

**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 9, 2023

ANIXA BIOSCIENCES, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-37492
(Commission
File Number)

11-2622630
(IRS Employer
Identification No.)

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

95118
(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:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
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 9, 2023, Anixa Biosciences, Inc. (the "Company") completed its 2023 annual meeting of stockholders (the "Annual Meeting"). The number of shares of stock entitled to vote at the Annual Meeting was 30,922,830 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 20,969,858 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, 2023. 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 2024 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:

<u>Nominee</u>	<u>Shares Voted For</u>	<u>Shares Withheld</u>	<u>Broker Non-Vote</u>
Dr. Amit Kumar	10,263,393	940,600	9,765,865
Dr. Arnold Baskies	10,273,898	930,095	9,765,865
Emily Gottschalk	10,055,355	1,148,638	9,765,865
Lewis H. Titterton, Jr.	9,825,204	1,378,789	9,765,865

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
9,166,107	1,816,322	221,564	9,765,865

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, 2023 was ratified. The voting results were as follows:

Shares Voted For	Shares Voted Against	Shares Abstaining	Broker Non-Vote
20,439,779	61,616	468,463	-

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:

<u>Exhibit No.</u>	<u>Description</u>
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 10, 2023

ANIXA BIOSCIENCES, INC.

By: /s/ Michael J. Catelani

Name: Michael J. Catelani

Title: President, Chief Operating Officer and
Chief Financial Officer



Amit Kumar, PhD
Chairman and CEO
ak@anixa.com

Mike Catelani
President, COO & CFO
mcatelani@anixa.com

NASDAQ:ANIX
Corporate Presentation
March 2023



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.

Investment Highlights

Anixa Biosciences is a clinical-stage company collaborating with world-renowned institutions to develop first-in-class products to prevent and treat serious, large market diseases

Robust Pipeline	<ul style="list-style-type: none">Highly Diversified Oncology Pipeline
Strong Clinical Data	<ul style="list-style-type: none">Two Clinical Trials in progress<ul style="list-style-type: none">Prophylactic and potentially therapeutic Breast Cancer vaccine showing positive resultsOvarian cancer CAR-T trial currently showing positive safety in first patient
Large TAM Opportunity	<ul style="list-style-type: none">As of 2019, there were an estimated ~3.8 million women living with female breast cancer in the United States⁽¹⁾ and over 80 million women in the U.S. potentially eligible for the vaccineAs of 2019, there were an estimated ~230,000 women living with ovarian cancer in the United States⁽¹⁾
Key Partnerships	<ul style="list-style-type: none">The Cleveland ClinicMoffitt Cancer CenterNational Cancer Institute (NIH/NCI)US Department of Defense (DOD)
Strong Financial Profile	<ul style="list-style-type: none">~\$30M of cash and no debtCapital efficient: ~4 years cash runway



(1) Source: National Cancer Institute.

