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): May 23, 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**	**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 7.01 Regulation FD Disclosure.

Attached as Exhibit 99.1 to this Current Report is the form of presentation that Anixa Biosciences, Inc. used in connection with its presentation at the B. Riley FBR Institutional Investor Conference on May 23, 2019.

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: May 23, 2019

ANIXA BIOSCIENCES, INC.

By: /s/ Amit Kumar

Name: Dr. Amit Kumar

Title: President and Chief Executive Officer

Anixa Biosciences, Inc.
May 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.

Anixa Corporate Background

General & Financial

- NASDAQ: ANIX
- Bay Area, CA Biotech
- **More than 1 year of cash**
- **No debt**
- Headcount: 6 Full-time
- Two high value programs

Strategy

- Invent/in-license technology platforms
- Develop technology with partners
  - Leverage existing infrastructure of partner
  - Low cash burn
- Sell, license or commercialize products

Low cost effective business model

Key Collaborators

NEW JERSEY UROLOGY Excellence in Care

Virtua

THE WISTAR INSTITUTE

MOFFITT CANCER CENTER

MD Anderson Cancer Center | Cooper

Making Cancer History®

Penn Medicine ABRAMSON CANCER CENTER

US. Department of Veterans Affairs

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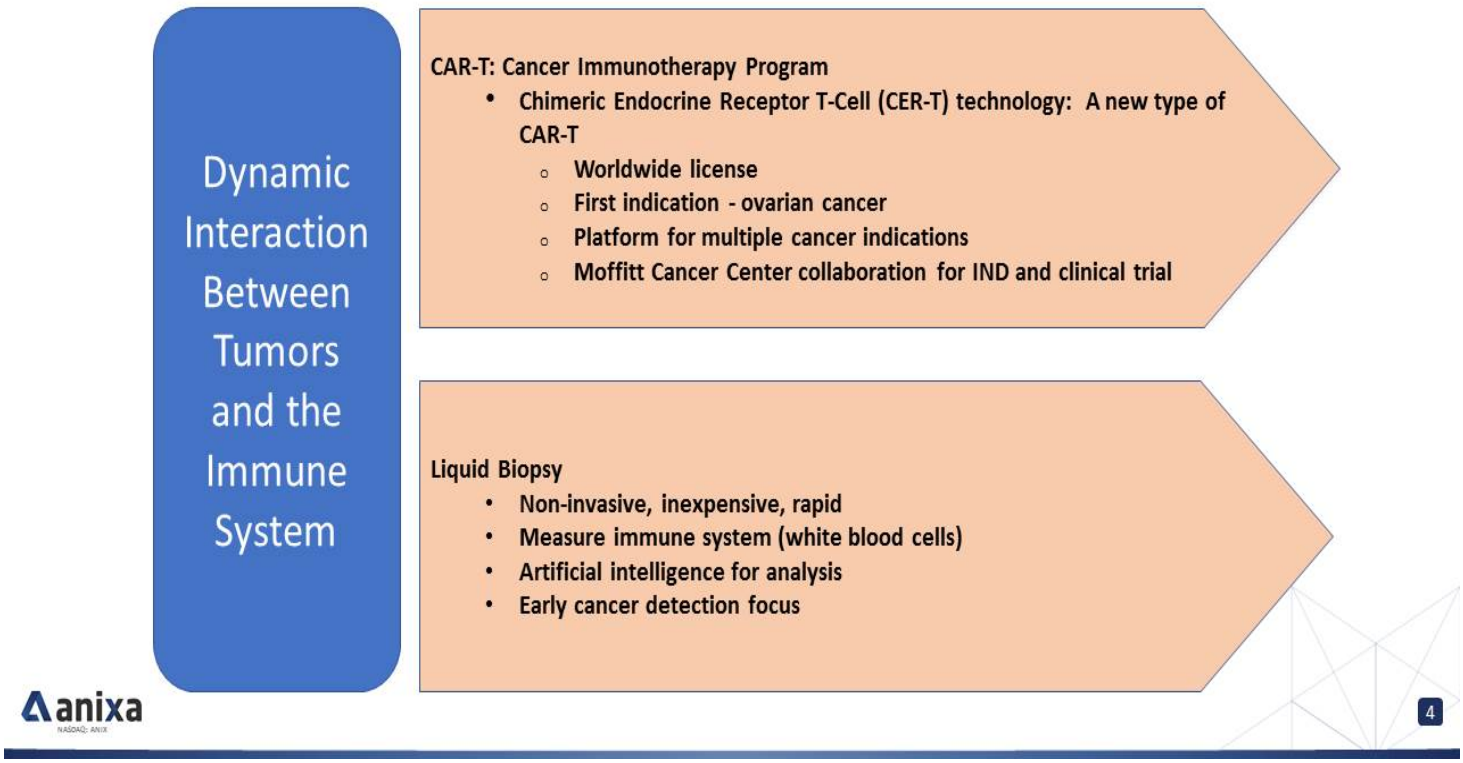
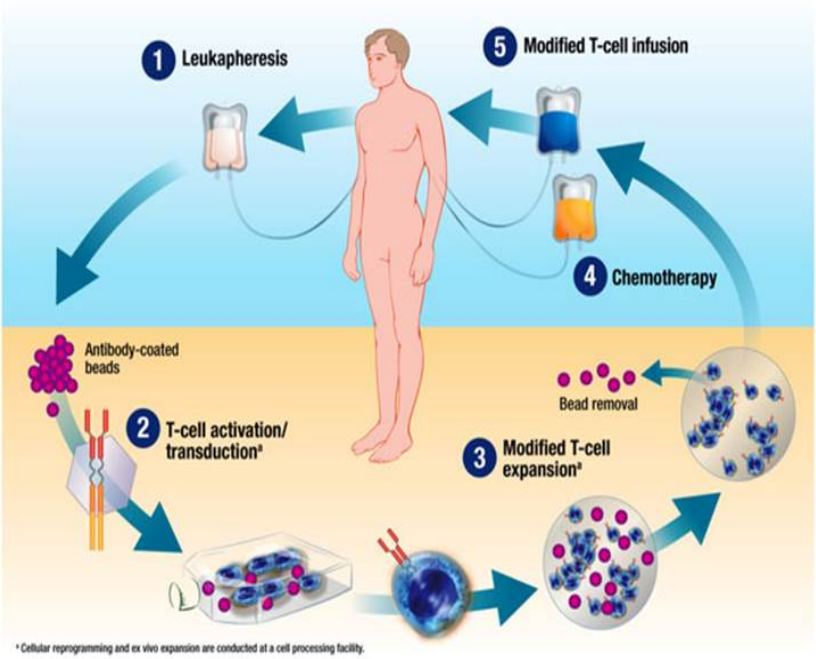
Two High Value Programs



