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): September 16, 2020

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

Delaware	**001-37492**	**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.

On September 16, 2020, Anixa Biosciences, Inc. (the "Company") presented at the 2020 H.C. Wainwright 22nd Annual Global Investment Conference. Attached as Exhibit 99.1 to this Current Report is the form of presentation of the Company which was used by management at the conference. 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: September 16, 2020

ANIXA BIOSCIENCES, INC.

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

Exhibit 99.1

September 16, 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
- **18-24 months of cash**
- **Capital Efficient**
- **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
- Multiple Orthogonal Projects
- **Sell or license products**

Key Collaborators

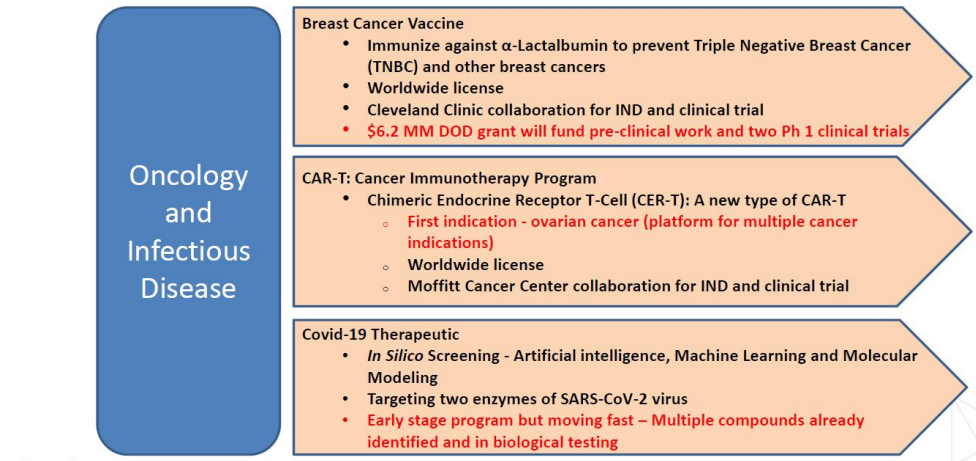
Cleveland Clinic

MOFFITT CANCER CENTER

THE WISTAR INSTITUTE

ontochem

Three High Value Programs



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Commercial Partnership and Monetization Strategy

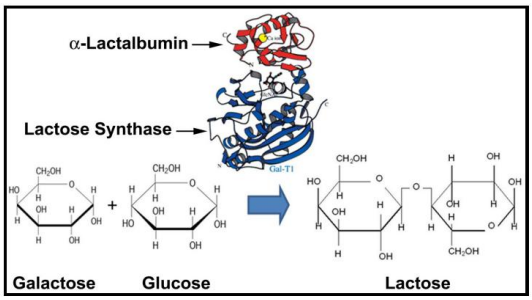
- Drug development is risky
  - We mitigate the risk by diversifying
  - We also work on programs that are relatively low cost
- Our strategy is to monetize our programs, through licensing partnerships, once we have positive Phase 1, first in human data
  - Upfront license payment
  - Funding for support of clinical trial costs
  - Milestones based on successes
  - Revenue share/royalty
  - Equity investments
- The size of the payments above depend on the quality of the data, the size of the market, and overall value of the product

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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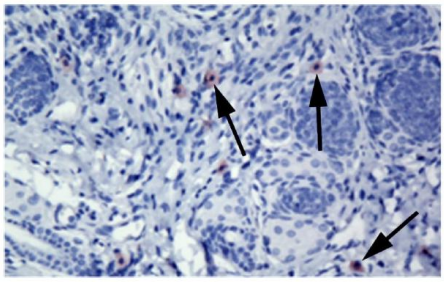
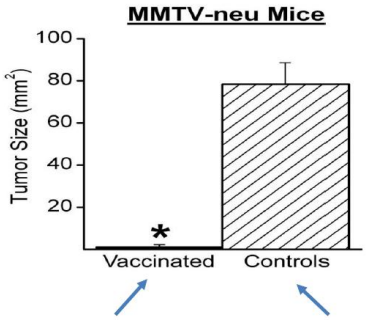
Vaccination Prevents Breast Cancer

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 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 (September/October 2020)
- Begin first clinical trial in 2020/2021
- 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

