January 2020
NASDAQ:ANIX

Amit Kumar
Chairman and CEO
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Forward-Looking Statements

Statements that are not historical fact may be considered forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements are not statements of historical facts, but rather reflect Anixa Biosciences' current expectations concerning future events and results. We generally use the words "believes," "expects," "intends," "plans," "anticipates," "likely," "will" and similar expressions to identify forward-looking statements. Such forward-looking statements, including those concerning our expectations, involve risks, uncertainties and other factors, some of which are beyond our control, which may cause our actual results, performance or achievements, or industry results, to be materially different from any future results, performance, or achievements expressed or implied by such forward-looking statements. These risks, uncertainties and factors include, but are not limited to, those factors set forth in "Item 1A – Risk Factors" and other sections of our most recent Annual Report on Form 10-K as well as in our Quarterly Reports on Form 10-Q and Current Reports on Form 8-K. We undertake no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law. You are cautioned not to unduly rely on such forward-looking statements when evaluating the information presented herein.

Corporate Background

General & Financial

- NASDAQ: ANIX
- Bay Area, CA Biotech
- More than 1 year of cash
- Capital Efficient Model
- No debt
- Three high value programs

Strategy: Low Cost Business Model

- Invent/in-license technology platforms
- Develop technology with partners
  - Leverage existing infrastructure of partner
  - Maintain low cash burn
- Sell, license or commercialize products

Collaborators

Cleveland Clinic

MOFFITT CANCER CENTER

THE WISTAR INSTITUTE

US. Department of Veterans Affairs

Penn Medicine ABRAMSON CANCER CENTER

MD Anderson Cancer Center | Cooper
Making Cancer History®

UNIVERSITY of MARYLAND BALTIMORE

NEW JERSEY UROLOGY
Excellence In Care

IDAHO UROLOGIC INSTITUTE

UROLOGY SAN ANTONIO

Urology CENTERS OF ALABAMA birmingham

HMU Houston Metro Urology

Genesis HEALTHCARE

potomac UROLOGY

Virtua Health

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Three High Value Programs

Dynamic Interaction Between Tumors and the Immune System

Breast Cancer Vaccine

- Immunize against α-Lactalbumin to prevent Triple Negative Breast Cancer (TNBC) and other breast cancers
- Worldwide license
- Cleveland Clinic collaboration for IND and clinical trial
- $6.2 MM DOD grant will fund pre-clinical work and two Ph 1 clinical trials

CAR-T: Cancer Immunotherapy Program

- Chimeric Endocrine Receptor T-Cell (CER-T): A new type of CAR-T
  - First indication - ovarian cancer (platform for multiple cancer indications)
  - Worldwide license
  - Moffitt Cancer Center collaboration for IND and clinical trial

Liquid Biopsy

- Non-invasive, inexpensive, and rapid early cancer detection focus
- Measure immune system (white blood cells)
- Artificial intelligence for analysis
- Many Collaborators
- Commercially launched first product for Prostate Cancer

Leadership Team

Key Members of Management

Amit Kumar, PhD, Chairman, CEO and President

- Co-Founder, Executive Chairman, Actym Therapeutics
- Member, Board of Directors, American Cancer Society
- Former President and CEO, CombiMatrix, acquired by Invitae (NASDAQ:NVTA)
- Entrepreneur in Residence, Oak Investment Partners, Senior Executive, IDEXX Laboratories (NASDAQ:IDXX)
- Co-Founder and advisor, Tacere Therapeutics (sold), Gamera BioSciences (sold), Coelocanth Corp (sold), Guava Technologies (sold), Aclara BioSciences (sold)
- Ph.D. Physical Chemistry, Caltech, Stanford; Post-doctoral Fellow Harvard

Mike Catelani, COO and CFO

- Co-Founder, Chairman, President and CFO, Tacere Therapeutics (sold)
- Board Member, CFO, Benitec Biopharma (ASX:BLT)
- CFO, Axon Instruments (sold)
- VP Finance, Media Arts Group
- Ernst & Young
- BS Sacramento State, MBA UC Davis

Board of Directors
Amit Kumar, PhD
Lew Titterton
John Monahan, PhD
Arnold Baskies, MD
David Cavalier
Emily Gottschalk

Scientific Advisory Board
Arnold Baskies, MD
Michael Shepard, PhD
Dmitry Gabrilovich, MD, PhD
Jose Conejo-Garcia, MD, PhD
Marco Davila, MD, PhD
Daniel Abate-Daga, PhD
Linda Kelley, PhD
Ian Frazer, PhD
Emanuele Ostune, Ph.D.

