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): April 17, 2023

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 April 17, 2023, Anixa Biosciences, Inc. ("we," "us," "our," or the "Company") issued a press release announcing that the Company and The Cleveland Clinic Foundation ("Cleveland Clinic") presented positive data for the Phase 1 study of its breast cancer vaccine. The press release, which is furnished as Exhibit 99.1 hereto, was issued following a presentation made by G. Thomas Budd, M.D. of Cleveland Clinic's Taussig Cancer Institute. Furnished hereto as Exhibit 99.2 is the poster utilized by Dr. Budd for the presentation.

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 our 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 clinical trials, 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 in this Current Report.

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	Press Release
99.2	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: April 17, 2023

ANIXA BIOSCIENCES, INC.

By: */s/ Michael J. Catelani*
Name: Michael J. Catelani
Title: President, Chief Operating Officer and Chief Financial Officer

Exhibit 99.1

Anixa Biosciences, Inc.
3150 Almaden Expressway
Suite 250
San Jose, CA 95118
408.708.9808
NASDAQ: ANIX

Anixa Biosciences and Cleveland Clinic Present Positive Data for Phase 1 Study of Breast Cancer Vaccine

Immune responses were observed at all dose levels

SAN JOSE, Calif., April 17, 2023 - - Anixa Biosciences, Inc. (NASDAQ: ANIX), a biotechnology company focused on the treatment and prevention of cancer today announced that Cleveland Clinic presented the most up-to-date data from the Phase 1 Trial of its breast cancer vaccine. The data presented showed that in the vaccinated women who have been tested to date, various levels of antigen-specific T cell responses were observed at all dose levels. The presentation was made by G. Thomas Budd, M.D., of Cleveland Clinic's Taussig Cancer Institute and principal investigator of the study. This breast cancer vaccine technology was invented at Cleveland Clinic, where the trial is being conducted, and Anixa is the exclusive worldwide licensee. The trial is funded by a grant from the U.S. Department of Defense to Cleveland Clinic.

The Phase 1a study is designed to evaluate the safety of the vaccine, identify the Maximum Tolerated Dose (MTD), and monitor the immune response in vaccinated women. All participants in the Phase 1a study are women who have had triple negative breast cancer (TNBC) within the last three years and have been curatively treated having undergone standard of care. At the time of vaccination, these participants are tumor-free, as determined by standard diagnostic techniques, but are at high risk of recurrence.

"We are testing this vaccine to determine if a vaccinated patient's immune system is trained to destroy cancer cells expressing α-lactalbumin, a protein found on TNBC cancer cells and not on normal cells. To evaluate the vaccination effect, immune mediated biomarkers of T cell activation and antibody production specific against α-lactalbumin are measured. We are heartened by the data, and look forward to additional studies," stated Dr. Amit Kumar, Chairman and CEO of Anixa Biosciences.

"We are pleased that varying degrees of antigen-specific T cell responses were observed at all dose levels tested to date, however, the Phase 1 trial is not designed to determine whether the responses are sufficient to prevent recurrence or primary tumorogenesis, said Dr. Budd. "We expect successive studies to determine how effective the immune responses are in preventing cancer."

About Triple-Negative Breast Cancer

One in eight women in the U.S. will be diagnosed with an invasive breast cancer at some point in their lives. Approximately 10-15% of those diagnoses are TNBC, however TNBC accounts for a disproportionately higher percentage of breast cancer deaths and has a higher rate of recurrence. This form of breast cancer is twice as likely to occur in African-American women, and approximately 70% to 80% of the breast tumors that occur in women with mutations in the BRCA1 genes are triple-negative breast cancer.

About Anixa Bioscience's Breast Cancer Vaccine

Anixa's breast cancer vaccine takes advantage of endogenously produced proteins that have a function at certain times in life, but then become "retired" and disappear from the body. One such protein is a breast-specific lactation protein, α-lactalbumin, which is no longer found post-lactation in normal, aging tissues, but is present in the majority of triple-negative breast cancers. Activating the immune system against this "retired" protein provides preemptive immune protection against emerging breast tumors that express α-lactalbumin. The vaccine also contains an adjuvant that activates an innate immune response, which allows the immune system to mount a response against emerging tumors to prevent them from growing. This vaccine technology was invented by the late Dr. Vincent Tuohy, who was the Mort and Iris November Distinguished Chair in Innovative Breast Cancer Research in the Department of Inflammation and Immunity at Cleveland Clinic's Lerner Research Institute. Dr. Tuohy was inventor of the technology, which Cleveland Clinic exclusively licensed to Anixa Biosciences. He was entitled to a portion of the commercialization revenues received by Cleveland Clinic and also held equity in Anixa.

About Anixa Biosciences, Inc.

