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): **December 6, 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 December 6, 2023, Anixa Biosciences, Inc. ("we," "us," "our," or the "Company") issued a press release announcing that the Company and Cleveland Clinic Foundation ("Cleveland Clinic") presented new and updated positive data from 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 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: December 7, 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 New Data from Phase 1 Study of Breast Cancer Vaccine

– Antigen-specific T cell responses were observed at all dose levels –

– IFNγ and IL-17, immune-mediated biomarkers of T cell activation, increased over time from baseline –

– Vaccine was safe and well tolerated –

– Conference call to commence today at 6:30 p.m. ET –

SAN JOSE, Calif., December 6, 2023 /PRNewswire/ — Anixa Biosciences, Inc. ("Anixa" or the "Company") (NASDAQ: ANIX), a biotechnology company focused on the treatment and prevention of cancer, today announced new and updated positive results from the Phase 1 clinical trial of its breast cancer vaccine. The trial is being conducted in collaboration with Cleveland Clinic with funding by a grant from the U.S. Department of Defense.

The data were presented at the 2023 San Antonio Breast Cancer Symposium by G. Thomas Budd, M.D., staff physician at Cleveland Clinic Cancer Institute and principal investigator of the study, in a poster entitled "Phase I Trial of alpha-lactalbumin vaccine in high-risk operable triple negative breast cancer (TNBC) and patients at high genetic risk for TNBC."

Patients who had been curatively treated for TNBC received three vaccinations given once every two weeks. IFNγ and IL-17, which are T cell immune response indicators (cellular immunity), and antibody production (B cell humoral immunity) were measured to evaluate the vaccination effect. Data from the 16 patients treated to date showed that:

- The majority of patients developed ELISpot (T-cell) responses that met the rigorous protocol-specified definition of an immune response, with a measurable but lesser magnitude of response noted in the remaining patients.
- 12 (75%) of the women had antigen-specific IFNγ and/or IL-17 ELISpot responses that were observed at all dose levels, while ELISA antibody responses were observed at Dose Level 2 and higher.
- A statistically significant (P = 0.03) increase in IFNγ over baseline (Day 0) was observed by Day 56; while a significant (P = 0.0001) increase in IL-17 over baseline was observed by Day 14.
- Among the doses studied, Dose Level 1 (10 mcg α-lactalbumin/10 mcg zymosan) was determined to be a usable immunologic dose as well as the maximum tolerated dose (MTD).
- No significant side effects were observed, at the MTD, besides irritation at the sites of injection. No myalgias, flu-like symptoms, or aberrant laboratory values were noted.

Anixa and Cleveland Clinic plan to investigate additional intermediate dose levels and continue studying the vaccine's safety and immunologic effects in two additional patient cohorts.

- The first cohort, which opened for enrollment in August 2023, is evaluating the combination of the Company's breast cancer vaccine with Keytruda® (pembrolizumab) in post-operative patients found to have residual disease following neoadjuvant chemo-immunotherapy.
- The second cohort will investigate the safety and immunologic effects of the vaccine in patients who are BRCA1, BRCA2, or PALB2 mutation positive and are planning prophylactic risk-reducing mastectomies.

"The data from our Phase 1 trial to date has exceeded our expectations, and we are pleased with our progress. This vaccine is designed to direct the immune system to destroy TNBC cancer cells through a mechanism that has never previously been utilized for cancer vaccine development," stated Dr. Amit Kumar, Chairman and CEO of Anixa Biosciences. "We look forward to reviewing additional data as the trial continues to completion, and we are in the planning stages of the Phase 2/3 studies of this vaccine. Our goal is to initially evaluate the vaccine's ability to prevent recurrence of cancer in survivors, and continue with extension studies to eventually determine its effectiveness in preventing the initial onset of TNBC."

"There is a large unmet need for preventing TNBC, an aggressive form of breast cancer with few targeted treatment options available," said Dr. Budd, Cleveland Clinic. "We are encouraged by the data gathered to date and look forward to determining the optimal vaccine dose in additional patient cohorts. Our hope is that future studies will demonstrate that the antigen-specific T cell responses we observed translate to the prevention of breast cancer recurrence."

Anixa is the exclusive worldwide licensee to the novel breast cancer vaccine technology invented at Cleveland Clinic, the site of the Phase 1 trial. The grant from the U.S. Department of Defense was made directly to Cleveland Clinic.

Conference Call Information

Anixa is pleased to invite all interested parties to participate in a conference call, during which this new data will be discussed.

Conference Call Details:

Presentation host:	Anixa management, with special guest speakers
Date and time:	Today, December 6, 2023, at 6:30 p.m. ET
Phone access:	**Registration Link** to receive your dial-in number and unique PIN
Webcast:	Available at www.anixa.com under "Events & Presentations"

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.