Therapeutic Program

- CAR-T Technology
  - Ovarian cancer
- Platform for other tumor indications

CAR-T Process



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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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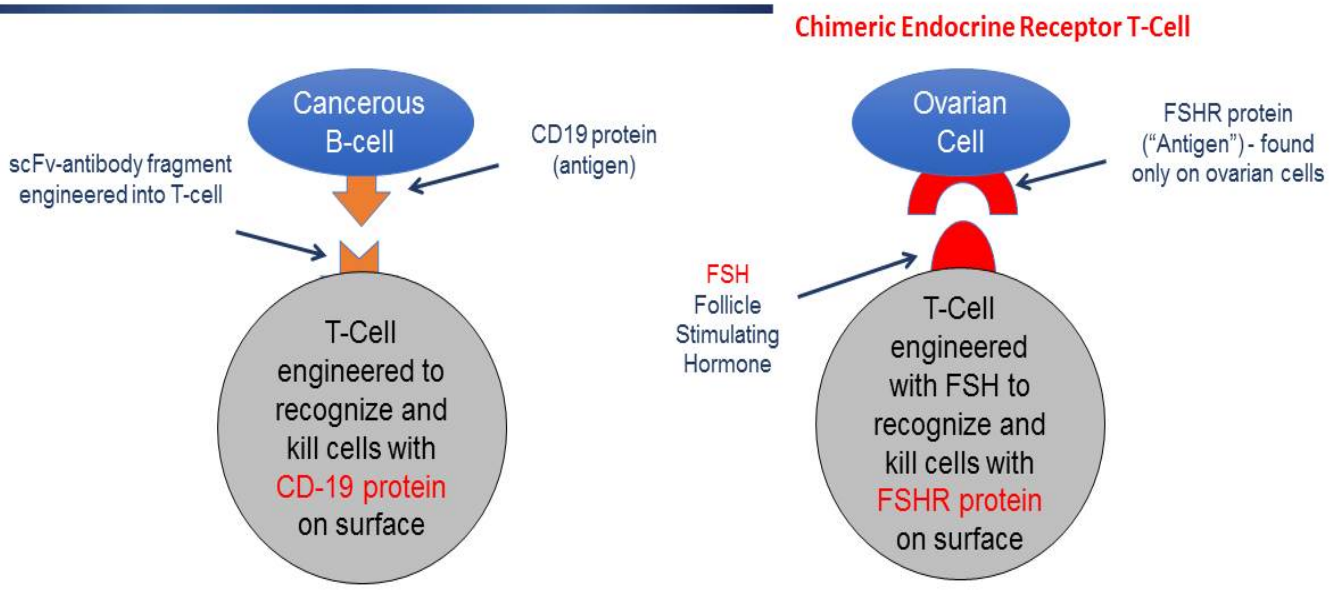
Anixa's Unique CER-T :Approach for Solid Tumors



