

**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 21, 2021

**ANIXA BIOSCIENCES, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction  
of incorporation)

**001-37492**  
(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:

<b>Title of each class</b>	<b>Trading Symbol(s)</b>	<b>Name of each exchange on which registered</b>
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 May 21, 2021, Anixa Biosciences, Inc. (the "Company") completed its 2021 annual meeting of stockholders (the "Annual Meeting"). The number of shares of stock entitled to vote at the Annual Meeting was 31,431,200 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 19,134,552 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, (iii) ratified the appointment of Haskell & White LLP as the Company's independent registered public accounting firm for the fiscal year ending October 31, 2021, (iv) did not approve an amendment to the Company's Certificate of Incorporation, as amended (the "Certificate of Incorporation"), to include a provision designating the state and federal courts of the State of Delaware, respectively, as the exclusive forums in which certain claims may be brought against the Company notwithstanding that 88% of the stockholders that voted on this proposal voted to approve this proposal because there was an insufficient number of votes cast in favor of this proposal and, (v) did not approve an amendment to the Company's Certificate of Incorporation, to include a provision eliminating director liability for monetary damages notwithstanding that 88% of the stockholders that voted on this proposal voted to approve this proposal because there was an insufficient number of votes cast in favor of this proposal. 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 2022 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:

<b>Nominee</b>	<b>Shares Voted For</b>	<b>Shares Withheld</b>	<b>Broker Non-Vote</b>
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Dr. Amit Kumar	9,720,841	143,273	9,270,438
Dr. Arnold Baskies	9,780,465	83,649	9,270,438
Emily Gottschalk	9,563,565	300,549	9,270,438
Lewis H. Titterton, Jr.	9,779,419	84,695	9,270,438

**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
8,030,320	1,668,104	165,690	9,270,438

**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, 2021 was ratified. The voting results were as follows:

Shares Voted For	Shares Voted Against	Shares Abstaining	Broker Non-Vote
18,825,574	68,792	240,186	-

**Proposal No. 4 – Addition of a forum selection clause to the Company’s Articles of Incorporation**

The amendment to the Certificate of Incorporation to include a provision to designate the state and federal courts of the State of Delaware, respectively, as the exclusive forums in which certain claims may be brought against the Company was not approved. This proposal was not approved because the Company needed to receive the affirmative vote of a majority of the outstanding shares of common stock entitled to vote on this matter (or 15,715,601 shares) to have the matter approved. The voting results were as follows:

Shares Voted For	Shares Voted Against	Shares Abstaining	Broker Non-Vote
8,691,333	1,140,017	32,764	9,270,438

**Proposal No. 5 – Elimination of director liability for monetary damages**

The amendment to the Certificate of Incorporation to include a provision eliminating director liability for monetary damages was not approved. This proposal was not approved because the Company needed to receive the affirmative vote of a majority of the outstanding shares of common stock entitled to vote on this matter (or 15,715,601 shares) to have the matter approved. The voting results were as follows:

Shares Voted For	Shares Voted Against	Shares Abstaining	Broker Non-Vote
8,639,778	1,167,887	56,449	9,270,438

**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	<a href="#">Corporate Presentation</a>

**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 27, 2021

ANIXA BIOSCIENCES, INC.

By: /s/ Amit Kumar

Name: Dr. Amit Kumar

Title: President and Chief Executive Officer



May 2021

NASDAQ:ANIX

Amit Kumar, PhD  
Chairman and CEO  
ak@anixa.com

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## 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
- **Capital Efficient**
- **Strong Balance Sheet**
  - **>\$35MM Cash, No debt**
- Four 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



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## Four High Value Programs

### Oncology and Infectious Disease

#### Breast Cancer Vaccine

- Immunize against  $\alpha$ -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
- Received FDA clearance to commence Phase 1 trials (trial to commence mid-year 2021)

#### 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
- Pre-Clinical work in progress
- Cleveland Clinic collaboration for IND and 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 (IND FILED in March 2021)

#### Covid-19 Therapeutic

- In Silico Screening - Artificial intelligence, Machine Learning and Molecular Modeling
- Targeting two enzymes of SARS-CoV-2 virus
- Early stage program but moving fast - Multiple compounds already identified and in biological testing
- One compound similar in potency as Remdesivir in vitro



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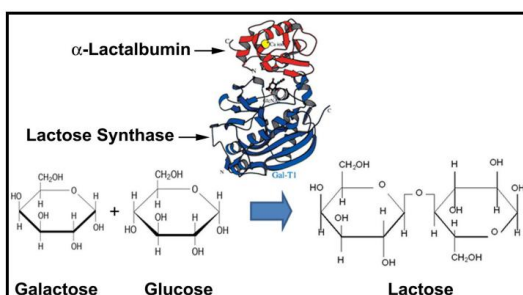
## Breast Cancer Vaccine- Retired Tissue Specific Protein

