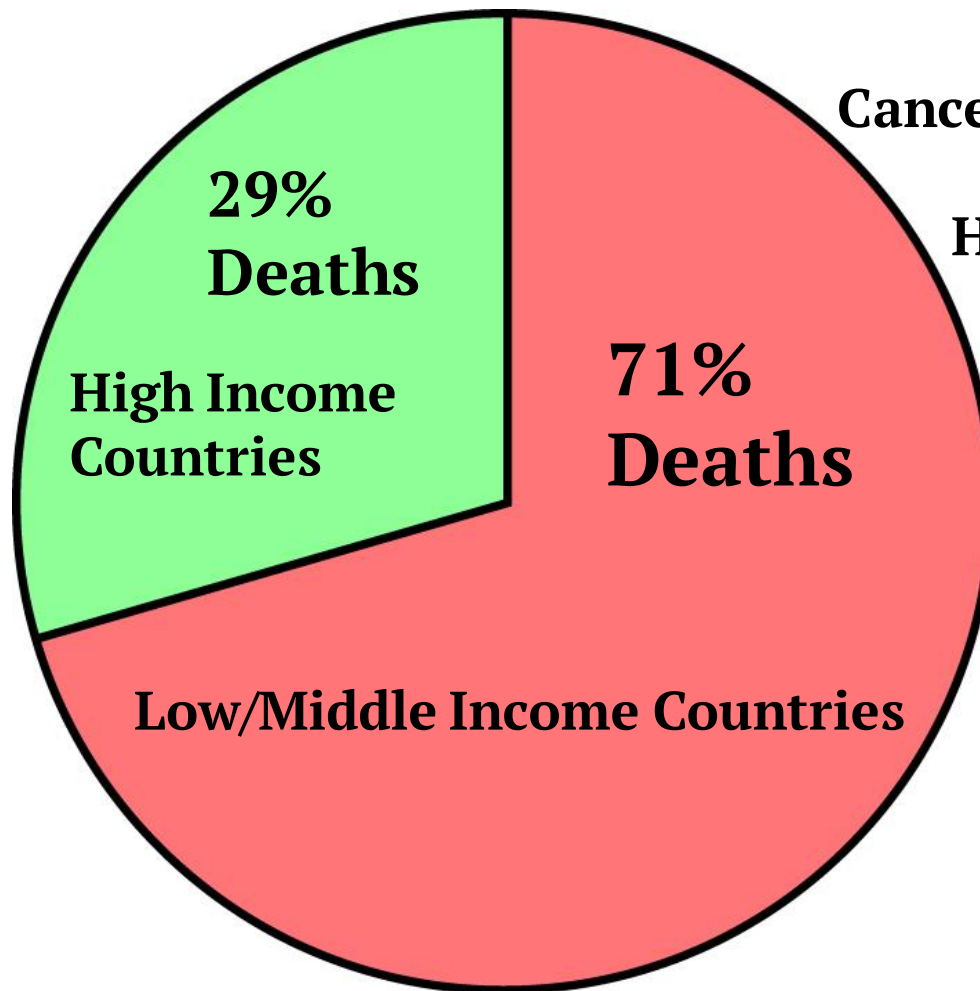


Let's end cancer.

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# The Problem: 10 Million People Die from Cancer Each Year



**Cancer is an Ugly Disease**

**How Do We End it Worldwide?**

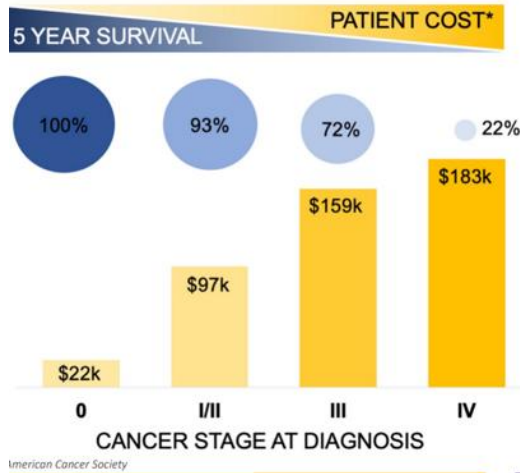
# Near Term Solution:

## Early Detection

+

## Vaccine to Treat

### Detect Cancer at Stage 1



### Treat with Off-the-Shelf Therapeutic Vaccine



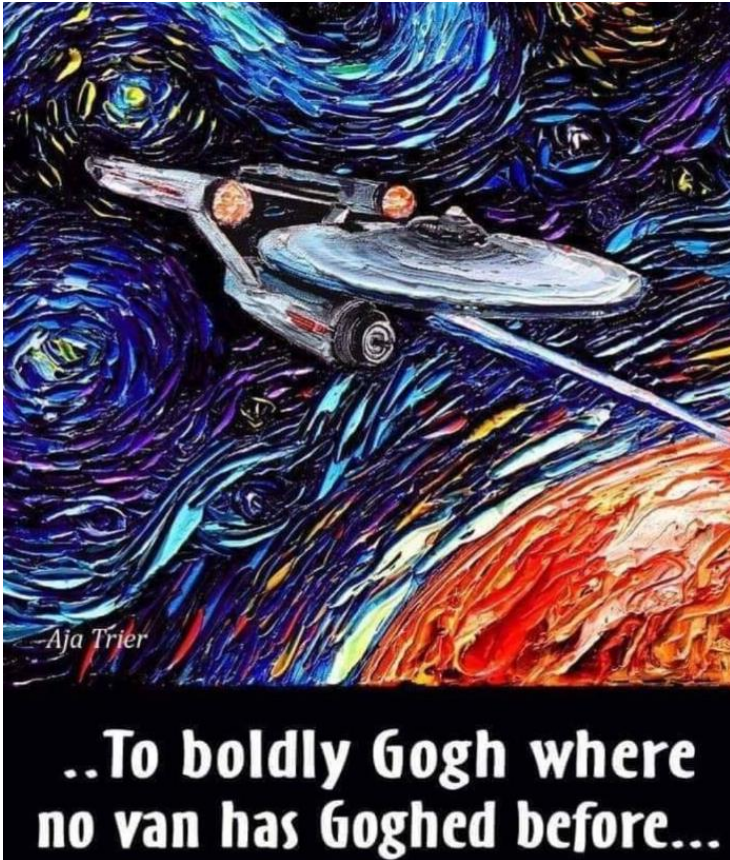
*We are Developing Simple, Antibody-Based Blood Tests for Screening*

*We are Developing Vaccines to Treat Any Stage 1 Cancer*

**The Only Tests with High Sensitivity for Stage 1 Cancers**

**The Only Pre-Made Therapeutic Vaccines for Any Cancer**

# Real Solution: A Vaccine to PREVENT Cancer in the First Place



- **Treat Cancer Like an Infectious Disease**
- **Only Calviri's Discoveries and Inventions Enable This Goal**



# Calviri's Products in Development

1. **Cancer Diagnostics**: Detect any cancer early, high sensitivity, low cost, little blood
2. **Therapeutic Cancer Vaccines**: Off shelf, any cancer, low cost. Companion treatments for diagnostics
3. **Preventative Cancer Vaccine**: Off shelf, all cancers, low cost



*For a Worldwide Market*

# Value of Calviri's Human Products (US only)

Product	Market	Price	Estimated Value
Human Preventative Cancer Vaccine	100M > 60 yro,	\$250 every 2 yrs	\$12.5B
Human Stage 1 Therapeutic Vaccine	2M cancers/yr	\$500	\$1B
Human Stage 1 Diagnostic Test	150M > 40 yro	\$250	\$37B
Total Estimated US Market Value : Human Health			\$51.7B

 = to be licensed

- License Early Diagnostic 2024
- License/Commercialization of Vaccines 2026-8

# Competition for Our Products

**Off the Shelf Therapeutic Vaccines: None**

**Broadly Preventative Vaccine: None**

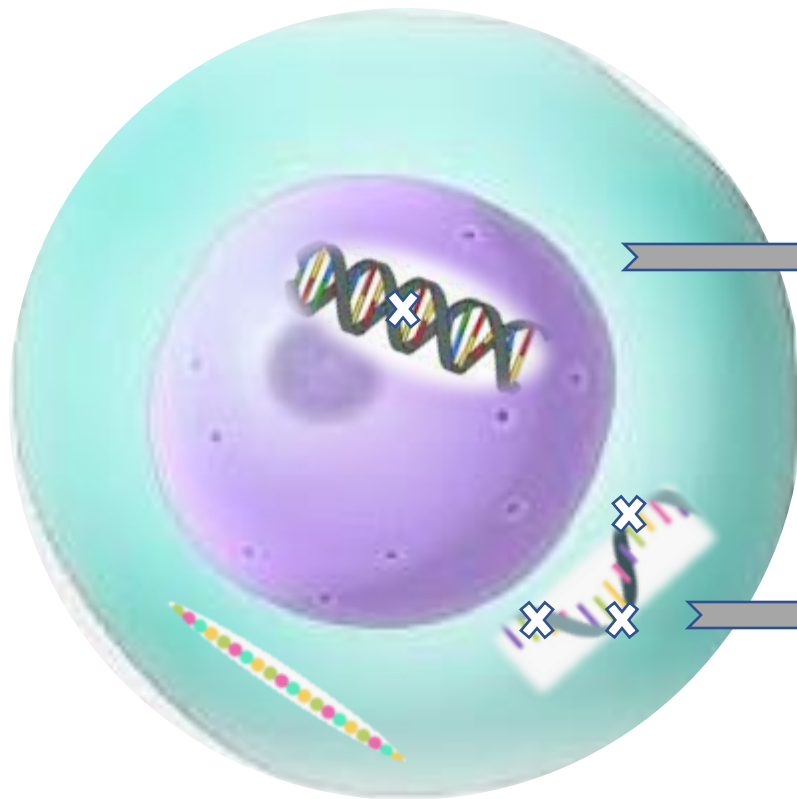
**Early-Stage Diagnostic: Nucleic acid companies, e.g. Grail**

