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): March 10, 2022

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 5.07 Submission of Matters to a Vote of Security Holders.

On March 10, 2022, Anixa Biosciences, Inc. (the "Company") completed its 2022 annual meeting of stockholders (the "Annual Meeting"). The number of shares of stock entitled to vote at the Annual Meeting was 30,132,319 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 19,313,612 shares. At the Annual Meeting, the Company's stockholders (i) re-elected Dr. Amit Kumar, Dr. Arnold Baskies, Emily Gottschalk, and Lewis H. Titterton, Jr. as directors, (ii) approved, on a non-binding, advisory basis, the Company's executive compensation, and (iii) ratified the appointment of Haskell & White LLP as the Company's independent registered public accounting firm for the fiscal year ending October 31, 2022. 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, Emily Gottschalk, and Lewis H. Titterton, Jr. were each re-elected to serve until the 2023 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	8,426,038	973,151	9,914,423
Dr. Arnold Baskies	8,417,697	981,492	9,914,423
Emily Gottschalk	8,427,137	972,052	9,914,423
Lewis H. Titterton, Jr.	9,159,566	239,623	9,914,423

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
6,670,331	2,450,849	188,009	9,914,423

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, 2022 was ratified. The voting results were as follows:

Shares Voted For	Shares Voted Against	Shares Abstaining	Broker Non-Vote
19,035,845	193,874	83,893	-

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
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

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: March 11, 2022

ANIXA BIOSCIENCES, INC.

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

NASDAQ:ANIX

March 2022

Amit Kumar, PhD
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 Biosciences: At-a-Glance

Anixa Biosciences is a clinical-stage company collaborating with world-renowned research Institutions to develop first-in-class treatments to prevent and treat unmet needs in oncology and infectious diseases

Overview

NASDAQ: ANIX
- Biotech Bay Area, CA

Strong Balance Sheet
- ~$35MM Cash, No debt

Capital Efficient
- Market Cap = $82M

Investment Highlights

- **Unique, Capital Light Business Model Relies on Partnering of All Laboratory Operations with World-Class Research Centers/Iconic Academic Institutions**
  - Technology exclusively in-licensed; programs developed by Moffitt and Cleveland Clinic
  - No build-out of immense fixed costs; modest rate of funding each program due to offset
- **Leading Therapeutic and Vaccine Candidates Have the Potential to Change the Treatment Landscape in High-Value Categories (Breast and Ovarian Cancer)**
  - FDA has cleared two INDs with one trial having commenced and the other initiating soon
- **Strong Cash Position With No Debt**
  - 4-5 years cash runway
  - Approximately $5M annual burn since 2017
- **Clinical Programs Represent Multi-Billion-Dollar Opportunities**
  - Leveraged for partnering and monetizing products for shareholders

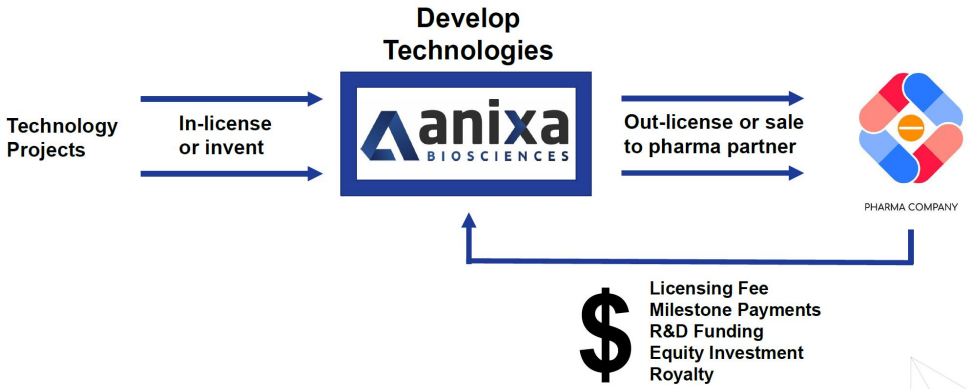
Unique Business Model: Overview

Strategy: Low-Cost Business Model
- Invent/in-license technology platforms
  - Develop technology and programs with partners
    - Leverage existing infrastructure of partner
    - Maintain low overhead and cash burn
    - Allows for multiple orthogonal projects
  - Out-license programs to pharma for late-stage clinical development and commercialization