Anixa is a clinical-stage biotechnology company focused on the treatment and prevention of cancer. Anixa's therapeutic portfolio consists of an ovarian cancer immunotherapy program being developed in collaboration with Moffitt Cancer Center, which uses a novel type of CAR-T, known as chimeric endocrine receptor T-cell (CER-T) technology. The company's vaccine portfolio includes a novel vaccine being developed in collaboration with Cleveland Clinic to prevent breast cancer – specifically triple negative breast cancer (TNBC), the most lethal form of the disease – as well as a vaccine to prevent ovarian cancer. These vaccine technologies focus on immunizing against "retired" proteins that have been found to be expressed in certain forms of cancer. Anixa's unique business model of partnering with world-renowned research institutions on clinical development allows the company to continually examine emerging technologies in complementary fields for further development and commercialization. To learn more, visit www.anixa.com or follow Anixa on Twitter, LinkedIn, Facebook and YouTube.

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's 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 in this press release.

Contact:

Mike Catelani
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408-708-9808

Abstract Presentation Number: 3035

Phase I trial of alpha-lactalbumin vaccine in high-risk operable triple-negative breast cancer

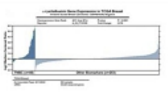
George Thomas Budd, Justin M. Johnson, Emily Rhoades, Halle Moore, Holly Levengood, Megan Kruse, Erin Roesch, Jame Abraham, Brenna Elliott, Elena Haury, Rachel Swartz, Holly Pederson, Zahraa Al Hilli, Vincent K. Tuohy
Cleveland Clinic, Cleveland, OH

Abstract Presentation Number: 3035

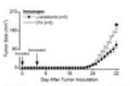
Abstract

Background: Triple-negative breast cancer (TNBC) has a poor prognosis and may be associated with germline mutations. α-lactalbumin (αLA) is expressed in lactating breasts but not at other times or in other tissues. Expression of αLA is found in 70% of TNBC (PMID: 27322324) so could be an immunologic target for TNBC based on the "retired protein hypothesis" (PMID: 31920646). In pre-clinical studies vaccination with αLA inhibited growth of established breast tumors and provided protection from development of autochthonous tumors in transgenic murine models of breast cancer and against 4T1 transplantable breast cancer in BALB/c mice (PMID: 20512124).
Methods: To determine the safety and immunogenicity of αLA, patients with early stage TNBC are being entered in a Phase I trial of αLA with GMP-grade zymosan adjuvant in Montanide ISA 51 VG vehicle. Subjects receive 3 vaccinations given once every 2 weeks. Events of Common Terminology Criteria for Adverse Events (CTCAE) grade ≥2 are considered dose-limiting toxicities (DLTs).
Results: CTCAE toxicity by dose level is summarized below. All DLTs were injection site reactions, with ulceration and need for incisional drainage representing the grade 3 events. ELISpot assays to determine frequencies of T cells producing IFNγ and IL-17 in response to recombinant αLA and ELISA assays of antibody response to αLA will be available in December 2022.
Conclusion: Dose level 2 appears to be the maximum tolerated dose. Accrual to dose levels 1 and 2 will be expanded to further define toxicity and immunologic effects. Accrual of patients with BRCA1 or PALB2 mutations planning to undergo prophylactic mastectomy is beginning in order to define the toxicity and immunologic effects in this group and to determine whether inflammatory changes from occult lactational foci will be produced.

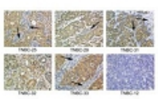
Introduction



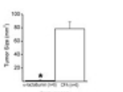
- α-lactalbumin normally expressed only in lactating breast tissue
- Oncomine database search of TCGA shows overexpression of α-lactalbumin gene in TNBC vs. other breast cancers



Inhibition of growth of 4T1 tumor growth with α-lactalbumin immunization 5 days after tumor inoculation (*P < 0.01).
Nat Med PMID: 20512124



Immunohistochemical detection of α-lactalbumin protein in parenchyma of human TNBC tumors. 5/6 (83%) showed reactivity ranging from weak (TNBC-32) to moderate (TNBC-33). Arrows show no immunostaining in tumor stroma.
Cancers PMID: 27322324



Growth of autochthonous breast tumors in 10-month-old MMTV-neu mice immunized with α-lactalbumin at 8 weeks of age (*P = 0.0004).
Nat Med PMID: 20512124

Contact

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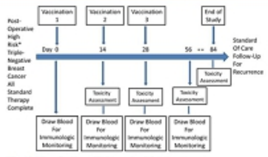
Funding

Department of Defense
Award Numbers:
W81XWH-17-1-0592
W81XWH-17-1-0593

Conflict of Interest Statement

The vaccine technology discussed in the abstract and poster has been licensed to Anixa Biosciences, Inc. (San Jose, CA). VKT and JMJ are the inventors on issued and pending patents related to the vaccine technology discussed in this manuscript and may earn royalties for such if the vaccine becomes commercially successful. In addition, VKT and JMJ have received equity in Anixa Biosciences, Inc. in the form of stock options. The abstract and poster were prepared without any input or coercion whatsoever from the licensee.