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



### $\alpha$ -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

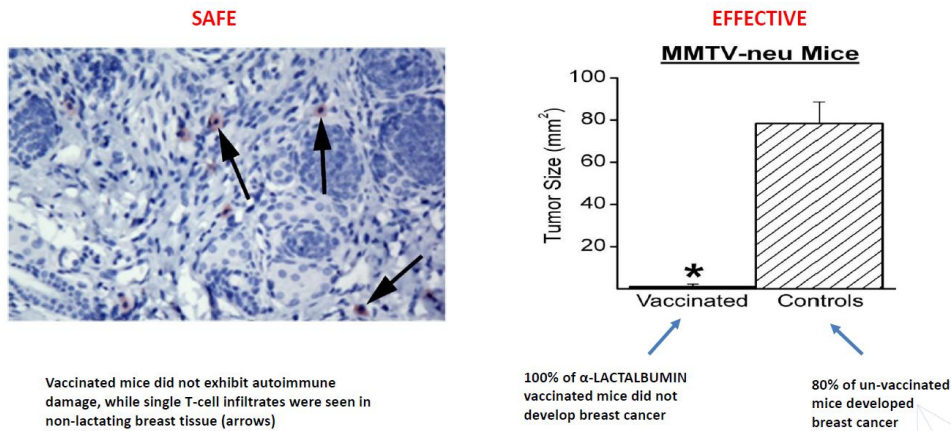
### Triple Negative Breast Cancer (TNBC)

- Most aggressive form of breast cancer
- Prevalent cancer in patients with breast cancer gene (BRCA) mutations



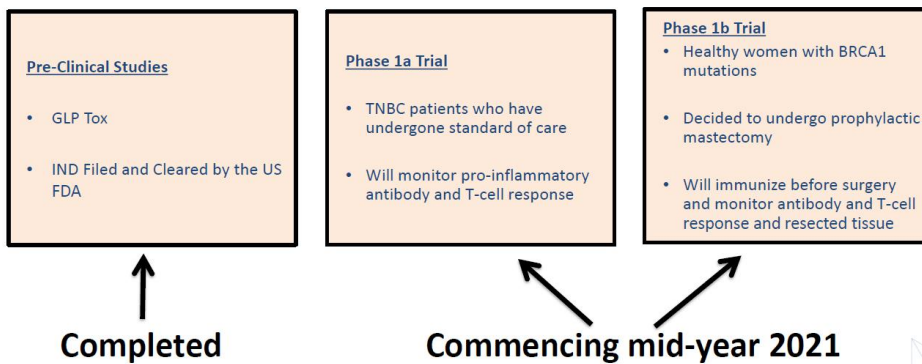
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## Vaccination Prevents Breast Cancer



## Breast Cancer Vaccine Clinical Trial Plan

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





## Summary: Breast Cancer Vaccine

### KEY ATTRIBUTES



Cleveland Clinic collaboration



DOD funded program; \$6.2 MM



IND filed and Cleared by US FDA



Initiate Clinical Trial mid-year 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

## 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

- Pre-Clinical R&D is being conducted at the Cleveland Clinic
- Animal Data published (*Cancer Prev. Res.* 2017, 10(11); 612-624)
- Market Opportunity in the multi-billions per year

## CAR-T Technology: Background & Opportunity

CAR- Technology has made great inroads in B-Cell cancers

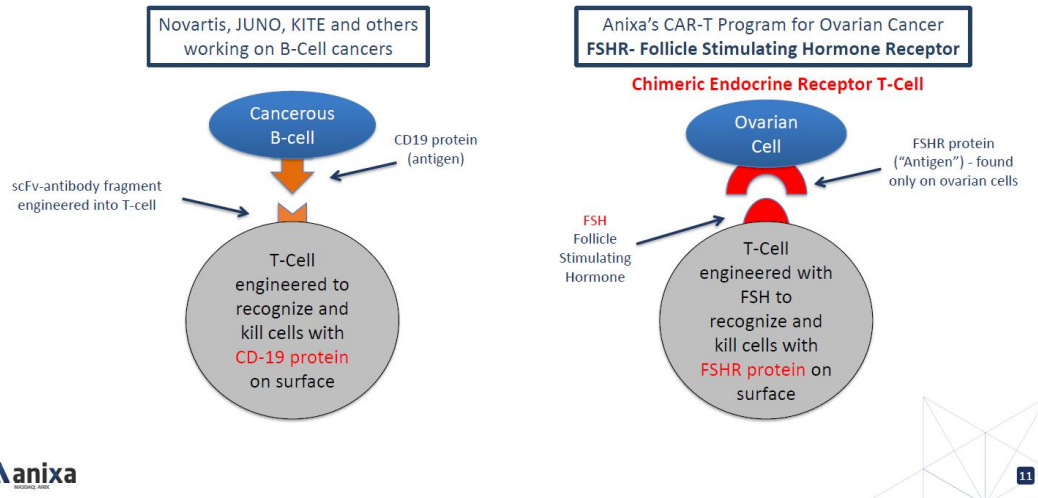
- Durable responses (50-80% of patients)
- Multibillion dollar valuations and big pharma deals
  - Novartis - First approved product by FDA
    - Kymriah for ALL- Acute Lymphoblastic Leukemia
    - Second approval for DLBCL-Diffuse large B-cell Lymphoma
  - KITE - \$12BB acquisition by GILD
  - JUNO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