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

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

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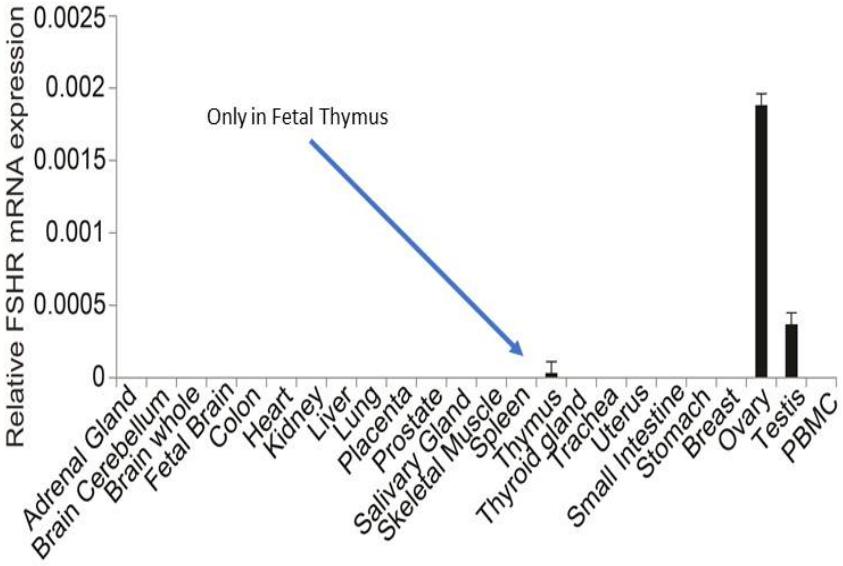
FSHR ONLY Expressed in Ovaries and Testis (in healthy humans)



- However, FSHR expressed on the blood vessels of many TUMORS.
- Therefore, 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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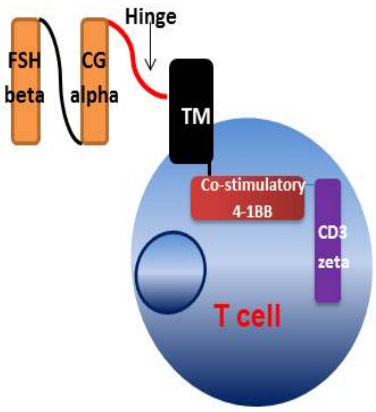
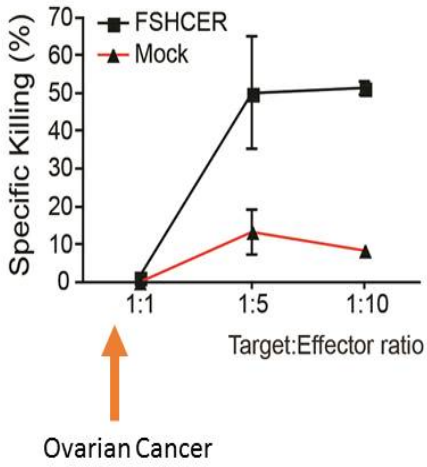
Pre-Clinical Data



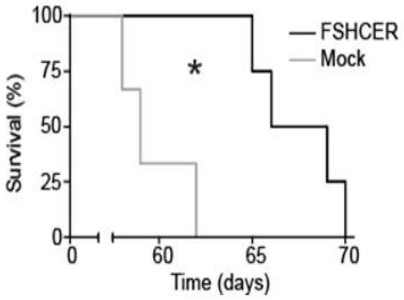
FSH-Targeted chimeric receptors re-direct primary human T cells against FSHR+ ovarian cancer cells



