
CALVIRI.
Let’s end cancer.

The Problem:
10 Million People Die from Cancer Each Year

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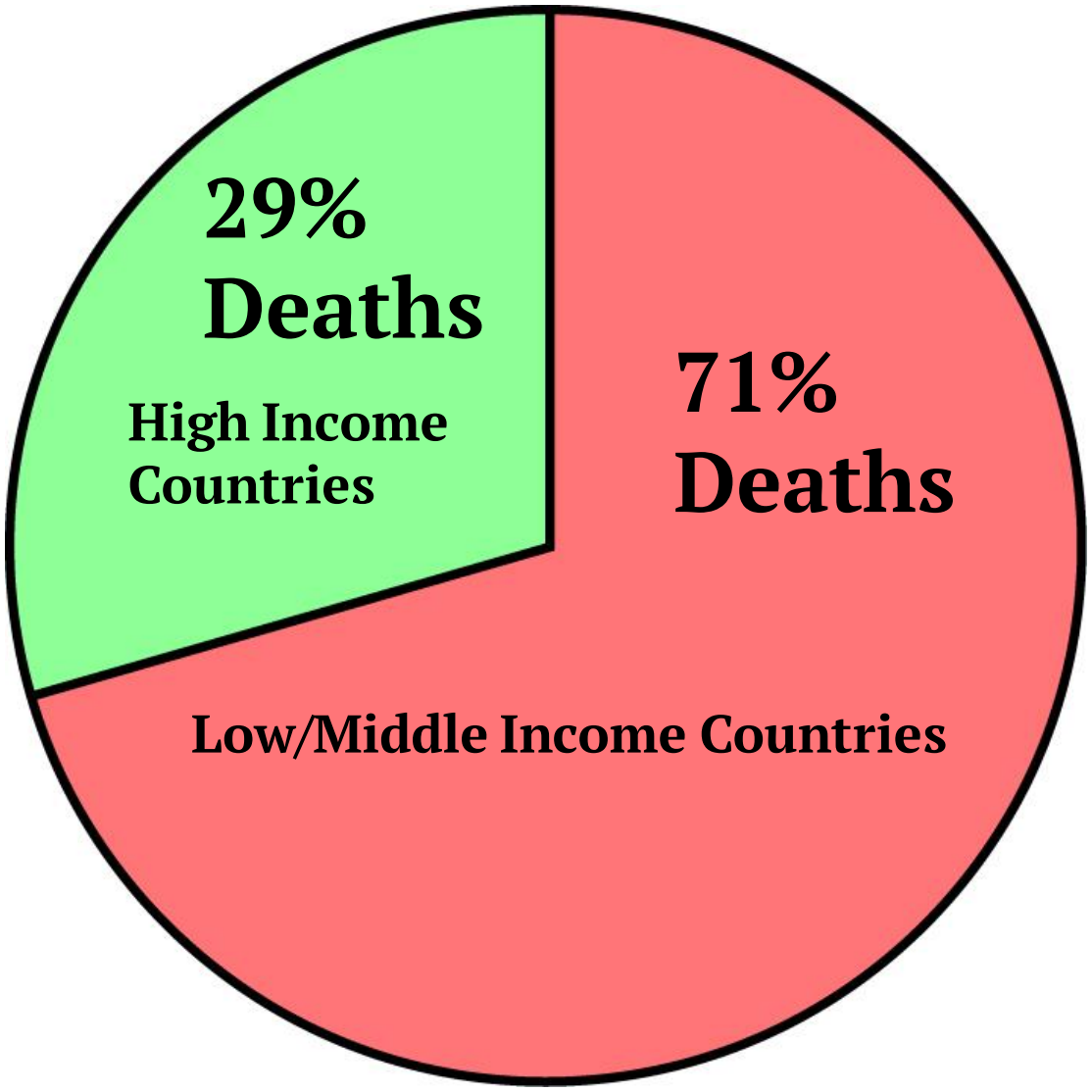

Cancer is an Ugly Disease
that Tortures People to Death

How Do We End This Worldwide?

