UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **March 21, 2024**

ANIXA BIOSCIENCES, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-37492**	**11-2622630**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

3150 Almaden Expressway, Suite 250 San Jose, CA	**95118**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: **(408) 708-9808**

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation to the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.01 per share	ANIX	The NASDAQ Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 5.07 Submission of Matters to a Vote of Security Holders.

On March 21, 2024, Anixa Biosciences, Inc. (the "Company") completed its 2024 annual meeting of stockholders (the "Annual Meeting"). The number of shares of stock entitled to vote at the Annual Meeting was 31,711,753 shares of common stock (the "Voting Stock"). The number of shares of Voting Stock present or represented by valid proxy at the Annual Meeting was 18,521,786 shares. At the Annual Meeting, the Company's stockholders (i) re-elected Dr. Amit Kumar, Dr. Arnold Baskies, Emily Gottschalk, and Lewis H. Titterton, Jr. as directors, (ii) approved, on a non-binding, advisory basis, the Company's executive compensation, and (iii) ratified the appointment of Haskell & White LLP as the Company's independent registered public accounting firm for the fiscal year ending October 31, 2024. The following is a tabulation of the voting on the proposals presented at the Annual Meeting:

Proposal No. 1 – Election of directors

Dr. Amit Kumar, Dr. Arnold Baskies, Emily Gottschalk, and Lewis H. Titterton, Jr. were each re-elected to serve until the 2025 annual meeting of stockholders or until their successors are elected and qualified or until their earlier resignation or removal. The voting results were as follows:

Nominee	Shares Voted For	Shares Withheld	Broker Non-Vote
Dr. Amit Kumar	7,894,499	82,654	10,544,633
Dr. Arnold Baskies	7,857,006	120,147	10,544,633
Emily Gottschalk	7,853,085	124,068	10,544,633
Lewis H. Titterton, Jr.	7,718,162	258,991	10,544,633

Proposal No. 2 – Approval, by non-binding advisory vote, of the Company's executive compensation

The Company's executive compensation, by non-binding advisory vote, was approved. The voting results were as follows:

Votes For	Votes Against	Abstentions	Broker Non-Votes
6,010,385	1,843,353	123,415	10,544,633

Proposal No. 3 – Ratification of the appointment of independent registered public accounting firm

The appointment of Haskell & White LLP as the Company's independent registered public accounting firm for the fiscal year ending October 31, 2024 was ratified. The voting results were as follows:

Shares Voted For	Shares Voted Against	Shares Abstaining	Broker Non-Vote
18,390,227	80,392	51,167	-

Item 7.01 Regulation FD Disclosure.

Attached as Exhibit 99.1 to this Current Report is the form of presentation of the Company which was used by management at its Annual Meeting. This presentation may be used by the Company in the future at meetings with investors, analysts or others, in whole or in part and possibly with modifications from time to time.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits

The following exhibits are filed with this Current Report on Form 8-K:

Exhibit No.	Description
99.1	Presentation
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: March 22, 2024

ANIXA BIOSCIENCES, INC.

By: */s/ Michael J. Catelani*
Name: Michael J. Catelani
Title: President, Chief Operating Officer and Chief Financial Officer

Exhibit 99.1


anixa
BIOSCIENCES
Dr. Amit Kumar
Chairman and CEO
NASDAQ:ANIX
March 21, 2024
Presentation at Annual Shareholder Meeting

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.

Anixa Snapshot

Clinical-stage company developing first-in-class products to treat & prevent cancer

Robust Pipeline

Strong Clinical Data

Strong Financial Profile

Key Partnerships

Significant TAM Opportunity

Clinical Programs & Development Partnerships

THERAPEUTIC AREA	MECHANISM OF ACTION	INDICATION	GEOGRAPHIC RIGHTS	STAGE	UPCOMING MILESTONES	PARTNERS
Oncology	Vaccine	Breast Cancer	Global	Phase 1	Additional Phase 1a,b,c data releases	Cleveland Clinic; U.S. Department of Defense
Oncology	Vaccine	Ovarian Cancer	Global	Pre-clinical	Initiate IND enabling studies	Cleveland Clinic; NIH National Cancer Institute
Oncology	CAR-T Therapeutic	Ovarian Cancer / Other Solid Tumors	Global	Phase 1	Periodic data releases (enrollment based)	Moffitt Cancer Center; The Wistar Institute

