

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): October 23, 2019

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 October 23, 2019, Anixa Biosciences, Inc. (the “Company”) completed its 2019 annual meeting of stockholders (the “Annual Meeting”). The number of shares of stock entitled to vote at the Annual Meeting was 20,207,261 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 14,851,237 shares. At the Annual Meeting, the Company’s stockholders (i) re-elected Dr. Amit Kumar, Dr. Arnold Baskies, David Cavalier, Dr. John Monahan and Lewis H. Titterton, Jr. and elected Emily Gottschalk as directors, (ii) approved, on a non-binding, advisory basis, the Company’s executive compensation, and (iii) approved, on a non-binding, advisory basis, the frequency of one year for the Company to hold advisory votes on its executive compensation and (iv) ratified the appointment of Haskell & White LLP as the Company’s independent registered public accounting firm for the fiscal year ending October 31, 2019. 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, Dr. John Monahan, Lewis H. Titterton, Jr. and Emily Gottschalk were elected to serve until the 2020 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	7,509,531	92,686	7,249,020
Dr. Arnold Baskies	7,048,938	553,279	7,249,020
David Cavalier	7,510,302	91,915	7,249,020
Dr. John Monahan	6,964,282	637,935	7,249,020
Lewis H. Titterton, Jr.	6,980,683	621,534	7,249,020
Emily Gottschalk	7,527,963	74,254	7,249,020

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
6,825,190	715,703	61,324	7,249,020

Proposal No. 3 – Approval, by non-binding advisory vote, on the frequency of advisory votes on the Company’s executive compensation

The frequency of one year for future advisory votes on the Company’s executive compensation was approved by non-binding advisory vote. The voting results were as follows:

3 Years	2 Years	1 Year	Abstentions	Broker Non-Votes
1,815,711	132,190	5,455,369	198,947	7,249,020

Proposal No. 4 – 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, 2019 was ratified. The voting results were as follows:

Shares Voted For	Shares Voted Against	Shares Abstaining	Broker Non-Vote
14,828,263	15,899	7,075	0

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	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: October 24, 2019

ANIXA BIOSCIENCES, INC.

By: /s/ Amit Kumar

Name: Dr. Amit Kumar

Title: President and Chief Executive Officer



Shareholder Meeting
October 23, 2019
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
- No debt
- Headcount: 7 Full-time
- Three high value programs

Strategy – Low Cost Effective 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

Key Collaborators



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
- Collaborations with The Wistar Institute, MD Anderson Cancer Center, Penn Medicine, New Jersey Urology, and multiple VA Medical Centers