Unique Business Model: Overview

Strategy: Low-Cost Business Model



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

Key Collaborators

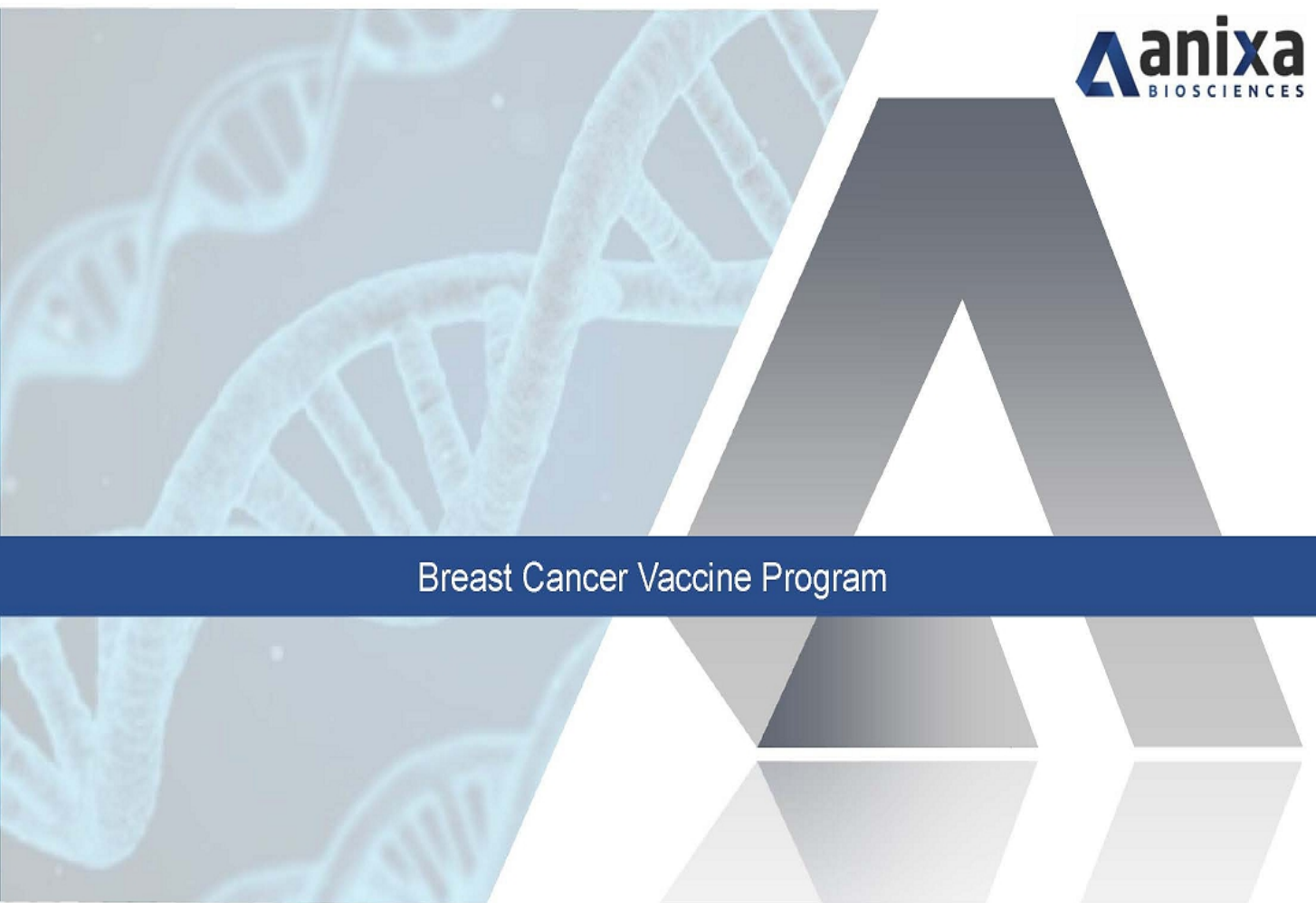


Anixa's Product Pipeline

Therapeutic Area	Mechanism of Action	Indication	Geographic Rights	Current Stage					Upcoming Milestones	Partners
				Discovery	Pre-clinical	Phase 1	Phase 2	Phase 3		
Oncology	Vaccine	Breast Cancer	Global						Ph 1a data release – Q2 '23 Ph 1b data release – TBD	 Cleveland Clinic 
Oncology	CAR-T	Ovarian Cancer / Other Solid Tumors	Global						Periodic data releases (enrollment based)	 
Oncology	Vaccine	Ovarian Cancer	Global						Initiate IND enabling studies	 Cleveland Clinic 
Anti-Infective	Protease Inhibitor	COVID-19	Global						May Cease Work	MolGenie

A dark blue horizontal bar with the text "Breast Cancer Vaccine Program" in white, centered within it.