VACCINE PROGRAM

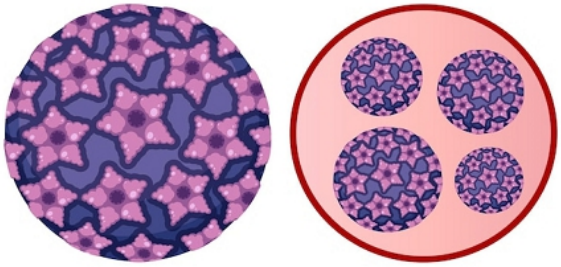
Background

Anixa

Preventative Cancer Vaccines Have Failed

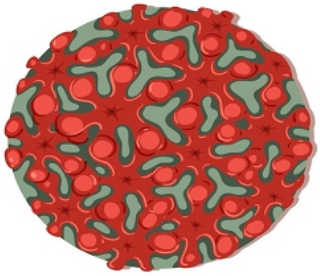
…except for cancers driven by infectious agents.

Human Papillomavirus (HPV)



Human papillomavirus (HPV) is a common sexually transmitted virus that can cause genital warts and several types of cancer, including cervical, vaginal, vulvar, anal, penile, and oropharyngeal (throat) cancer.

Hepatitis B Virus (HBV)

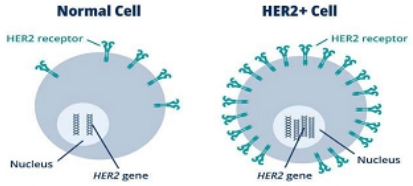


Hepatitis B is caused by the hepatitis B virus (HBV). Hepatitis B is a viral infection that attacks the liver and can cause severe liver damage, liver cancer, and death. It spreads through contact with infected blood, unprotected sex, and from mother to baby during childbirth.

While these vaccines are generally called Cancer vaccines, from a molecular standpoint, they are really vaccines against infections.

Why Have Preventative Cancer Vaccines Failed?

Cancer vaccines typically target proteins overexpressed on tumors.



Mechanisms exist to limit immune response against self-proteins.

- Proteins overexpressed on cancer cells (Self-Proteins) are also ubiquitously expressed on many healthy tissues
  —*Examples : Her-2 Neu, Mesothelin, Muc-1*
- It is challenging to overcome Thymic Deletion and other mechanisms, many yet to be discovered
- These mechanisms exist to prevent autoimmune disorders

Autoimmune disorders are created by vaccination.

- With powerful adjuvants, we may be able to create suitable immune responses against self-proteins
- If we create immune response against over-expressed self protein, we also create autoimmune disorders against healthy tissues and organs

  —*OK for therapeutics because we can withdraw drug if side-effects are intolerable*

  —*Not OK for preventative vaccines- because once you induce the immune system, we can't pull it back*

RETIRED TISSUE-SPECIFIC PROTEINS HYPOTHESIS

A New Paradigm for Prophylactic Cancer Vaccines

Proposed by the late Dr. Vincent Tuohy, Cleveland Clinic

Retired Tissue-Specific Proteins for Prophylactic Cancer Vaccines

Retired tissue-specific protein definition:

- Protein that is expressed, in a particular tissue, at certain times in life for a particular function
- After function is no longer necessary, that protein is no longer expressed
- The protein is again expressed in emerging cancer cells

Why is this a good antigen for prophylactic vaccines?

- Vaccination is performed at an age after which that function is no longer needed
- Protein is expressed only on cancer cells and no healthy cells and tissue
- Therefore, we can induce an immune response against cancer but no autoimmune response against healthy tissues or organs

The molecular approach has never been utilized for vaccines

Breast Cancer Vaccine

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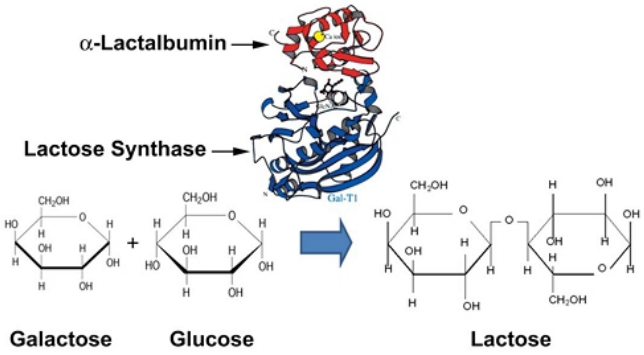
Breast Cancer Vaccine: Retired Tissue Specific Protein