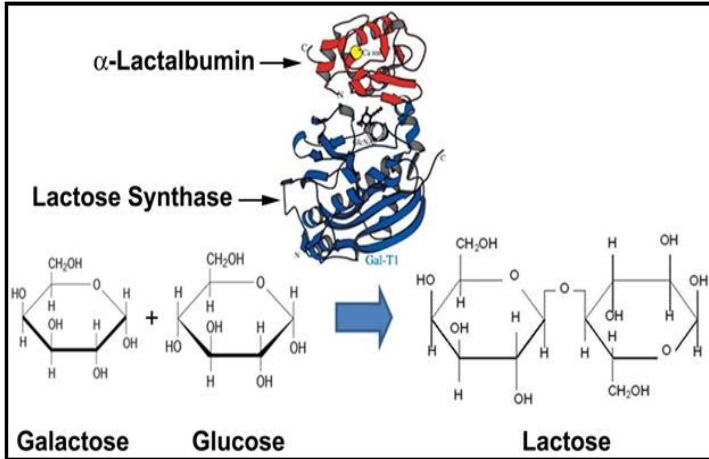
Breast Cancer Vaccine

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

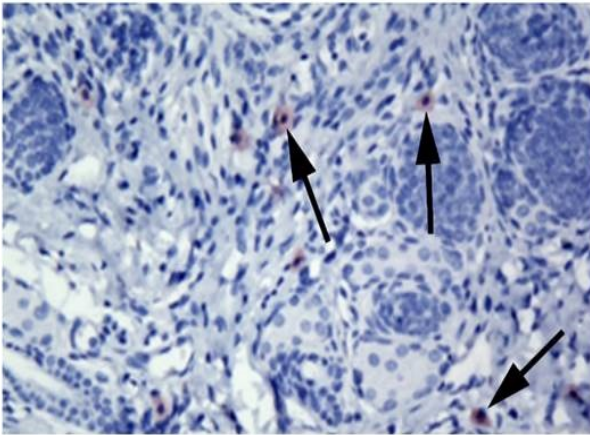
- Expressed **only** in the breast and **only** during lactation
- Expressed in tumor cells, especially Triple Negative Breast Cancer (TNBC)
- Our vaccine targets this retired protein
 - Once vaccinated, the patient's immune system is ready to destroy cells expressing the protein as they arise, disallowing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

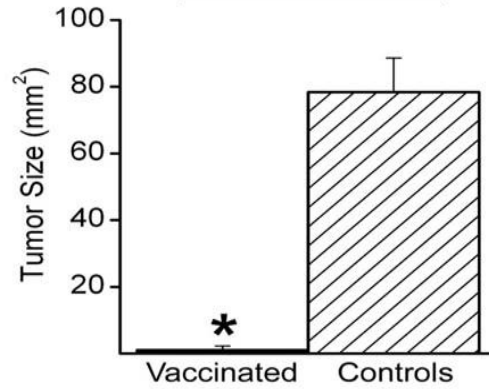
SAFE



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

EFFECTIVE

MMTV-neu Mice



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

80% of un-vaccinated mice developed breast cancer

Breast Cancer Vaccine- Market Opportunity

- Prophylactic (preventative) vaccines are administered to all eligible participants, not just the small number of sick patients
 - US >50 MM women older than 40
 - Each year, an additional 5 MM women age into that category
 - 1-2% of breast cancer occurs in men, and studies show these cells express alpha-lactalbumin, resulting in an additional 150 MM men in the US as potential candidates
- Considering the whole world, the numbers are exponential
- Currently, the cervical cancer vaccine costs a few hundred dollars with exceptional margins
- The market opportunity for this product is potentially greater than \$10s of billions
- **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**
- **This is very exciting, but we must temper our enthusiasm with the understanding that we have to prove it works in humans as well as it did in animals**

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

- Cleveland Clinic collaboration
- DOD funded program; \$6.2 Million
 - Pre-clinical
 - Two phase 1 clinical trials
- Pre-IND meeting with FDA completed
- Plan to file IND by end of 2019
- Begin first clinical trial in 2020
- Data published: *Cancers*, **2016**, 8, 56.

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
 - Many other CAR-T companies have large valuations

Our Opportunity

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

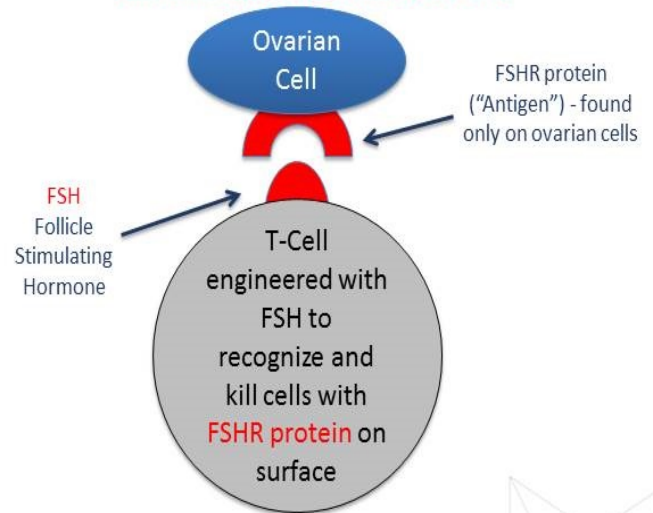
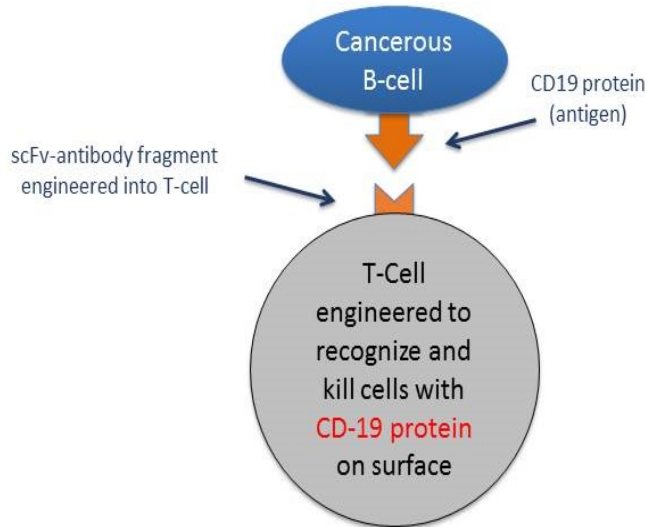
MAGIC BULLET → Anixa has a unique approach to making CAR-T work for solid tumors using its CAR-T platform, which may work in multiple tumors