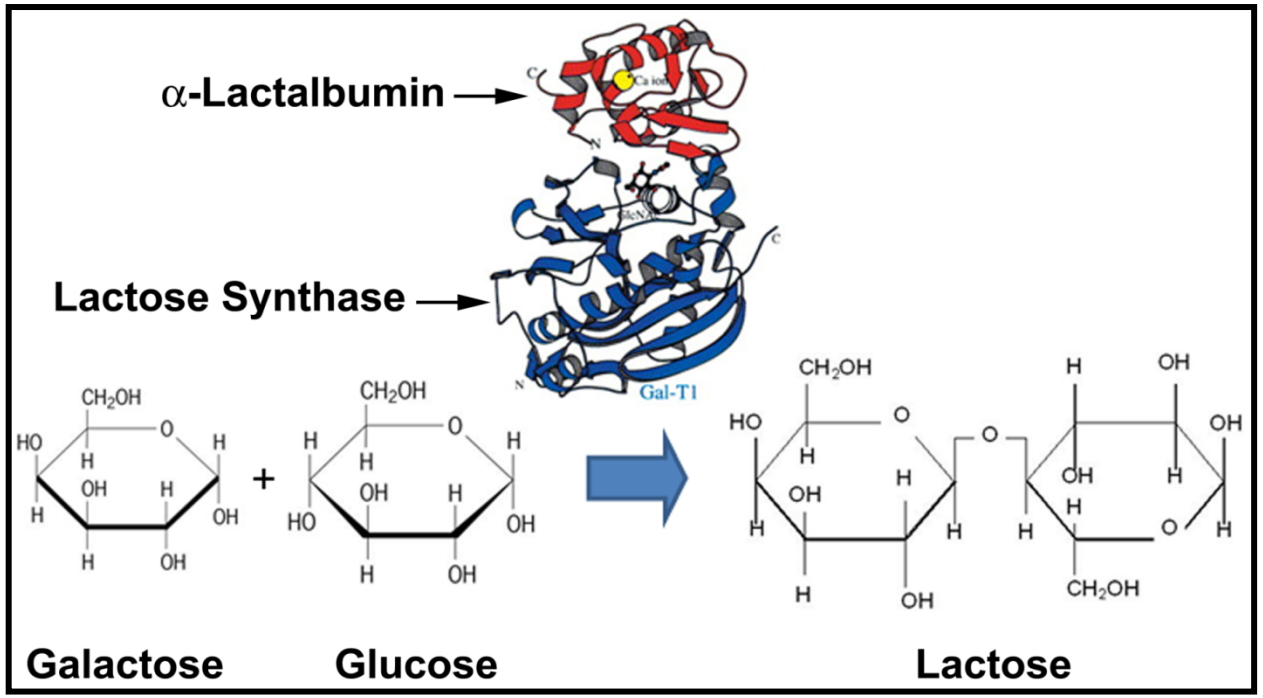
Breast Cancer Vaccine

Inventor and PI: Vincent K. Tuohy, Ph.D.

Mort and Iris November Distinguished Chair in Innovative Cancer Research, Cleveland Clinic

Retired Tissue Specific Protein

- Expressed at periods of life, but no longer expressed as we age



α-LACTALBUMIN

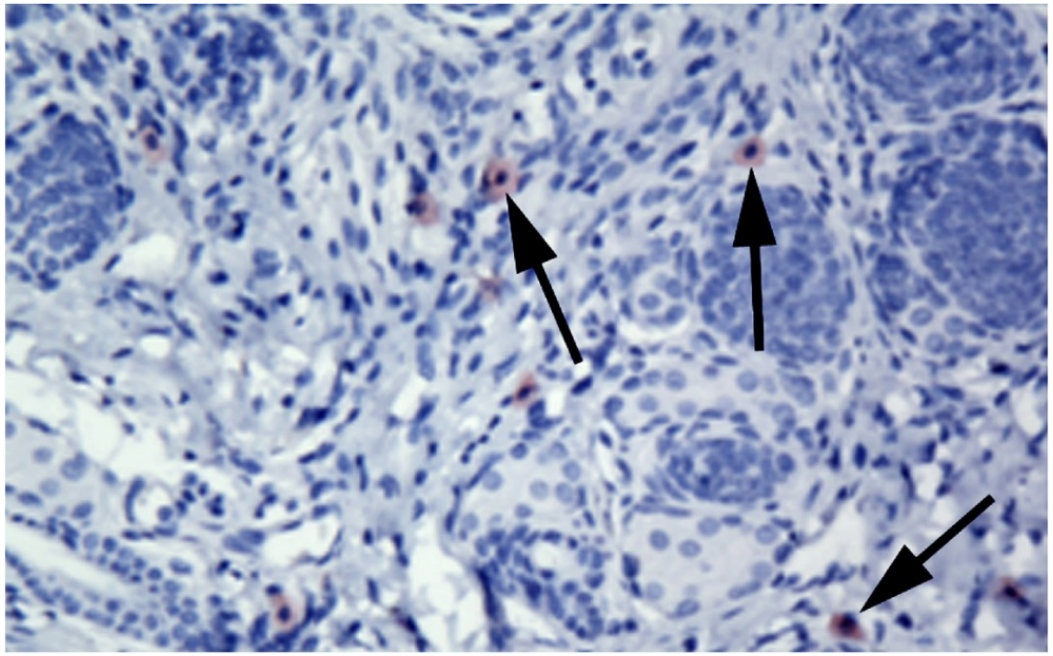
- Expressed **only** in the breast and **only** during lactation
- Expressed in tumor cells, especially Triple Negative Breast Cancer (**TNBC**)
- Our vaccine targets this retired protein
  - Once vaccinated, the patient's immune system is ready to destroy cells expressing the protein as they arise, disallowing cancer to gain critical mass

Triple Negative Breast Cancer (TNBC)

- Most aggressive form of breast cancer
- Prevalent cancer in patients with breast cancer gene (**BRCA**) mutations

