UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-K

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended October 31, 2023

or

□ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from _____ to _____

Commission file number: 001-37492

ANIXA BIOSCIENCES, INC.
(Exact Name of Registrant as Specified in its Charter)

Delaware	**11-2622630**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)

3150 Almaden Expressway, Suite 250
San Jose, CA 95118
(408) 708-9808
(Address, Including Zip Code, and Telephone Number, Including Area Code, of Registrant's Principal Executive Offices)

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class:	**Trading Symbol**	**Name of Each Exchange on Which Registered:**
Common Stock, $0.01 par value	ANIX	The NASDAQ Stock Market LLC

Securities registered pursuant to Section 12(g) of the Act:
None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes □ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes □ No ☒

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No □

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No □

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer □	Accelerated filer □
Non-accelerated filer ☒	Smaller reporting company ☒
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. □

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. □

Indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. □

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). □

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes □ No ☒

Aggregate market value of the voting stock (which consists solely of shares of common stock) held by non-affiliates of the registrant as of April 28, 2023 (the last business day of the registrant's most recently completed second fiscal quarter), computed by reference to the closing sale price of the registrant's common stock on the NASDAQ on such date ($4.08): $120,568,574.

On January 16, 2024, the registrant had outstanding 31,699,701 shares of common stock, par value $0.01 per share, which is the registrant's only class of common stock.

DOCUMENTS INCORPORATED BY REFERENCE:
NONE

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CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

Information included in this Annual Report on Form 10-K (this "Report") contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). 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 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 this Report under "Item 1A. – Risk Factors" below. Except as required by applicable law, including the securities laws of the United States, we undertake no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise. You are cautioned not to unduly rely on such forward-looking statements when evaluating the information presented in this Report.

CERTAIN TERMS USED IN THIS REPORT

References in this Report to "we," "us," "our," the "Company" or "Anixa" means Anixa Biosciences, Inc. unless otherwise indicated.

PART I

Item 1. Business.

Overview

Anixa Biosciences, Inc. is a biotechnology company developing vaccines and therapies that are focused on critical unmet needs in oncology. Our vaccine programs include (i) the development of a preventative vaccine against triple negative breast cancer ("TNBC"), the most lethal form of breast cancer, as well other forms of breast cancer and (ii) the development of a preventative vaccine against ovarian cancer. Our therapeutics programs include (i) the development of a chimeric endocrine receptor T cell therapy, a novel form of chimeric antigen receptor T cell ("CAR-T") technology, initially focused on treating ovarian cancer, which is being developed at our subsidiary, Certainty Therapeutics, Inc. ("Certainty"), and (ii) until March 2023, the development of anti-viral drug candidates for the treatment of COVID-19 focused on inhibiting certain protein functions of the virus.

We hold an exclusive worldwide, royalty-bearing license to use certain intellectual property owned or controlled by The Cleveland Clinic Foundation ("Cleveland Clinic") relating to certain breast cancer vaccine technology developed at Cleveland Clinic. The license agreement requires us to make certain cash payments to Cleveland Clinic upon achievement of specific development milestones. Utilizing this technology, we are working in collaboration with Cleveland Clinic to develop a method to vaccinate women against contracting breast cancer, focused initially on TNBC. The focus of this vaccine is a specific protein, α-lactalbumin, that is only expressed during lactation in a healthy mother's mammary tissue. This protein disappears when the mother is no longer lactating, but reappears in many forms of breast cancer, especially TNBC. Studies have shown that vaccinating against this protein prevents breast cancer in mice.

In October 2021, following the U.S. Food and Drug Administration's ("FDA") authorization to proceed, we commenced dosing patients in a Phase 1 clinical trial of our breast cancer vaccine. This study, which is being funded by a U.S. Department of Defense grant to Cleveland Clinic, is a multiple-ascending dose Phase 1 trial to determine the maximum tolerated dose ("MTD") of the vaccine in patients with early-stage, triple-negative breast cancer as well as monitor immune response. The study is being conducted at Cleveland Clinic. The first segment of the study, Phase 1a, will consist of 18 to 24 patients who have completed treatment for early-stage, triple-negative breast cancer within the past three years and are currently tumor-free but at high risk for recurrence. Studies show that 42% of TNBC patients will have a recurrence of their cancer, with most of the recurrences occurring in the first two to three years after standard of care treatment. During the course of the Phase 1a study, participants will receive three vaccinations, each two weeks apart, and will be closely monitored for side effects and immune response. In January 2023, the number of participants in each dose cohort was expanded, and as of August 2023, we had completed vaccinating all patients in these expanded cohorts. In December 2023, we presented the immunological data collected to date at the San Antonio Breast Cancer Symposium. The data presented show that in the vaccinated women who had been tested to date, various levels of antigen-specific T cell responses were observed at all dose levels. We have begun vaccinating participants in up to three additional dose cohorts at dose levels higher than the currently determined MTD and lower than the highest dose where we observed dose limiting toxicity. Further, we have commenced vaccination of participants in the second segment of the trial, Phase 1b, that includes participants who have never had cancer, but carry certain genetic mutations such as BRCA1, BRCA2 or PALB2, that indicate a greater risk of developing TNBC in the future, and have elected to have a prophylactic mastectomy. Finally, we are currently enrolling participants in the third segment of the trial, Phase 1c, that includes post-operative TNBC patients that have residual disease following neoadjuvant chemo-immunotherapy and are currently undergoing treatment with pembrolizumab (Keytruda®).

In November 2020, we executed a license agreement with Cleveland Clinic pursuant to which the Company was granted an exclusive worldwide, royalty-bearing license to use certain intellectual property owned or controlled by Cleveland Clinic relating to certain ovarian cancer vaccine technology. The license agreement requires us to make certain cash payments to Cleveland Clinic upon achievement of specific development milestones. This technology pertains to among other things, the use of vaccines for the treatment or prevention of ovarian cancers which express the anti-Mullerian hormone receptor 2 protein containing an extracellular domain ("AMHR2-ED"). In healthy tissue, this protein regulates growth and development of egg-containing follicles in the ovary. While expression of AMHR2-ED naturally and markedly declines during menopause, this protein is expressed at high levels in the ovaries of postmenopausal women with ovarian cancer. Researchers at Cleveland Clinic believe that a vaccine targeting AMHR2-ED could prevent the occurrence of ovarian cancer.

In May 2021, Cleveland Clinic was granted acceptance for our ovarian cancer vaccine technology into the National Cancer Institute's ("NCI") PREVENT program. The NCI is a part of the National Institutes of Health ("NIH"). The PREVENT program is a peer-reviewed agent development program designed to support pre-clinical development of innovative interventions and biomarkers for cancer prevention and interception towards clinical trials. The scientific and financial resources of the PREVENT program are being used for our ovarian cancer vaccine technology to perform virtually all pre-clinical research and development, manufacturing and Investigational New Drug ("IND") application enabling studies. This work is being performed at NCI facilities, by NCI scientific staff and with NCI financial resources and will require no material financial expenditures by the Company, nor the transfer of any rights of the Company's assets.

Our subsidiary, Certainty, is developing immuno-therapy drugs against cancer. Certainty holds an exclusive worldwide, royalty-bearing license to use certain intellectual property owned or controlled by The Wistar Institute ("Wistar"), the nation's first independent biomedical research institute and a leading NCI designated cancer research center, relating to Wistar's chimeric endocrine receptor targeted therapy technology. We have initially focused on the development of a treatment for ovarian cancer, but we also may pursue applications of the technology for the development of treatments for additional solid tumors. The license agreement requires Certainty to make certain cash and equity payments to Wistar upon achievement of specific development milestones. With respect to Certainty's equity obligations to Wistar, Certainty issued to Wistar shares of its common stock equal to five percent (5%) of the common stock of Certainty, such equity stake subject to dilution by further funding of Certainty's activities by the Company. Due to such Company funding, Wistar's equity stake in Certainty was 4.6% as of October 31, 2023.