Anixa's Unique CER-T Approach for Solid Tumors

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

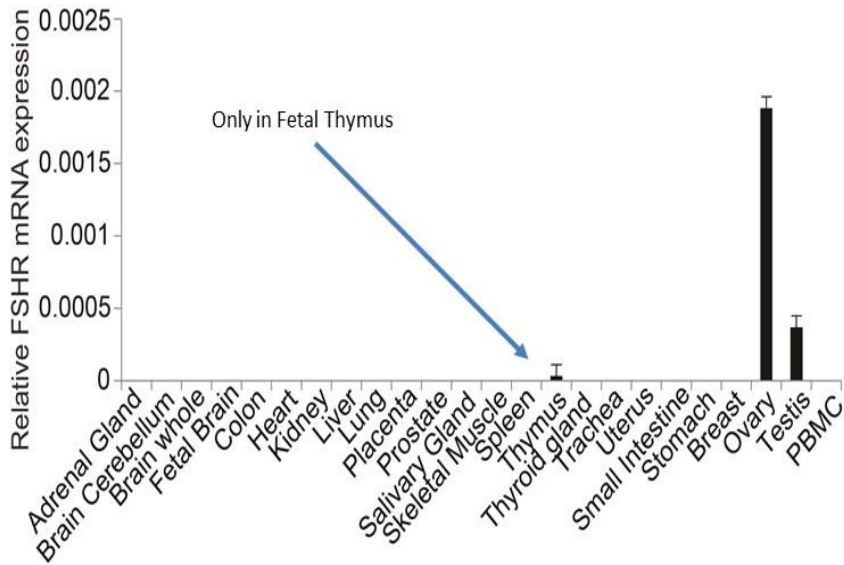
Anixa's CAR-T Program for Ovarian Cancer
FSHR- Follicle Stimulating Hormone Receptor

Chimeric Endocrine Receptor T-Cell



FSHR **ONLY** Expressed in Ovaries and Testis

In Healthy Humans

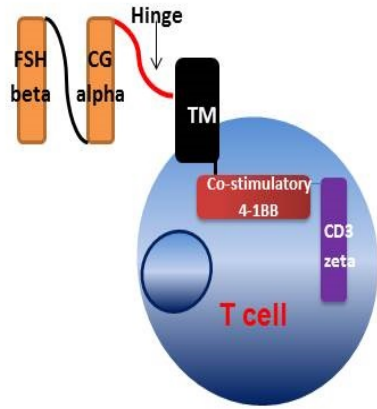


- FSHR expressed on the blood vessels of many **TUMORS**
- This therapy will be anti-angiogenic for many types of cancer, enabling a portfolio of therapies for multiple cancers

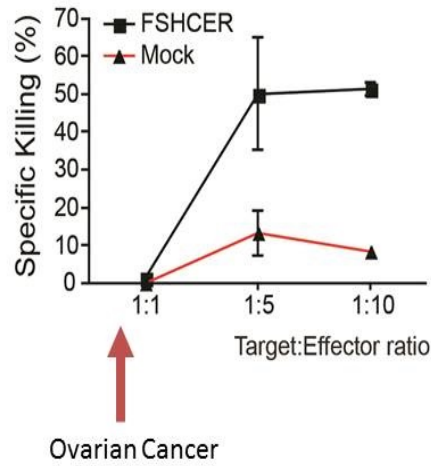
Source: Perales-Puchalt et al. "Follicle-stimulating hormone receptor is expressed by most ovarian cancers subtypes and is a safe and effective immunotherapeutic target." *Clinical Cancer Research*. 2017.