## Early-Stage Diagnostic Tests Compared

Specification	Calviri	Grail
Sensitivity	90%+	<50%
Blood Volume	5ul	>8ml
Simplicity	+	Large Volume Complex Assay
Price	~\$100	\$1000
COGs	Low	High
Signal Amplification	$10^{11}$	-
Companion Vaccine	+	-

# Our Products are Based Our Discovery: RNA-Error Derived Neoantigens (REDNs)

**Tumor cell**



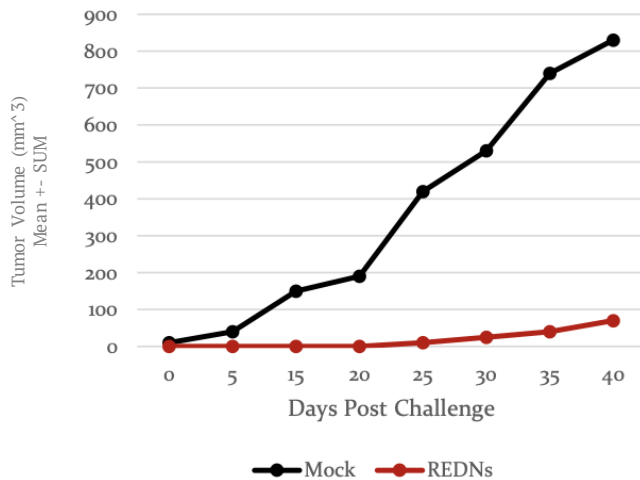
*DNA Error-Encoded  
Neoantigens are Personal  
and Infrequent*

*RNA Error-Encoded  
Neoantigens are Shared  
and Frequent*

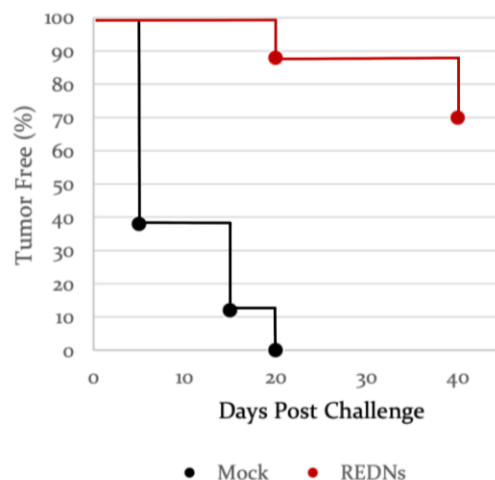


# Our Pre-Clinical, Published Studies Show REDNs are Shared and Protective in Multiple Cancer Models

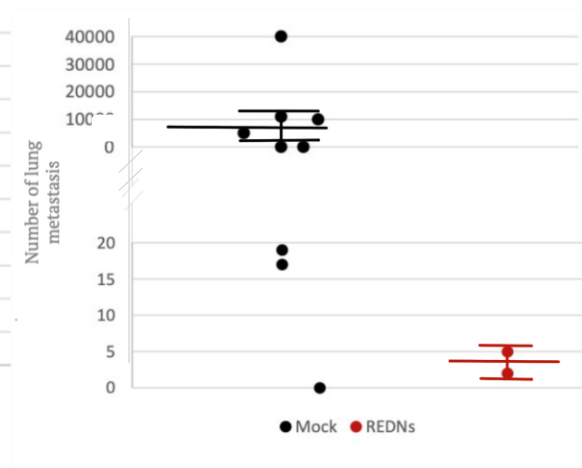
### Slow Tumor Growth



### Increase Tumor-Free Survival



### Prevent Metastasis



Three shared REDNs protect in multiple mouse models of cancer

## Challenge:

*To Create Off the Shelf Therapeutic and Preventative Vaccines and Diagnostics, thousands of tumor samples would need to be screened to identify those REDNs that are **Broadly Shared and Immunogenic***