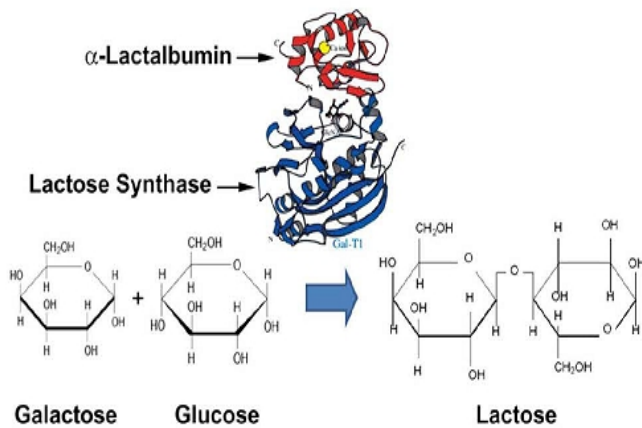
Breast Cancer Vaccine Program



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

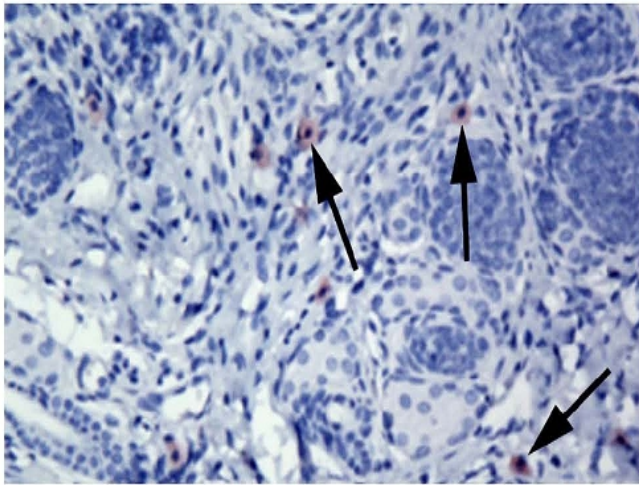
- Expressed *only* in the breast and *only* during lactation
- Expressed in tumor cells, especially Triple Negative Breast Cancer ("TNBC")
- Our vaccine targets this retired protein
 - Once vaccinated, the patient's immune system is ready to destroy cells expressing the protein as they arise, disallowing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

TNBC Overview

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

Pre-Clinical Studies: Vaccination Prevents Breast Cancer

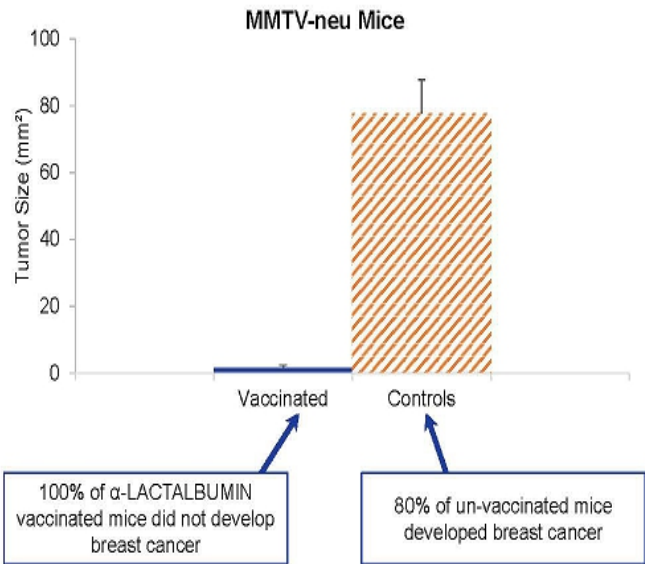
Well-Tolerated



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

Data published: *Cancers*, 2016, 8, 56.

Robust Pre-Clinical Response



Breast Cancer Vaccine Phase 1 Trial

Conducted by Cleveland Clinic, Funded by US Department of Defense

An open-label, Phase 1 dose-escalation trial

Phase 1a (in progress)

- 18-24 Patients who have been treated for TNBC
- Safety will be monitored
- **Immune Response will be monitored**
- Maximum Tolerated Dose ("MTD") determined.