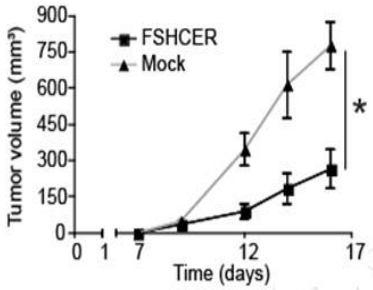
Ovarian Cancer

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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Summary of Data on Anixa's CAR-T

- Published: Clinical Cancer Research, 23(2)January 15, 2017, 441-453
- Tested Human CAR-T in immunocompromised mice against human Ovarian Cancer
- Tested Murine CAR-T in immunocompetent mice with murine ovarian cancer
- Tested Human CAR-T in immunocompromised mice against implanted Breast Cancer (proof of concept)
- **Clinical Trial: Human CAR-T against Human Ovarian Cancer**

If our CAR-T works in human ovarian cancer, it could be a billion dollar asset. If it also works on other cancers, it could be a multi-billion dollar asset

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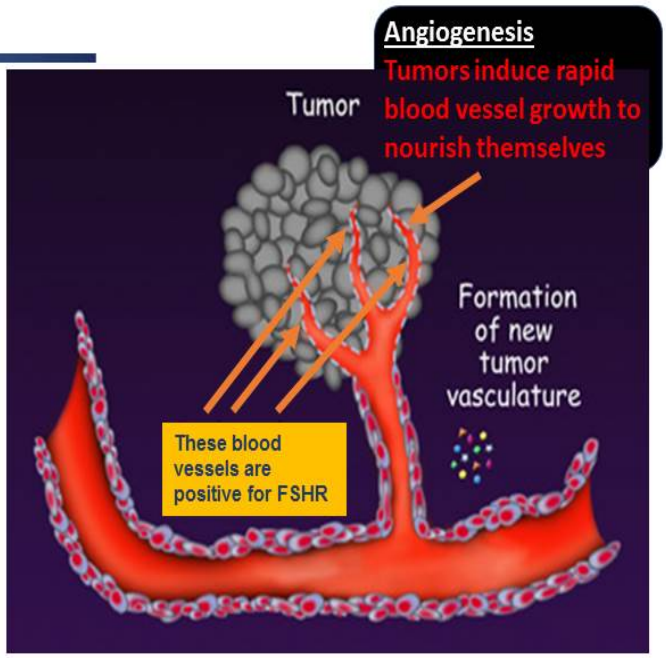
Our Magic Bullet

- 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 $7 BB



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

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Our CAR-T Program

Clinical Cancer Research, 23(2)January 15, 2017, 441-453

- Exclusive World Wide License from The Wistar Institute
- Pre-IND work at Moffitt Cancer Center lead by highly experienced team
- Cost for Pre-IND work is about $1.1 MM

- 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 is less than $2 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**

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Diagnostic Program

- Liquid Biopsy
  - Prostate and breast cancer
- Platform for other tumor indications

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

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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

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**

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Artificial Intelligence (AI) Analysis