Near Term Solution

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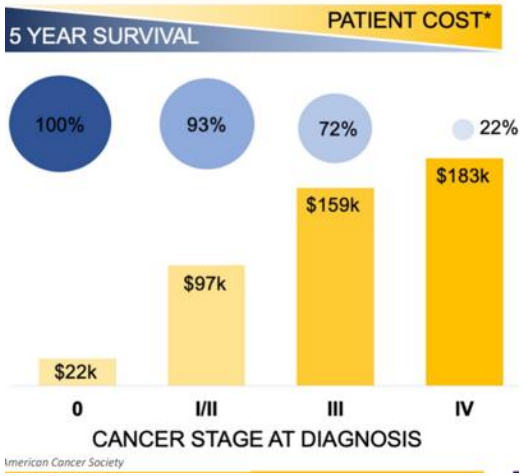
Early Detection

+

Vaccine to Treat

Detect Cancer at Stage 1



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

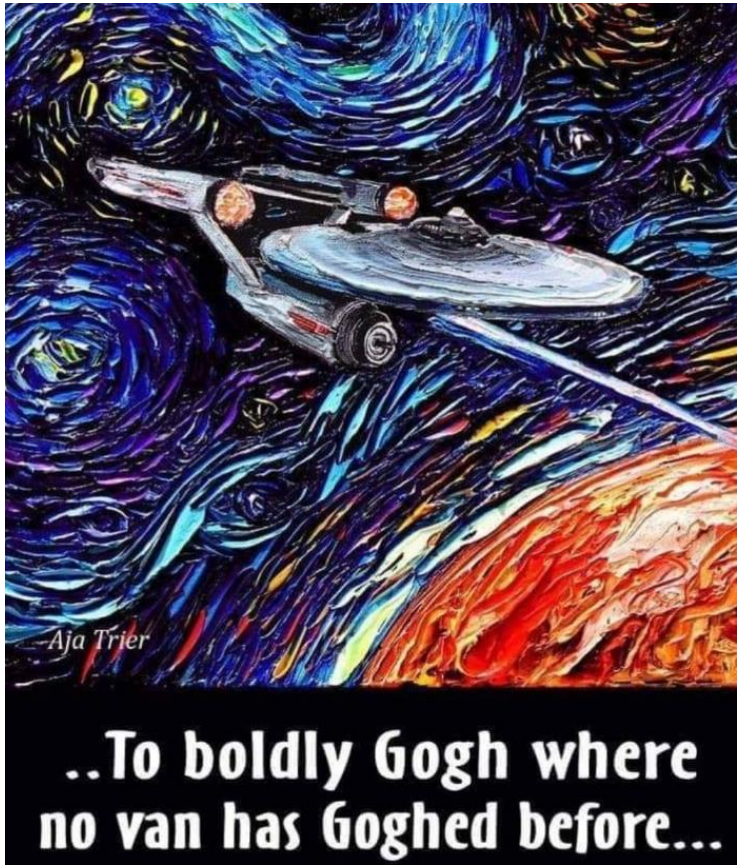
The Only Tests with High Sensitivity for Stage 1 Cancers

Treat with Off-the-Shelf Therapeutic Vaccine

We are Developing Vaccines to Treat Any Stage 1 Cancer

The Only Pre-Made Therapeutic Vaccines for Any Cancer

Ultimate 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

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1. **Cancer Diagnostics: Detect any cancer early, high sensitivity, low cost, little blood.**

2. **Therapeutic Cancer Vaccines: Off shelf, any cancer, low cost.**

3. **Preventative Cancer Vaccine: Off shelf, all cancers, low cost**

For a Worldwide Market

Value of Calviri's Human Products (US only)

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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**

- **License Early Diagnostic 2024** = to be licensed
- **License/Commercialization of Vaccines 2026-8**

Competition for our products

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Off the Shelf Therapeutic Vaccines: None