Design

Participants will receive three vaccinations, each two weeks apart, and will be closely monitored for side effects and immune response.

Phase 1b (enrollment open)

- Healthy women with BRCA mutations
- Each woman decided to undergo prophylactic mastectomy
- Will immunize before surgery and monitor antibody and T-cell 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**

- Data to date shows no significant safety concerns, and good indications of an immune response
- Data Will be Presented at AACR Meeting in April 2023
- We would like to see a high percentage (or all) participants exhibiting an immune response



US Department of Defense



NASDAQ: ANIX

Breast Cancer Vaccine Clinical Results as of March 2023

- Enrollment of women who have had TNBC and have undergone standard of care, but are at risk of recurrence
- Over a dozen patients dosed
- MTD Reached in Q4 2022
- Initial indications show positive immune response as expected and desired
- While a short period of time since vaccination, none of the patients have shown recurrence of their cancer
- Additional Elispot and ELISA data expected to be presented at AACR in mid-April

- Clinical Advisory Board (CAB) formed to provide advice and guidance on designing the Phase 2 trial
 - Members of the CAB are pre-eminent breast cancer researchers and clinicians
 - May add other members as appropriate

- Recruitment for Phase 1b has begun

Breast Cancer Vaccine: A Significant Market Opportunity

- Prophylactic (preventative) vaccines are administered to the total eligible population
- We expect reimbursement for this vaccine to be similar to the cervical cancer vaccine (~\$400 retail cost)

U.S. (Total Eligible Population)

- More than 80 million women are currently 40 or older in the U.S. alone
 - Millions more age into this group annually

Outside U.S. (Billions of Candidates)

- Approximately 1.4 billion women are 40 and older outside the U.S.

Breast cancer became the most common cancer globally as of 2021, accounting for 12% of all new annual cancer cases worldwide, according to the World Health Organization⁽¹⁾

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

A dark blue horizontal bar containing the text "Ovarian Cancer CAR-T Program" in a white, sans-serif font. The background of the slide features a large, stylized letter 'A' composed of geometric shapes, with a faint DNA double helix visible on the left side.

CAR-T Technology: Background and Opportunity

Chimeric Antigen Receptor T-cell

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 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

Unique Approach →

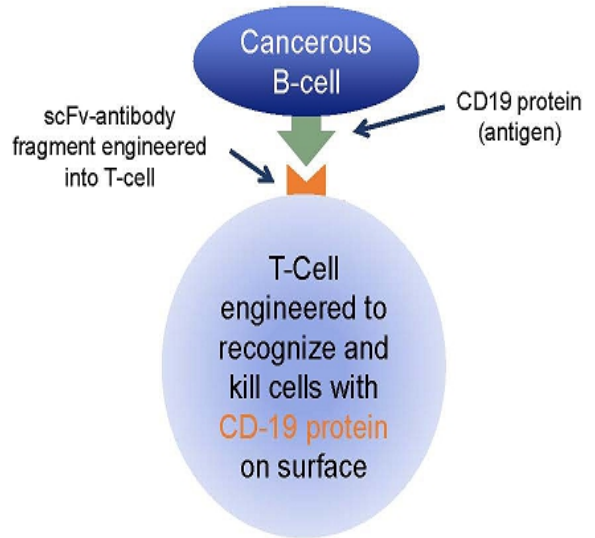
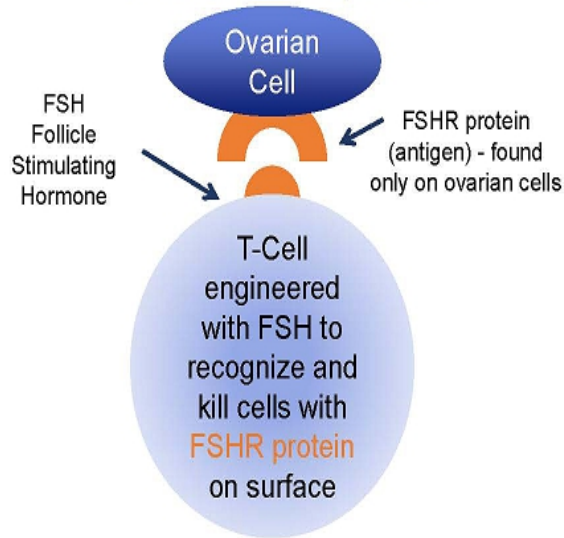
Anixa has a novel technology for making CAR-T work in multiple solid tumors, beginning with Ovarian Cancer