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Phase I Trial of alpha-lactalbumin vaccine in high risk operable triple negative breast cancer (TNBC) and patients at high genetic risk for TNBC

PO2-17-12

Justin M. Johnson, Emily E. Rhoades, Holly Levengood, Halle Moore, Megan L. Kruse, Erin Roesch, Jame Abraham, Brenna Elliott, Rachel Swartz, Holly J. Pederson, Elena Haury, Azka Ali, Tiffany Onger, Andrew Sciallis, Zahraa AlHilli, Auston Wei, Thaddeus Stappenbeck, George Thomas Budd

San Antonio Breast Cancer Symposium®
December 5-9, 2023

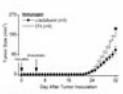
Abstract

Background: Triple-negative breast cancer (TNBC) has a poor prognosis and may be associated with germline mutations. α-Lactalbumin (aLA) is expressed in lactating breasts but not at other times or in other tissues. Expression of aLA is found in 70% of TNBC (PMID: 27322324) so could be an immunologic target for TNBC based on the "retired protein hypothesis" (PMID: 31926846). In pre-clinical studies, vaccination with aLA provided protection from development of autochthonous tumors in transgenic murine models of breast cancer and inhibited growth of established 4T1 transplantable breast tumors in BALB/c mice (PMID: 20512124). **Methods:** To determine the safety and immunogenicity of aLA, patients with early stage TNBC are being entered in a Phase I trial of aLA 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. 12 of 16 patients assayed to date have met protocol specified definitions of an immune response based on ELISpot assays to determine frequencies of T cells producing IFNγ or IL-17 in response to recombinant aLA. **Conclusion:** Dose level 1 appears to be the maximum tolerated dose. Based on immune response, additional intermediate dose levels will be studied. An additional cohort of patients receiving concurrent anti-PD1 treatment is being accrued. Accrual of patients with BRCA1/2 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.

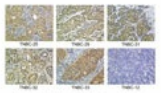
Funding Source: Department of Defense (W81XWH-17-1-0592 and W81XWH-17-1-0593).

Background

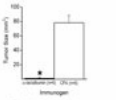
- α-lactalbumin normally expressed only in lactating breast tissue
- Oncomine database search of TCGA shows overexpression of α-lactalbumin gene in TNBC vs. other breast cancers



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).
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

Cleveland Clinic

Study Design

Subject Eligibility

- Pathologic Stage IIA-IIIC or residual disease following neo-adjuvant chemotherapy
- Completed all standard therapy
- Within 3 years of initial therapy for triple-negative breast cancer
- No evidence of recurrence or metastasis on restaging scans
- Normal serum prolactin and no prolactin-raising medications
- Adequate major organ function
- Performance Status 0-1

Trial Schema

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

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	802
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
016	57	White	G1 P1 A0 L1	No	T1 N1 M0	IIA	AC-T, Abraxane, Keytuda	646
018	62	White	G4 P4 A0 L4	Yes	T3 N3 M0	IIIC	TC-AC, Pembro, Keytuda	305
020	61	White	G3 P3 A0 L3	No	T1 N0 M0	IB	TC-AC, Keytuda	171
007	71	White	G6 P5 A1 L4	Yes	T1 N1 M0	IIB	AC-T, Keytuda	348
009	57	Asian	G2 P2 A0 L2	N/A	T2 N0 M0	IIB	AC-T	515
010	75	White	G1 P1 A0 L1	No	T2 N0 M0	IIA	AC-T	467
014	53	White	G0 P0 A0 L0	N/A	T2 N0 M0	IIA	AC-T, Keytuda	280
015	53	Afr. Am.	G2 P2 A0 L2	Yes	T1 N1 M0	IIA	AC-T, Keytuda	30
019	81	White	G2 P2 A0 L2	No	T1 N0 MX	IIA	AC-TCb, Keytuda	671
011	71	White	G3 P1 A1 L1	No	T3 N0 M0	IIB	AC-TCb, Keytuda	703
012	45	White	G2 P2 A0 L2	Yes	T2 N1 M0	IIB	TC-AC, Pembro	41
013	59	White	G1 P1 A0 L1	No	T2 N1 M0	IIB	AC-T, Keytuda	772
004	50	White	G5 P3 A2 L3	Yes	T2 N2 M0	IIIB	AC-T, Keytuda	43

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/Nacetrine; cb, carboplatin

Safety: Worst Toxicity by Dose Level

Dose Level	Alpha-Lac dose (mcg)	Zymosan dose (mcg)	n Patients	n Grade 1	n Grade 2	n Grade 3
1	10	10	6	6		
2	100	10	6	5		1*
3	500	10	3	1**		2
Original 2	100	100	1			1***