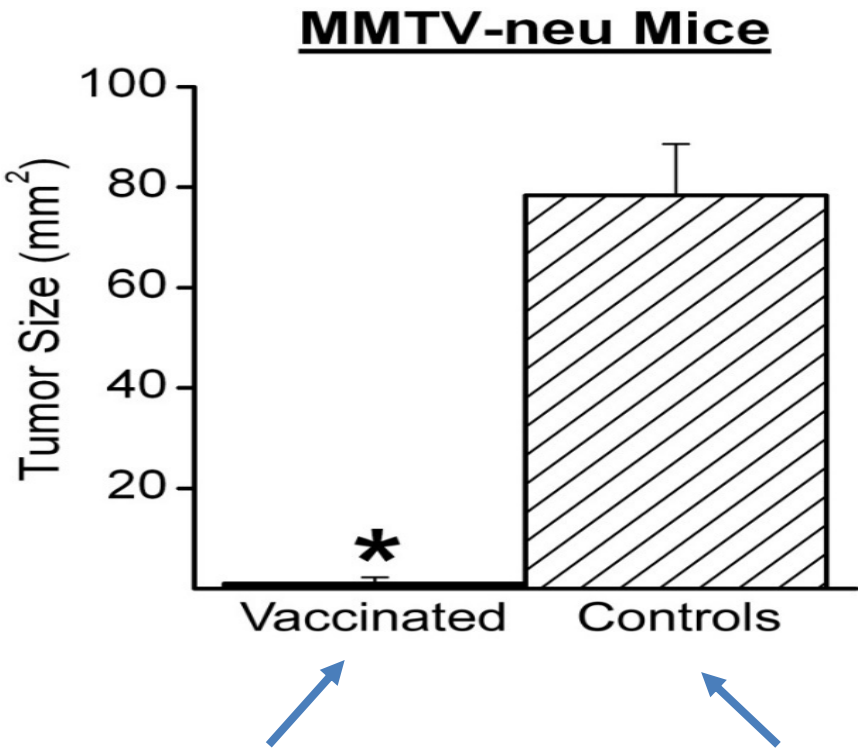
Vaccination Prevents Breast Cancer

SAFE



Vaccinated mice did not exhibit autoimmune damage, while single T-cell infiltrates were seen in non-lactating breast tissue (arrows)

EFFECTIVE



100% of α-LACTALBUMIN vaccinated mice do not develop breast cancer

80% of un-vaccinated mice developed breast cancer

Breast Cancer Vaccine Clinical Trial Plan

Funded by Department of Defense (DOD) Grant $6.2 MM

Pre-Clinical Studies

- GLP Tox
- IND filing

Phase 1a Trial

- TNBC patients who have undergone standard of care
- Will monitor pro-inflammatory T-cell response

Phase 1b Trial

- Healthy women with BRCA1 mutations
- Decided to undergo prophylactic mastectomy
- Will immunize before surgery and monitor resected tissue

Summary: Breast Cancer Vaccine

KEY ATTRIBUTES

- Cleveland Clinic collaboration
- DOD funded program; $6.2 Million
  - Pre-clinical
  - Two phase 1 clinical trials
- Pre-IND meetings with FDA completed
- Plan to file IND in 2020
- Begin first clinical trial in 2020
- Data published: *Cancers*, 2016, *8*, 56.

MARKET OPPORTUNITY (Estimates)

- **Prophylactic (preventative) vaccines are administered to all eligible, not the small number of sick patients**
- **Expect reimbursement for this vaccine to be similar to the Cervical Cancer Vaccine (approximately $400)**
- United States
  - Greater than 75 MM Women over 40
  - Greater than 150 MM Men are candidates
  - 10-20 MM aging into this category annually
- Outside US **(Billions of candidates)**
  - Developed world
  - Rest of world
- Greater than $10's of billions opportunity

Imagine a world where there is no breast cancer, and our healthcare system does not spend the billions finding and treating it, and the millions of women and a few men who do not have to die from this disease

CAR-T Technology: Background & Opportunity

CAR- Technology has made great inroads in B-Cell cancers

- **Durable responses (50-80% of patients)**
- **Multibillion dollar valuations and big pharma deals**
  - **Novartis - First approved product by FDA**
    - **Kymriah for ALL- Acute Lymphoblastic Leukemia**
    - **Second approval for DLBCL-Diffuse large B-cell Lymphoma**
  - **KITE - $12BB acquisition by GILD**
  - **JUNO - $9BB acquisition by CELG**