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

TNBC Overview

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

Proof of Concept* -Published in 2012

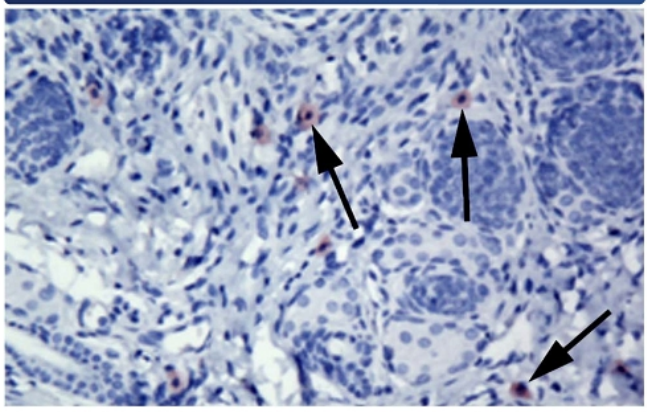
- After vaccination mice were mated and allowed to have a litter.
- The pups were perfectly normal at birth.
- **Mothers were unable to produce milk.**

This proves that vaccination targeting a-lactalbumin enables the immune system to destroy all cells producing that protein.

*SOURCE: AMERICAN J. OF PATHOLOGY, **181**, SEPTEMBER 2012, 775-783.

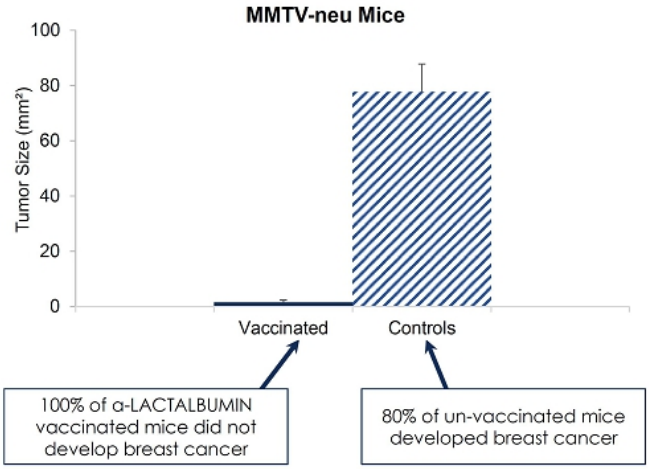
Pre-Clinical Studies: Vaccination Prevents Breast Cancer

Well-Tolerated



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

Robust Pre-Clinical Response



Data published: Cancers, 2016, 8, 56.

Phase 1 Trial

Conducted by Cleveland Clinic, funded by U.S. Department of Defense (DOD)

An open-label Phase 1 dose-escalation trial

Design	Phase 1a (in progress)	Phase 1b (in progress)	Phase 1c (enrollment open)
Participants will receive three vaccinations, each two weeks apart, and will be closely monitored for side effects and immune response	▪ 18-24 Patients who have been treated for TNBC ▪ Safety will be monitored ▪ Immune Response will be monitored ▪ Maximum Tolerated Dose ("MTD") determined	▪ Healthy women w/mutations ▪ Chosen to undergo prophylactic mastectomy ▪ Vaccinate before surgery and evaluate immune response and resected tissue ▪ **Unique opportunity to garner supplemental data after studying breast tissue to determine if T cells are surveilling the tissue without any visible cancer tumors**	▪ **Additional cohort combining vaccine with Keytruda** ▪ Patients treated for TNBC ▪ Combine Keytruda w/ vaccine to evaluate if there is synergy

