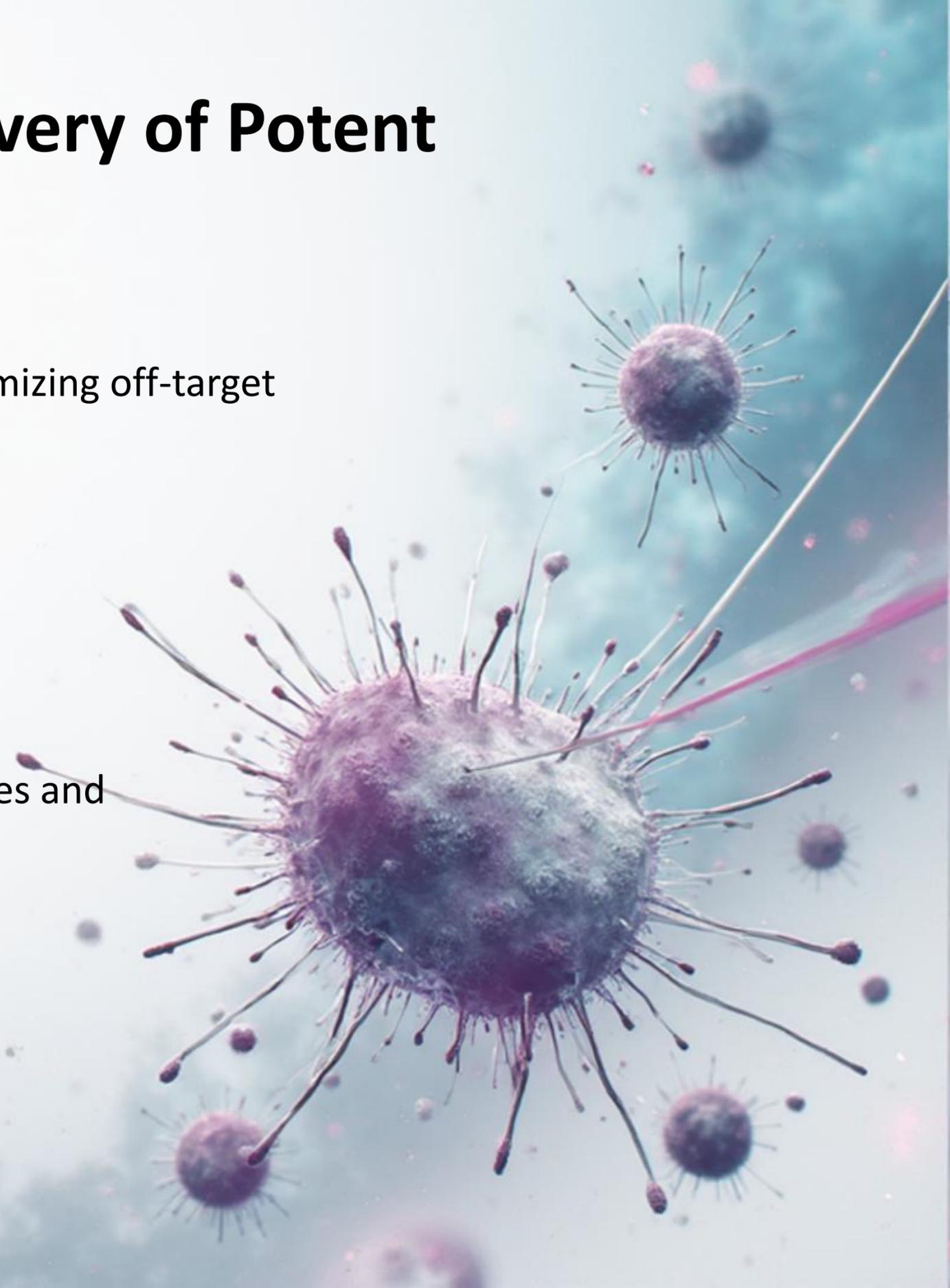


# Mechanism of Action: Targeted Delivery of Potent Cytotoxics

SBB001 ADC is designed to maximize tumor cell killing while minimizing off-target toxicity.