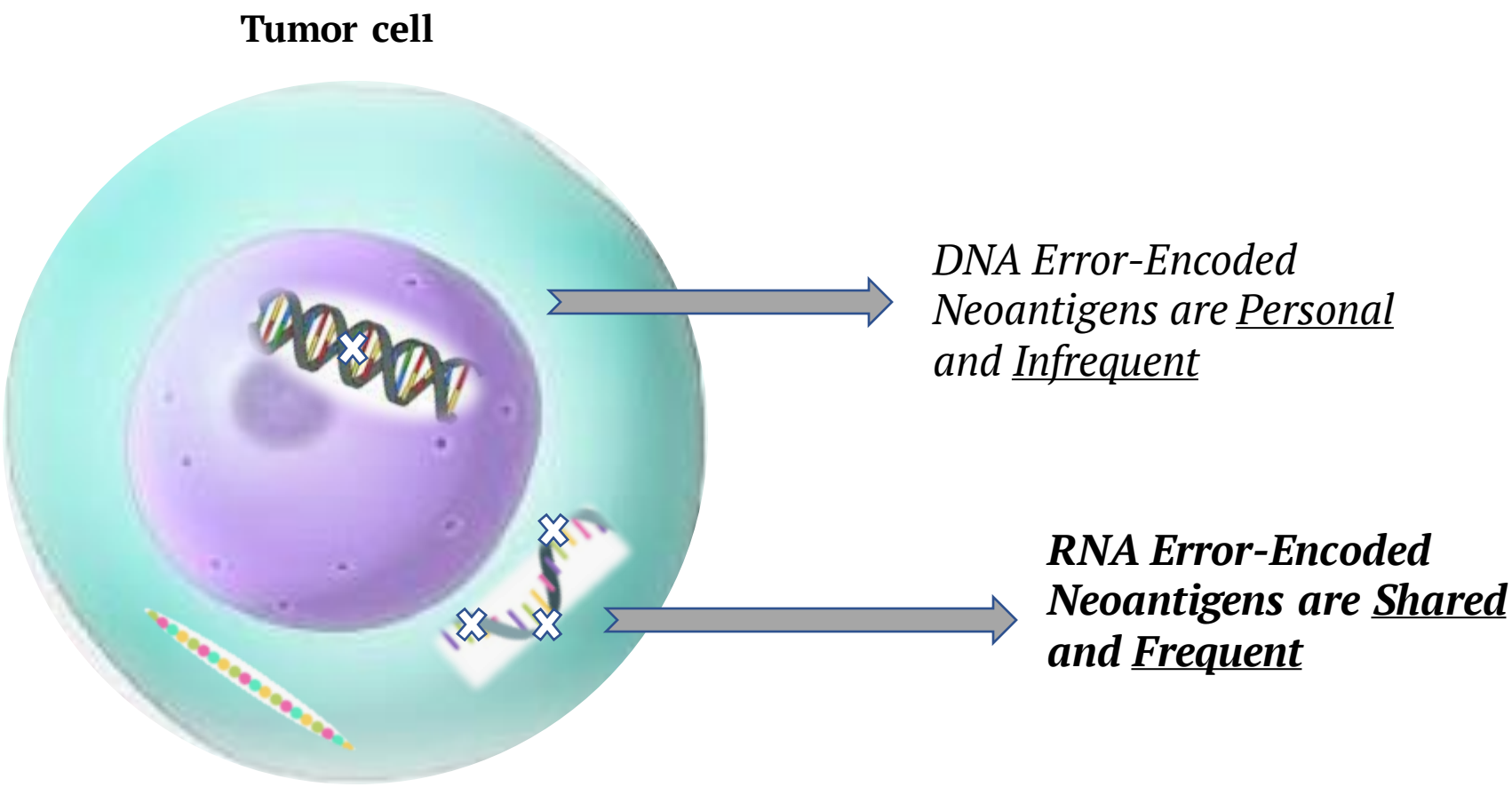
Broadly Preventative Vaccine: None

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	+	-

Calviri's Products are Based Our Discovery: RNA-Error Derived Neoantigens (REDN)