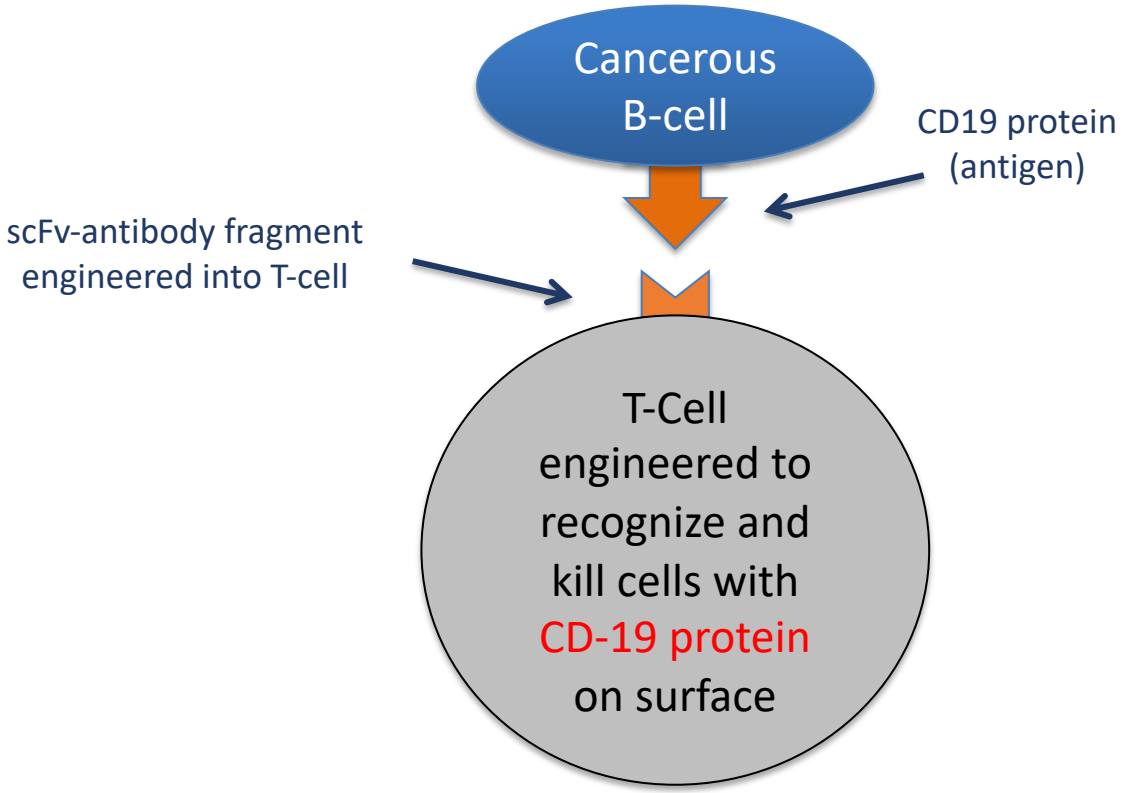
Our Opportunity

- **Conventional CAR-T has <u>not</u> worked clinically in solid tumors**

MAGIC BULLET → Anixa has a unique approach to making CAR-T work for multiple solid tumors, beginning with Ovarian Cancer

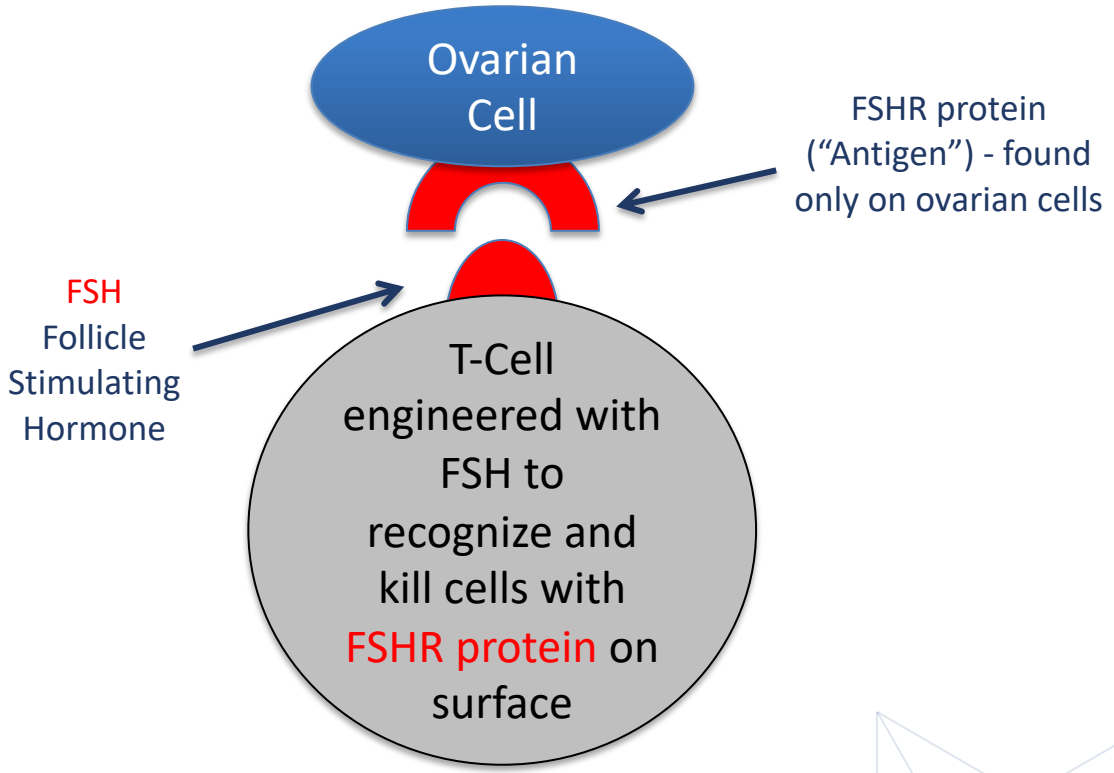
Anixa's Unique CER-T Approach for Solid Tumors