Certainty, in collaboration with the H. Lee Moffitt Cancer Center and Research Institute, Inc. ("Moffitt"), has begun human clinical testing of the CAR-T technology licensed by Certainty from Wistar aimed initially at treating ovarian cancer. After receiving authorization from the FDA, we commenced enrollment of patients in a Phase 1 clinical trial and treated the first patient in August 2022. Further, in May 2023 and August 2023, we treated the second and third patients in the trial, respectively, at the same dose level as the first patient, and the treatment appears to have been well-tolerated by all patients treated to date. We anticipate that we will begin enrolling the successive patient cohort, that we expect to give a three-times higher dose of cells, in the first calendar quarter of 2024. This study is a dose-escalation trial with two arms based on delivery method—intraperitoneal or intravenous—to determine the maximum tolerated dose in patients with recurrent epithelial ovarian cancer and to assess persistence, expansion and efficacy of the modified T cells. The study is being conducted at Moffitt and will consist of 24 to 48 patients who have received at least two prior lines of chemotherapy. The study is estimated to be completed in two to four years depending on multiple factors including when maximum tolerated dose is reached, the rate of patient enrollment, and how long we maintain the two different delivery methods.

In April 2020, we entered into a collaboration with OntoChem GmbH ("OntoChem") which was later assigned to MolGenie GmbH, a company spun-out from OntoChem focused on drug discovery and development, to discover and ultimately develop anti-viral drug candidates against COVID-19. Through this collaboration, we identified compounds that appeared to be effective in disrupting the main protease of SARS-CoV-2, the virus that causes the disease COVID-19. While our compounds have shown promise as an effective treatment, results of animal studies indicate that there is not sufficient oral bioavailability, and it is unclear whether an orally delivered treatment may be developed. We do not currently believe that there is a viable market for an injectable treatment given the current oral treatments available. Furthermore, we believe the needed additional investment in research for alternative delivery methods would divert resources from more promising projects. Therefore, in March 2023, we decided to pause further development of our COVID-19 therapeutic. We continue to prosecute our U.S. patent applications of this technology and may decide to restart development at some time in the future.

Over the next several quarters, we expect the development of our vaccines and therapeutics to be the primary focus of the Company. As part of our legacy operations, the Company remains engaged in limited patent licensing activities of its various patent portfolios. We do not expect these activities to be a significant part of the Company's ongoing operations nor do we expect these activities to require material financial resources or attention of senior management.

Over the past several years, our revenue was derived from technology licensing and the sale of patented technologies, including revenue from the settlement of litigation (during the year ended October 31, 2023, we derived approximately $210,000 of revenue from these activities). We have not generated any revenue to date from our vaccine or therapeutics programs. In addition, while we pursue our vaccine and therapeutics programs, we may also make investments in and form new companies to develop additional emerging technologies. We do not expect to begin generating revenue with respect to any of our current vaccine or therapy programs in the near term. We hope to achieve a profitable outcome by eventually licensing our technologies to large pharmaceutical companies that have the resources and infrastructure in place to manufacture, market and sell our technologies as vaccines or therapeutics. The eventual licensing of any of our technologies may take several years, if it is to occur at all, and may depend on positive results from human clinical trials.

Breast and Ovarian Cancer vaccines

We licensed certain technology from Cleveland Clinic to develop vaccines for the treatment or prevention of TNBC and other breast cancers which express the α-lactalbumin protein. This protein is only expressed during lactation in healthy women, but may also be expressed in individuals with certain breast cancers, most notably TNBC, the most lethal form of breast cancer. Further, we have licensed certain technology from Cleveland Clinic to develop vaccines for the treatment or prevention of ovarian cancers which express AMHR2-ED. This protein regulates growth and development of egg-containing follicles in the ovary and its expression naturally and markedly declines after menopause. However, AMHR2-ED is expressed at high levels in the ovaries of postmenopausal women with ovarian cancer.

Typically, vaccines harness the immune system to protect people from infectious diseases. Broad-based vaccination programs have essentially eliminated some of the most deadly and debilitating diseases in history, small pox and polio among them. However, there has been little success developing a preventative (prophylactic) vaccine against cancer.

Vaccines work by exposing a benign form of a disease agent to an individual's immune system. The immune system identifies the agent and learns to attack and destroy it, retaining a memory of the agent so the immune system knows to react quickly if an individual is exposed to the disease agent months or years later.

Most vaccines attack pathogens, such as viruses and bacteria. The immune system is better able to assail these agents because they come from outside the body. Cancer, however, is caused by aberrant cells that arise out of our resident cells, which can make it difficult for our immune system to find the diseased cells, especially as advancing age weakens our immune system. Once these aberrant cells gain critical mass, they become cancer.

Despite the lack of success with cancer vaccines, recently gained knowledge about the human immune system has led to the development, approval and commercialization of revolutionary immuno-therapy drugs. These drugs do not attack cancer directly, but rather modulate the immune system in ways that enable it to destroy or dramatically impair cancer cells.

The breast cancer vaccine technology licensed from Cleveland Clinic has identified a protein, alpha-lactalbumin, that is present in healthy breast tissue only when a woman is lactating and disappears when she stops nursing her child. Alpha-lactalbumin is never present on any other cell in the body. However, it does show up in many types of breast cancer, including TNBC, an aggressive and deadly form of the disease. By developing a vaccine that targets alpha-lactalbumin, we feel the immune system can destroy these breast cancer cells as they arise and ultimately prevent breast tumors from forming.

Cleveland Clinic researchers have demonstrated in animal studies that vaccination against alpha-lactalbumin completely prevented breast cancer in mice that were specifically bred to develop breast cancer. Data on this technology, including the animal studies showing efficacy, was published in March 2016 in the journal, Cancers.

The ovarian cancer vaccine technology licensed from Cleveland Clinic has identified the AMHR2-ED protein, the expression of which is involved in egg production in the ovaries and is no longer expressed after menopause. AMHR2-ED is not meaningfully present on any other cell in the body. However, it does appear in many cases of epithelial ovarian cancers, the most common type of ovarian cancer. By developing a vaccine that targets AMHR2-ED, we feel the immune system can destroy these ovarian cancer cells as they arise and ultimately prevent tumors from forming. Data on this technology, including animal studies showing efficacy, was published in November 2017 in the journal, Cancer Prevention Research.

While the data thus far for both of our cancer vaccines has been positive, there are many uncertainties in drug development, and most drugs fail to reach commercialization.

In October 2021, Cleveland Clinic began treating patients in a Phase 1 clinical trial of our breast cancer vaccine. In addition, we and our partners at Cleveland Clinic continue working with the NCI who are or will be performing pre-clinical research and development, manufacturing and IND-enabling studies to advance our ovarian cancer vaccine technology toward human clinical testing.

The Breast Cancer Market

According to American Cancer Society statistics, breast cancer accounts for over 30% of all female cancer cases, and 15% of cancer deaths in women. It has been estimated that in 2023, 301,000 new cases of breast cancer would be diagnosed in the U.S. and 43,000 women would die from this disease. Despite continuous advances made in the field of cancer research every year, invasive female breast cancer incidence rates have been increasing by approximately 0.5% per year over the past 15 years.

The market for prophylactic cancer vaccines is sizable—bigger in fact than the market for any type of cancer therapeutic. After all, doctors administer cancer drugs only after a patient has been diagnosed, while a prophylactic vaccine may be administered to all people who have a possibility of developing the disease.

While in the U.S., 301,000 women were estimated to be diagnosed with breast cancer in 2023, there are approximately 82 million women age 40 and over—the time in life when women face an increased risk of developing breast cancer. Worldwide, the number is dramatically larger.

