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 21, 2019

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

Delaware	**000-11254**	**11-2622630**
(State or other jurisdiction of incorporation)	(Commission File Number)	(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 7.01 Regulation FD Disclosure.

Attached as Exhibit 99.1 to this Current Report is the form of presentation of Anixa Biosciences, Inc., which may be used 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: August 21, 2019

ANIXA BIOSCIENCES, INC.

By: /s/ Amit Kumar

Name: Dr. Amit Kumar

Title: President and Chief Executive Officer

August 2019
NASDAQ:ANIX

Amit Kumar, Ph.D.
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: 6 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

Cleveland Clinic

New Jersey Urology – Excellence in Care

Virtua

The Wistar Institute

Moffitt Cancer Center

MD Anderson Cancer Center – Making Cancer History

Cooper

Penn Medicine – Abramson Cancer Center

US. Department of Veterans Affairs

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3

Leadership Team

Key Members of Management

Amit Kumar, PhD, Chairman, CEO and President

- Co-Founder, Executive Chairman of Actym Therapeutics
- Member, Board of Directors, American Cancer Society
- Former President and CEO CombiMatrix, recently 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

Scientific Advisory Board
Arnold Baskies, MD
Michael Shepard, PhD
Dmitry Gabrilovich, MD, PhD
Jose Conejo-Garcia, MD, PhD
Marco Davila, MD, PhD
Daniel Abate-Daga, PhD
Linda Kelley, PhD

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

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5

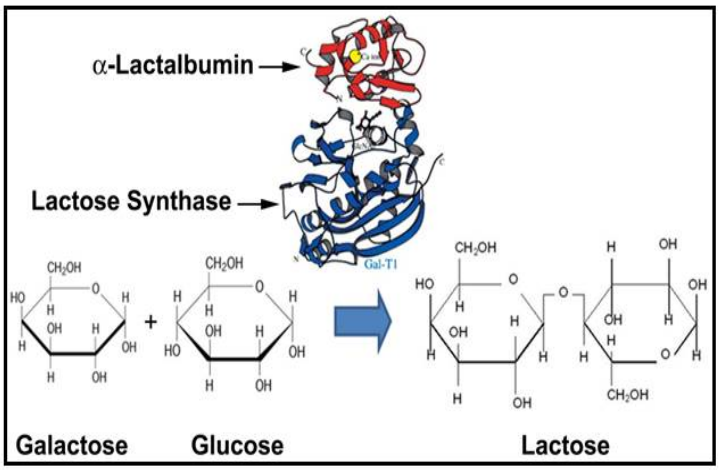
Breast Cancer Vaccine

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

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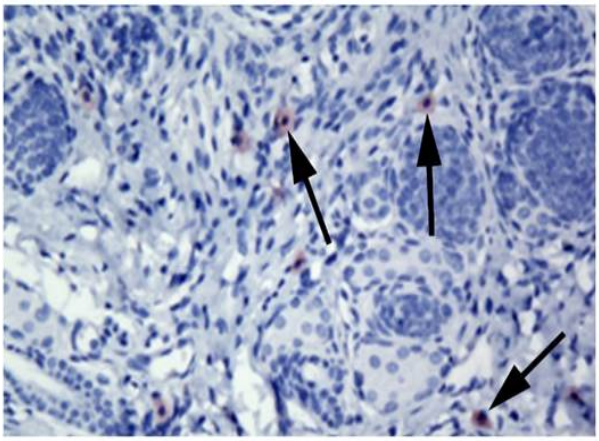
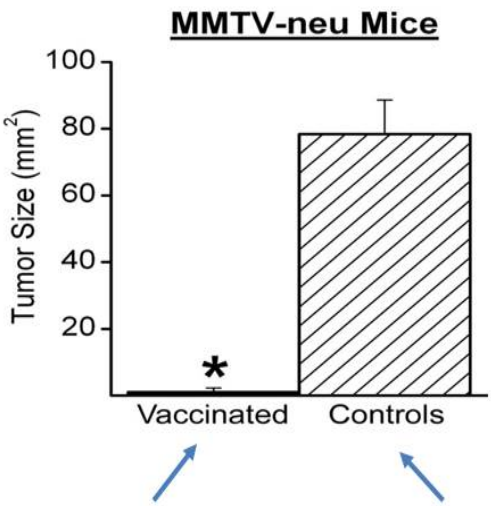
Vaccination Prevents Breast Cancer

SAFE



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

EFFECTIVE



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

80% of un-vaccinated mice developed breast cancer

Breast Cancer Vaccine Clinical Trial Plan

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

Pre-Clinical Studies

- GLP Tox
- IND filing

Phase 1a Trial

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

Phase 1b Trial

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

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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 <u>not</u> 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