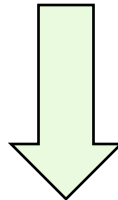
# Calviri has Informativly PREDICTED All REDNs that Human and Dog Tumors Can Produce

## Possible REDNs in Tumors designed as 14-mers

- **Microsatellite-transcription slipping: 22,367**
- **Exon Mis-Splicing and Exon 1 mis-initiation: 1,171,149**
- **Intron Retention: 1,244,416**
- **W-Bumps: 445,583**
- **Non-Coding RNAs (Dark proteome): 161,899**

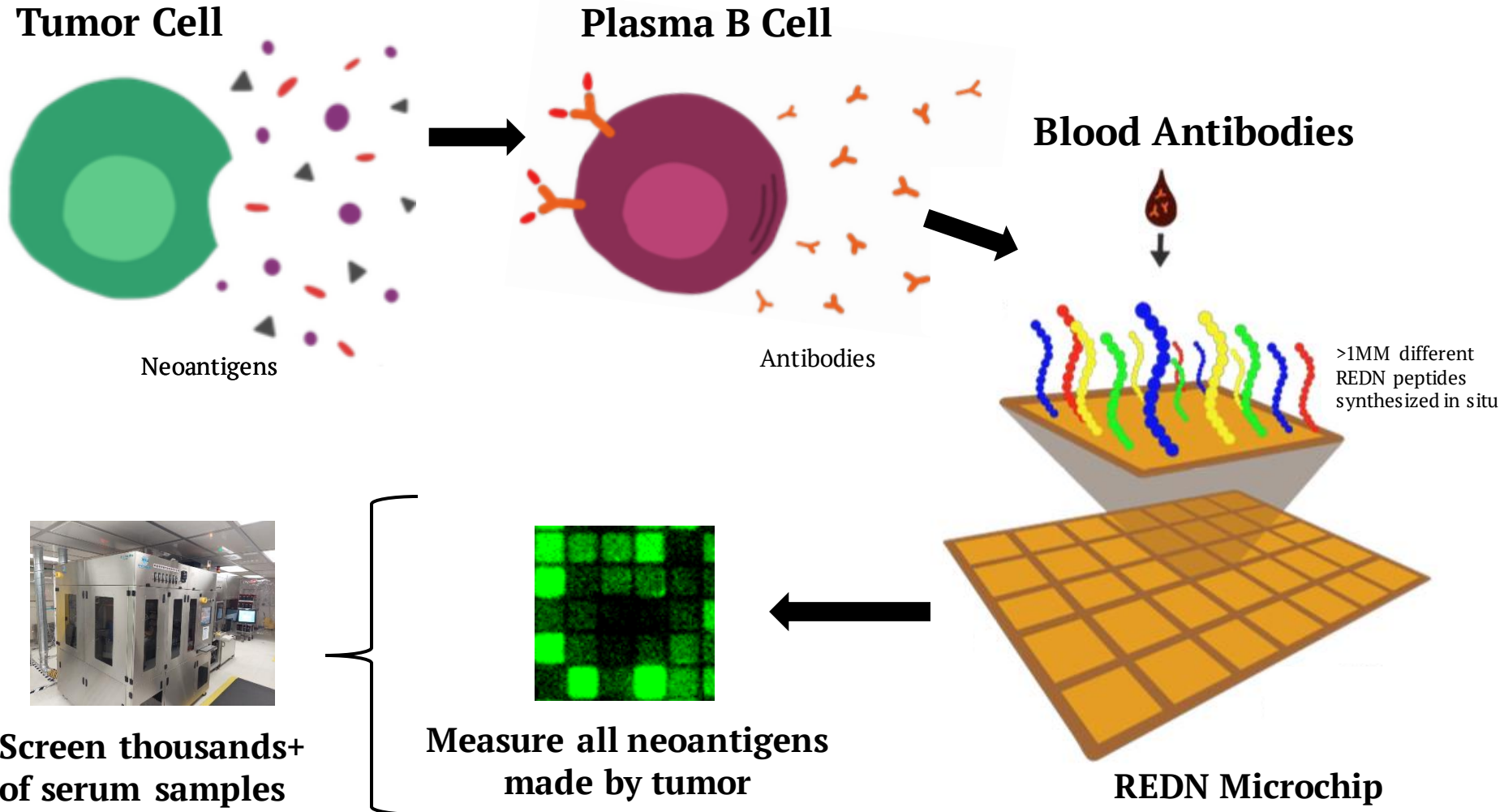
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**= There are ~2.1M Human REDNs and ~1.4M Dog Predicted REDNs**  
(Only a small % of each class will be *expressed* and *immunogenic*)