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

Anixa's CAR-T Program for Ovarian Cancer
Follicle Stimulating Hormone Receptor ("FSHR")-mediated CAR-T Technology

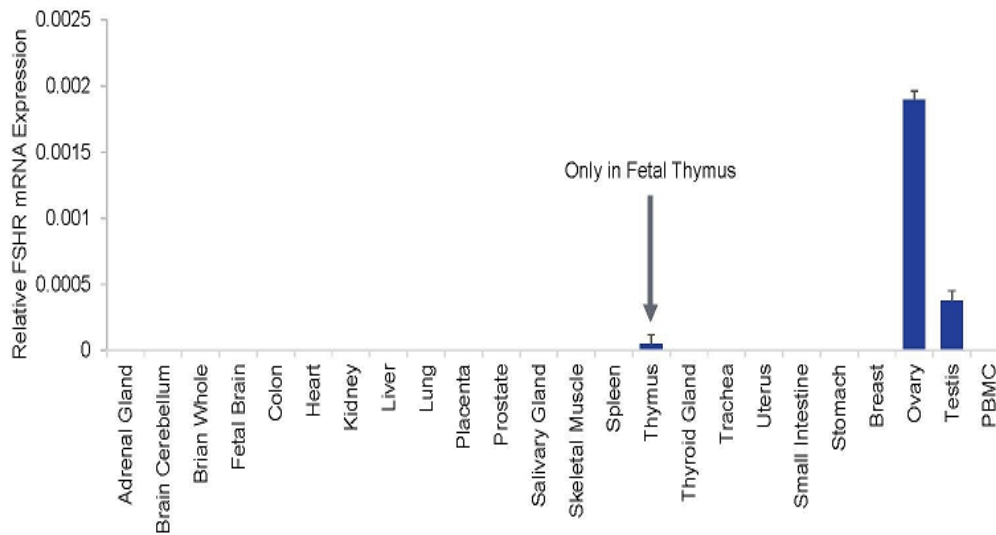
Other CAR-T Programs:
Novartis, JUNO, KITE and others working on B-Cell cancers

Chimeric Endocrine Receptor T-Cell



FSHR ONLY Expressed in Ovaries and Testes

In Healthy Humans



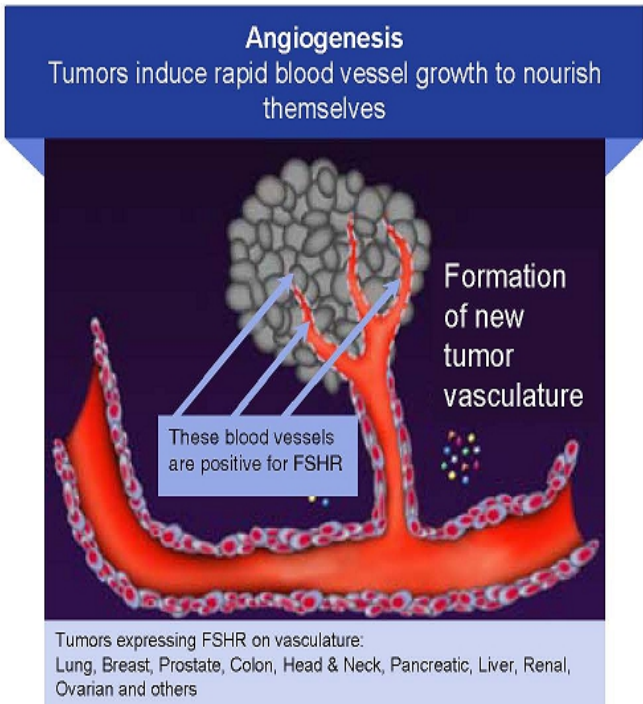
FSHR expressed on the blood vessels of many tumors