The Ovarian Cancer Market

According to American Cancer Society statistics, ovarian cancer accounts for just 2% of all female cancer cases, but nearly 5% of cancer deaths in women due to the disease's low survival rate. It has been estimated that in 2023, 20,000 new cases of ovarian cancer would be diagnosed and 13,000 American women would die from this disease. Despite continuous advances made in the field of cancer research every year, we believe there remains a significant unmet medical need, as the overall five-year relative survival rate for ovarian cancer patients is 50%. However, ovarian cancer survival varies substantially by age, with the overall five-year survival rate for women 65 and older of only 32%.

The market for prophylactic cancer vaccines is sizable—bigger in fact than the market for any type of cancer therapeutic. While in the U.S., 20,000 women were estimated to be diagnosed with ovarian cancer in 2023, there are approximately 41 million women age 60 and over—the time in life when women face an increased risk of developing ovarian cancer. Worldwide, the number is dramatically larger.

Competition

The biopharmaceutical industry is characterized by intense and dynamic competition to develop new technologies and proprietary therapies. Any product candidates that we successfully develop and commercialize will have to compete with existing therapies and new therapies that may become available in the future. While we believe that our proprietary breast and ovarian cancer vaccine technologies and scientific expertise in the field of cell therapy provide us with competitive advantages, we face potential competition from various sources, including larger and better-funded pharmaceutical and biotechnology companies, as well as from academic institutions, governmental agencies and public and private research institutions.

Many of our competitors, either alone or with their strategic partners, have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery and development of product candidates, obtaining FDA and other regulatory approvals of vaccines and commercializing those vaccines. Accordingly, our competitors may be more successful than us in obtaining approval for vaccines and achieving widespread market acceptance. Our competitors' vaccines may be more effective, or more effectively marketed and sold, than any vaccine we may commercialize and may render our vaccines obsolete or non-competitive before we can recover the expenses of developing and commercializing any of our vaccines.

Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated among a smaller number of our competitors. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical study sites and subject registration for clinical studies, as well as in acquiring technologies complementary to, or necessary for, our programs. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

We anticipate that we will face intense and increasing competition as new drugs and vaccines enter the market and advanced technologies become available. We expect any vaccines that we develop and commercialize to compete on the basis of, among other things, efficacy, safety, convenience of administration and delivery, price and the availability of reimbursement from government and other third-party payers.

Our commercial opportunities could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other regulatory approvals for their products more rapidly than we may obtain approvals for ours, which could result in our competitors establishing a strong market position before we are able to enter the market.

CAR-T therapeutics

Certainty was formed to develop immuno-therapy drugs against cancer, and in November 2017, we entered into a license with Wistar whereby we obtained rights to certain intellectual property surrounding Wistar's chimeric endocrine receptor targeted therapy technology.

CAR-T therapeutics have demonstrated positive results in B-cell cancers, but very little progress has been made on solid tumors. Our CAR-T technology is initially focused on ovarian cancer and is based on engineering killer T cells with the Follicle Stimulating Hormone ("FSH") to target ovarian cells that express the FSH-Receptor. Data on this technology, including the animal studies showing efficacy, was published in January 2017 in the journal, Clinical Cancer Research. The FSH-Receptor has been shown to be a very exclusive protein found on a large percentage of ovarian cancer cells, but not on a significant number of non-ovarian healthy tissues in adult females.

Studies have shown that the FSH-Receptor is also expressed in endothelial cells of the vasculature of neoplasias. We anticipate performing further studies to evaluate the ability of our CAR-T to disrupt the vasculature of other cancers, after we have analyzed data from clinical trials of this technology against ovarian cancer.

We have been working with researchers at Moffitt to develop our CAR-T therapy. Moffitt is one of the top cancer centers in the country with pre-clinical and clinical expertise with CAR-T technology. Moffitt has conducted many of the highest profile CAR-T trials in the world.

We performed numerous studies in preparation for human clinical studies. In those studies, several groups of tumor free, female mice were intra-peritoneally infused with increasing concentrations of the murine CAR-T construct and their health status was monitored for up to five months. The following summarizes the results of these studies:

- No treated mice showed any signs of pain/stress, difficulty breathing or increased respiratory rate, reduced movement, reduced grooming or feeding, dehydration, anorexia or any other sign of distress. Control mice also did not show any distress.
- The treated mice did not show any weight loss. Control mice also did not show any weight loss.
- One cohort of treated mice also had blood drawn periodically for measurement of markers for liver function (AST-Aspartate transaminase/ALT-Alanine transaminase), kidney function (creatinine), and metabolic function (glucose). No abnormal values were observed, as was the case for control mice.
- Serum IL-6 (interleukin-6) increased in the treated mice, as well as mice treated with control T cells. This indicated that the T cells were inducing the expected inflammatory response.
- Histological analysis of the ovaries showed that 60% of the treated mice had significant reduction in ovarian mass, while the control mice exhibited no reduction. This observation confirms that the CAR-T was successfully attacking the ovaries, as we hoped and expected.

While these results are positive, there are many uncertainties in drug development, and most drugs fail to reach commercialization. In the future, we hope to achieve a profitable outcome by eventually licensing our technology to a large pharmaceutical company that has the resources and infrastructure in place to manufacture, market and sell our technology as a cancer treatment.

The Market

We believe that our CAR-T technology may be used as an effective treatment against multiple solid tumor types, however, we have initially focused on ovarian cancer. According to American Cancer Society statistics, ovarian cancer accounts for just 2% of all female cancer cases, but nearly 5% of cancer deaths in women due to the disease's low survival rate. It has been estimated that in 2023, approximately 20,000 new cases of ovarian cancer would be diagnosed and 13,000 American women would die from this disease. Despite continuous advances made in the field of cancer research every year, there remains a significant unmet medical need, as the overall five-year relative survival rate for ovarian cancer patients is 50%. However, ovarian cancer survival varies substantially by age, with the overall five-year survival rate for women 65 and older of only 32%.

Competition

The biopharmaceutical industry is characterized by intense and dynamic competition to develop new technologies and proprietary therapies. Any product candidates that we successfully develop and commercialize will have to compete with existing therapies and new therapies that may become available in the future. While we believe that our proprietary FSH-Receptor targeted immuno-therapy platform for treating solid tumors and scientific expertise in the field of cell therapy provide us with competitive advantages, we face potential competition from various sources, including larger and better-funded pharmaceutical and biotechnology companies, as well as from academic institutions, governmental agencies and public and private research institutions.

Many of our competitors, either alone or with their strategic partners, have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery and development of product candidates, obtaining FDA and other regulatory approvals of treatments and commercializing those treatments. Accordingly, our competitors may be more successful than us in obtaining approval for treatments and achieving widespread market acceptance. Our competitors' treatments may be more effective, or more effectively marketed and sold, than any treatment we may commercialize and may render our treatments obsolete or non-competitive before we can recover the expenses of developing and commercializing any of our treatments.

Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated among a smaller number of our competitors. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical study sites and subject registration for clinical studies, as well as in acquiring technologies complementary to, or necessary for, our program. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

We anticipate that we will face intense and increasing competition as new drugs enter the market and advanced technologies become available. We expect any treatments that we develop and commercialize to compete on the basis of, among other things, efficacy, safety, convenience of administration and delivery, price and the availability of reimbursement from government and other third-party payers.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market.

Employees

As of October 31, 2023, we had five employees, four full-time and one part time, working for our Company and subsidiaries. In addition, we work with research teams at Moffitt and Cleveland Clinic, as well as their and our subcontractors, to develop each of our projects.

Summary Risk Factors

The risk factors described below are a summary of the principal risk factors associated with an investment in us. These are not the only risks we face. You should carefully consider these risk factors, together with the risk factors set forth in Item 1A. of this Report and the other reports and documents filed by us with the SEC.

Risks Relating to Our Financial Condition and Operations

- We have a history of losses and may incur additional losses in the future.
- We will need additional funding in the future which may not be available on acceptable terms, or at all, and, if available, may result in dilution to our stockholders.
- We may have difficulty in raising capital and may consume resources faster than expected.