Novartis, JUNO, KITE and others working on B-Cell cancers

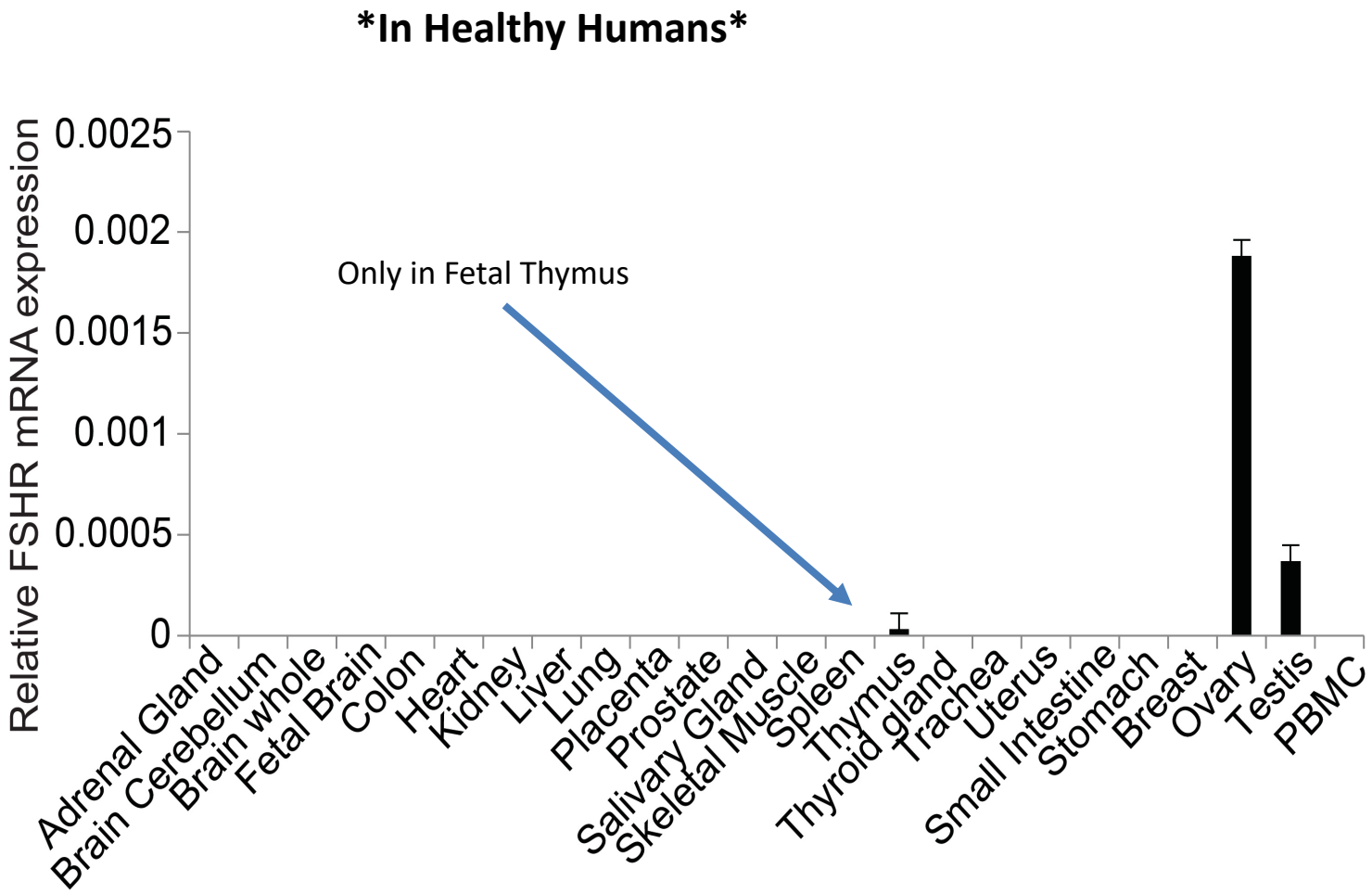


Anixa's CAR-T Program for Ovarian Cancer
FSHR- Follicle Stimulating Hormone Receptor

Chimeric Endocrine Receptor T-Cell



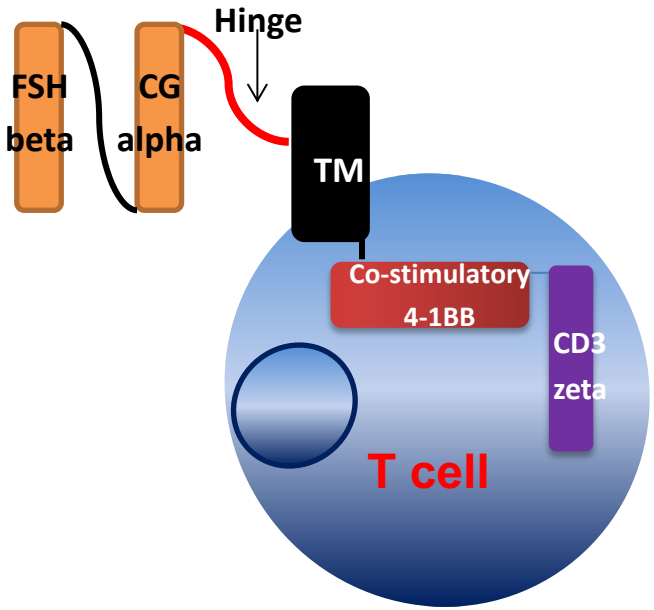
FSHR ONLY Expressed in Ovaries and Testis



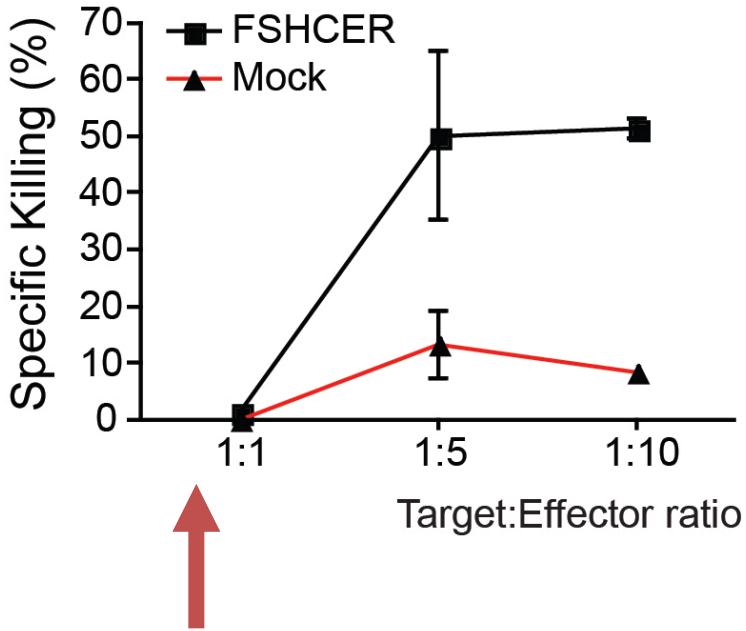
- FSHR expressed on the blood vessels of many **TUMORS**
- This therapy will be anti-angiogenic for many types of cancer, enabling a portfolio of therapies for multiple cancers

Source: Perales-Puchalt et al. "Follicle-stimulating hormone receptor is expressed by most ovarian cancers subtypes and is a safe and effective immunotherapeutic target." **Clinical Cancer Research**. 2017.

