

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): August 13, 2020

ANIXA BIOSCIENCES, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

000-11254
(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:

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 August 13, 2020, Anixa Biosciences, Inc. (the “Company”) completed its 2020 annual meeting of stockholders (the “Annual Meeting”). The number of shares of stock entitled to vote at the Annual Meeting was 23,521,336 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 17,491,948 shares. At the Annual Meeting, the Company’s stockholders (i) re-elected Dr. Amit Kumar, Dr. Arnold Baskies, David Cavalier, Emily Gottschalk, Dr. John Monahan, and Lewis H. Titterton, Jr. as directors, (ii) approved, on a non-binding, advisory basis, the Company’s executive compensation, (iii) ratified the appointment of Haskell & White LLP as the Company’s independent registered public accounting firm for the fiscal year ending October 31, 2020 and (iv) approved an amendment to Article FOURTH of the Company’s Certificate of Incorporation, as amended (the “Certificate of Incorporation”), to increase the number of authorized shares of common stock from 48,000,000 to 100,000,000. 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, David Cavalier, Emily Gottschalk, Dr. John Monahan and Lewis H. Titterton, Jr. were elected to serve until the 2021 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	8,113,395	206,081	9,172,472
Dr. Arnold Baskies	8,242,514	76,962	9,172,472
David Cavalier	8,242,651	76,825	9,172,472
Emily Gottschalk	8,249,455	70,021	9,172,472
Dr. John Monahan	8,242,474	77,002	9,172,472
Lewis H. Titterton, Jr.	8,246,516	72,960	9,172,472

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
7,642,807	558,359	118,310	9,172,472

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, 2020 was ratified. The voting results were as follows:

Shares Voted For	Shares Voted Against	Shares Abstaining	Broker Non-Vote
17,446,149	30,586	15,213	0

Proposal No. 4 – Increase of authorized shares of common stock

The amendment to Article FOURTH of the Certificate of Incorporation to increase the number of authorized shares of common stock from 48,000,000 to 100,000,000 was approved. The voting results were as follows:

Shares Voted For	Shares Voted Against	Shares Abstaining	Broker Non-Vote
13,589,302	3,725,832	176,814	0

Item 5.03 Amendments to Articles of Incorporation or Bylaws; Change in Fiscal Year.

On August 14, 2020, following receipt of stockholder approval at the Annual Meeting, the Company filed a Certificate of Amendment to the Certificate of Incorporation with the Secretary of State of the State of Delaware to increase the number of authorized shares of common stock from 48,000,000 to 100,000,000, effective August 17, 2020. The Certificate of Amendment is attached to this Current Report as Exhibit 3.1. All descriptions of the Certificate of Amendment herein are qualified in their entirety to the text of Exhibit 3.1 hereto, which is incorporated herein by reference.

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
3.1	Certificate of Amendment
99.1	Corporate Presentation

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: August 17, 2020

ANIXA BIOSCIENCES, INC.

By: /s/ Amit Kumar

Name: Dr. Amit Kumar

Title: President and Chief Executive Officer

CERTIFICATE OF AMENDMENT TO THE
CERTIFICATE OF INCORPORATION
OF ANIXA BIOSCIENCES, INC.

The undersigned, for the purposes of amending the Certificate of Incorporation of Anixa Biosciences, Inc. (the "Corporation"), a corporation organized and existing under and by virtue of the General Corporation Law of the State of Delaware (the "DGCL"), does hereby certify that:

FIRST: The Board of Directors of the Corporation (the "Board") duly adopted in accordance with Section 141(f) of the DGCL on May 22, 2020, a resolution proposing and declaring advisable the following amendment to replace Article FOURTH of the Certificate of Incorporation of said Corporation:

"FOURTH: The total number of shares of stock that the Corporation shall have authority to issue is one hundred million twenty thousand (100,020,000), of which one hundred million (100,000,000) shall be Common Stock of the par value of \$0.01 per share and twenty thousand (20,000) shall be Preferred Stock of the par value of \$100 per share. The 20,000 shares of Preferred Stock may be issued from time to time in one or more series, each of such series to have such voting powers, full or limited, or no voting powers, designations, preferences and relative participating, optional or other special rights and qualifications and limitations or restrictions as are stated and expressed in the resolutions providing for the issue of such series adopted by the Board of Directors as hereinafter provided. Authority is hereby expressly granted to the Board of Directors to establish and designate one or more series of Preferred Stock and to fix the relative rights, preferences and limitations of each series, including without limitation:

1. The number of shares to constitute such series and the distinctive designations thereof;
2. The dividend rate to which such shares shall be entitled and the restrictions, limitations and conditions upon the payment of such dividends, whether dividends shall be cumulative, the date or dates from which dividends (if cumulative) shall accumulate and the dates on which dividends (if declared) shall be payable;
3. Whether or not the shares of such series shall be redeemable and, if so, the terms, limitations and restrictions with respect to such redemption, including without limitation the manner of selecting shares for redemption if less than all shares are to be redeemed, and the amount, if any, in addition to any accrued dividends thereon, which the holders of shares of such series shall be entitled to receive upon the redemption thereof, which amount may vary at different redemption dates and may be different with respect to shares redeemed through the operation of any purchase, retirement or sinking fund and with respect to shares otherwise redeemed;
4. The amount in addition to any accrued dividends thereon which the holders of shares of such series shall be entitled to receive upon the voluntary or involuntary liquidation, dissolution or winding up of the Corporation, which amount may vary at different dates and may vary depending on whether such liquidation, dissolution or winding up is voluntary or involuntary;

5. Whether or not the shares of such series shall be subject to the operation of a purchase, retirement or sinking fund and, if so, the terms, limitations and restrictions with respect thereto, including without limitation whether such purchase, retirement or sinking fund shall be cumulative or non—cumulative, the extent to and the manner in which such fund shall be applied to the purchase, retirement or redemption of the shares of such series for retirement or to other corporate purposes and the terms and provisions relative to the operation thereof;
6. Whether or not the shares of such series shall have conversion privileges and, if so, prices or rates of conversion and the method, if any, of adjusting the same;
7. The voting powers, if any, of such series; and
8. Any other relative rights, preferences and limitations thereof as shall not be inconsistent with this Article.”

SECOND: The holders of a majority of the issued and outstanding voting stock of the Corporation have voted in favor of said amendment at a duly convened meeting of the stockholders of the Corporation.

THIRD: The aforesaid amendment was duly adopted in accordance with the applicable provisions of Section 242 of the DGCL.

FOURTH: The aforesaid amendment shall be effective as of 10:00 A.M. Eastern Time on August 17, 2020.

IN WITNESS WHEREOF, the Corporation has caused this Amendment to the Certificate of Incorporation of the Corporation to be duly executed by the undersigned this 14th day of August, 2020.

ANIXA BIOSCIENCES, INC.

By: /s/Amit Kumar
Name: Dr. Amit Kumar
Title: President and Chief Executive Officer



August 13, 2020
NASDAQ:ANIX

Amit Kumar
Chairman and CEO
ak@anixa.com

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 or license products

Key Collaborators



Three High Value Programs

Oncology and Infectious Disease

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

Covid-19 Therapeutic

- *In Silico* Screening - Artificial intelligence, Machine Learning and Molecular Modeling
- Targeting two enzymes of SARS-CoV-2 virus
- **Early stage program but moving fast – Multiple compounds already identified and in biological testing**

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
Jose Conejo-Garcia, MD, PhD
Marco Davila, MD, PhD
Daniel Abate-Daga, PhD
Linda Kelley, PhD
Ian Frazer, PhD
Emanuele Ostuni, PhD