### Our Opportunity

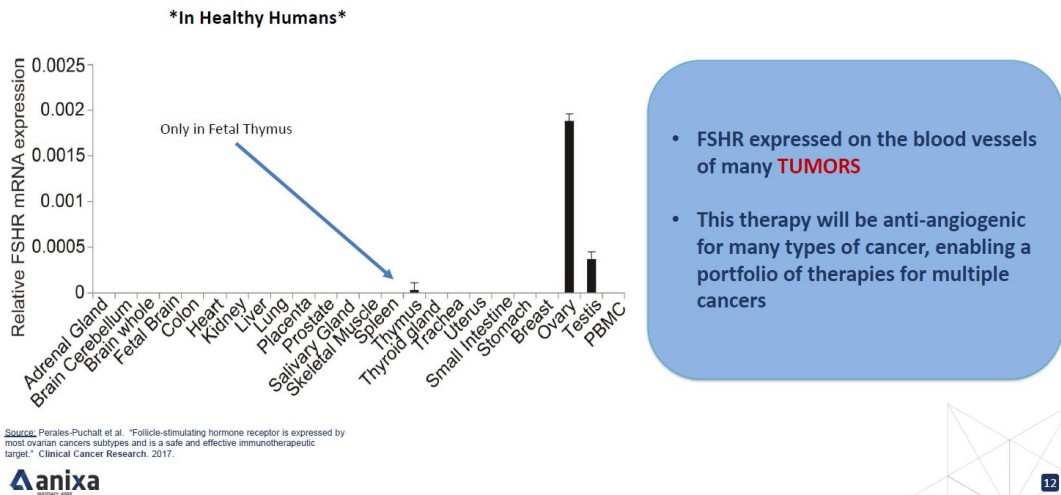
- Conventional CAR-T has not worked clinically in solid tumors

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

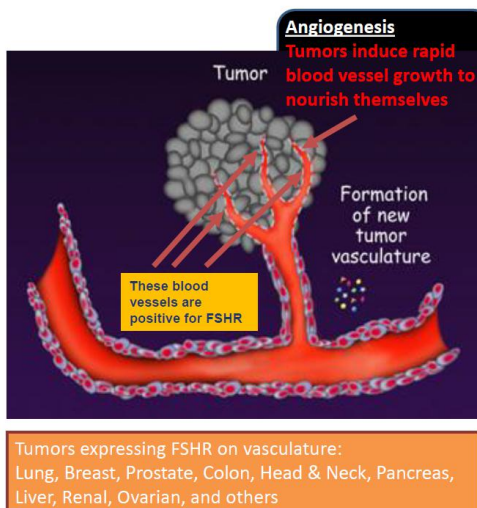


## FSHR ONLY Expressed in Ovaries and Testes



## 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
- IND filed in March 2021**
- 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
  - Clinical trial to commence 2021

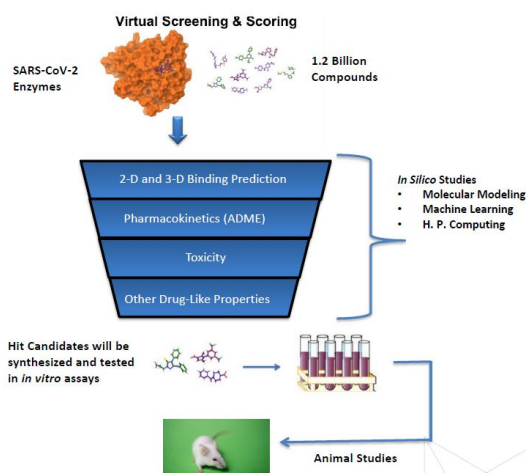
WE BELIEVE OUR CAR-T WILL WORK IN SOLID TUMORS, ESPECIALLY OVARIAN CANCER, WHILE OTHERS HAVE FAILED

- FSHR- UNIQUE TARGET
- FSH- NATURAL LIGAND- NOT SYNTHETIC
- ANTI-ANGIOGENIC SYNERGY

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

## Covid-19 Program

- Initiated April 20, 2020 with partner MolGenie, GmbH
  - Virtual Screening (1.2 BB compounds)
  - Targets: Main Protease (M<sup>pro</sup>), 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
  - Proof of concept animal studies in progress
- Goals-
  - Inexpensive, orally administered pill, outpatient setting
  - Assuming POC animal studies are promising, we will commence Pre-IND Studies





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## Anixa's Value-Creating Near-Term Milestones

### **Breast Cancer Vaccine**

- Initiation of Clinical Trial- mid-year 2021
- Clinical Data Release

### **CAR-T Program**

- 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

### **Covid-19 Therapeutics**

- Identify additional potential compounds
- Preliminary Animal Studies
- Seek Government Research Funding
- Strategic alliances

### **Ovarian Cancer Vaccine**

- R&D Data release and publications
- Initiate-IND enabling studies
- Seeking Government funding and alliances
- File IND Application

### **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