Cleveland Clinic

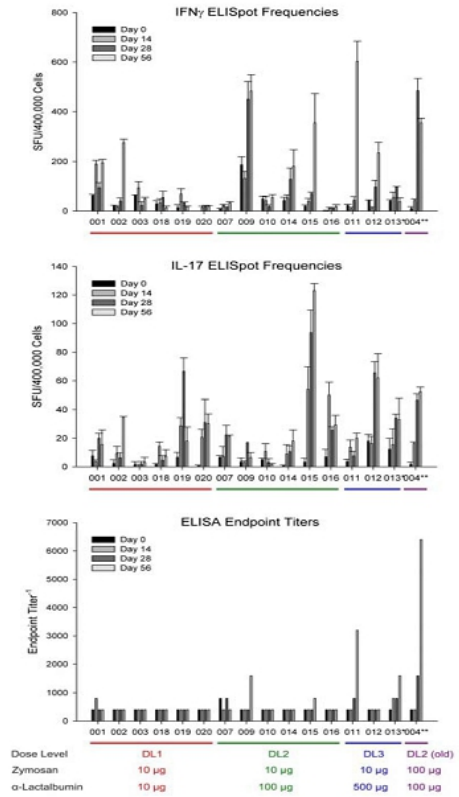
DOD

Positive Clinical Results

- Enrollment of women who have had TNBC and have undergone standard of care, but are at risk of recurrence
- 42% of TNBC survivors will relapse within 5 years
- MTD reached
- Data from all vaccinated women tested to date presented at San Antonio Breast Cancer Symposium in December 2023
- 25 patients dosed through March 2024

- **No safety concerns**
- **Immune responses observed at all dose levels**
- **All patients had some immune response**
- **Intensity of responses varied with patients**

First 16 Patients



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Breast Cancer Vaccine: A Significant Market Opportunity

- Successive to appropriate clinical trials, a prophylactic (preventative) vaccines may be eventually administered to the total eligible population
- Multi-billion Dollar Market opportunity

U.S. *(Total Eligible Population)*	Outside U.S. *(Potential Future Candidates)*
▪ Over 3.8 MM breast cancer survivors in the US[1] ▪ Millions more harbor mutations placing them at high risk ▪ More than 80 million women are currently 40 or older in the U.S. alone o Millions more age into this group annually	▪ Tens of millions of women who are breast cancer survivors ▪ Large numbers of women harbor high risk mutations ▪ Approximately 1.4 billion women are 40 and older outside the U.S.

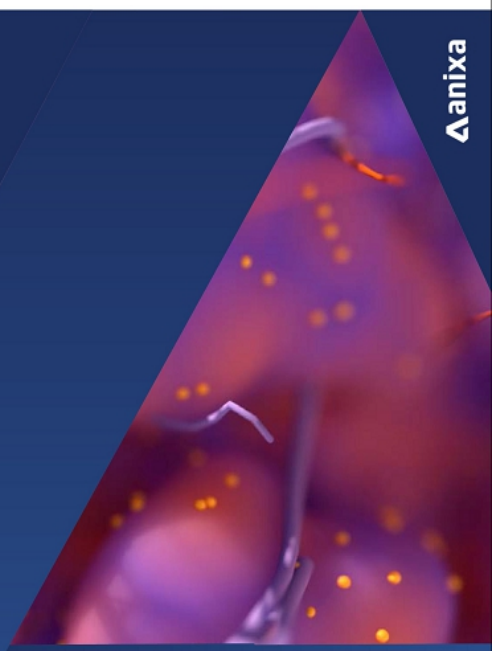
If this vaccine works as we hope and expect, every woman in the world may be eligible

1) National Cancer Institute.

Thoughts About Adaptive Phase 2/3 Trial

- Multiple Sites (10-20)- Academic as well as community (including sites that may enable diverse group of participants)
- Roughly 600 TNBC Survivors (final numbers to be determined)
  - —*Standard of Care (SOC) + Vaccine*
  - —*SOC only*
- Randomized but not blinded
- Efficacy based on improvement in invasive disease
  - —*Disease-free survival above SOC*
- Five-year duration but with interim views
- Could extend size of trial to achieve registrational data

Ovarian Cancer Vaccine



Novel Target: ED-AMHR2

Also a retired tissue-specific self-protein

Collaboration	Cleveland Clinic
Funding & Collaboration	NIH NATIONAL CANCER INSTITUTE