This therapy will be anti-angiogenic for many types of cancer, enabling a portfolio of therapies for multiple cancers

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 and starve or shrink the tumor, disrupting FSH from both the inside and outside



Our FSHR-Mediated CAR-T Program: 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
4. Our CAR-T may execute a dual mechanism of action in destroying the tumor

Previous Challenges:

- The CAR-T cells may not be susceptible to the highly suppressive tumor microenvironment ("TME")
- As the CAR-T cells are destroying vasculature, they make it leakier, enabling simultaneous, localized delivery of other agents including chemotherapy
- CAR-T mediated cell death may be more powerful than other anti-angiogenesis drugs

- Treated first patient August 2022
- First patient is exhibiting no major safety concerns to date and is alive 9 months post progression
- Second patient ready to go

A light blue, semi-transparent DNA double helix structure is visible in the background on the left side of the slide.A large, dark grey, stylized letter 'A' graphic is positioned on the right side of the slide, partially overlapping the DNA background.

Other Programs- preclinical

Ovarian Cancer Vaccine: Retired Tissue Specific Protein

- Retired Tissue Specific Protein--Expressed at periods of life, but no longer expressed as we age
 - Collaboration with the Cleveland Clinic
 - Funding and Collaboration with The National Cancer Institute
- The 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 is a candidate
 - Multi-billion dollar market opportunity
 - Pre-clinical data published (*Cancer Prev. Res.* 2017, 10(11); 612-624)

Latest Reported Financial Summary

- \$29.6M cash, cash equivalents and short-term investments as of October 31, 2022

- ~\$5-6M annual cash burn since 2017; ~4 years of cash runway
 - Amit Kumar, Ph.D. Appointed CEO on July 7, 2017
 - Current management team and board has managed the company for only a little over 5 years

- 30.9M shares outstanding as of October 31, 2022

- No debt

Value-Creating Near-Term Clinical Catalysts

Multiple catalysts over the next year across our clinical pipeline

Program	Phase	H1 2023	H2 2023
Oncology			
Breast Cancer Vaccine	Phase 1a	Phase 1a data release	
Breast Cancer Vaccine	Phase 1b	First dosing	Preliminary Phase 1b data release subject to enrollment
Ovarian Cancer CAR-T	Phase 1	Periodic data releases subject to patient enrollment	Periodic data releases subject to patient enrollment

Many other potential catalysts as well

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<p>Robust Pipeline</p>	<ul style="list-style-type: none"> Highly Diversified Oncology Pipeline 	
<p>Strong Clinical Data</p>	<ul style="list-style-type: none"> Two Clinical Trials in progress <ul style="list-style-type: none"> Prophylactic and potentially therapeutic Breast Cancer vaccine showing positive results Ovarian cancer CAR-T trial currently showing positive safety result in first patient 	
<p>Large TAM Opportunity</p>	<ul style="list-style-type: none"> As of 2019, there were an estimated ~3.8 million women living with female breast cancer in the United States⁽¹⁾ and over 80 million women in the U.S. potentially eligible for the vaccine As of 2019, there were an estimated ~230,000 women living with ovarian cancer in the United States⁽¹⁾ 	
<p>Key Partnerships</p>	<ul style="list-style-type: none"> The Cleveland Clinic Moffitt Cancer Center 	<ul style="list-style-type: none"> National Cancer Institute (NIH/NCI) US Department of Defense DOD)
<p>Strong Financial Profile</p>	<ul style="list-style-type: none"> ~\$30M of cash and no debt Capital efficient: ~4 years cash runway 	



(1) Source: National Cancer Institute.