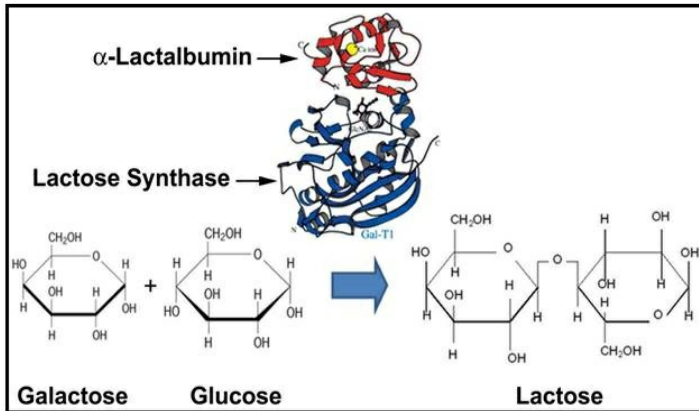
Breast Cancer Vaccine

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

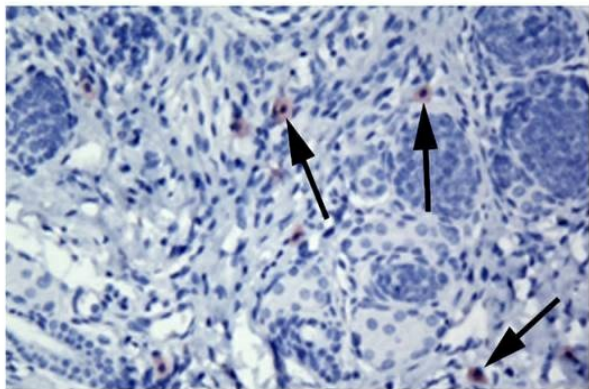
- Expressed **only** in the breast and **only** during lactation
- Expressed in tumor cells, especially Triple Negative Breast Cancer (TNBC)
- Our vaccine targets this retired protein
 - Once vaccinated, the patient's immune system is ready to destroy cells expressing the protein as they arise, disallowing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

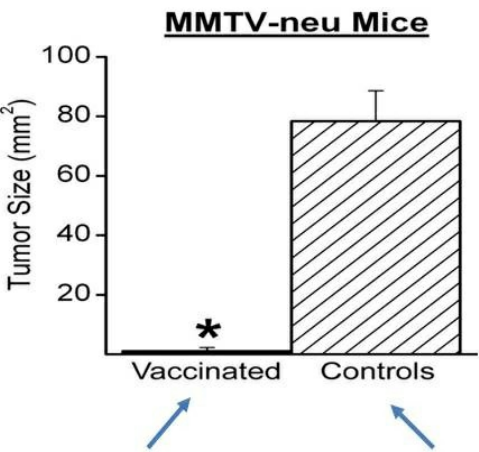
Vaccination Prevents Breast Cancer

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 did 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
 - 10-20 MM aging into this category annually
 - Greater than 150 MM Men are candidates
- 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