- Extracellular domain of the anti-mullerian hormone receptor 2 (ED-AMHR2) is primarily expressed in the ovaries, **but disappears as a woman reaches and advances through menopause**
- AMHR2 is expressed again in majority of ovarian cancers, as well as some other gynecological malignancies
- If we properly immunize a woman against this protein, after she has reached menopause, we should be able to prevent the occurrence of ovarian cancer
- Majority of ovarian cancer diagnoses occur after menopause

- NCI-PREVENT Program supporting pre-clinical development through IND submission
- If vaccine works as we hope and expect, once approved, every woman in the world past menopause may be a candidate
- Multi-billon dollar market opportunity
- Pre-clinical data published[1]

1) Cancer Prev. Res. 2017, 10(11); 612-624

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Additional Thoughts on Vaccines

- We may be able to use the Breast Cancer Vaccine in the neo-adjuvant setting
  - *—Animal data shows that the the vaccine will inhibit growth in 4T1 Tumors*
  - *—Could we use biopsy and IHC to verify alpha-lactalbumin expression before utilization?*
- Ovarian Cancer Vaccine is in Pre-Clinical Development in a collaboration between Cleveland Clinic and NCI
  - *—NCI PREVENT- evaluating peptide and mRNA versions*
  - *—PI is Dr. Robert Shumaker at NCI*
  - *—PI is Dr. CV Rao at U. of Oklahoma*
- Can we discover suitable Retired Tissue-Specific Proteins for other broad cancer indications (Lung, Prostate, Colon)

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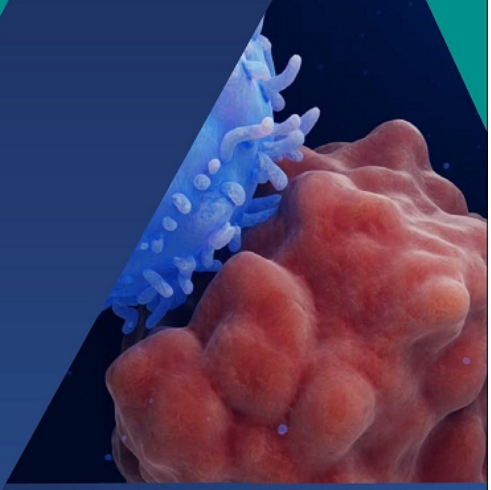
THERAPEUTIC CAR-T PROGRAM

Ovarian Cancer



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CAR-T Technology

Background & opportunity

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Chimeric Antigen Receptor T cell

CAR- T 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 Acute Lymphoblastic Leukemia (ALL)
    - Second approval for Diffuse large B-cell Lymphoma (DLBCL)
  - KITE - $12BB acquisition by GILD
  - JUNO - $9BB acquisition by CELG

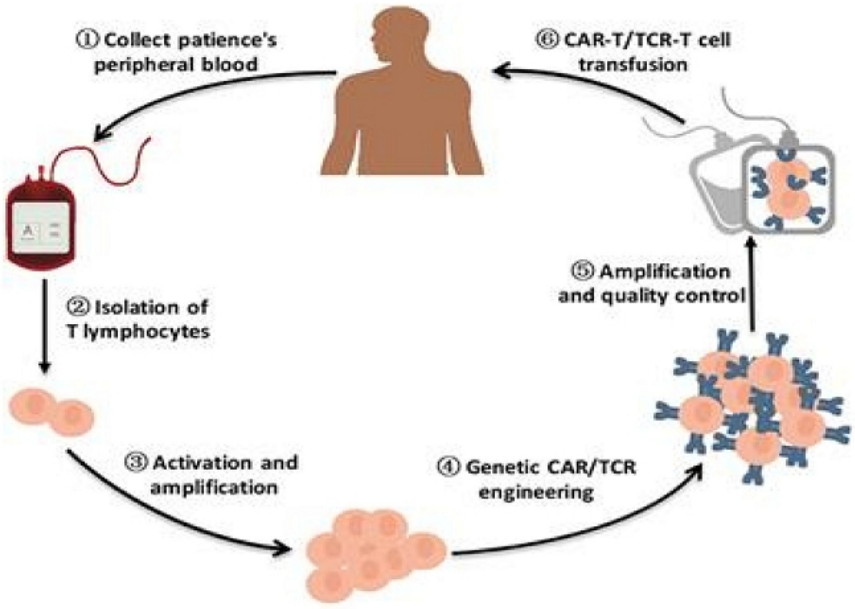
Our Opportunity

- Conventional CAR-T has not worked clinically in solid tumors

Our Unique Approach

- Anixa has a novel technology for making CAR-T work in multiple solid tumors, beginning with Ovarian Cancer