Pre-Clinical Data

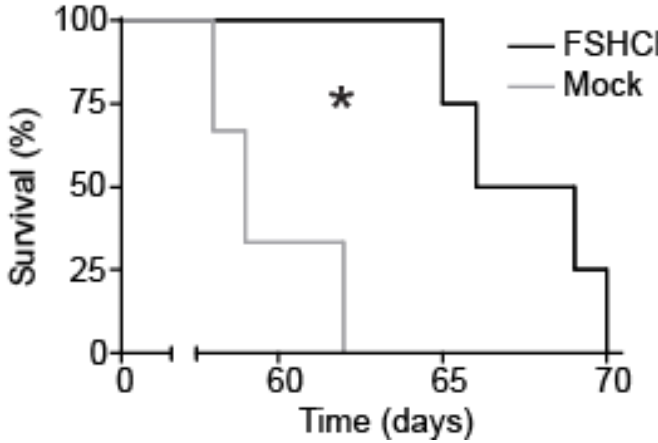


FSH-Targeted chimeric receptors re-direct primary human T cells against FSHR+ ovarian cancer cells

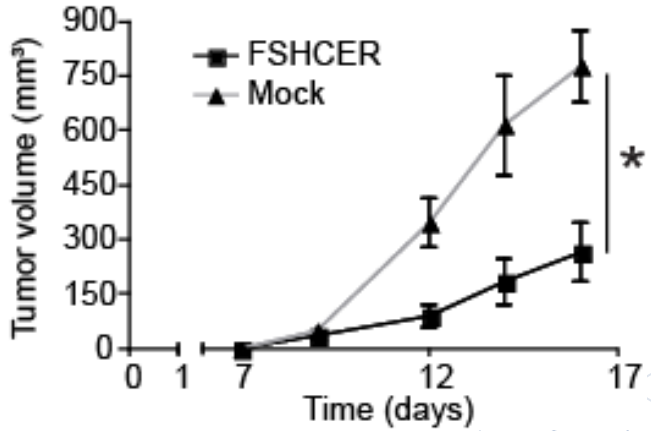


Ovarian Cancer

FSH-re-directed mouse T cells effectively target FSHR+ tumors *in vivo*



N=15 mice/group
3 independent experiments



Breast Cancer

Source: Perales-Puchalt et al. "Follicle-stimulating hormone receptor is expressed by most ovarian cancers subtypes and is a safe and effective immunotherapeutic target." **Clinical Cancer Research**. 2017.

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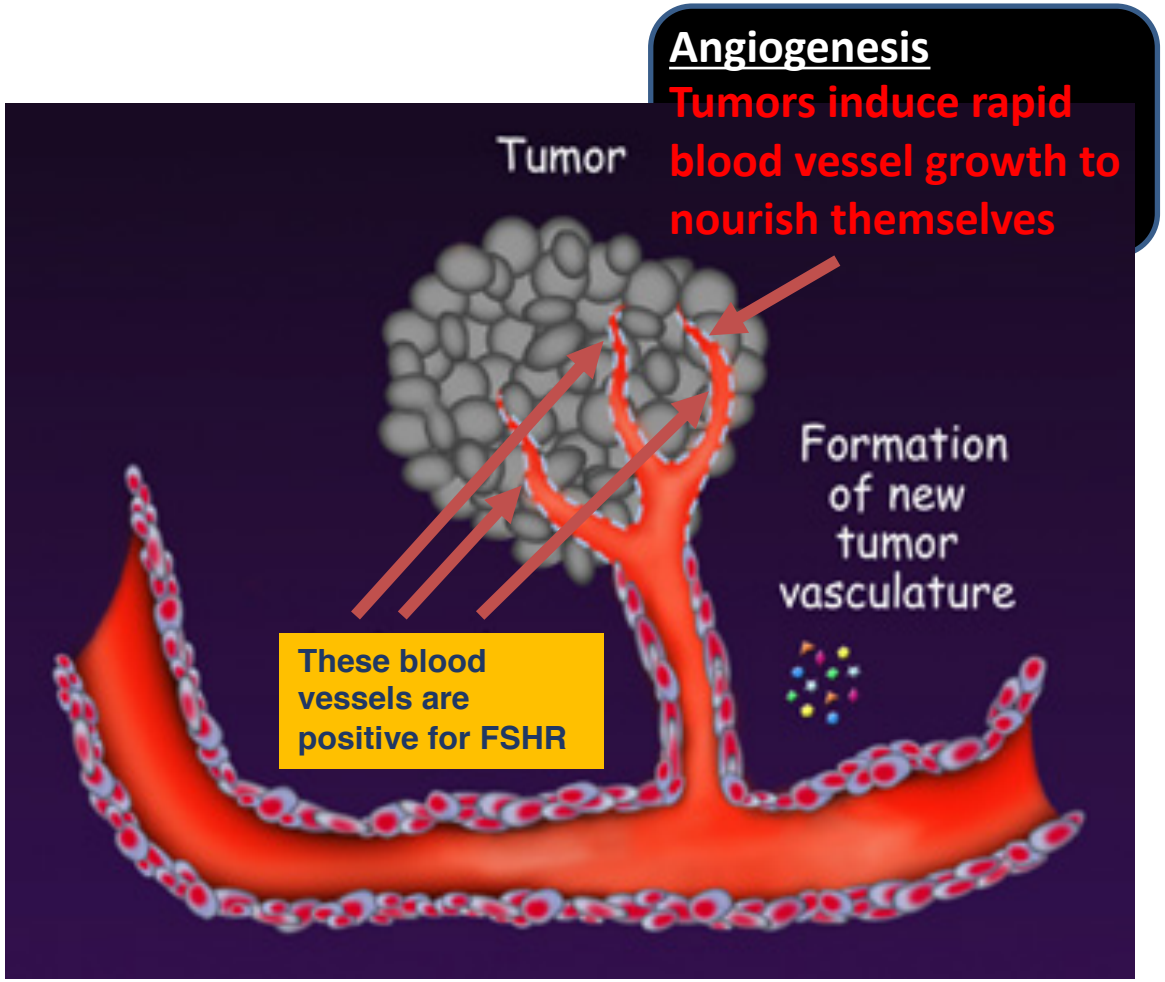
Our Magic Bullet