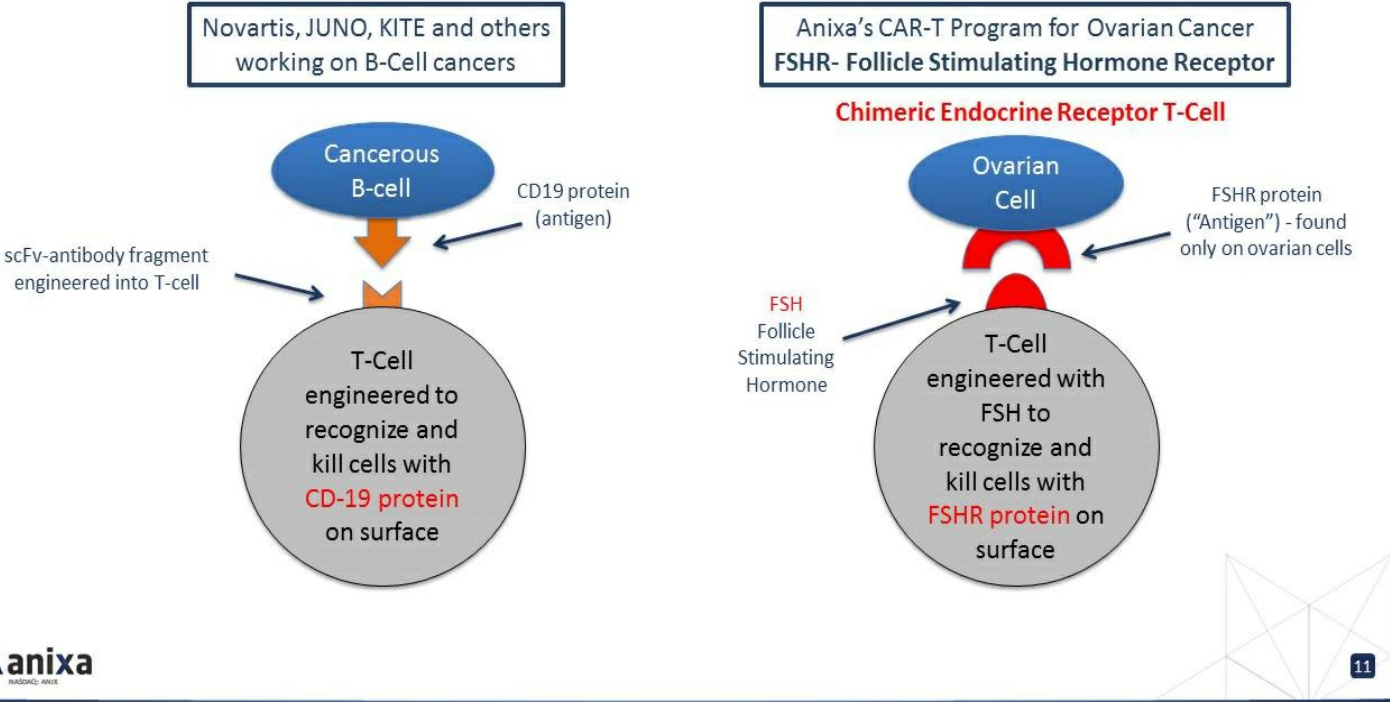
- Durable responses (50-80% of patients)
- Multibillion dollar valuations and big pharma deals
 - Novartis - First approved product by FDA
 - Kymriah for ALL- Acute Lymphoblastic Leukemia
 - Second approval for DLBCL-Diffuse large B-cell Lymphoma
 - KITE - \$12BB acquisition by GILD
 - JUNO - \$9BB acquisition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

Our Opportunity

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

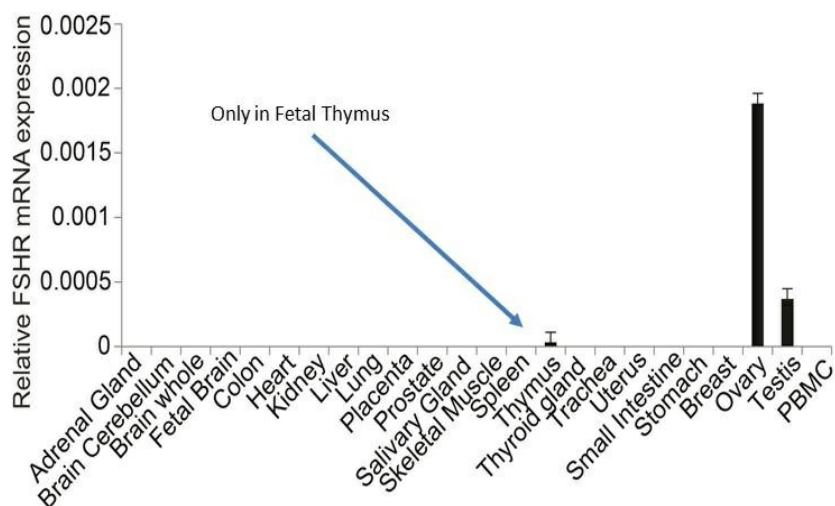
MAGIC BULLET → Anixa has a unique approach to making CAR-T work for multiple solid tumors, beginning with Ovarian Cancer