Key Collaborators

MOFFITT CANCER CENTER
Cleveland Clinic
THE WISTAR INSTITUTE
DEPARTMENT OF DEFENSE
NIH NATIONAL CANCER INSTITUTE
MolGenie

Anixa Business Model



Key Benefits of Anixa Business Model

- **Low Burn (historically ~$5 MM per year)**
  - Requires minimal dilutive financing
  - Current cash can last for 4-5 years
  - Delays are not as detrimental
- **Modest Staffing (4 full time employees)**
  - Dozens of staff at partner organizations
  - Small headcount means fewer dilutive incentive stock options granted
  - Working with the pre-eminent scientists in particular fields
- **Diversified portfolio of projects**
  - No fixed infrastructure to limit type of project
  - Enables multiple shots on goal
- **Monetize Programs Early**
  - Drug Development can take years to commercialize
  - Partnership enables early monetization and faster commercialization

Four High Value Programs in 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 trials
- $6.2 MM DOD grant to fund pre-clinical work and two Phase 1 clinical trials

Phase 1 trial has commenced

Ovarian Cancer Vaccine

- Immunize against the Extracellular Domain of the Anti-Mullerian Hormone Receptor 2 to prevent Epithelial Ovarian Cancer and other gynecological cancers
- Worldwide license
- Cleveland Clinic collaboration for IND and clinical trials
- Pre-Clinical work in progress
- NCI-PREVENT Program supporting pre-clinical development through IND submission

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 (IND cleared, August 2021)

Covid-19 Therapeutic

- Targeting main protease (Mpro) of SARS-CoV-2
- Shelf-stable, orally administered pill
- Animal POC studies show comparability to Remdesivir
- Performing combinatorial medicinal chemistry to optimize pharmacokinetics and increase potency

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Breast Cancer Vaccine Program

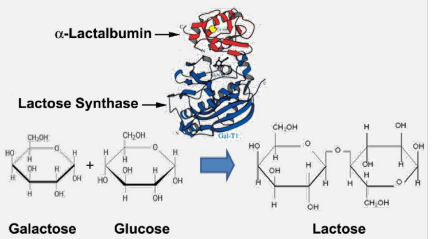
Breast Cancer Vaccine: Retired Tissue Specific Protein

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

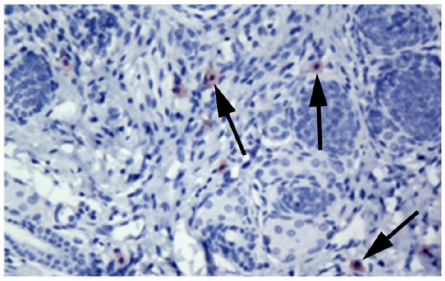
- Expressed ***only*** in the breast and ***only*** during lactation
- Expressed in tumor cells, especially Triple Negative Breast Cancer (**TNBC**)
- Our vaccine targets this retired protein
  - Once vaccinated, the patient's immune system is ready to destroy cells expressing the protein as they arise,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

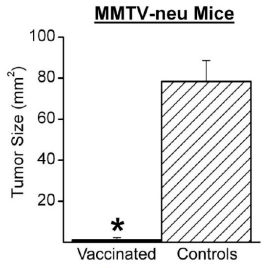
Pre-Clinical Studies: Vaccination Prevents Breast Cancer

Well-Tolerated



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

Robust Pre-Clinical Response



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

80% of un-vaccinated mice developed breast cancer

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Data published: *Cancers*, 2016, *8*, 56.

Breast Cancer Vaccine Trial:

Conducted by Cleveland Clinic, Funded by US Department of Defense

An open-label, Phase I dose-escalation trial in which successive cohorts of participants with high-risk for triple-negative breast cancer will be treated with successively higher doses of α-lactalbumin and zymosan

Phase 1a will enroll 18-24 patients who have completed treatment for early-stage, triple-negative breast cancer within the past three years and are currently tumor-free but at high risk for recurrence

Objective (Phase 1A)

To determine the maximum tolerated dose (MTD), dose-limiting toxicity (DLT) incidence and lowest immunologic dose (LID) of the vaccine in patients with early-stage, triple-negative breast cancer as well as monitor immune response.

Design

Participants will receive three vaccinations, each two weeks apart, and will be closely monitored for side effects and immune response.

Data Readout

The study is estimated to be completed in the third quarter of 2022

Phase 1b

- Healthy women with BRCA mutations
- Each woman decided to undergo prophylactic mastectomy
- Will immunize before surgery and monitor antibody and T-cell response and resected tissue

Evaluating the vaccine in breast cancer patients first, prior to healthy women with the BRCA mutations (target population)

Unique opportunity to garner supplemental data after studying breast tissue to determine if T-cells are surveilling the tissue without any visible cancer tumors

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Cleveland Clinic

Breast Cancer Vaccine: A Significant Market Opportunity

- Prophylactic (preventative) vaccines are administered to the **total** eligible population
- We expect reimbursement for this vaccine to be similar to the cervical cancer vaccine (~$400 retail cost)

U.S.
(Total Eligible Population)

- More than 80 million women are currently 40 or older in the U.S. alone
  - Millions more age into this group annually

Outside U.S.
(Billions of Candidates)

- Approximately 1.4 billion women are 40 and older outside the U.S.