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

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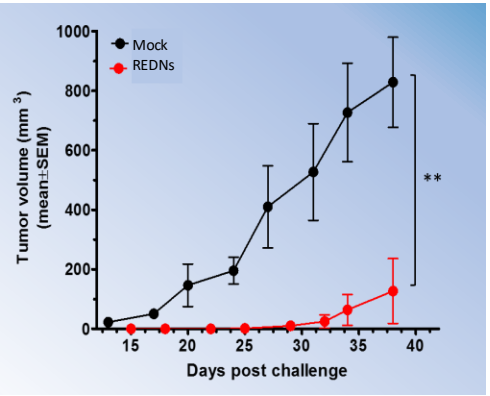
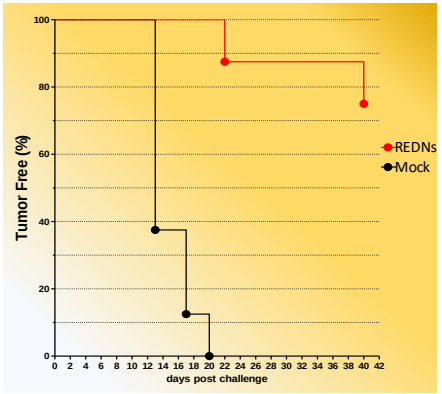
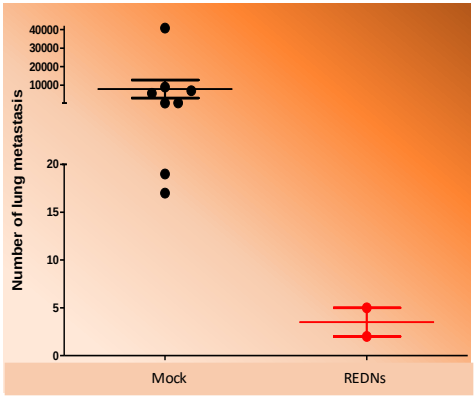
Slow Tumor Growth



Increase Tumor-Free Survival



Prevent Metastasis



Three <u>shared</u> REDNs protect in <u>different</u> 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 Informatically PREDICTED All REDNs that Human and Dog Tumors Can Produce

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Possible REDNs in Tumors designed as 14-mers

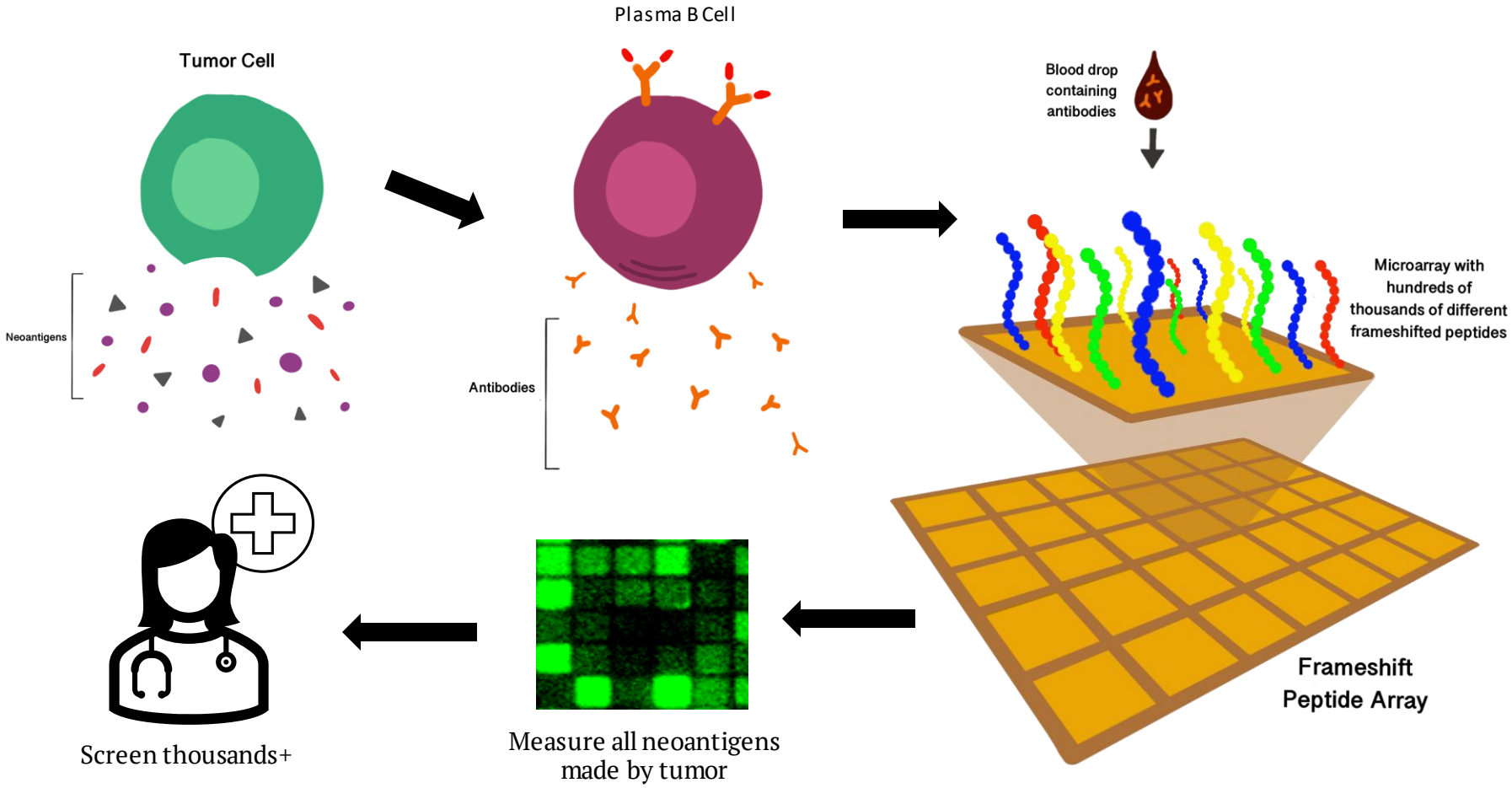
- **Microsatellite- transcription slipping** **22,367**
- **Exon Mis-Splicing and exon 1 mis-initiation** **1,171,149**
- **Intron Retention** **1,244,416**
- **W-Bumps** **445,583**
- **Non-Coding RNAs (Dark proteome)** **161,899**

