May 19, 2025

Anixa Biosciences CEO Provides Letter to Shareholders Outlining Significant Progress and Advancement Towards Potentially Transformative Milestones

SAN JOSE, Calif., May 19, 2025 /PRNewswire/ -- Anixa Biosciences, Inc. ("Anixa" or the "Company") (NASDAQ: ANIX), a biotechnology company focused on the treatment and prevention of cancer, today released a letter to shareholders from Chairman and CEO Dr. Amit Kumar, detailing significant progress across its programs and outlining key milestones for the remainder of the year.

To our valued shareholders,

I am pleased to highlight our recent achievements and share a vision for the road ahead. In the first five months of 2025, we have advanced both clinical and pre-clinical development programs while maintaining our hallmark fiscal discipline.

Since my appointment as CEO in July 2017, Anixa has been guided by a dual focus on scientific innovation and capital efficiency. Our average annual cash burn has been approximately $5–6 million—significantly below what is typical for development-stage biotechnology companies. In the most recent fiscal year, while advancing two clinical trials, our burn was limited to just $7 million—a notably lower rate than that of our peers.

This capital discipline has enabled us to weather market volatility that has impacted much of the sector. We ended the most recent quarter with over $17 million in cash and no debt—providing more than two years of operational runway and strategic flexibility.

We have also preserved a very clean capital structure, with approximately 32 million common shares outstanding and no warrants. Since 2017, our directors, senior management, and I have been consistent buyers of our stock on the open market, collectively investing millions of dollars. This long-standing commitment underscores our belief in Anixa's long-term value and alignment with shareholders.

We believe 2025 marks an inflection point for Anixa, as our clinical programs advance

toward milestones that could reshape the oncology treatment landscape. Our approach—lean, capital-disciplined, and partner-driven—sets us apart in the sector.

CAR-T Therapy: Hope for Treatment-Resistant Ovarian Cancer

Our CAR-T program with Moffitt Cancer Center, targeting recurrent, platinum-resistant ovarian cancer, is progressing steadily.

We have completed three dose-escalation cohorts, in the Phase 1 trial, and are about to begin the fourth. Though designed for safety evaluation at these early, sub-therapeutic doses, the study has produced encouraging signs of efficacy. While we have not yet demonstrated statistically relevant, protocol-defined response rates, one patient has survived two years post-treatment and another for over one year, significantly exceeding the typical four-month median survival in this population.

These cases suggest biological activity and support continued dose escalation for ovarian cancer patients who have no alternatives. We expect to report further clinical observations later this year. Our partnership with Moffitt—a leader in cellular immunotherapy—continues to be a vital asset in developing this novel technology.

Please stay tuned to see how successive patients receiving higher doses respond.

Breast Cancer Vaccine: Advancing Toward Prevention and Cure

Our breast cancer vaccine, developed in collaboration with Cleveland Clinic, targets newly diagnosed patients, recurrence prevention in the adjuvant setting, and ultimately, primary prevention in those who have never had breast cancer.

The Phase 1 trial, fully funded by a U.S. Department of Defense grant awarded to Cleveland Clinic, is nearing enrollment completion. Monitoring and data analysis will continue over the next three to four months, and we hope to present final results at the San Antonio Breast Cancer Symposium in early December 2025.

The trial includes three cohorts:

- **Recurrence Group**: Survivors of triple-negative breast cancer (TNBC) concerned about recurrence post-treatment. These women are being treated in the adjuvant (post-surgery) setting.

- **Prevention Group**: Women who are cancer-free but carry genetic mutations placing them at high risk of developing breast cancer and have elected to voluntarily have a preventative mastectomy to lower their risk.

- **Therapeutic Group**: Women with residual disease following standard-of-care treatment, where the vaccine is combined with Keytruda (pembrolizumab), another immunotherapy.

Preliminary results show the vaccine is well tolerated, with over 70% of patients showing protocol-defined immune responses. These very promising findings have informed planning for Phase 2 trials, which will follow FDA consultations, protocol development, manufacturing, and clinical site selection.

Although the field of cancer vaccines has historically been challenging, this vaccine is based on a molecular mechanism of action that has never been tried before—offering the potential to create a new paradigm in immuno-oncology.

We are also preparing to extend this platform to target prostate, lung, and colon cancers. Cleveland Clinic's collaboration with the National Cancer Institute on an ovarian cancer vaccine, which has also been licensed to Anixa, continues to progress. We also continue to strengthen our intellectual property portfolio to support these efforts.

The breast cancer market—especially for TNBC and high-risk populations—presents a substantial unmet need. Our vaccine could provide a differentiated, immunologic pathway for prevention and treatment.

Key Milestones Ahead (2H 2025)

- Final Phase 1 data (Breast Cancer Vaccine) – Targeting SABCS, December 2025
- Anticipated FDA interaction and protocol development for Phase 2 – Following final data readout
- Initiation of Cohort 4 (CAR-T Ovarian Cancer)
- Ongoing patient monitoring and emerging data across trials – Throughout 2H 2025

We are entering a dynamic period with multiple potential catalysts. Our strategy is designed to maximize value while managing risk through capital discipline and scientific rigor.

Thank you for your continued support. We are committed to maintaining transparency and delivering on our mission to transform cancer treatment through innovation.

Sincerely,

Dr. Amit Kumar
Chairman and CEO
Anixa Biosciences

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. This technology is differentiated from other cell therapies as the natural ligand of the FSHR receptor, FSH, binds to the FSHR receptor on the tumor cell instead of an antibody fragment. Moffitt is a world leader in cancer immunotherapy treatments, pioneering next-generation cell therapies such as CAR-T, and tumor infiltrating lymphocytes (TILs) to harness the power of the immune system. The Company's vaccine portfolio includes vaccines being developed in collaboration with Cleveland Clinic to treat and prevent breast cancer and ovarian cancer, as well as additional cancer vaccines to address many intractable cancers, including high incidence malignancies in lung, colon, and prostate. These vaccine technologies focus on immunizing against "retired" proteins that have been found to be expressed in certain forms of cancer. The breast and ovarian cancer vaccines were developed at Cleveland Clinic and exclusively licensed to Anixa. Cleveland Clinic is entitled to royalties and other commercialization revenues from the Company related to these vaccine technologies.

Anixa's unique business model of partnering with world-renowned research institutions on all stages of 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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