- **Many tumors have blood vessels where FSHR is expressed even though healthy tissue does not show such expression**
  - Physiologically, FSHR must be helpful in enabling tumors to create vasculature
  - Outside of the tumor margin, FSHR on blood vessels disappears
- **Our FSHR targeted CAR-T may destroy tumor vasculature and starve or shrink the tumor**
- **CAR-T mediated cell death may be more powerful than other anti-angiogenesis drugs**
- **First anti-angiogenic CAR-T drug**
- **The CAR-T cells may not be susceptible to the highly suppressive TME**
- **As the CAR-T cells are destroying vasculature, they make it more leaky, enabling simultaneous, localized delivery of other agents including chemotherapy**
- **Anti-angiogenesis drugs are a multi-billion dollar class of drugs, with Avastin the leader with 2017 sales of $7BB**



Tumors expressing FSHR on vasculature:
Lung, Breast, Prostate, Colon, Head & Neck, Pancreas, Liver, Renal, Ovarian, and others

Summary: CAR-T Program

- Exclusive worldwide license from The Wistar Institute
  - Tested human CAR-T in immunocompromised mice against human ovarian cancer
  - Tested murine CAR-T in immunocompetent mice against murine ovarian cancer
  - Tested human CAR-T in immunocompromised mice against human breast cancer (proof of concept)

- Pre-IND work at Moffitt Cancer Center led by highly experienced team

- Ovarian Cancer Clinical Trial
  - Single site, open label, dose-escalation trial
    - Moffitt Cancer Center
    - Safety focused trial with window to efficacy
  - Pre-IND meeting with FDA occurred in October 2018
  - Anticipate IND filing end of 2020
  - Clinical trial to commence 2021

WE BELIEVE OUR CAR-T WILL WORK IN SOLID TUMORS, ESPECIALLY OVARIAN CANCER, WHILE OTHERS HAVE FAILED

1. **FSHR- UNIQUE TARGET**
2. **FSH- NATURAL LIGAND- NOT SYNTHETIC**
3. **ANTI-ANGIOGENIC SYNERGY**

- Data published: *Clinical Cancer Research*, 23(2)January 15, 2017, 441-453

Early Cancer Detection – Liquid Biopsy

Anixa is developing a blood test for early cancer detection called Cchek™

Cchek™
Early Cancer Detection

Goal: To determine a patient's cancer status from a simple blood draw without a biopsy

Competing Liquid Biopsy Approaches

- Circulating tumor DNA (ctDNA)
- Circulating tumor Cells (CTCs)
- Circulating tumor Exosomes
- Other biomarkers coming directly from tumor

All these approaches require the tumor to be large enough to shed these markers into the blood stream

All these approaches tend to be very expensive

Anixa's Orthogonal Approach

- We measure white blood cells to determine if a patient is tumor bearing
- White blood cells make up the human immune system
- We are letting the immune system amplify and signal to us the presence of a tumor, just like it signals the presence of an infection
- Flow cytometry with our artificial intelligence is very inexpensive and quick