***The Challenge: Find the REDNs Useful For Vaccines and Diagnostics***

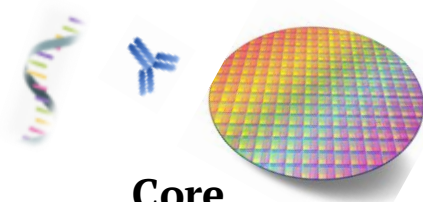
# REDNs Elicit Antibodies that can be Measured on Our REDN-Peptide Microchips, Enabling Comprehensive Searches of REDN Space



# Calviri's Discovery of REDNs and Development of a Simple Assay Enable Our Unique Products



# Calviri's Business Strategy: Dogs to Humans



**Core  
Technologies  
& Discoveries**



- Diagnostics:
- Early Detection
- Therapeutic Vaccines:  
Off-the-Shelf
- Preventative Vaccines



- Demonstrate Safety
- Proof of Efficacy
- Early Revenues
- Regulatory: USDA for Vaccines
- No Regulatory for Diagnostics

**2023-2026**



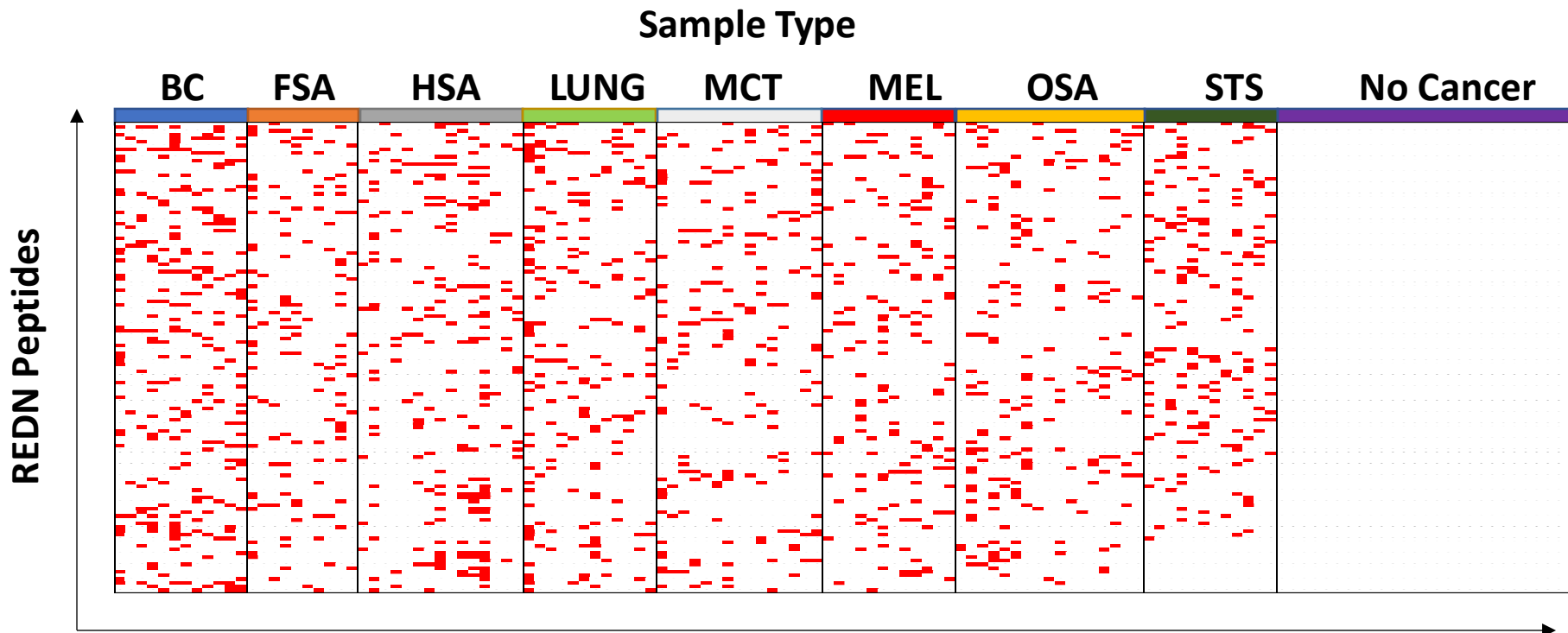
- Human Clinical Trials
- Early Diagnostic
- Therapeutic Vaccines
- Preventative Vaccine