1. Antibody selectively binds HERV-K on tumor cell surface
2. Antibody-antigen complex internalizes efficiently
3. Cytotoxic payload is released intracellularly
4. Selective tumor cell death occurs in HERV-K-positive cells

This mechanism has been validated across multiple cancer cell lines and xenograft models.



# Preclinical Proof of Concept: Robust Anti-Tumor Activity Across Solid Tumor Models

SBB001 ADC demonstrates consistent and meaningful efficacy in vivo.

- Significant tumor growth inhibition compared to vehicle and antibody controls
- ADC efficacy exceeds antibody-only treatment
- Clear dose-response relationship observed
- Activity correlates with HERV-K expression levels

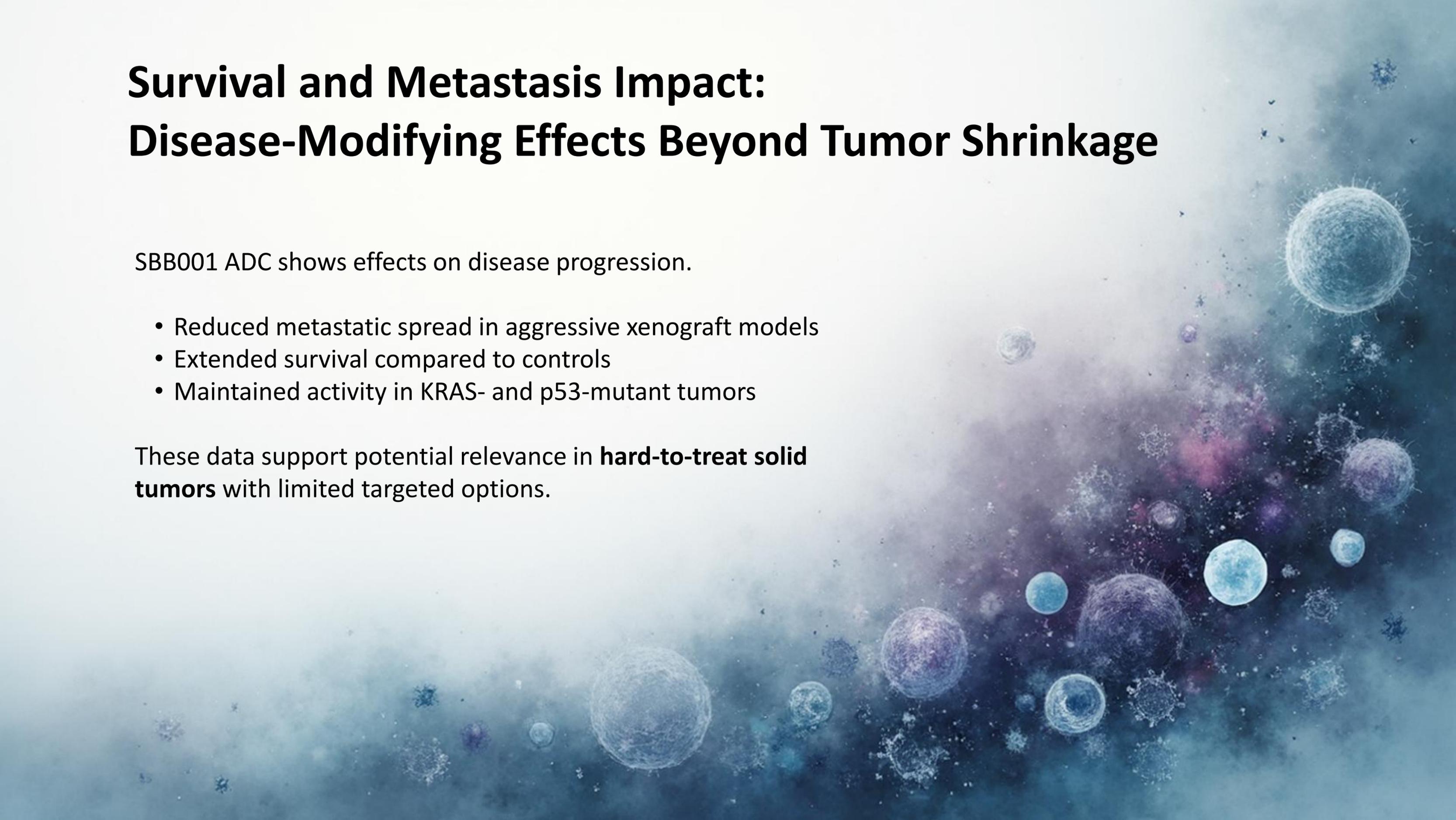
Efficacy demonstrated across breast, lung, ovarian, pancreatic, and colon cancer models.