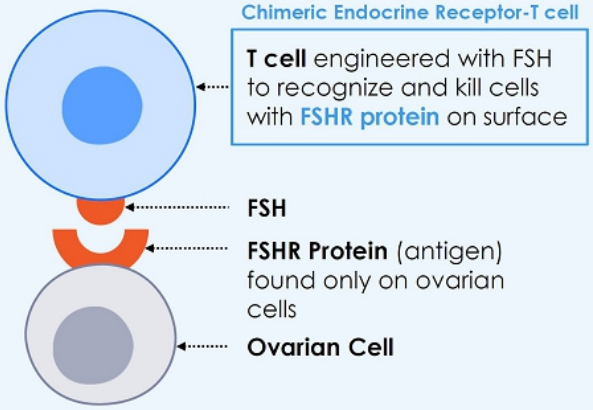
CAR-T Procedure: Chimeric Antigen Receptor-T cell



Anixa's Unique & Targeted CER-T Approach for Solid Tumors

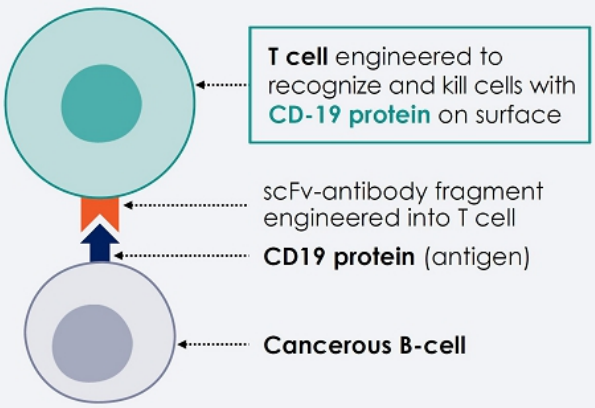
Anixa's CAR-T Program for Ovarian Cancer

Follicle Stimulating Hormone Receptor ("FSHR")-mediated CAR-T Technology

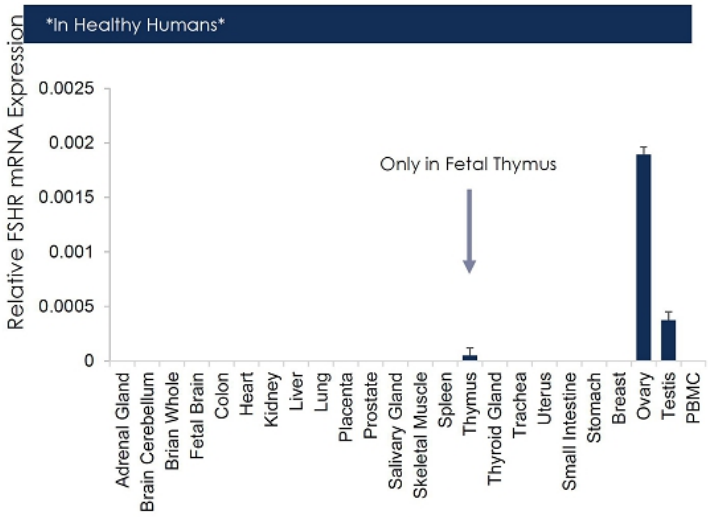


Other CAR-T Programs

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



FSHR ONLY Expressed in Ovaries and Testes and Tumor Blood Vessels



The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Expression of Follicle-Stimulating Hormone Receptor in Tumor Blood Vessels

Aurelian Radu, Ph.D., Christophe Pichon, Ph.D., Philippe Camparo, M.D., Martine Antoine, M.D., Yves Allory, M.D., Anne Couvelard, M.D., Gaëlle Fromont, M.D., Mai Thu Vu Hai, Ph.D., and Nicolae Ghinea, Ph.D.