Risks Related to our Research & Development, Clinical and Commercialization Activities

- Our therapeutic and vaccine programs are pre-revenue, and subject to the risks of an early-stage biotechnology company.
- Our current business model relies on strategic collaborations with commercial partners to provide the resources and infrastructure to manufacture and ultimately market and/or sell our technologies. We may have difficulty in timing the establishment of these partnerships to achieve the greatest economic benefit for the Company, or in establishing these partnerships at all.
- If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.
- We have never generated any revenue from biotechnology and pharmaceutical product sales and our biotechnology and pharmaceutical products may never be profitable.
- The therapeutics and vaccines that we are developing are novel and present significant challenges to successfully reaching market.
- While pre-clinical testing and the limited human clinical testing of our product candidates has been positive, we may experience unfavorable results once we collect statistically significant data from human clinical trials.
- We are dependent on third parties to conduct our pre-clinical and clinical trials.
- If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.
- We face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively.

Risks Related to our Intellectual Property

- We rely on licenses from Wistar for our CAR-T technology and Cleveland Clinic for our breast and ovarian cancer vaccine technologies, and if we lose any of these licenses it may remove or limit our ability to develop and commercialize products and technology covered by these license agreements and we may be subjected to future litigation.

Risks Related to our Common Stock

- The issuance or sale of shares in the future, including in connection with our current at-the-market offering program, to raise money or for strategic purposes could reduce the market price of our common stock.
- We have issued a significant number of securities pursuant to our incentive plans and may continue to do so in the future. The vesting and, if applicable, exercise of these securities and the sale of the shares of common stock issuable thereunder may dilute stockholders' percentage ownership interest and may also result in downward pressure on the price of our common stock.

Other

We were incorporated on November 5, 1982 under the laws of the State of Delaware. Our principal executive offices are located at 3150 Almaden Expressway, San Jose, California 95118, our telephone number is (408) 708-9808 and our Internet website address is www.anixa.com. We make available free of charge on or through our Internet website our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, proxy statements on Schedule 14A, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable after we electronically file such materials with, or furnish them to, the Securities and Exchange Commission (the "SEC"). Alternatively, you may also access our reports at the SEC's website at www.sec.gov.

Item 1A. Risk Factors.

Our business involves a high degree of risk and uncertainty, including the following risks and uncertainties:

Risks Related to Our Financial Condition and Operations

We have a history of losses and may incur additional losses in the future.

On a cumulative basis, we have sustained substantial losses and negative cash flows from operations since our inception. As of October 31, 2023, our accumulated deficit was approximately $228,196,000. As of October 31, 2023, we had approximately $23,844,000 in cash, cash equivalents and short-term investments, and working capital of approximately $23,328,000. In fiscal year 2023, we incurred losses of approximately $9,930,000 and we experienced negative cash flows from operations of approximately $6,209,000. We expect to continue incurring material research and development and general and administrative expenses in connection with our operations. As a result, we anticipate that we will incur losses in the future.

We will need additional funding in the future which may not be available on acceptable terms, or at all, and, if available, may result in dilution to our stockholders.

Based on currently available information as of January 16, 2024, we believe that our existing cash, cash equivalents and short-term investments will be sufficient to fund our activities for at least the next 12 months. However, our projections of future cash needs and cash flows may differ from actual results. If current cash on hand, cash equivalents and short-term investments are insufficient to continue to operate our business, or if we elect to invest in or acquire a company or companies that are synergistic with or complementary to our technologies, we may be required to obtain more working capital. We may seek to obtain working capital through sales of our equity securities, including through our current at-the-market offering program, or through bank credit facilities or public or private debt from various financial institutions where possible. We cannot be certain that additional funding will be available on acceptable terms, or at all. If we do identify sources for additional funding, the sale of additional equity securities or convertible debt could result in dilution to our stockholders. Additionally, the sale of equity securities or issuance of debt securities may be subject to certain security holder approvals or may result in the downward adjustment of the exercise or conversion price of our outstanding securities. We can give no assurance that we will generate sufficient cash flows in the future to satisfy our liquidity requirements or sustain future operations, or that other sources of funding, such as sales of equity or debt, would be available or would be approved by our security holders, if needed, on favorable terms or at all. If we fail to obtain additional working capital as and when needed, such failure could have a material adverse impact on our business, results of operations and financial condition. Furthermore, such lack of funds may inhibit our ability to respond to competitive pressures or unanticipated capital needs, or may force us to reduce operating expenses, which would significantly harm the business and development of operations.

We may have difficulty in raising capital and may consume resources faster than expected.

We currently do not generate any revenue from our therapeutics or vaccines nor do we generate any other recurring revenues and as of October 31, 2023, the Company had approximately $23,844,000 in cash, cash equivalents and short-term investments. Therefore, we have a limited source of cash to meet our future capital requirements, which may include the expensive process of obtaining FDA approvals for our CAR-T ovarian cancer therapeutic and our breast and ovarian cancer vaccines. We do not expect to generate significant revenues for the foreseeable future, which would leave us without resources to continue our operations and force us to resort to raising additional capital in the form of equity or debt financings, which may not be available to us. We may have difficulty raising needed capital in the near or longer term as a result of, among other factors, the very early stage of our therapeutics and vaccine businesses and our lack of revenues as well as the inherent business risks associated with an early stage, biotechnology company and present and future market conditions. Also, we may consume available resources more rapidly than currently anticipated, resulting in the need for additional funding sooner than anticipated. Our inability to raise funds could lead to decreases in the price of our common stock and the failure of our therapeutics and vaccine businesses which would have a material adverse effect on the Company.

Failure to effectively manage our potential growth could place strains on our managerial, operational and financial resources and could adversely affect our business and operating results.

Our business strategy and potential growth may place a strain on managerial, operational and financial resources and systems. Although we may not grow as we expect, if we fail to manage our growth effectively or to develop and expand our managerial, operational and financial resources and systems, our business and financial results will be materially harmed.

We may use our financial and human resources to pursue a particular research program or product candidate and fail to capitalize on programs or product candidates that may be more profitable or for which there is a greater likelihood of success.

Because we have limited resources, we may forego or delay pursuit of opportunities with certain programs or product candidates or for indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs for product candidates may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through strategic collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate, or we may allocate internal resources to a product candidate which it would have been more advantageous to enter into a partnering arrangement.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

We have incurred net losses since our inception and we may never achieve or sustain profitability. Generally, losses incurred will carry forward until such losses expire (for losses generated prior to January 1, 2018) or are used to offset future taxable income, if any. Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the "Internal Revenue Code"), if a corporation undergoes an "ownership change," generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a three-year period, the corporation's ability to use its pre-change net operating loss, or NOL, carryforwards and other pre-change tax attributes (such as research tax credits) to offset its post-change income or taxes may be limited. We have not completed a study to assess whether an ownership change for purposes of Section 382 or 383 has occurred, or whether there have been multiple ownership changes since our inception. We may have experienced ownership changes in the past and may experience ownership changes in the future as a result of shifts in our stock ownership (some of which shifts are outside our control). As a result, if we earn net taxable income, our ability to use our pre-change NOL carryforwards to offset such taxable income may be subject to limitations. Similar provisions of state tax law may also apply to limit our use of accumulated state tax attributes. As a result, even if we attain profitability, we may be unable to use a material portion of our NOL carryforwards and other tax attributes, which could adversely affect our future cash flows.

Risks Related to our Research & Development, Clinical and Commercialization Activities

Our therapeutic and vaccine programs are pre-revenue, and subject to the risks of an early-stage biotechnology company.

Since the Company's primary focus for the foreseeable future will likely be our therapeutics and vaccine businesses, shareholders should understand that we are primarily an early-stage biotechnology company with no history of revenue-generating operations, and our only assets consist of our proprietary and licensed technologies and the know-how of our officers and employees. Therefore, we are subject to all the risks and uncertainties inherent in a new business, in particular new businesses engaged in CAR-T cancer therapeutics and cancer vaccines, as well as whether our current business plan is sound. Our CAR-T ovarian cancer therapeutic and our breast and ovarian cancer vaccines are in their early stages of development, and we still must establish and implement many important functions necessary to commercialize the technologies.