Only a small % of each class will be *expressed* and *immunogenic*

There are ~2.1M Human REDNs
and ~1.4M Dog Predicted REDNs

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

REDNs Elicit Antibodies that can be Measured on Our Peptide Microchips– Enabling Searches of REDN Space



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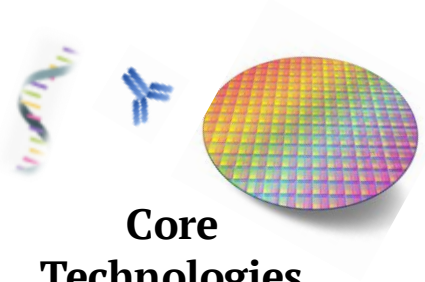
Calviri's Discovery of REDNs and Development of a Simple Assay Enable Our Unique Products

Calviri's Business Strategy: Dogs to Humans



Core Technologies & Discoveries

Enable

- 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

Facilitate & Fund

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

2023-2026

2024→

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

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

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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 5th year of the 5-year trial

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

$6.4 million

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

800 dogs

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

Clinical research sites

FLINT ANIMAL CANCER CENTER
COLORADO STATE UNIVERSITY

COLLEGE OF VETERINARY MEDICINE AND BIOMEDICAL SCIENCES
COLORADO STATE UNIVERSITY

UCDAVIS VETERINARY MEDICINE

SCHOOL OF VETERINARY MEDICINE
Advancing animal and human health with science and compassion

VACCS Preventative Cancer Vaccine Trial Tumor Results to Date

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

Conclusions:

- ***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)