# Survival and Metastasis Impact: Disease-Modifying Effects Beyond Tumor Shrinkage

SBB001 ADC shows effects on disease progression.

- Reduced metastatic spread in aggressive xenograft models
- Extended survival compared to controls
- Maintained activity in KRAS- and p53-mutant tumors

These data support potential relevance in **hard-to-treat solid tumors** with limited targeted options.



# Safety and Therapeutic Index: Encouraging Preclinical Tolerability Profile

Preclinical safety data support a favorable therapeutic window.

- No significant body-weight loss at efficacious doses
- Minimal activity observed in non-malignant cell lines
- No overt toxicity signals following repeat dosing
- Target biology suggests limited on-target normal tissue risk

**Next Milestone:** Formal GLP toxicology studies in rodent and non-rodent species.

# Competitive Landscape: Differentiation at the Target Level

**Most ADC Programs compete around a small number of established targets.**

Feature	HER2 ADCs	TROP2 ADCs	<b>SBB001 (HERV-K)</b>
Tumor prevalence	~15-20%	~40-60%	<b>~70-80%</b>
Normal tissue expression	Moderate	High	<b>Low / None</b>
Competitive intensity	Very crowded	Crowded	<b>Open</b>

**Strategic Advantage:** Broad applicability with reduced competitive density.

# Clinical Development Strategy: Capital-Efficient Path to Human Proof of Concept

SunnyBay is pursuing a focused Phase 1 strategy.

- Initial enrollment in solid tumors with high HERV-K expression
- Biomarker-driven patient selection using IHC
- Dose escalation followed by focused expansion cohorts
- Primary endpoints:
  - Safety and tolerability
  - Pharmacokinetics
  - Preliminary efficacy