Pre-Clinical Data



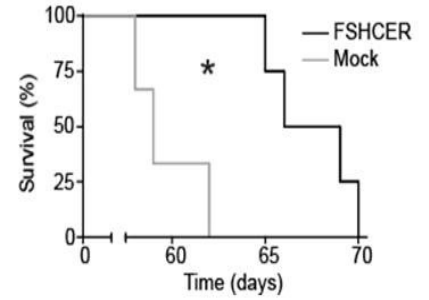
FSH-Targeted chimeric receptors re-direct primary human T cells against FSHR+ ovarian cancer cells



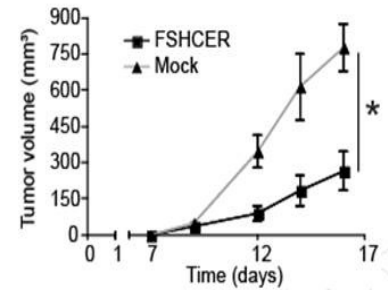
Ovarian Cancer

Breast Cancer

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



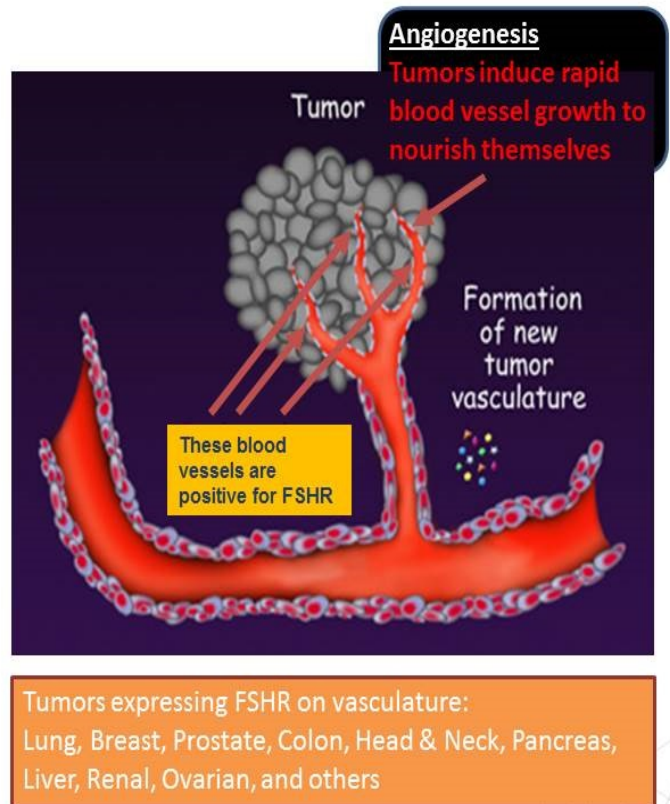
N=15 mice/group
3 independent experiments



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 2019
 - Clinical trial to commence 2019/20
 - Estimated cost for Phase 1 \$3-6 MM
- Data published: *Clinical Cancer Research*, 23(2)January 15, 2017, 441-453

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**

Early Cancer Detection – Liquid Biopsy

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



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



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)

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)

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

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™ - Prostate Cancer Confirmation (PCC)

Early Cancer Detection

- Prostate cancer typically diagnosed by elevated PSA level and prostate examination, followed by biopsy
- 1.5 million prostate biopsies in the US annually
 - Nearly 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

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

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

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**

Anticipate launching 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



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-Q4 2019
- Approval of IND by FDA
- Patient recruitment
- First patient dosed and initiation of clinical trial

CAR-T Program

- Filing of IND for clinical trial-Q4 2019
- Approval of IND by FDA
- Patient recruitment
- First patient dosed and initiation of clinical trial
- Initiate pre-clinical work on other tumors - Magic Bullet

Diagnostics Program

- Commercial launch of Cchek™-Prostate Cancer Confirmation as laboratory developed test-Q4 2019
- Scientific presentations and publications
- Strategic alliances

Corporate Activity

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