Accordingly, you should consider the Company's prospects in light of the costs, uncertainties, delays and difficulties frequently encountered by companies in their pre-revenue generating stages, particularly those in the biotechnology field. Shareholders should carefully consider the risks and uncertainties that a business with limited operating history will face. In particular, shareholders should consider that there is a significant risk that we will not be able to:

- successfully enroll sufficient numbers of qualified patients to participate in our clinical trials;
- obtain sufficient quantity and quality of materials manufactured for use in our clinical trials;
- successfully meet the primary endpoints in our clinical trials;
- implement or execute our current business plan;
- raise sufficient funds in the capital markets or otherwise to fully effectuate our business plan;
- maintain our management team;
- determine that the processes and technologies that we have developed or will develop are commercially viable; and/or
- attract, enter into or maintain contracts with potential commercial partners such as licensors of technology and suppliers or licensees of our technologies.

Any of the foregoing risks may adversely affect the Company and result in the failure of our business. In addition, we expect to encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. Over the next several quarters, we will need to continue broadening our focus from a research and development company to a company capable of supporting clinical trials and commercial activities, or enter into collaborations with partners that may provide those capabilities. We may not be able to reach such achievements, which would have a material adverse effect on our Company.

Our current business model relies on strategic collaborations with commercial partners to provide the resources and infrastructure to manufacture and ultimately market and/or sell our technologies. We may have difficulty in timing the establishment of these partnerships to achieve the greatest economic benefit for the Company, or in establishing these partnerships at all.

We do not currently have the resources and infrastructure to manufacture, market or sell our products or technologies. While our technologies have generated interest from multiple potential strategic partners, due to the early stage of development of our technologies, we can give no assurance that we will be able to successfully establish any strategic partnerships. Further, even if we elect to engage with a potential strategic partner, development of these partnerships can take an extended period of time in which significant analysis is performed by the potential strategic partner on our technologies and our intellectual property, as well as on the market opportunities and how well our technologies may fit strategically with the partner's existing business. Accordingly, it will be difficult for us to time the establishment of a strategic partnership to achieve the greatest economic benefit for the Company.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.

We will face an inherent risk of product liability as a result of the ongoing and upcoming human clinical testing and commercialization of our product candidates. For example, we may be sued if our product candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit or cease commercialization of our product candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our product candidates;
- injury to our reputation;
- withdrawal of clinical trial participants;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to clinical trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of potential revenue;
- exhaustion of any available insurance and our capital resources;
- the inability to commercialize any product candidate; and
- a decline in our share price.

While we carry product liability insurance, claims could be asserted that could result in damages in excess of such insurance coverage. If we do not maintain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims, the lack of sufficient coverage could prevent or inhibit the development and commercialization of any products we develop, alone or with corporate collaborators.

If we cannot license rights to use technologies on reasonable terms, we may not be able to commercialize new products in the future.

In the future, we may identify third-party technology we need, including to develop or commercialize new products or services. In return for the use of a third party's technology, we may agree to pay the licensor royalties based on sales of our products or services. Royalties are a component of cost of products or services and affect the margins on our products or services. We may also need to negotiate licenses to patents or patent applications before or after introducing a commercial product. We may not be able to obtain necessary licenses to patents or patent applications, and our business may suffer if we are unable to enter into the necessary licenses on acceptable terms or at all, if any necessary licenses are subsequently terminated, if the licensors fail to abide by the terms of the licenses or fail to prevent infringement by third parties, or if the licensed patents or other rights are found to be invalid or unenforceable.

Biotechnology and pharmaceutical product development is a highly speculative undertaking and involves a substantial degree of uncertainty. We have never generated any revenue from biotechnology and pharmaceutical product sales and our biotechnology and pharmaceutical products may never be profitable.

We are in the pre-clinical stage of developing our ovarian cancer vaccine technology and in the clinical stage with our CAR-T therapeutic technology and with our breast cancer vaccine technology. Our ability to generate revenue depends in large part on our ability, alone or with partners, to successfully complete the development of, obtain the necessary regulatory approvals for, and commercialize, product candidates. We do not anticipate generating revenues from sales of such products for the foreseeable future. Our ability to generate future revenues from product sales of our technologies depends heavily on our success in:

- progressing our discovery stage programs into pre-clinical testing;
- progressing our pre-clinical programs into human clinical trials;
- completing requisite clinical trials through all phases of clinical development of our product candidates;
- seeking and obtaining marketing approvals for our product candidates that successfully complete clinical trials, if any;
- launching and commercializing our product candidates for which we obtain marketing approval, if any, with a partner or, if launched independently, successfully establishing a manufacturing, sales force, marketing and distribution infrastructure;
- identifying and developing new product candidates;
- establishing and maintaining supply and manufacturing relationships with third parties;
- maintaining, protecting, expanding and enforcing our intellectual property; and
- attracting, hiring and retaining qualified personnel.

Because of the numerous risks and uncertainties associated with biologic and pharmaceutical product development, we are unable to predict the likelihood or timing for when we may receive regulatory approval of our product candidates or when we will be able to achieve or maintain profitability, if ever. If we are unable to establish a development and or commercialization partnership, or do not receive regulatory approvals, our business, prospects, financial condition and results of operations will be adversely affected. Even if we or a partner obtain the regulatory approvals to market and sell one or more of our product candidates, we may never generate significant revenues from any commercial sales for several reasons, including because the market for our products may be smaller than we anticipate, or products may not be adopted by physicians and payors or because our products may not be as efficacious or safe as other treatment options. If we fail to successfully commercialize one or more products, by ourselves or through a partner, we may be unable to generate sufficient revenues to sustain and grow our business and our business, prospects, financial condition and results of operations will be adversely affected.

Cancer vaccines are novel and present significant challenges.

The development of preventive and therapeutic cancer vaccines is difficult, with very few cancer vaccines successfully reaching the market. The only vaccines shown to be effective in preventing cancer have been vaccines against cancer causing agents, not the cancer itself. Vaccines work by exposing a benign form of a disease agent to an individual's immune system. The immune system identifies the agent and learns to attack and destroy it, retaining a memory of the agent so the immune system knows to react quickly if an individual is exposed to the disease agent months or years later. Most vaccines attack pathogens, such as viruses and bacteria. The immune system is better able to assail these agents because they come from outside the body. Cancer, however, is caused by aberrant cells that arise out of our resident cells, which can make it difficult for our immune system to find the diseased cells, especially as advancing age weakens our immune system. Once these aberrant cells gain critical mass, they become cancer.

CAR-T cell therapies are novel and present significant challenges.

CAR-T product candidates represent a relatively new field of cellular immunotherapy. Advancing this novel and personalized therapy creates significant challenges for us, or a partner, including:

- obtaining regulatory approval, as the FDA and other regulatory authorities have limited experience with commercial development of T cell therapies for cancer;
- sourcing clinical and, if approved, commercial supplies for the materials used to manufacture and process our product candidates;
- developing a consistent and reliable process, while limiting contamination risks, for engineering and manufacturing T cells *ex vivo* and infusing the engineered T cells into the patient;
- educating medical personnel regarding the potential benefits, as well as the challenges, of incorporating our product candidates into their treatment regimens;
- establishing sales and marketing capabilities upon obtaining any regulatory approval to gain market acceptance of a novel therapy; and
- the availability of coverage and adequate reimbursement from third-party payors for our novel and personalized therapy.

Our inability to successfully develop CAR-T cell therapies or develop processes related to the manufacture, sales and marketing of these therapies would adversely affect our business, results of operations and prospects.

While CAR-T technology has shown positive results in B-cell cancers by others, its safety and efficacy has not been seen in solid tumors and we cannot guarantee our CAR-T technology will be safe or effective in ovarian or other cancers.