**Objective:** Generate human data to support partnering or Series B financing.

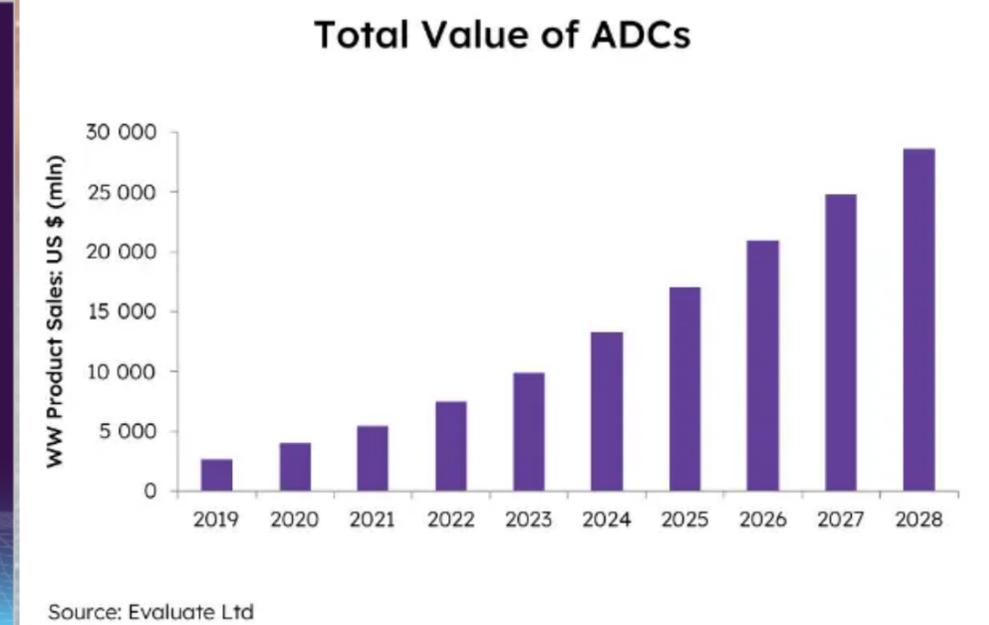
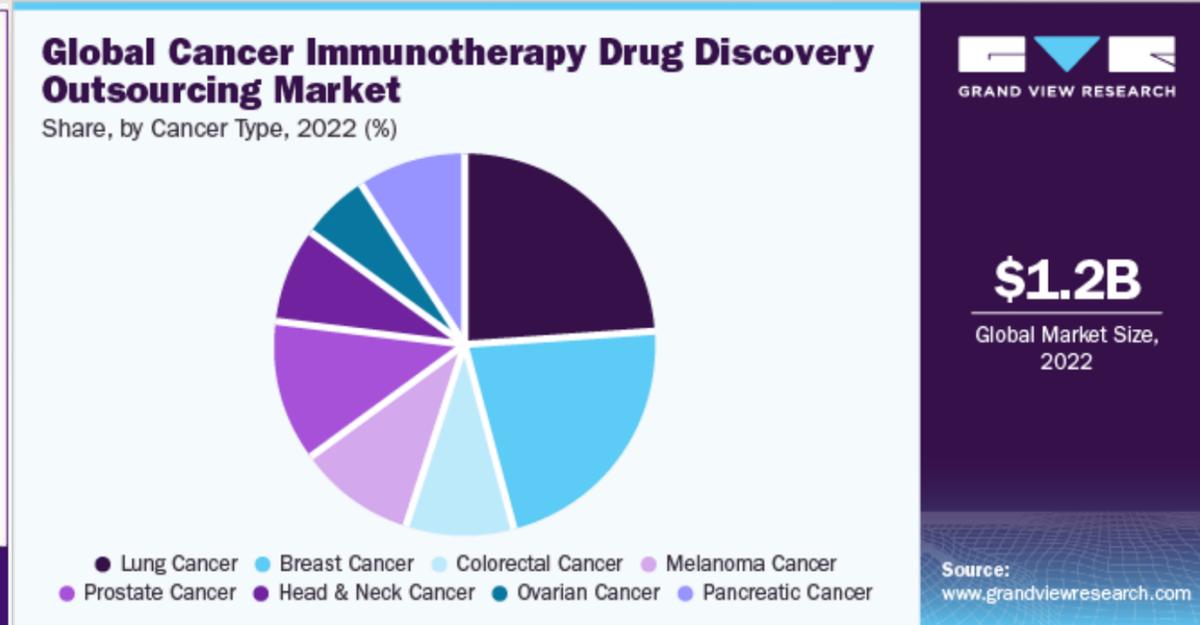
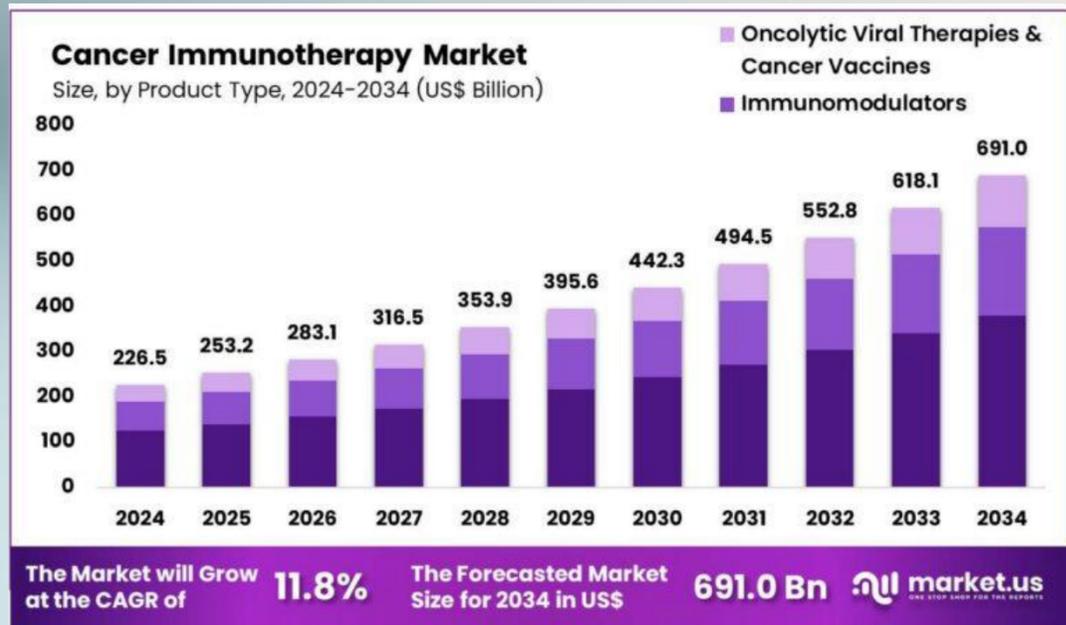