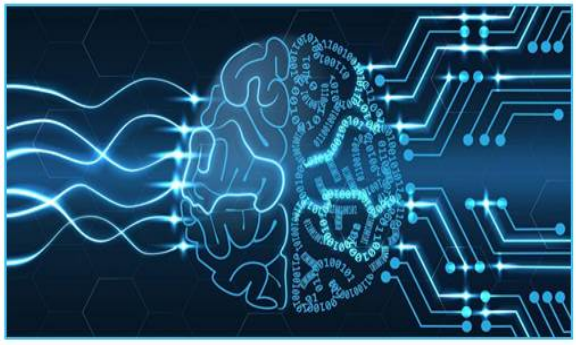
Training

Calls

Neural Network

Normal Patient Samples

Cancer Patient Samples



Patient Sample

Malignancy or Normal

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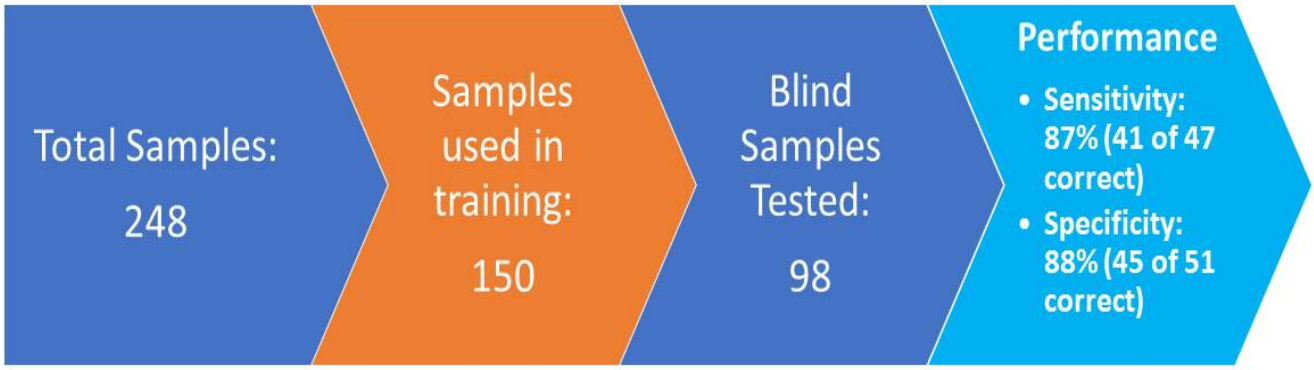
Early Studies: Multiple Cancer Types (Stages 1- 4)



Tumor Types

Multiple Samples			
Breast	Prostate	Lung	Colon
Pancreatic	Melanoma	Ovarian	Liver
Bladder	Cervical	Endometrial	Thyroid
Gastric	Head & Neck	Testicular	

Single Sample
Osteosarcoma (bone cancer)
Leiomyosarcoma (cancer of the soft tissue)
Liposarcoma (cancer of the connective tissue)
Vulvar
Appendiceal

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Breast Cancer Screening Study
(Stages 1 and 2)

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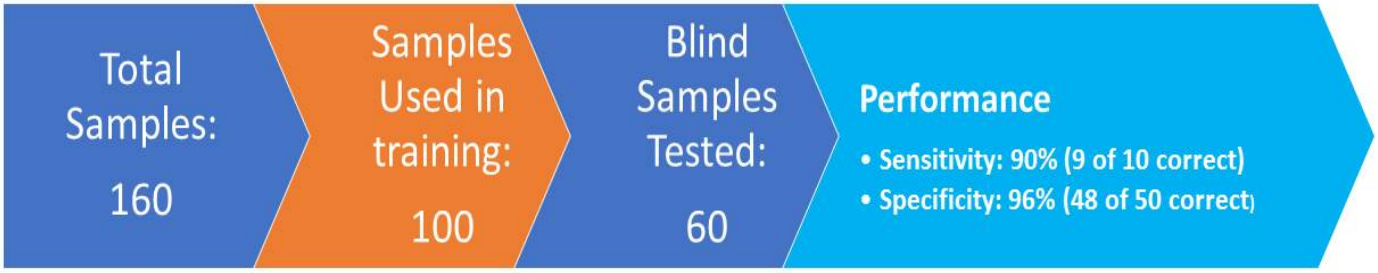
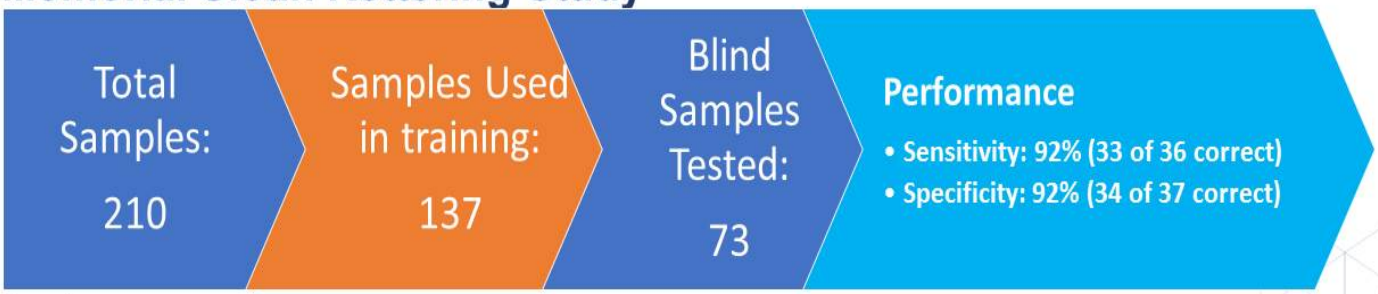
Prostate Cancer Screening Studies (Stages 1 -4)

Internal Study



Memorial Sloan Kettering Study



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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 Q3-2019

Long Term Vision- Pan Cancer Screening Test

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Anixa's Value-Creating, Near-Term Milestones

Therapeutic Program

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

Diagnostics Program

- Scientific presentations and publications
- Additional meetings with FDA
- Strategic alliances
- Commercial launch as laboratory developed test in third quarter of 2019

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