CAR-T therapies function through the binding of a genetically engineered killer T cell to a cancer cell. However, these engineered T cells destroy the cell they are bound to whether it is a cancer cell or a healthy cell. Therefore, the engineered T cells must be designed to only bind to either cancer cells or other target cells to minimize toxicity. Our CAR-T technology relies on the natural affinity of FSH to FSH-Receptor. Research by others has shown that in women the FSH-Receptor protein is found on ovary cells and generally in no other healthy tissue, and therefore, we engineer our T cells with FSH. However, as the research in this field is still new, we cannot guarantee that there is no FSH-Receptor on any other healthy tissue in the human body.

While pre-clinical testing and the limited human clinical testing of our product candidates has been positive, we may experience unfavorable results once we collect statistically significant data from human clinical trials.

We have limited human clinical data from our breast cancer vaccine and our CAR-T ovarian cancer therapeutic, and we have not initiated clinical trials for our ovarian cancer vaccine and we may not be able to commence clinical trials on the time frames we expect. As our discovery stage product candidate has only been tested in animals and our clinical stage candidates currently have limited human data, we face significant uncertainty regarding how effective and safe they will be in human patients and the results from pre-clinical studies may not be indicative of the results of clinical trials. Pre-clinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in pre-clinical studies and clinical trials have nonetheless failed to obtain marketing approval for their products.

Even if clinical trials are successfully completed, the FDA or foreign regulatory authorities may not interpret the results as we do, and more clinical trials could be required before we submit our product candidates for approval. To the extent that the results of our clinical trials are not satisfactory to the FDA or foreign regulatory authorities for support of a marketing application, approval of our product candidates may be significantly delayed, or we may be required to expend significant additional resources, which may not be available to us, to conduct additional clinical trials in support of potential approval of our product candidates.

We are dependent on third parties to conduct our pre-clinical studies and clinical trials.

We depend and will continue to depend upon independent investigators and collaborators, such as universities, medical institutions, and strategic partners such as Moffitt for our CAR-T therapy and Cleveland Clinic for our breast and ovarian cancer vaccines to conduct our pre-clinical studies and clinical trials under agreements with us. Negotiations of budgets and contracts with study sites may result in delays to our development timelines and increased costs. We will rely heavily on these third parties over the course of our clinical trials, and we control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with applicable protocol, legal, regulatory and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. We and these third parties are required to comply with current good clinical practices, or cGCPs, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development. Regulatory authorities enforce these cGCPs through periodic inspections of clinical trial sponsors, principal investigators and clinical trial sites. If we or any of these third parties fail to comply with applicable cGCP regulations, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities could require us to perform additional clinical trials before approving our marketing applications. It is possible that, upon inspection, such regulatory authorities could determine that any of our clinical trials fail to comply with the cGCP regulations. In addition, our clinical trials must be conducted with biologic product produced under current good manufacturing practices, or cGMPs, and will require a large number of test patients. Our failure or any failure by these third parties to comply with these regulations or to recruit a sufficient number of patients may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

Any third parties conducting our clinical trials are not and will not be our employees and, except for remedies available to us under our agreements with these third parties, we cannot control whether they devote sufficient time and resources to our ongoing pre-clinical, clinical and nonclinical programs. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities, which could affect their performance on our behalf. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to complete development of, obtain regulatory approval of or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.

Switching or adding third parties to conduct our clinical trials involves substantial cost and requires extensive management time and focus. In addition, there is a natural transition period when a new third party commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines.

If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the study until its conclusion. The enrollment of patients depends on many factors, including:

- the patient eligibility criteria defined in the clinical trial protocol;
- the size of the patient population required for analysis of the trial's primary endpoints;
- the proximity of patients to the study site;
- the design of the clinical trial;
- our ability to retain clinical trial investigators with the appropriate competencies and experience;
- our ability to obtain and maintain patient consents;
- the risk that patients enrolled in clinical trials will drop out of the clinical trials before completion; and
- competing clinical trials and approved therapies available for patients.

In particular, our Phase 1 CAR-T ovarian cancer clinical trial is enrolling patients with late-stage ovarian cancer who have failed conventional treatment, and are willing and able to be treated at Moffitt. Our Phase 1a breast cancer vaccine clinical trial is enrolling patients who have undergone standard of care treatment for TNBC. Our Phase 1b breast cancer vaccine clinical trial is enrolling healthy women who, as a result of, among other things, testing positive for the BRCA1, BRCA2 or PALB2 gene mutations which are leading predictors of future incidence of breast cancer, have elected to have prophylactic mastectomies. Our Phase 1c breast cancer vaccine clinical trial is enrolling post-operative TNBC patients who have residual disease following neoadjuvant chemo-immunotherapy and are being treated with pembrolizumab (Keytruda®). These potential trial participants must be willing and able to undergo treatment at the Cleveland Clinic.

Our clinical trials will compete with other companies' clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our clinical trials may instead opt to enroll in a trial being conducted by one of our competitors. We expect to conduct our clinical trials at the same clinical trial sites that some of our competitors may use, which will reduce the number of patients who are available for our clinical trial in these clinical trial sites. Moreover, because our product candidates represent a departure from more commonly used methods for cancer treatment, potential patients and their doctors may be inclined to use experimental therapies that use conventional technologies, such as chemotherapy and antibody therapy, rather than enroll patients in our clinical trials. Patients may also be unwilling to participate in our clinical trials because of negative publicity from adverse events in the biotechnology or gene therapy industries.

Delays in patient enrollment may result in increased costs or may affect the timing or outcome of our planned clinical trials, which could prevent completion of the clinical trials and adversely affect our ability to advance the development of our ovarian cancer CAR-T therapy and our breast cancer vaccine.

Any adverse developments that occur during any clinical trials conducted by academic investigators, our collaborators or other entities conducting clinical trials under independent IND applications may negatively affect the conduct of our clinical trials or our ability to obtain regulatory approvals or commercialize our product candidates.

CAR-T, vaccines and other immuno-therapy technologies are being used by third parties in clinical trials for which we are collaborating or in clinical trials which are completely independent of our development programs. We have little to no control over the conduct of those clinical trials. If serious adverse events occur during these or any other clinical trials using technologies similar to ours, the FDA and other regulatory authorities may delay our clinical trial, or could delay, limit or deny approval of our product candidates or require us to conduct additional clinical trials as a condition to marketing approval, which would increase our costs. If we receive regulatory approval for any product candidate and a new and serious safety issue is identified in connection with clinical trials conducted by third parties, the applicable regulatory authorities may withdraw their approval of our products or otherwise restrict our ability to market and sell our products. In addition, treating physicians may be less willing to administer our products due to concerns over such adverse events, which would limit our ability to commercialize our products.

Adverse side effects or other safety risks associated with our product candidates could cause us to suspend or discontinue clinical trials or delay or preclude approval.

In third party clinical trials involving CAR-T cell therapies, the most prominent acute toxicities included symptoms thought to be associated with the release of cytokines, such as fever, low blood pressure and kidney dysfunction. Some patients also experienced toxicity of the central nervous system, such as confusion, cranial nerve dysfunction and speech impairment. Adverse side effects attributed to CAR-T therapies were severe and life-threatening in some patients. The life-threatening events were related to kidney dysfunction and toxicities of the central nervous system or other organ failure. Severe and life-threatening toxicities occurred primarily in the first two weeks after cell infusion and generally resolved within three weeks. In the past, several patients have also died in clinical trials by others involving CAR-T cell therapies.

Side effects of our breast cancer vaccine may include mild effects such as injection site pain or irritation, or more severe side effects such as fever, inflammation, organ failure or other adverse effects.