# Global Cancer Immunotherapy Market

Product Type (Monoclonal Antibodies, Immunomodulators, and Oncolytic Viral Therapies & Cancer Vaccines)

Application (Lung Cancer, Breast Cancer, Colorectal Cancer, Melanoma, Prostate Cancer, Head and Neck Cancer, Ovarian Cancer, Pancreatic Cancer, and Others),

Total value of ADCs



# Platform Optionality: Long-Term Upside Without Near-Term Burn

Beyond the lead ADC, SunnyBay's HERV-K platform enables:

- Additional ADC variants
- BiTEs
- CAR-T and TCR therapies
- Cancer vaccines
- Cancer prevention
- Companion diagnostics
- Characterize immune profiles at a single cell level
- Identify T cells that can kill tumor cells at a single cell level
- Identify B cell that can kill tumor cells at a single cell level

These programs represent **future optionality** and do not drive near-term capital requirements.

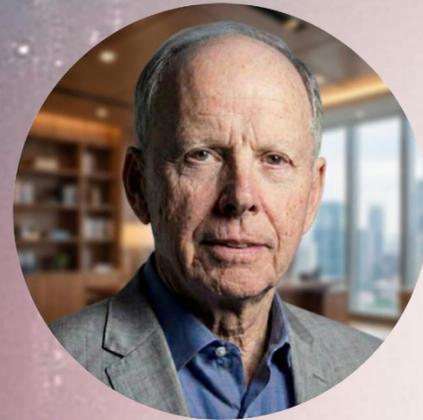


# Intellectual Property: Broad and Defensible IP Portfolio

SunnyBay has built an extensive international IP estate.

- Multiple PCT filings covering:
  - Antibodies and ADCs
  - Cellular therapies
  - Vaccines
  - Diagnostics
- Composition-of-matter and method-of-use protection
- Coverage aligned with clinical and partnering strategies

# Board / Collaborators



**Franklin Rice, MBA**  
Strategic Advisor



**Lawrence Florin, MBA**  
LBF BioPharma  
Consulting, LLC



**Dr. Toufigh Gordi**  
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Rigel Pharmaceuticals Inc.



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Cancer Center



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Executive | Clinical  
Development & Strategy



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President and Founder,  
CatalystBio



**Dr. Michael Boyne**  
Co-Founder and Principal  
CatalystBio

# Financing and Milestones

## Series A to First-in-Human Data

**Raising:** \$12–15M Series A

**Runway:** ~18–24 months

## Use of Funds

- IND-enabling studies
- GLP toxicology (two species)
- GMP antibody and ADC manufacturing
- IND submission and Phase 1 initiation

## Key Value Inflection Points

- IND allowed to proceed
- First patient dosed
- Initial human safety and PK data



# Why Invest Now

## Compelling Risk-Adjusted Opportunity

- Novel, biologically validated tumor-associated target
- Broad solid tumor relevance
- Strong preclinical efficacy and safety signals
- Capital-efficient path to human data
- Clear alignment with pharma ADC strategies and partnering interest

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Thank you