Anixa's Unique CER-T Approach for Solid Tumors



FSHR **ONLY** Expressed in Ovaries and Testis

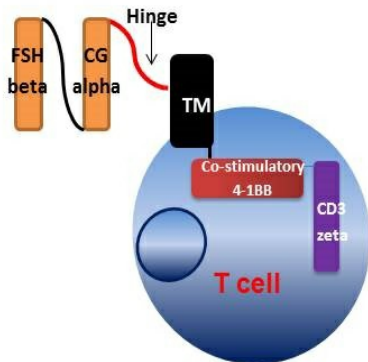
In Healthy Humans



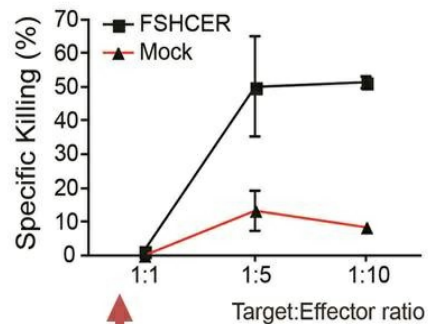
- FSHR expressed on the blood vessels of many **TUMORS**
- This therapy will be anti-angiogenic for many types of cancer, enabling a portfolio of therapies for multiple cancers

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



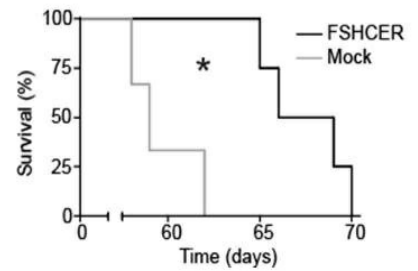
FSH-Targeted chimeric receptors re-direct primary human T cells against FSHR+ ovarian cancer cells



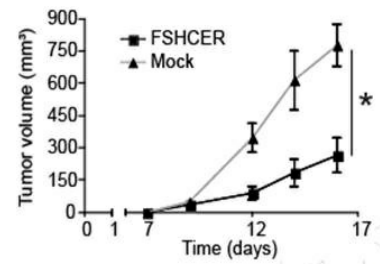
Ovarian Cancer

Breast Cancer

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



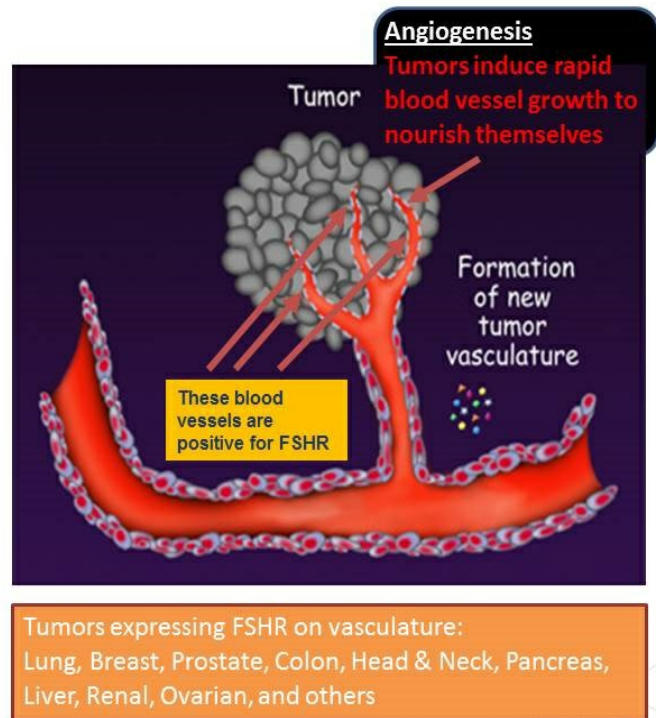
N=15 mice/group
3 independent experiments



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.