Methods and Materials



*Stage IIA-IIIC or residual disease following neo-adjuvant chemotherapy
**Subjects in the Prevention Cohort will have prophylactic mastectomy between days 57 and 84

Endpoints:

- Maximum Tolerated Dose (MTD)
- Lowest Immunologic Dose:
  The lowest dose producing significant increases in IFNγ and IL-17 in response to α-lactalbumin by ELISpot assay
- Optimal Immunologic Dose (Recommended for Phase II):
  The lowest tolerated dose producing a maximal immunologic response

Dose Levels

Dose Level	α-Lactalbumin	Zymosan	Notes
1	10 μg	10 μg	
2	100 μg	10 μg	
3	500 μg	10 μg	DLT experienced, dose will not be used
Original 2	100 μg	100 μg	DLT experienced, dose will not be used
2b	100 μg	30 μg	
2c	100 μg	60 μg	
2d	200 μg	10 μg	If dose level 2b proves too toxic
2e	200 μg	30 μg	If dose level 2c proves too toxic

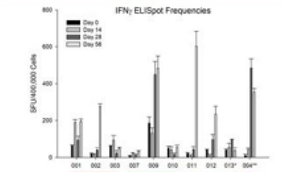
Results

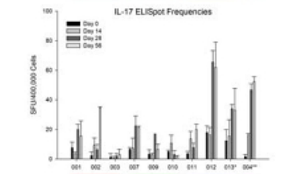
Patient Characteristics

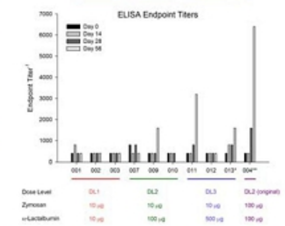
Subject ID	Age	Race	Reproductive History	Breast Fed?	TNM	Stage	Treatment Regimen	Prior Treatment -> Vaccine (d)
001	44	White	G3 P3 A0 L3	No	T1 N0 M0	IIA	AC-T	862
002	66	White	G3 P2 A1 L2	No	T2 N2 M0	IIIC	AC-Tcb	735
003	65	White	G2 P2 A0 L2	No	T2 N0 M0	IIA	AC	478
007	71	White	G5 P5 A1 L4	Yes	T1 N1 M0	IIB	AC-T Xeloda	348
009	67	Asian	G0 P0 A0 L0	N/A	T2 N0 M0	IIB	AC-T	515
010	78	White	G1 P1 A0 L1	No	T2 N0 M0	IIA	AC-T	467
014*	33	White	G0 P0 A0 L0	N/A	T2 N0 M0	IIIA	AC-T Xeloda	280
015*	53	Afr. Am.	G2 P2 A0 L2	Yes	T1 N1 M0	IIIA	AC-T Xeloda	30
016*	61	White	G2 P2 A0 L2	No	T1 N0 MX	IIIA	AC-Tcb Xeloda	671
011	71	White	G2 P1 A1 L1	No	T3 N0 M0	IIB	AC-Tcb Xeloda	753
012	45	White	G2 P2 A0 L2	Yes	T2 N1 M0	IIB	TC-AC pembro	41
013	58	White	G1 P1 A0 L1	No	T2 N1 M0	IIB	AC-T Xeloda	172
004	58	White	G5 P3 A2 L3	Yes	T2 N2 M0	IIIB	AC-T Xeloda	40

Dose Levels of α-lactalbumin/zymosan (mcg) are color-coded: 10/10; 100/10; 500/10; 100/100
Treatment: A, adriamycin; C, cyclophosphamide; T, taxol/taxotere; cb, carboplatin
* Immunologic studies pending

Results







Immunologic responses from trial subjects tested to date. ELISpot frequencies are presented as spot forming units (SFU) per 400,000 PBMCs in culture minus background. ELISA endpoint titers are presented as the greatest dilution at which signal (mean optical density of sample minus background) was reliably detected. In all cases, background wells contained all components except antigen. All data are from individuals coded by subject ID. All error bars represent ±SD.

*Third dose reduced to DL2 due to DLT in cohort.
**No third dose administered due to DLT in subject.

Results

Worst Toxicity by Dose Level							
Dose Level	α-Lac dose (mcg)	Zymosan dose (mcg)	Cumulative Number				
			Patients	Grade 0	Grade 1	Grade 2	Grade 3
1	10	10	3		3		
2	100	10	6		6		
3	500	10	3		2		1
Original 2	100	100	1				1

Toxicity has consisted predominantly of injection site reactions characterized by erythema, swelling, lump formation, pruritis, and in severe cases ulceration with delayed healing.

Discussion, Conclusions, and Plans

- Varying degrees of antigen-specific T cell responses were observed at all dose levels
- Per protocol, dose levels 1 and 2 are being expanded to 6 subjects each
- Based on current data, dose level 2 appears to be the maximum tolerated dose
- Additional dose levels will be explored
- Dose expansion cohorts in BRCA1/PALB2 carriers planning to undergo prophylactic bilateral mastectomy have opened
- Dose expansion cohort with concurrent pembrolizumab in the adjuvant setting is planned

Cleveland Clinic