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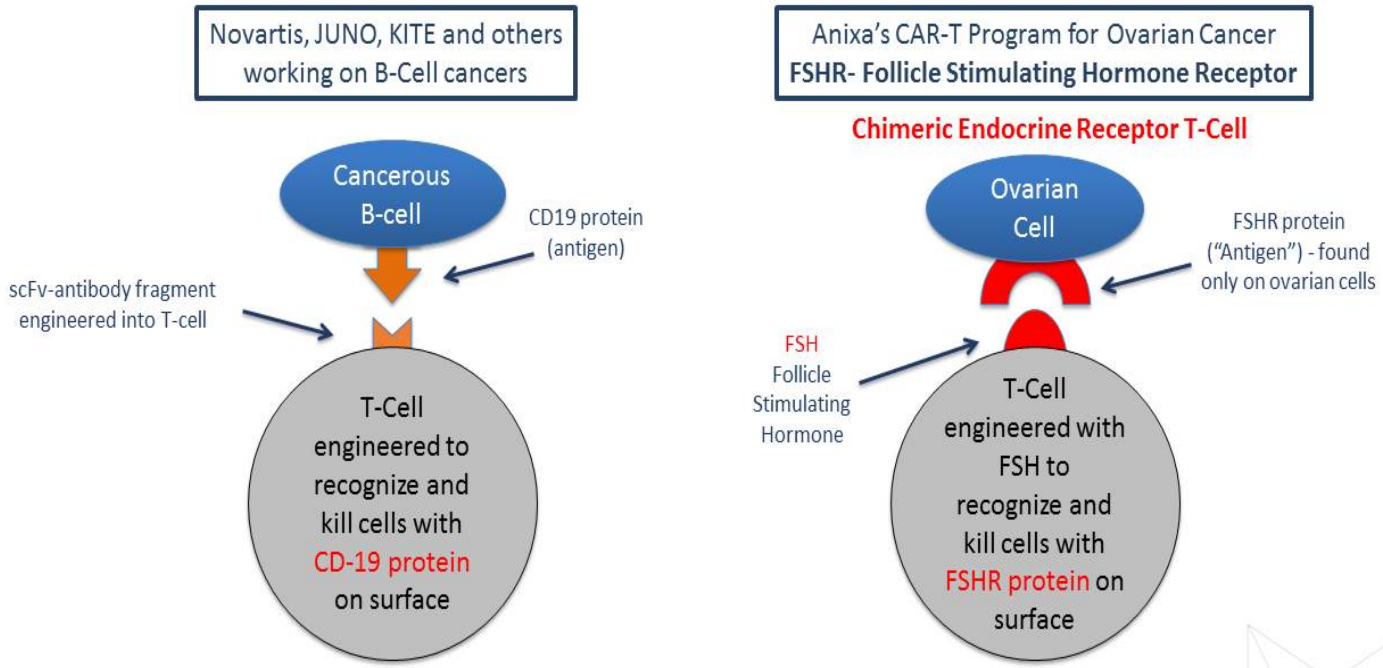
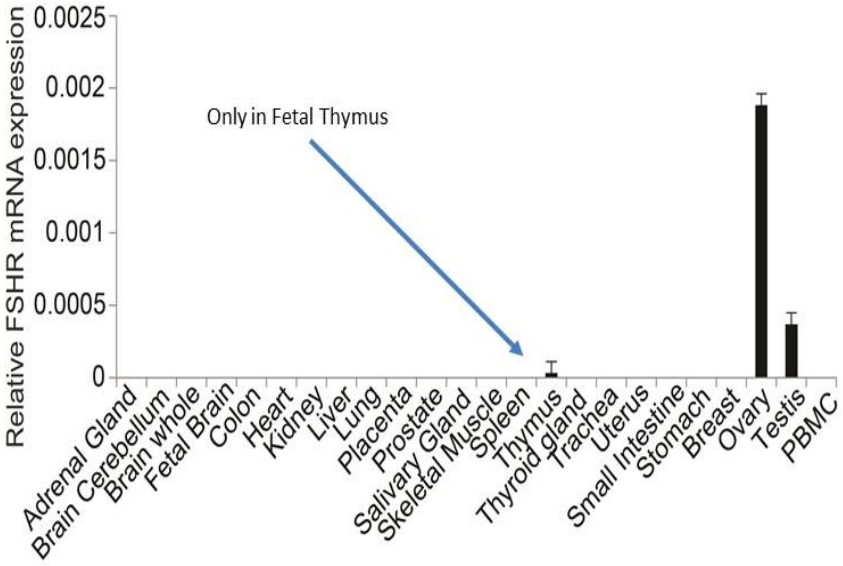
10

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.