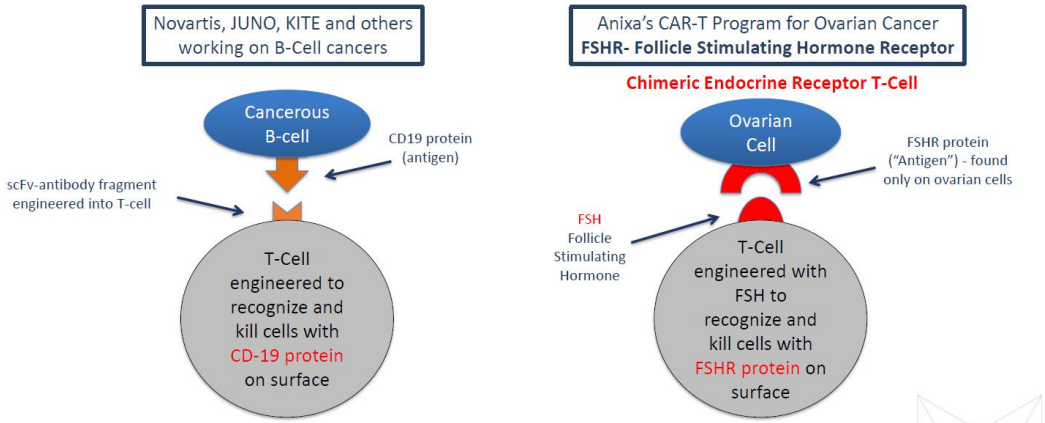
- Durable responses (50-80% of patients)
- Multibillion dollar valuations and big pharma deals
  - Novartis - First approved product by FDA
    - Kymriah for ALL- Acute Lymphoblastic Leukemia
    - Second approval for DLBCL-Diffuse large B-cell Lymphoma
  - KITE - $12BB acquisition by GILD
  - JUNO -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

Our Opportunity

- Conventional CAR-T has <u>not</u> worked clinically in solid tumors

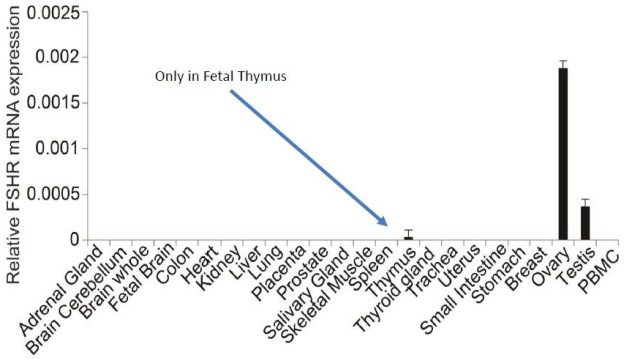
MAGIC BULLET → Anixa has a unique approach to making CAR-T work for multiple solid tumors, beginning with Ovarian Cancer

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.

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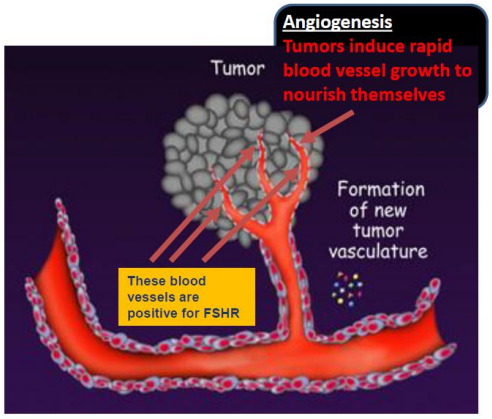
Our Magic Bullet

- **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 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**

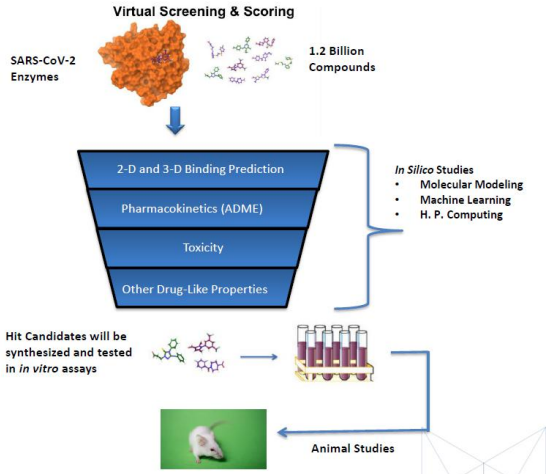
- Data published: *Clinical Cancer Research*, 23(2)January 15, 2017, 441-453

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

- **Goals-**
  - Identify One or two candidate drugs by end of year, followed by Proof-of concept animal studies in Q1-2021
  - Assuming POC animal studies are promising, we will seek funding for Pre-IND Studies and Clinical Trials



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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