Undesirable side effects observed in our clinical trials, whether or not they are caused by our product candidates, could result in the delay, suspension or termination of clinical trials, by the FDA or other regulatory authorities or us for a number of reasons. In addition, because the patients who will be enrolled in our clinical trials may be suffering from a life-threatening disease and may often be suffering from multiple complicating conditions it may be difficult to accurately assess the relationship between our product candidate and adverse events experienced by very ill patients. If we elect or are required to delay, suspend or terminate any of our clinical trials, the commercial prospects of such therapy will be harmed and our ability to generate product revenues from such therapy will be delayed or eliminated. In addition, serious adverse events observed in clinical trials could hinder or prevent market acceptance of the product candidate at issue. Any of these occurrences may harm our business, prospects, financial condition and results of operations significantly.

Clinical trials are expensive, time consuming and difficult to design and implement.

Human clinical trials are expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. Because our CAR-T ovarian cancer therapy is based on relatively new technology and engineered on a patient-by-patient basis, we expect that it will require extensive research and development and have substantial manufacturing and processing costs. In addition, costs to treat patients with relapsed/refractory cancer and to treat potential side effects that may result from therapies such as our current and future product candidates can be significant. Accordingly, our clinical trial costs are likely to be significantly higher than for more conventional therapeutic technologies or drug products. In addition, our proposed personalized product candidates involve several complex and costly manufacturing and processing steps, the costs of which will be borne by us.

In one of our breast cancer vaccine clinical trials, we will treat healthy women who, as a result of testing positive for certain gene mutations, have elected to have prophylactic mastectomies. Delivering an experimental treatment to a healthy individual is more complex and subject to more rigorous regulatory requirements and is more difficult to design and implement. In addition, in future clinical trials we will need to determine efficacy of the breast cancer vaccine as a cancer prevention which will be a considerably more complex clinical trial and will have significantly greater costs.

The costs of our clinical trials may increase if the FDA does not agree with our clinical development plans or requires us to conduct additional clinical trials to demonstrate the safety and efficacy of our product candidates.

We face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively.

The biopharmaceutical industry is characterized by intense competition and rapid innovation. Our competitors may be able to develop other compounds or drugs that are able to achieve similar or better results. Our potential competitors include major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies and universities and other research institutions. Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff and experienced marketing and manufacturing organizations and well-established sales forces. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors, either alone or with collaborative partners, may succeed in developing, acquiring or licensing on an exclusive basis drug or biologic products that are more effective, safer, more easily commercialized or less costly than our product candidates or may develop proprietary technologies or secure patent protection that we may need for the development of our technologies and products.

Cell-based therapies rely on the availability of specialty raw materials, which may not be available to us on acceptable terms or at all.

Gene-modified cell therapy manufacturing requires many specialty raw materials, some of which are manufactured by small companies with limited resources and experience to support a commercial product. Some suppliers typically support biomedical researchers or blood-based hospital businesses and may not have the capacity to support commercial products manufactured under cGMP by biopharmaceutical firms. The suppliers may be ill-equipped to support our needs, especially in non-routine circumstances like FDA inspections or medical crises, such as widespread contamination. We also do not have commercial supply arrangements with many of these suppliers, and may not be able to contract with them on acceptable terms or at all. Accordingly, we may experience delays in receiving key raw materials to support clinical or commercial manufacturing.

In addition, some raw materials are currently available from a single supplier, or a small number of suppliers. We cannot be sure that these suppliers will remain in business, or that they will not be purchased by one of our competitors or another company that is not interested in continuing to produce these materials for our intended purpose.

We may form or seek strategic alliances or enter into additional licensing arrangements in the future, and we may not realize the benefits of such alliances or licensing arrangements.

We may form or seek strategic alliances, create joint ventures or collaborations and enter into additional licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our product candidates and any future product candidates that we may develop. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business. In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy. If we license products or businesses, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture. It is possible that, following a strategic transaction or license, we may not achieve the revenue or specific net income that justifies such transaction. Any delays in entering into new strategic partnership agreements related to our product candidates could delay the development and commercialization of our product candidates in certain geographies for certain indications, which would harm our business prospects, financial condition and results of operations.

The FDA regulatory approval process is lengthy and time-consuming, and we may experience significant delays in the clinical development and regulatory approval of our product candidates.

We have not previously submitted a Biologics License Application ("BLA") or a New Drug Application ("NDA") to the FDA, or similar approval filings to other foreign authorities. A BLA or NDA must include extensive pre-clinical and clinical data and supporting information to establish the product candidate's safety, purity and potency for each desired indication. It must also include significant information regarding the chemistry, manufacturing and controls for the product. We expect the novel nature of our product candidates to create further challenges in obtaining regulatory approval. For example, the FDA has limited experience with commercial development of T cell therapies and vaccines for cancer. The regulatory approval pathway for our product candidates may be uncertain, complex, expensive and lengthy, and approval may not be obtained.

We may also experience delays in completing planned clinical trials for a variety of reasons, including delays related to:

- the availability of financial resources to commence and complete our planned clinical trials;
- reaching agreement on acceptable terms with prospective clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different clinical trial sites;
- recruiting suitable patients to participate in a clinical trial;
- having patients complete a clinical trial or return for post-treatment follow-up;
- clinical trial sites deviating from clinical trial protocol, failing to follow cGCPs, or dropping out of a clinical trial;
- adding new clinical trial sites; or
- manufacturing sufficient quantities of qualified materials under cGMPs and applying them on a subject-by-subject basis for use in clinical trials.

Also, before a clinical trial can begin at an NIH-funded institution, that institution's independent institutional review board, or IRB, and its Institutional Biosafety Committee must review the proposed clinical trial to assess the safety of the trial. In addition, adverse developments in clinical trials of gene therapy products conducted by others may cause the FDA or other regulatory bodies to change the requirements for approval of any of our product candidates.

We could also encounter delays if physicians encounter unresolved ethical issues associated with enrolling patients in clinical trials of our product candidates in lieu of prescribing existing treatments that have established safety and efficacy profiles. Further, a clinical trial may be suspended or terminated by us, the IRBs for the institutions in which such clinical trials are being conducted, the Data Monitoring Committee for such clinical trial, or by the FDA or other regulatory authorities due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or clinical trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product candidate, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. If we experience termination of, or delays in the completion of, any clinical trial of our product candidates, the commercial prospects for our product candidates will be harmed, and our ability to generate product revenue will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product development and approval process and jeopardize our ability to commence product sales and generate revenue.

Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may ultimately lead to the denial of regulatory approval of our product candidates.

Even if we obtain regulatory approval of our product candidates, the products may not gain market acceptance among physicians, patients, hospitals, cancer treatment centers, third-party payors and others in the medical community.

The use of engineered T cells as a potential cancer treatment and the use of therapeutic and prophylactic cancer vaccines are recently developed technologies and may not become broadly accepted by physicians, patients, hospitals, cancer treatment centers, third-party payors and others in the medical community. Many factors will influence whether our product candidates are accepted in the market, including:

- the clinical indications for which our product candidates are approved;
- physicians, hospitals, cancer treatment centers and patients considering our product candidates as a safe and effective treatment;
- the potential and perceived advantages of our product candidates over alternative treatments;
- the prevalence and severity of any side effects;
- product labeling or product insert requirements of the FDA or other regulatory authorities;
- limitations or warnings contained in the labeling approved by the FDA or other regulatory authorities;
- the extent and quality of the clinical evidence supporting the efficacy and safety of our product candidates;
- the timing of market introduction of our product candidates as well as competitive products;
- the cost of treatment in relation to alternative treatments;
- the availability of adequate reimbursement and pricing by third-party payors and government authorities;
- the willingness and ability of patients to pay out-of-pocket in the absence of coverage by third-party payors, including government authorities;
- relative convenience and ease of administration, including as compared to alternative treatments and competitive therapies; and
- the effectiveness of our or any of our strategic partners' sales and marketing efforts.

If our product candidates are approved but fail to achieve market acceptance among physicians, patients, hospitals, cancer treatment centers or others in the medical community, we will not be able to generate significant revenue. Even if our products achieve market acceptance, we may not be able to maintain that market acceptance over time if new products or technologies are introduced that are more favorably received than our products, are more cost effective or render our products obsolete.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain intellectual property protection, our competitive position will be harmed.