Artificial Intelligence (AI) Analysis

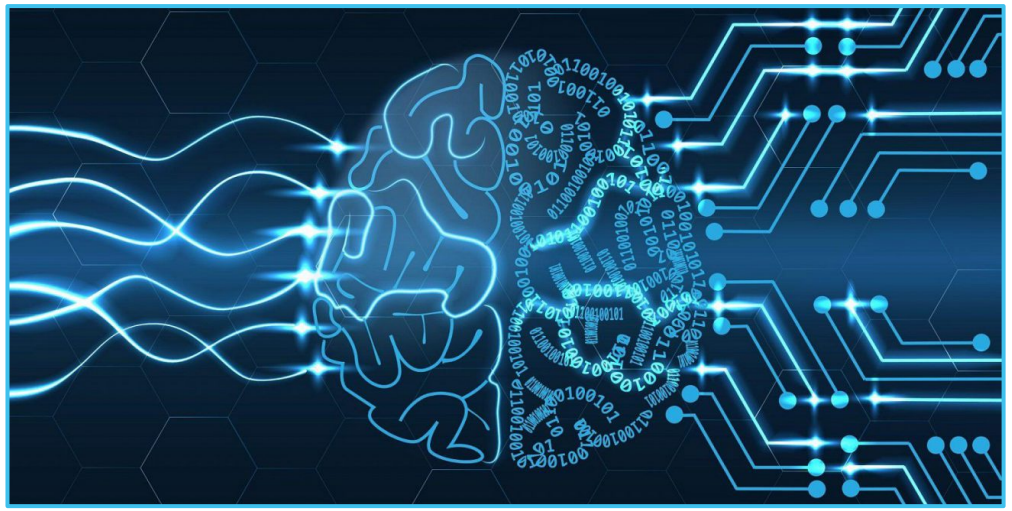
Training

Calls

Neural Network

Normal Patient Samples

Cancer Patient Samples



Patient Sample

Malignancy or Normal

Anixa's Cchek™ Early Cancer Detection Technology

Early Screening Studies:
Multiple Cancer Types
Stages 1-4

Total Samples: 248
Training Samples: 150
Blind Samples: 98

Sensitivity: 87% (41 of 47 right)
Specificity: 88% (45 of 51 right)

Multiple Samples			Single Sample
Breast	Prostate	Lung	Osteosarcoma
Colon	Melanoma	Ovarian	Leiomyosarcoma
Pancreas	Liver	Thyroid	Liposarcoma
Bladder	Cervical	Endometria	Vulvar
Gastric	Head & Neck	Testicular	Appendiceal

Breast Cancer Screening Study:
Stages 1-2 only

Total Samples: 179
Training Samples: 132
Blind Samples: 47

Sensitivity: 89% (25 of 28 right)
Specificity: 95% (18 of 19 right)

Prostate Cancer Screening Study:
All Gleason Scores
Internal Study

Total Samples: 160
Training Samples: 100
Blind Samples: 60

Sensitivity: 90% (9 of 10 right)
Specificity: 96% (48 of 50 right)

Prostate Cancer Screening Study:
Stages 3-4
Memorial Sloan Kettering

Total Samples: 210
Training Samples: 137
Blind Samples: 73

Sensitivity: 92% (33 of 36 right)
Specificity: 92% (34 of 37 right)

Cchek™ Early Cancer Detection -Prostate Cancer Confirmation (PCC)

- Prostate cancer typically diagnosed by elevated PSA level and prostate examination, followed by biopsy
- 1-1.5 MM prostate biopsies in the US annually
  - Nearly 65%-90% are negative
- Cchek™-PCC can distinguish cancer from other benign conditions, such as BPH
  - Could eliminate nearly half of all unnecessary biopsies

Prostate Cancer Confirmation Study:
Predicting prostate cancer in at-risk men

R&D Study

Total Samples: 271
Training Samples: 154
Blind Samples: 117

Sensitivity: 92% (47 of 51 correct)
Specificity: 41% (27 of 66 correct)

CLIA Validation

Total Samples: 239
Training Samples: 110
Blind Samples: 129

Sensitivity: 95.9% (20 of 21 correct)
Specificity: 45.4% (49 of 108 correct)

Anixa's Liquid Biopsy

- We monitor the patient's white blood cells to detect tumors
  - We let the the patients body tell tell us there is a tumor
  - We do NOT measure tumor DNA, circulating tumor cells or tumor exosomes
- We combine flow cytometry and artificial intelligence to perform the analysis
- May work for all cancers
- Rapid turnaround time
- Cost to run test is **less than $100**

Launched prostate test in Q4 2019

Long term vision-pan cancer screening test

Anixa's Commercial Partnership and Monetization Strategy and Potential Deal Structures

Vaccine and CAR-T therapy

- Drugs are developed through a three phase human trial process
- We have capital to complete the Phase 1 studies for both the BC vaccine and the CAR-T
- Phase 2 and 3 will take more money and more time
- We plan to partner and monetize both programs once we have Phase 1, first in human data, if it is positive
- Partnerships are very common in therapy development
- Typical Partnership is comprised of the following, in exchange for getting access to the product:
  - Upfront license payment
  - Funding for support of clinical trial costs
  - Milestones based on successes
  - Revenue share/royalty
- The size of the payments above depend on the quality of the data, the size of the market, and overall value of the product

Cchek™ Early Cancer Detection Diagnostic

- Partnership dynamics for diagnostics are different than for drugs due to the risk profiles, the potential margins and the rate and process for market penetration
- Our strategy after launch of our first test for prostate cancer is to demonstrate three things:
  - CLIA Launch
  - Reimbursement
  - KOL experience and reference
- Then we would partner with a large national scale laboratory, that has sales force, distribution, and marketing infrastructure
- Deal structure will be similar to that for drugs but the numbers are typically smaller, but dependent on the overall value of the product

Anixa's Value-Creating Near-Term Milestones

Breast Cancer Vaccine
- Filing of IND for clinical trials- 2020
- Approval of IND by FDA
- Patient recruitment
- First patient dosed and initiation of clinical trial
- Data Release

Diagnostics Program
- Commercial launch of Cchek™-Prostate Cancer
- Reimbursement Activity
- Key Opinion Leader Use
- Scientific presentations and publications
- Strategic alliances

CAR-T Program
- Filing of IND for clinical trial- 2020
- Approval of IND by FDA
- Patient recruitment
- First patient dosed and initiation of clinical trial
- Clinical Data Release
- Initiate pre-clinical work on other tumors - Magic Bullet

Corporate Activity
- Investor relations
- Raise visibility, market capitalization and liquidity
- Increase institutional ownership
- Garner additional analyst coverage
- No immediate need to do a financing deal
- If we raise capital, a little goes a long way with our low-cost, leverageable strategy