ABSTRACT

BACKGROUND

In adult humans, the follicle-stimulating hormone (FSH) receptor is expressed only in the granulosa cells of the ovary and the Sertoli cells of the testis. It is minimally expressed by the endothelial cells of gonadal blood vessels.

METHODS

We used immunohistochemical and immunoblotting techniques involving four separate FSH-receptor-specific monoclonal antibodies that recognize different FSH receptor epitopes and in situ hybridization to detect FSH receptor in tissue samples from patients with a wide range of tumors. Immunoelectron microscopy was used to detect FSH receptor in mouse tumors.

RESULTS

In all 1336 patients examined, FSH receptor was expressed by endothelial cells in tumors of all grades, including early T1 tumors. The tumors were located in the prostate, breast, colon, pancreas, urinary bladder, kidney, lung, liver, stomach, testis, and ovary. In specimens obtained during surgery performed to remove tumors, the FSH receptor was not expressed in the normal tissues located more than 10 mm from the tumors. The tumor lymphatic vessels did not express FSH receptor. The endothelial cells that expressed FSH receptor were located at the periphery of the tumors in a layer that was approximately 10 mm thick; this layer extended both into and outside of the tumor. Immunoelectron microscopy in mice with xenograft tumors, after perfusion with anti–FSH-receptor antibodies coupled to colloidal gold, showed that the FSH receptor is exposed on the luminal endothelial surface and can bind and internalize circulating ligands.

CONCLUSIONS

FSH receptor is selectively expressed on the surface of the blood vessels of a wide range of tumors. (Funded by INSERM.)

From Mount Sinai School of Medicine, New York (A.R.); and INSERM Unité 753, Villejuif (C.P.), Val-de-Grâce Hospital, Paris (P.C.), Tenon Hospital, Paris (M.A.), INSERM Unité 955-Eq 07, Université Paris-Est, Créteil (Y.A., M.T.V.H., N.G.), Beaujon Hospital, Clichy (A.C.), and Centre Hospitalier Universitaire de Poitiers, Poitiers (G.F.) — all in France. Address reprint requests to Dr. Ghinea at INSERM Unité 955-Eq 07, 8 rue du Général Sarrail, Université Paris-Est, Créteil, France, or at nicolae.ghinea@inserm.fr.

N Engl J Med 2010;363:1621-30.

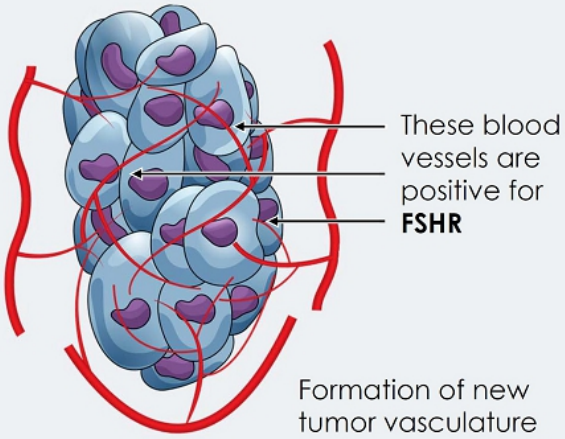
Our FSHR-Mediated CAR-T Technology

Dual mechanism of action

- Many tumors have blood vessels where FSHR is expressed even though healthy tissue does not show such expression
  - Physiologically, FSHR may be helpful in enabling tumors to create vasculature
  - Elegant target: outside of the tumor margin, FSHR on blood vessels disappears
- Anti-angiogenesis drugs are a multi-billion-dollar class of drugs, with Avastin the leader with 2021 sales of $3 billion

Our FSHR targeted CAR-T may destroy tumor vasculature <u>and</u> starve or shrink the tumor, disrupting FSH from both the inside and outside