Breast cancer became the most common cancer globally as of 2021, accounting for 12% of all new annual cancer cases worldwide, according to the World Health Organization [1]

[1] Breastcancer.org

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Ovarian Cancer Vaccine Program

Ovarian Cancer Vaccine: Retired Tissue Specific Protein

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

- The Extracellular Domain of the Anti-Mullerian Hormone Receptor 2 (ED-AMHR2) is primarily expressed in the ovaries but disappears as a woman reaches and advances through menopause
- The majority of ovarian cancer diagnoses occur after menopause
- AMHR2 is expressed again in the majority of ovarian cancers as well as some other gynecological malignancies
- If we properly immunize a woman against this protein, after she has reached menopause, we should be able to prevent the occurrence of ovarian cancer

Profile: Ovarian Cancer Vaccine

Cleveland Clinic

NIH NATIONAL CANCER INSTITUTE

Key Attributes

- Cleveland Clinic collaboration
- NCI funding support via its peer-reviewed **PREVENT** development program
- **PREVENT** is supporting pre-clinical innovative interventions and biomarkers for cancer prevention and interception
- Pre-IND work is being conducted at the NCI under the **PREVENT** Program
- Pre-clinical data published (*Cancer Prev. Res.* 2017, 10(11); 612-624)

A significant market opportunity:
Eligible candidates for the ovarian cancer vaccine will be similar to the breast cancer patient population only slightly older in age. Though a less common cancer, it's one of the most aggressive reproductive cancers and the prognosis is dire.

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Ovarian Cancer CAR-T Program

CAR-T Technology: Background and 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

Unique Approach →

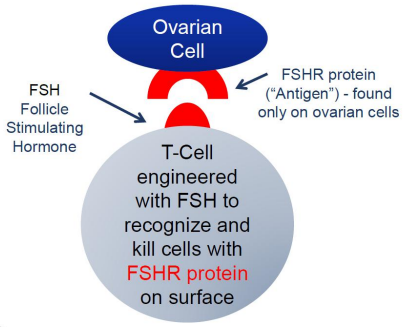
Anixa has a novel technology for making CAR-T work in multiple solid tumors, beginning with Ovarian Cancer

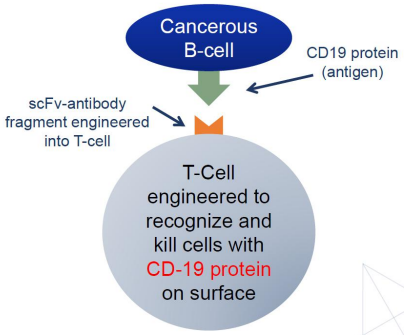
Anixa's Unique and Targeted CER-T Approach for Solid Tumors

Anixa's CAR-T Program for Ovarian Cancer
Follicle Stimulating Hormone Receptor (FSHR)-mediated CAR-T Technology

Other CAR-T Programs:
Novartis, JUNO, KITE and others working on B-Cell cancers

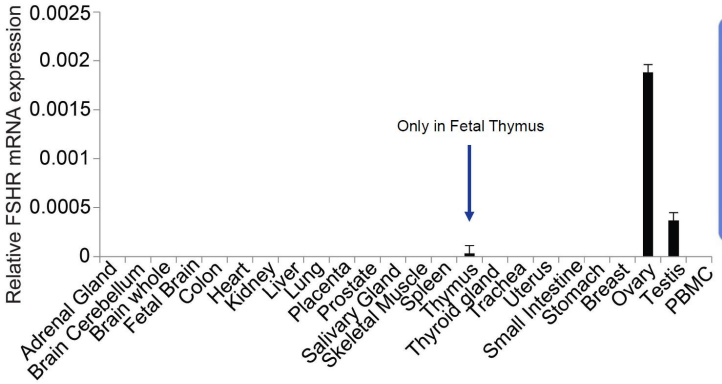
Chimeric Endocrine Receptor T-Cell





FSHR ONLY Expressed in Ovaries and Testes

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

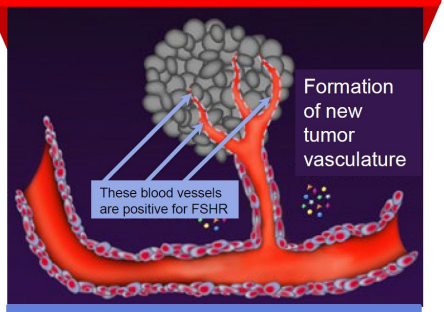
Source: Perales-Puchalt et al. "Follicle-stimulating hormone receptor is expressed by most ovarian cancers subtypes and is a safe and effective immunotherapeutic target." Clinical Cancer Research. 2017.