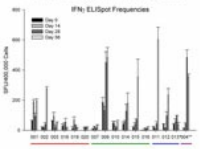
*Grade 3 after recurrence and pembrolizumab (reviewed with DSMC)

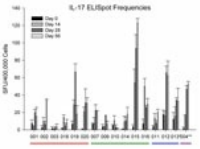
**3rd dose reduced in one subject after a Grade 3 event in a different subject at that dose level

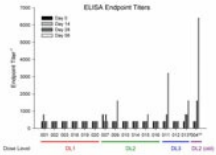
***3rd dose held

Results

Immunologic Assessment







Dose Level	DL1	DL2	DL3	DL2 (old)
Zymosan	10 µg	10 µg	10 µg	100 µg
α-Lactalbumin	10 µg	100 µg	500 µg	100 µg

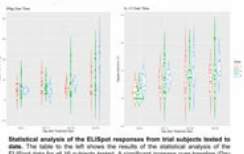
Immunologic responses from trial subjects tested to date. ELISpot frequencies are presented as spot forming units (SFU) per 400,000 PBMCs in culture minus background. ELISA endpoint titers are presented as the greatest dilution at which signal (mean optical density of sample minus background) was reliably 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.

Statistical Analysis

Statistical Analysis of IFNγ and IL-17 ELISpot Results by Visit and Dose*

Cytokine	Factor	Level	Estimated Mean	95% LCL	95% UCL	P-value
IFNγ	Visit	Day 0	29.58	7.03	67.68	
		Day 14	39.93	12.47	82.94	0.03
		Day 28	58.77	23.80	109.29	
		Day 56	102.86	54.17	167.34	
	Dose	1	36.53	7.58	87.09	
		2	60.71	20.28	122.77	0.65
		3	69.61	13.74	168.45	
IL-17	Visit	Day 0	2.43	0.18	7.26	
		Day 14	12.31	5.62	21.58	0.0001
		Day 28	17.03	8.83	27.71	
		Day 56	17.13	9.00	27.84	
	Dose	1	9.20	2.22	17.93	
		2	9.22	2.77	18.42	0.57
		3	16.81	4.69	36.42	

*The linear mixed model can account for correlations between measurements over time within the same patient. Due to right skewness, raw data was transformed to square root scale and estimated were back-transformed to raw scale for reporting. P-values were calculated by likelihood ratio test. Red font indicates significance.



Statistical analysis of the ELISpot responses from trial subjects tested to date. The table to the left shows the results of the statistical analysis of the ELISpot data for all 16 subjects tested. A significant increase over baseline (Day 0) was observed by Day 56 in the IFNγ ELISpot ($P < 0.03$) and by Day 14 in the IL-17 ELISpot ($P < 0.0001$). Although the estimated mean spot frequencies for both cytokines increased with dose, this effect was not significant. No significance was observed across visit or dose in the ELISA data (not shown). The violin plots above illustrate the table data with visits represented by the x-axis and dose levels color coded.

Discussion, Conclusions, and Plans

- Among the doses studied, Dose Level 1 is the maximum tolerated dose (MTD)
- IFNγ and IL-17 ELISpot responses were seen at all dose levels
- IFNγ and IL-17 ELISpot responses were seen in the majority of patients
- A statistically significant increase over baseline with time was observed in both ELISpot assays
- No statistically significant dose response was observed in either ELISpot assay
- Humoral responses by ELISA were detected only at high dose levels
- ELISA results may be due to assay sensitivity limit with plasma diluted ≥ 1:400; will re-test in the 1:50 – 1:400 range
- Dose Level 1 is a usable optimal immunologic dose based on toxicity and IFNγ and IL-17 ELISpot responses, but additional dose levels between DL1 and DL2 will be examined:

Dose Level	Alpha-Lac dose (mcg)	Zymosan dose (mcg)	n Patients
1b	50	10	3-6
1c	50	50	3-6
1d*	50	30	3-6

*If dose level 1c is too toxic

- 2 new cohorts are being studied:
  1. Patients receiving post-operative pembrolizumab after having been found to have residual disease following neoadjuvant chemo-immunotherapy
  2. BRCA1, BRCA2, and PALB2 carriers planning prophylactic risk-reducing mastectomies.

Contact
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216-444-6480

Conflict of Interest Statement
The vaccine technology discussed in the abstract and poster has been licensed to Anixa Biosciences, Inc. (San Jose, CA). JMJ is an inventor on issued and pending patents related to the vaccine technology presented here and may earn royalties for such in an amount not considered personally successful. In addition, 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.