**2024→**

- ✓ *Calviri Will Partner/License Diagnostics and Therapeutic Vaccines*
- ✓ *Calviri Will Develop the Preventative Vaccines*

# Screen of Cancer versus No Cancer Sera for *Shared* REDN Peptides



220,00 REDNs Screened

Total 127 REDNs  
(>10% positive rate, 6SD)



31 Chosen for Vaccine



# Calviri is Testing a Vaccine to PREVENT Cancer in the World's Largest Dog Cancer Trial

## Biggest in the world

Calviri is conducting the world's largest study, Vaccine Against Canine Cancer Study (VACCS) among 800+ dogs  
We are in the 5<sup>th</sup> year of the 5-year trial

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## All major cancers

Objective is to test the efficacy (over 5 years) of a preventative vaccine against the 8 most common cancers in a double blind, equal arms study

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## \$6.4 million

Study funded by a \$6.4M grant from Open Philanthropy Project and Calviri, Inc.

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## 800 dogs

804 Dogs Fully Enrolled  
No Vaccine Safety Issue  
Possible extension to 6 years

## Clinical research sites





We've demonstrated a  
preventative cancer vaccine

*works*

# VACCS Preventative Cancer Vaccine Trial Tumor Results to Date

	Placebo	Vaccine Responders	Chi Square p value
Tumor Incidence	85	30	16 0.0001
Tumor Deaths	29	10	9.2 0.002

### Conclusions:

- *A Vaccine Can Prevent Cancer Incidence and Death*
- *Improvements can be Made to Components and Delivery Method to Increase Vaccine Takes*

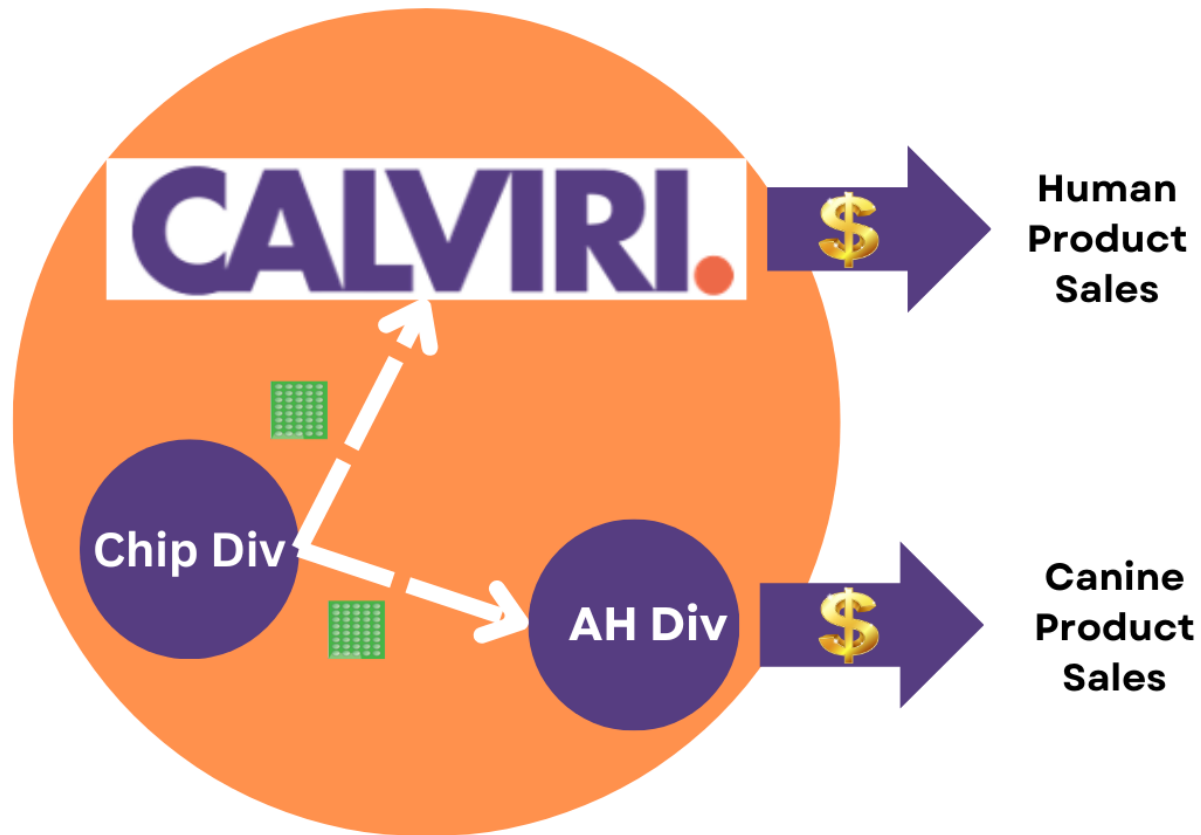
# Value of Calviri's Dog Products (US only)