Our FSHR-Mediated CAR-T Technology: Dual MoA

- Many tumors have blood vessels where FSHR is expressed even though healthy tissue does not show such expression
  - Physiologically, FSHR may be helpful in enabling tumors to create vasculature
  - Elegant target: outside of the tumor margin, FSHR on blood vessels disappears
- Anti-angiogenesis drugs are a multi-billion-dollar class of drugs, with Avastin the leader with 2017 sales of $7BB

Our FSHR targeted CAR-T may destroy tumor vasculature and starve or shrink the tumor, disrupting FSH from both the inside and outside

Angiogenesis
Tumors induce rapid blood vessel growth to nourish themselves



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

Our FSHR-Mediated CAR-T Program: The First Potential Anti-Angiogenic CAR-T Therapy

Exclusive worldwide license from The Wistar Institute

We Believe Our CER-T Approach Will Work In Solid Tumors, Especially Ovarian Cancer, Where Others Have Failed

1. FSHR is a unique target
2. FSH is a natural ligand (not synthetic)
3. Our approach may provide anti-angiogenic synergy
4. Our CAR-T will execute a dual mechanism of action in destroying the tumor

Previous Challenges:

- The CAR-T cells may not be susceptible to the highly suppressive tumor microenvironment (TME)
- As the CAR-T cells are destroying vasculature, they make it leakier, enabling simultaneous, localized delivery of other agents including chemotherapy
- CAR-T mediated cell death may be more powerful than other anti-angiogenesis drugs

Summary: Our FSHR-Mediated CAR-T Program

- Pre-clinical testing
  - 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
- **IND Cleared in August 2021**
- Ovarian Cancer Clinical Trial
  - Single site, open label, dose-escalation trial
    - Lead by Moffitt Cancer Center
    - Safety focused trial with window to efficacy
  - Clinical trial to commence Q1 '22

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

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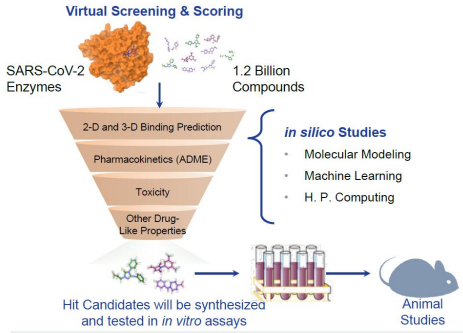
COVID-19 Therapy Program

Covid-19 Therapy Program: A Highly Targeted vs. Repurposed Therapy



- Initiated April 20, 2020 with partner MolGenie, 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
- ✓ Identified compounds with comparable potency to Remdesivir
- ✓ Completed proof-of-concept animal studies
- ✓ **Identified compound that is 5x potent compared to authorized drug**

Goals

- ☐ Inexpensive, orally-administered pill, outpatient setting
- ☐ Perform combinatorial medicinal chemistry around best compound from animal POC study to increase potency and optimize pharmacokinetics
- ☐ Commence Pre-IND studies

anixa NASDAQ: ANIX

Value-Creating Near-Term Milestones

Breast Cancer Vaccine

- **Phase 1a trial fully enrolled**
- First patient dosed in Phase 1b
- Clinical data release

Q3 2022 trial completion
Mid-2022 read out of topline data

Ovarian Cancer Vaccine

- **R&D Data release and publications**
- Initiate IND-enabling studies
- File IND application

CAR-T Program

- **Initiation of Clinical Trial**
- Patient recruitment
- First patient dosed
- Clinical data release
- Initiate pre-clinical work on other tumors; anti-angiogenesis

Early 2022 clinical trial initiation
Data planned for Q3 2022

Covid-19 Therapeutics

- **Selection of clinical candidate**
- Initiate IND-enabling studies
- Seek government research funding
- Strategic alliances
- File IND application

Near-Term Shareholder Goals

- Raise visibility, market capitalization and liquidity
- Diversify investor base
- Maintain conservative cash position

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NASDAQ: ANIX

Seasoned Management Team

Amit Kumar, Ph.D.
Chairman,
President and CEO

American Cancer Society
CombiMatrix
IDEXX

Michael J. Catelani
Chief Operating Officer and
Chief Financial Officer

Tacere therapeutics
BENITEC BIOPHARMA
silencing genes for life

Pamela D. Garzone, Ph.D.
Chief Development Officer

Calibr
Pfizer

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