

**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 3, 2024**

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:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
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 1.01. Entry Into a Material Definitive Agreement

On May 3, 2024, Anixa Biosciences, Inc. (the "Company") and the Cleveland Clinic Foundation (the "CCF") entered into a Joint Development and Option Agreement (the "Agreement"). Pursuant to the Agreement, the parties agreed on the terms and conditions under which the parties will collaborate in efforts to develop vaccines for the prevention or treatment of cancers in the Fields. In consideration of its Agreement, the Company will pay CCF a non-refundable, option fee on or before May 23, 2024. The Company will also provide development funding in three tranches, the first payment will be paid on May 8, 2024, the second payment will be paid on January 31, 2025 and the third payment will be paid on January 31, 2026 (collectively, the development fees). All costs, fees and/or expenses incurred in connection with the Agreement will be paid by the party incurring such costs, fees and/or expenses.

The Agreement is effective as of May 3, 2024 and will remain in effect, unless earlier terminated, upon the later of (i) thirty six months after the effective date and (ii) completion by CCF of its activities under the Work Plan (as defined in the Agreement). The Company may terminate the Agreement or any Work Plan at any time for any reason by giving written notice to CCF at least sixty (60) days before the last day of the then current Contract Period (as defined in the Agreement), provided that the Company cannot terminate a Work Plan if CCF has substantially performed all work under the specified Work Plan. CCF may terminate the Agreement if circumstances beyond its control preclude continuation of the Project (as defined in the Agreement) by giving written notice to Company at least thirty (30) days before such termination becomes effective. Upon termination of the Agreement or a Work Plan by the Company, the Company will be required to pay any then due or past due development fees. The Company may also terminate a specific statement of work without terminating the Agreement or other Work Plans. In such instance, the Company shall lose its option in connection with such terminated statement of work and the development fees due by the Company will be decreased as described in the Agreement.

Inventions made during the performance of any project during the term of the Agreement and option period, together with all IP therein, will be owned exclusively by the party that made the invention, provided that Joint Inventions (as defined in the Agreement) will be owned jointly. Pursuant to the Agreement, CCF has also agreed to grant the Company an exclusive option to obtain an exclusive, royalty-bearing, worldwide license, with the right to sublicense, subject to the terms and conditions of the License Agreement, any Patent Rights (as defined in the Agreement) relating to a CCF Invention (as defined in the Agreement) or Joint Invention. To the extent that, pursuant to the Agreement, there is a CCF Invention or Joint Invention which constitutes a modification of or improvement or enhancement to an existing technology developed pursuant to (i) the exclusive license agreement, dated July 8, 2019, as amended, by and between the Company and CCF related to the company's existing breast cancer technology or (ii) the

exclusive license agreement, dated October 20, 2020, as amended, by and between the Company and CCF related to the company's existing ovarian cancer technology, the terms of such license agreement shall govern. The Agreement provides for the procedure and terms of the exercise of the option. The Company's option to the license described herein is predicated upon the Company's payment of the option fee and all development fees.

The Company has agreed to indemnify CCF in connection with the Agreement and has also agreed to maintain certain insurance.

The Agreement contains typical representations, warranties and covenants. Pursuant to the Agreement, CCF retains the right to practice and use such Licensed Patents and the subject matter described and/or claimed therein, and to permit others at academic, government, and not-for-profit institutions to practice and use such Licensed Patents and the subject matter described and/or claimed therein, for its and their own research (including without limitation, pre-clinical, non-clinical and clinical research), testing, educational, internal or patient-care purposes.

Item 7.01. Regulation FD Disclosure.

On May 8, 2024, the Company issued a press release announcing the Agreement. The press release is furnished hereto as Exhibit 99.1.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits

The following exhibits are filed with this Current Report on Form 8-K:

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release, dated May 8, 2024
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: May 8, 2024

ANIXA BIOSCIENCES, INC.

By: /s/ Michael J. Catelani

Name: Michael J. Catelani

Title: President, Chief Operating Officer and Chief Financial Officer



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 408.708.9808
 NASDAQ: ANIX

Anixa Biosciences Expands Partnership with Cleveland Clinic to Develop Additional Cancer Vaccines

– Company currently collaborates with Cleveland Clinic on breast cancer and ovarian cancer vaccines –

SAN JOSE, Calif., May 8, 2024 /PRNewswire/ -- [Anixa Biosciences, Inc.](#) (“Anixa” or the “Company”) (NASDAQ: ANIX), a clinical-stage biotechnology company focused on the treatment and prevention of cancer, today announced that it has entered into a joint development agreement with Cleveland Clinic to develop novel vaccines for various cancer types. Cleveland Clinic is currently conducting a Phase 1 clinical trial targeting triple negative breast cancer (TNBC), the most aggressive and lethal form of breast cancer, and an ovarian cancer vaccine is in pre-clinical development in collaboration with the National Cancer Institute.

The vaccines focus on a novel scientific mechanism never used before in a cancer vaccine. By developing vaccines that immunize against “retired” proteins found to be expressed in specific forms of cancer, the researchers are investigating if certain cancer cells can be destroyed as they arise, and ultimately prevent tumors from forming. The vaccines were developed at Cleveland Clinic and licensed to Anixa Biosciences. Cleveland Clinic is entitled to royalties and other commercialization revenues from the Company.

The research under this new JDA will be led at Cleveland Clinic by Thaddeus Stappenbeck, MD, PhD, Department Chair of Inflammation and Immunity, and will include Justin Johnson, PhD, one of the co-inventors of the breast and ovarian cancer vaccines along with the late Vincent Tuohy, PhD.

Anixa Chairman and CEO Dr. Amit Kumar stated, “Cleveland Clinic is a valued partner to Anixa in the development of both breast and ovarian cancer vaccines. The progress we’ve made to date in the breast cancer vaccine program, including promising [preliminary data](#), drives our confidence in pursuing research and development for additional vaccines and cancer types using the same technology platform. Assuming the breast cancer clinical studies continue to exhibit positive results, we believe the search for ‘retired’ protein antigens will be pursued by many cancer researchers. We are seeking to maintain our lead in this potentially game-changing arena of cancer research.”

“We look forward to expanding our relationship with Anixa in this endeavor,” said Dr. Stappenbeck. “As we begin the discovery effort to evaluate which cancer types will be best for targeting, we hope to address many intractable cancers, including high incidence malignancies in the lung, colon, and prostate.”

Company Presentation

Dr. Kumar will be presenting an overview of the Company, its clinical programs, and more information on the expansion of its cancer vaccine program with Cleveland Clinic at the Sidoti Micro-Cap Virtual Conference on May 9, 2024. All interested parties are invited to attend the conference.

Conference details:

Presentation: Thursday, May 9, 2024, at 11:30 am ET*
Presentation link: [Click here](#) to register; available via Zoom
Conference registration: Available on the [conference website](#)

The presentation will be available [here](#) on the Company’s website after the conference.

*The presentation date and time are subject to change. Participants should refer to the final program agenda for up-to-date information.

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:

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