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



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

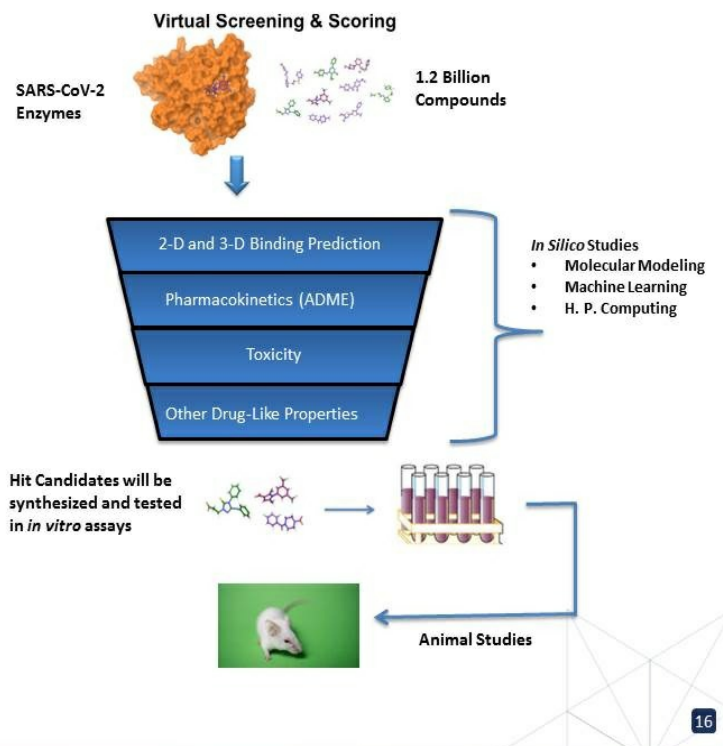
1. FSHR- UNIQUE TARGET
2. FSH- NATURAL LIGAND- NOT SYNTHETIC
3. ANTI-ANGIOGENIC SYNERGY

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



Covid-19 Program

- Initiated April 20, 2020 with partner OntoChem, GmbH
 - Virtual Screening (1.2 BB compounds)
 - Targets: Main Protease (M^{Pro}), Endoribonuclease (NSP-15)
- *In Silico* Hits
 - Utilize Molecular Modeling, Screening algorithms
 - “Hits” will be synthesized and tested *in vitro*
 - Candidate Drugs will be tested in animal models
- Pre-IND Testing
- Clinical Trials
- Current Status
 - Completed Initial Screening
 - Identified several Hit compounds
 - Synthesis and *in vitro* testing in progress



Commercial Partnership and Monetization Strategy

- Drug development is risky
 - We mitigate the risk by diversifying
 - We also work on programs that are relatively low cost
- Drugs and vaccines are developed through a three phase human clinical 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
 - The clinical trial process takes years before approval and sales/revenue
- Our strategy is to monetize our programs, through licensing deals, long before approval
 - We may partner and monetize our programs as early as once we have positive Phase 1, first in human data
- Partnerships and licensing deals are the norm in drug development
- 72% of all drugs approved in the last few years were initially developed by emerging companies and licensed to large pharma
- Typical partnerships are 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
 - Equity investment
- The size of the payments above depend on the quality of the data, the size of the market, and overall value of the product

Impact of Covid-19 on Anixa's Programs

- Impact of Covid-19
 - Our Partners (Cleveland Clinic and Moffitt Cancer Center) and multiple vendors have been impacted by the pandemic as well as mandated social distancing constraints
 - We are trying to mitigate the impacts as much as possible
 - The pandemic is ongoing, and while we are hopeful that there will not be further impact to our programs, we cannot predict future effects of the pandemic



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
- Clinical Data Release

Covid-19 Therapeutics

- Identify additional potential compounds
- Results of in vitro biological and viral replication assays
- Preliminary Animal Studies
- Seek Government Research Funding
- 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