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

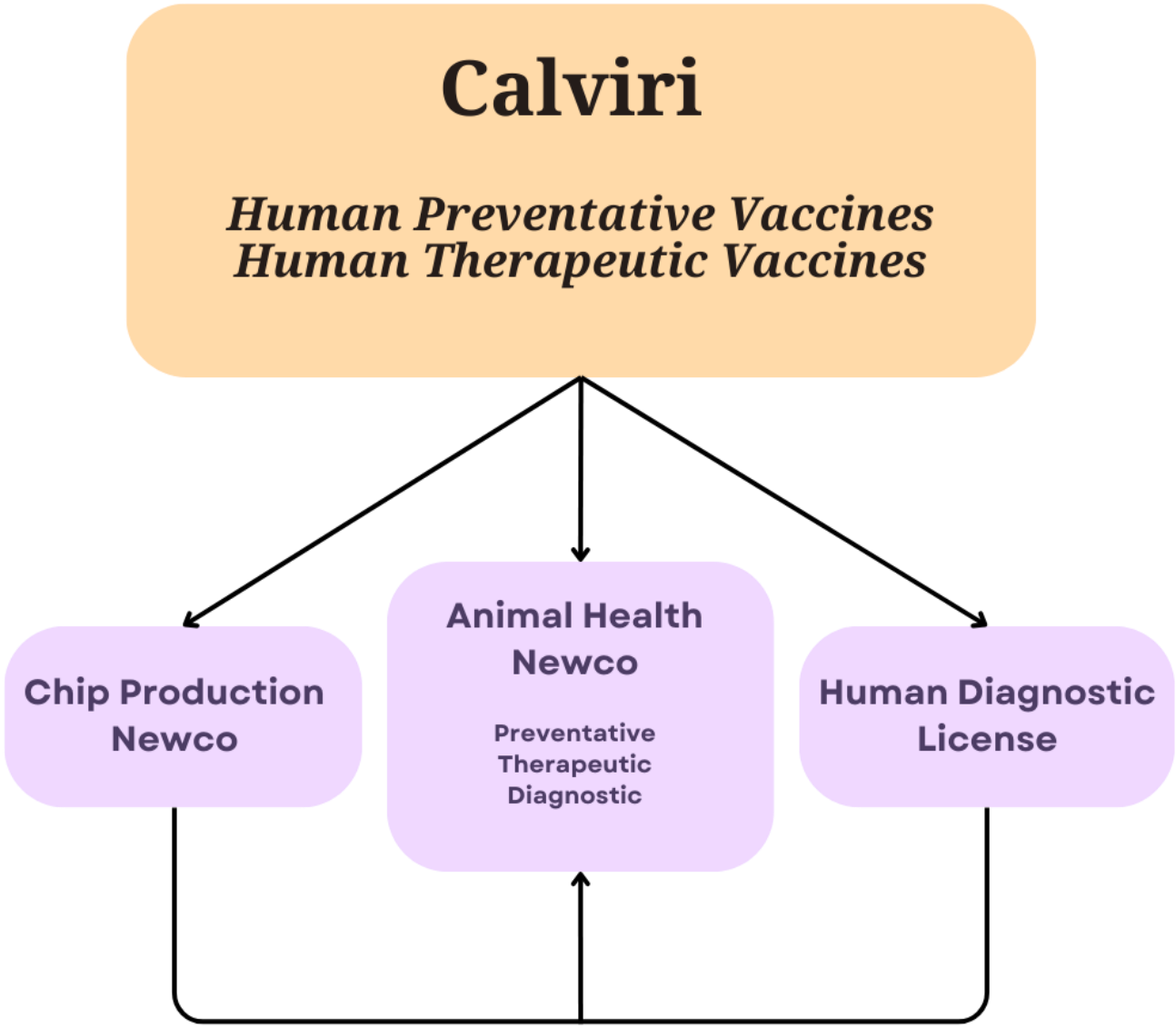
License and Commercialization by 2025

= License

Going through the sound barrier

Of CANCER

Calviri Business Plan



Calviri Today

- Formed: 2018
- Funding: $21M ($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

How Much for What?

Current Raise: $30M from Investment and Licensing

Major Uses Over 3 Years:

- Dog Preventative Cancer Vaccine Licensure Trial
- Establish Scaled Manufacturing for Licensing to Diagnostic Partner
- Human Phase 1/2 Trials
- Large Scale Demonstration of Human Diagnostic
- Prospective Sample Collections

Growing Leadership Team

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

COO

CMO

VBD

Board of Directors

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

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

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

Michael Chambers Founder Aldevron

Jeff Le Benger Executive Chairman of the board Summit Health

Scientific Advisory Board

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John Ballantyne, Ph.D.

Founder / former SO of Aldevron
>23' years experience

John Ballantyne, Ph.D., has over 23 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-adjuvanting 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 Cytyc 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: Cytyc 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 National 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.


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