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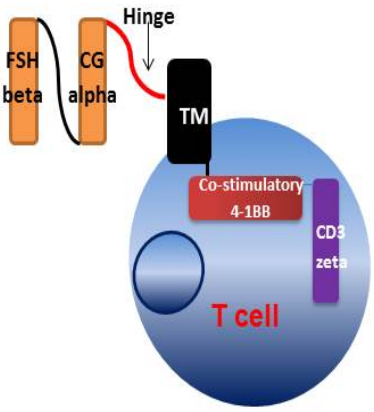
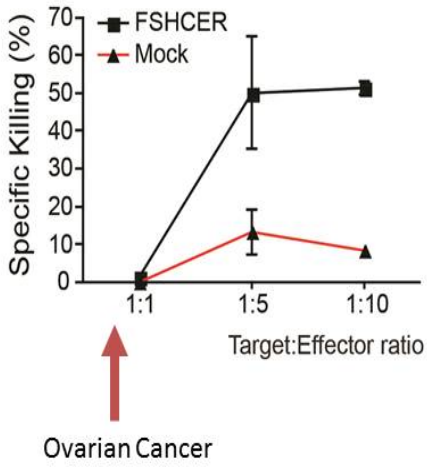
Pre-Clinical Data



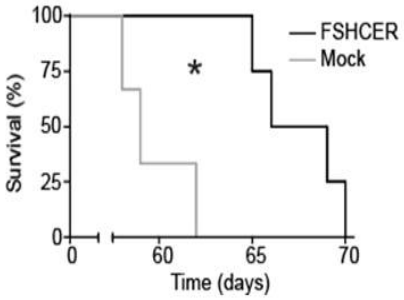
FSH-Targeted chimeric receptors re-direct primary human T cells against FSHR+ ovarian cancer cells



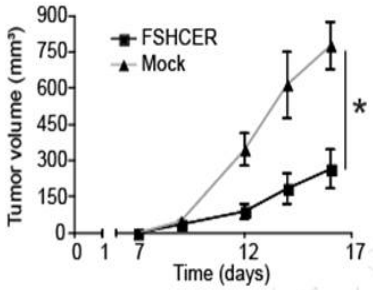
Ovarian Cancer

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.

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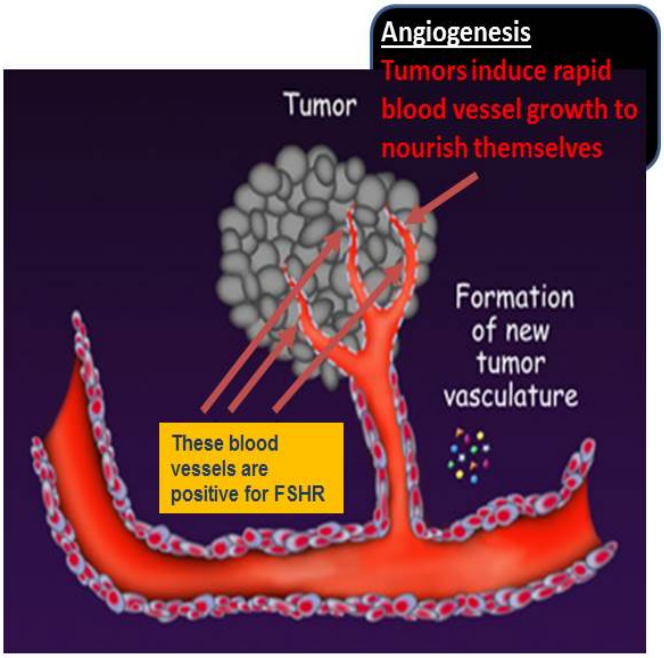
Our Magic Bullet

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



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

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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 $2-3 MM

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

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

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

Early Cancer Detection – Liquid Biopsy

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

Cchek™
Early Cancer Detection

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

Competing Liquid Biopsy Approaches

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

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

All these approaches tend to be very expensive

Anixa's Orthogonal Approach

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

Artificial Intelligence (AI) Analysis

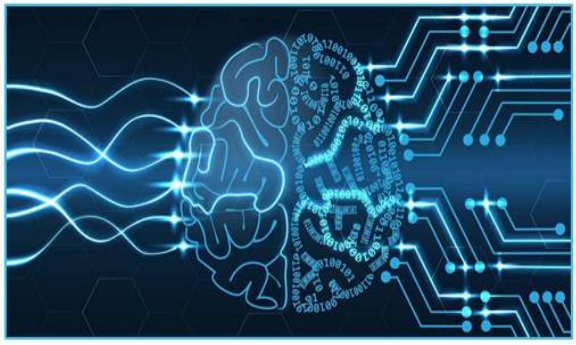
Training

Calls

Neural Network

Normal Patient Samples

Cancer Patient Samples



Patient Sample

Malignancy or Normal

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18

Anixa's Chek™ Early Cancer Detection Technology

Early Screening Studies:
Multiple Cancer Types
Stages 1-4

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

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

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

Breast Cancer Screening Study:
Stages 1-2 only

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

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

Prostate Cancer Screening Study:
All Gleason Scores
Internal Study

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

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

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

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

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

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19

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

- 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

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21

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