Angiogenesis
Tumors induce rapid blood vessel growth to nourish themselves



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

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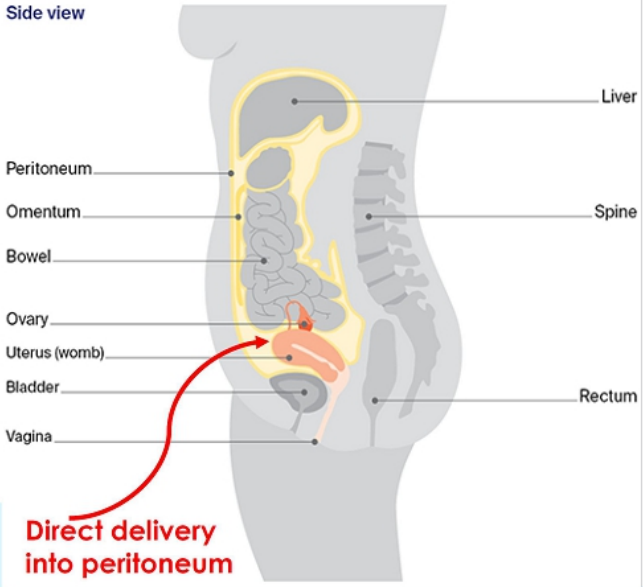
Intraperitoneal Delivery (IP) Is Another Key Advantage

- Most, if not all, ovarian cancer lesions remain within the peritoneal cavity and ascites
- By delivering through an IP catheter, the engineered T cells will largely remain in the peritoneal cavity
- Very few, if any, engineered T cells escape into body
  - Minimizes side effects like CRS
  - Perhaps will enable us to go to much higher concentrations than available with IV administration

We will also test IV delivery, but to date all patients have been treated via IP delivery



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The First Potential Anti-Angiogenic CAR-T Therapy

Exclusive worldwide license from The Wistar Institute

We believe our CER-T approach will work in solid tumors, especially ovarian cancer, where others have failed

1. FSHR is a unique target
2. FSH is a natural ligand (not synthetic)
3. Our approach may provide anti-angiogenic synergy, enabling a dual mechanism of action
4. **Intraperitoneal delivery may enable better trafficking to the tumor and fewer side effects**

Current Phase 1 Trial at Moffitt Cancer Center

- Treated Three Patients at Subtherapeutic Dose (1×10^5 Cells/Kg)- Cohort 1
- First patient treated at 3x dose (Cohort 2)
- Excellent Safety Profile
- **Some anecdotal indicators of efficacy:**
  - **Tumor size was variable and there was indication of cell infiltration into tumor**
  - **Latest scan showed tumor necrosis**

- **We will increase cell concentration by multiples of three in successive cohorts**
- **We will also lympho-delete in a future cohort**
- **We will also evaluate IV delivery**

In Summary

Capital Efficient

Low-cost business model

- Develop programs with partners
  - ✓ Leverage existing infrastructure of partner
  - ✓ Maintain low overhead and cash burn
  - ✓ Allows for multiple orthogonal projects
- Potentially out-license programs to pharma for late-stage clinical development and commercialization
- Burning approximately $6M/year

Key Collaborators

MOFFITT CANCER CENTER

Cleveland Clinic

THE WISTAR INSTITUTE

NIH NATIONAL CANCER INSTITUTE

Financial Summary

NASDAQ:ANIX

$24M cash, cash equivalents and short-term investments as of January 31, 2024

~$5-6M annual cash burn since 2017

32M shares outstanding as of January 31, 2024

No debt

Value-Creating Near-Term Clinical Catalysts

Multiple catalysts over the next 12 months across our clinical pipeline

Program	Phase	H1 2024	H2 2024
Oncology			
Breast Cancer Vaccine	Phase 1a	Additional Phase 1a data release	Final Phase 1a data release
Breast Cancer Vaccine	Phase 1b	Preliminary Phase 1b data release	Additional Phase 1b data release
Breast Cancer Vaccine	Phase 1c	Preliminary Phase 1c data release	Additional Phase 1c data release
Ovarian Cancer CAR-T	Phase 1	Periodic data releases subject to patient enrollment	

Many other potential catalysts as well

Investment Highlights

Robust Pipeline

focused on prevention or treatment of cancer

Strong Clinical Data

2 clinical trials in progress, showing positive results

Strong Financial Profile

~$24M of cash, no debt, and capital efficient business model

Key Partnerships

- The Cleveland Clinic
- Moffitt Cancer Center
- NIH/NCI
- DOD

Significant TAM Opportunity (U.S.)

- ~3.8M women living with female breast cancer[1]
- Over 80M women potentially eligible for vaccine
- ~230,000 women living with ovarian cancer [1]

1) National Cancer Institute.

anixa BIOSCIENCES

Thank you

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