Product	Market	Price	Estimated Value
<b>Dog Preventative Cancer Vaccine</b>	45M > 5yro	\$250 every 2 yrs	<b>\$5.5B</b>
<b>Dog Therapeutic Stage 1</b>	6M cancers/yr	\$250	<b>\$1.2B</b>
<b>Dog Stage 1 Diagnostic</b>	45M > 5yro	\$100 1/year	<b>\$4.5B</b>
<b>Total Estimated US Market Value : Animal Health</b>			<b>\$11.2B</b>

**License and Commercialization by 2025**

 = License

# Business Plan



# Return on Investment

<b>Division</b>	<b>Potential for IPO, M&amp;A</b>
<b>Animal Health: Diagnostics, Vaccines</b>	<b>2025</b>
<b>Human Health: Diagnostics, Vaccines</b>	<b>2026</b>
<b>Diagnostic Chip Production</b>	<b>2026</b>



# Calviri Today

- **Formed: 2018**
- **Funding: \$22M (+ \$6.4M non-dilutive)**  
**Private Investors/Family Offices (30)**  
**Common Stock, No Debt**
- **People: 32**
- **Business Development: Term Sheet Dog Therapeutic Vaccines**  
**Term Sheet Dog Preventative Vaccine**  
**Negotiations with Diagnostic Strategic**  
**Negotiations for Animal Health Spin-Out**
- **IP: 60 Patents Granted/Pending for Diagnostics and Vaccines**  
**Chip Production Protected by Trade Secrets**

# Major Near-Term (18 mos.) Milestones

- **Expand Management Team**
- **Dog Preventative Cancer Vaccine Licensure Trial**
- **Revenue from Preventative Vaccine Sales**
- **Initiate Dog Therapeutic Vaccine Trial**
- **Establish Scaled Manufacturing for Diagnostic**
- **Revenue from Diagnostic Sales**
- **Initiate Human Phase 1/2 Trials**
- **Large Scale Demonstration of Human Diagnostic**

# Leadership Team

## Existing



**Stephen Albert Johnston,**  
Chair, Calviri CEO, Co-  
Founder, 60 patents, member  
National Academy of  
Inventors



**Kathryn Sykes, Ph.D.,**  
Calviri V.P., Research &  
Product Dev't,  
Co-Founder



**Terrence O'Neil,**  
Calviri Director of  
Operations

## Growth

COO

CMO

VP, BD

# Board of Directors



**Jeff Le Benger, MD**  
Calviri Chairman of the Board,  
Executive Chairman of the board Summit Health



**Kathryn Sykes, Ph.D.,**  
Calviri V.P., Research & Product Dev't,  
Co-Founder



**Michael McCallister**  
CEO & Chairman of the Board, Humana (retired);  
Board of Directors for Zoetis, Inc.



**Stephen Albert Johnston,**  
Calviri CEO, Co-Founder, 60 patents, member National Academy of Inventors



**Michael Chambers**  
Founder Aldevron  
Former CEO and Chair of BOD



**Jacque Sokolov, M.D.**  
Chairman at SSB Solutions;  
Phoenix Children's Hospital;  
GlobalMed; Veterans Accountable Care Group, LLC

# Scientific Advisory Board



**John Ballantyne, Ph.D.**  
Founder / former SO of Aldevron  
>23' years experience

John Ballantyne, Ph.D., has over 25 years of experience in the development and manufacture of DNA, RNA and proteins across the research, diagnostic and licensed drug product spectrum. He co-founded Aldevron (now a Danaher operating company) directly out of graduate school in 1998 and has served as its Chief Scientific Officer since inception. Much of his focus outside of industrialization of biologicals manufacturing has been dedicated to working with military researchers to produce countermeasures to high threat/weaponizable viruses and in the development of systems for "n of 1" therapies in the oncology space. Dr. Ballantyne also has an interest in the anti-cancer and molecular-adjuncting properties of a novel class of superantigens and has supported the technical and clinical maturation of these moieties through his research and development group for over a decade. His areas of expertise include large-scale biologicals production, purification systems and novel ligand/matrix designs, pharmacokinetics, and clinical path forward design and support. Dr. Ballantyne received his undergraduate degrees in Pharmacy at the Central Institute of Technology and the University of Otago in New Zealand and his doctorate from the Department of Pharmaceutical Sciences at North Dakota State University.



**Steven W. Dow, DVM, Ph.D.**  
Director of the Center for Immune and Regenerative Medicine at CSU

Steven W. Dow, DVM, Ph.D., is currently a professor of immunology in the Department of Clinical Sciences and the director of the Center for Immune and Regenerative Medicine at Colorado State University (CSU). The Dow Laboratory at CSU investigates tumor immune responses and develops new cancer immunotherapies. The laboratory also develops immunotherapies to prevent respiratory tract infections in cattle, dogs and cats, as well as for treatment of ocular viral infections and ocular cancer in horses and cats. A third program focuses on stem cell therapy for treatment of chronic infections and for wound healing, with studies in rodent models and pet dogs. Dr. Dow received his DVM from the University of Georgia and completed a residency in small animal internal medicine at Colorado State University. He then completed a PhD program in Comparative Pathology in the laboratory of Ed Hoover at Colorado State University. After that, Dr. Dow completed a post-doctoral fellowship at the National Jewish Center in the laboratory of Dr. Terry Potter, before joining the faculty of the Department of Clinical Sciences at CSU in 2002.



**Stan Lapidus**  
Founding CEO of Cytoc Corp. and EXACT Sciences  
Inventor and >35 years' experience

Stan Lapidus, is an inventor and entrepreneur who currently serves on a number of healthcare and medical technology boards. He was the founding CEO of three medical diagnostics companies. Two of them have been among the most successful diagnostics startups of all time: Cytoc Corp., which he founded in 1987, revolutionized early detection of cervical cancer through its development of the modern Pap test – the ThinPrep. The two ThinPrep prototypes are at the Smithsonian's American Museum of Natural History. EXACT Sciences, which he founded in 1995, pioneered non-invasive early detection of colorectal cancer through its Cologuard test. Since its introduction, Cologuard has become the fastest growing test in the history of the diagnostics industry. Stan holds 37 patents, primarily in methods for early detection of cancer. He served as an instructor at MIT from 2001 to 2017. Stan graduated from Cooper Union in New York City with a BS degree in electrical engineering.



**Peter P. Lee, M.D.**  
Chair of Department of Immuno-Oncology, Beckman Research Institute of City of Hope

Peter P. Lee, M.D., is currently the chair of the Department of Immuno-Oncology at Beckman Research Institute of City of Hope and a beneficiary of The Christopher Family Endowed Innovation Fund for Alzheimer's Disease and Breast Cancer Research in Honor of Vineta Christopher. He is co-leader of the Cancer Immunotherapeutics Program, professor in the Department of Hematology & Hematopoietic Cell Transplantation and the Billy and Audrey L. Wilder Professor in Cancer Immunotherapeutics. Dr. Lee received his medical degree at University of California San Diego and completed fellowships at both Stanford University and University of California San Francisco. The focus of his research is on understanding how cancer impacts host immune responses in patients, with the goal of developing novel treatments to restore/enhance immune function in cancer patients.



**Terry A. McInnis, M.D., MPH, CPE**  
President / founder Blue Thorn Inc.  
>25 years' experience

Terry A. McInnis, M.D., MPH, CPE, is currently President and Founder of Blue Thorn Inc. Dr. McInnis interacts nationally with government, providers, payers, academia, patient advocacy groups, and plans to help forge a more financially sustainable and quality enhanced delivery system. Dr. McInnis has over 25 years of senior executive and clinical experience in various employer, military (US Air Force - Flight Surgeon), and hospital/group practice health management segments. Prior to joining GSK, she was the Corporate Medical Director for Michelin North America where she helped engineer the redesign of the healthcare benefits for nearly 50,000 beneficiaries and worked as a committee member of the National Business Group on Health's - An Employer's Guide to Behavioral Health Services. Earlier as GE Power Systems Assoc. Medical Director and Health Care Manager, Dr. McInnis was responsible for the occupational health and employee programs in addition to the successful re-bid and risk-reward contracting of the medical benefits for all GE beneficiaries. Dr. McInnis received her Doctor of Medicine degree from Wake Forest Medical School being designated a NIH student clinical scholar. She completed a residency in Occupational Medicine as an OPSF scholar, and a MPH (high honors) at the University of Oklahoma. She is Board Certified in Preventive and Occupational Medicine, a Fellow of the American College of Occupational and Environmental Medicine, and a Former Course Advisor to the Department of Continuing Education of Harvard University.



Let's end cancer.

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