Our ability to compete and to achieve sustained profitability will be impacted by our ability to protect our CAR-T cancer therapeutics technologies, our breast cancer vaccine technologies, our ovarian cancer vaccine technologies and other proprietary discoveries and technologies. We expect to rely on a combination of patent protection, copyrights, trademarks, trade secrets, know-how, and regulatory approvals to protect our technologies. Our intellectual property strategy is intended to help develop and maintain our competitive position. While we have been granted multiple patents related to our technologies, there is no assurance that we will be able to obtain further patent protection for our technologies or any other technologies, nor can we be certain that the steps we will have taken will prevent the misappropriation and unauthorized use of our technologies. If we are not able to obtain and maintain patent protection our competitive position may be harmed, including our ability to license any product if we choose to have other parties commercialize them.

Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.

Our commercial success depends upon our ability to develop, manufacture, market and sell our CAR-T therapeutics, our breast cancer vaccine, our ovarian cancer vaccine and other proprietary discoveries and technologies without infringing, misappropriating or otherwise violating the proprietary rights or intellectual property of third parties. We may become party to, or be threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our CAR-T therapeutics, our breast cancer vaccine, our ovarian cancer vaccine and other proprietary discoveries and technologies. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future. If we are found to infringe a third party's intellectual property rights, we could be required to obtain a license from such third party to continue developing our CAR-T therapeutics, our breast cancer vaccine, our ovarian cancer vaccine and other proprietary discoveries and technologies. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. We could be forced, including by court order, to cease developing the infringing technology or product. In addition, we could be found liable for monetary damages. Claims that we have misappropriated the confidential information or trade secrets of third parties can have a similar negative impact on our business.

We rely on licenses from Wistar for our CAR-T technology and Cleveland Clinic for our breast and ovarian cancer vaccine technologies, and if we lose any of these licenses we may be subjected to future litigation.

We are party to royalty-bearing license agreements that grant us rights to use certain intellectual property, including patents and patent applications. We may need to obtain additional licenses from others to advance our research, development and commercialization activities. Our license agreements impose, and we expect that future license agreements if necessary will impose, various development, diligence, commercialization and other obligations on us.

In spite of our efforts, our licensors might conclude that we have materially breached our obligations under such license agreements and might therefore terminate the license agreements, thereby removing or limiting our ability to develop and commercialize products and technology covered by these license agreements. If these in-licenses are terminated, or if the underlying patents fail to provide the intended exclusivity, competitors or other third parties might have the freedom to seek regulatory approval of, and to market, products identical to ours and we may be required to cease our development and commercialization activities. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

Moreover, disputes may arise with respect to any one of our licensing agreements, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our product candidates, technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights under the licensing agreement and our collaborative development relationships;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

If we do not prevail in such disputes, we may lose any of such license agreements.

In addition, the agreements under which we currently license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on our business, financial conditions, results of operations and prospects.

Our failure to maintain such licenses could have a material adverse effect on our business, financial condition and results of operations. Any of these licenses could be terminated, such as if either party fails to abide by the terms of the license, or if the licensor fails to prevent infringement by third parties or if the licensed patents or other rights are found to be invalid or unenforceable. Absent the license agreements, we may infringe patents subject to those agreements, and if the license agreements are terminated, we may be subject to litigation by the licensor. Litigation could result in substantial costs and be a distraction to management. If we do not prevail, we may be required to pay damages, including treble damages, attorneys' fees, costs and expenses, royalties or, be enjoined from selling our products, which could adversely affect our ability to offer products, our ability to continue operations and our financial condition.

If our efforts to protect the proprietary nature of our technologies are not adequate, we may not be able to compete effectively in our market.

Any disclosure to or misappropriation by third parties of our confidential proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in our markets. Certain intellectual property which is covered by our in-license agreements has been developed at academic institutions which have retained non-commercial rights to such intellectual property.

There are several pending U.S. and foreign patent applications in our portfolio, and we anticipate additional patent applications will be filed both in the U.S. and in other countries, as appropriate. However, we cannot predict:

- if and when patents will issue;
- the degree and range of protection any issued patents will afford us against competitors including whether third parties will find ways to invalidate or otherwise circumvent our patents;
- whether or not others will obtain patents claiming aspects similar to those covered by our patents and patent applications; or
- whether we will need to initiate litigation or administrative proceedings which may be costly whether we win or lose.

Composition of matter patents for biological and pharmaceutical products are generally considered to be the strongest form of intellectual property. We cannot be certain that the claims in our pending patent applications directed to compositions of matter for our product candidates will be considered patentable by the U.S. Patent and Trademark Office (the "USPTO") or by patent offices in foreign countries, or that the claims in any of our issued patents will be considered valid by courts in the U.S. or foreign countries. Method of use patents have claims directed to the use of a product for the specified method. This type of patent does not prevent a competitor from making and marketing a product that is identical to our product for an indication that is outside the scope of the patented method. Moreover, even if competitors do not actively promote their product for our targeted indications, physicians may prescribe these products "off-label." Although off-label prescriptions may infringe or contribute to the infringement of method of use patents, the practice is common and such infringement is difficult to prevent or prosecute.

The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our product candidates or uses thereof in the U.S. or in other foreign countries. Even if the patents do successfully issue, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, patents in our portfolio may not adequately exclude third parties from practicing relevant technology or prevent others from designing around our claims. If the breadth or strength of our intellectual property position with respect to our product candidates is threatened, it could dissuade companies from collaborating with us to develop, and threaten our ability to commercialize, our product candidates. Further, if we encounter delays in our clinical trials, the period of time during which we could market our product candidates under patent protection would be reduced. Since patent applications in the U.S. and most other countries are confidential for a period of time after filing, it is possible that patent applications in our portfolio may not be the first filed patent applications related to our product candidates. Furthermore, for U.S. applications in which all claims are entitled to a priority date before March 16, 2013, an interference proceeding can be provoked by a third-party or instituted by the USPTO, to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. For U.S. applications containing a claim not entitled to priority before March 16, 2013, there is a greater level of uncertainty in the patent law with the passage of the America Invents Act (2012) which brings into effect significant changes to the U.S. patent laws that are yet untried and untested, and which introduces new procedures for challenging pending patent applications and issued patents. A primary change under this reform is the creation of a "first to file" system in the U.S. This will require us to be cognizant going forward of the time from invention to filing of a patent application.

Obtaining and maintaining our patents depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent position could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. Such noncompliance events are outside of our direct control for (1) non-U.S. patents and patent applications owned by us, and (2) patents and patent applications licensed to us by another entity. In such an event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

Issued patents covering our product candidates could be found invalid or unenforceable if challenged in court or the USPTO.

If we or one of our licensing partners initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that the patent covering our product candidate, as applicable, is invalid and/or unenforceable. In patent litigation in the U.S., defendant counterclaims alleging invalidity and/or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Third parties may also raise similar claims before administrative bodies in the U.S. or abroad, even outside the context of litigation. Such mechanisms include re-examination, post grant review, and equivalent proceedings in foreign jurisdictions, for example, opposition proceedings. Any such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover our product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art and that prior art that was cited during prosecution, but not relied on by the patent examiner, will not be revisited. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patents directed to our product candidates. A loss of patent rights could have a material adverse impact on our business.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our products.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve both technological and legal complexity, and is therefore costly, time-consuming and inherently uncertain. In addition, the U.S. has recently enacted and is currently implementing wide-ranging patent reform legislation. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. For example, in the case, Assoc. for Molecular Pathology v. Myriad Genetics, Inc., the U.S. Supreme Court held that certain claims to DNA molecules are not patentable. While we do not believe that any of the patents owned or licensed by us will be found invalid based on this decision, we cannot predict how future decisions by the courts, the U.S. Congress or the USPTO may impact the value of our patents.

We have limited foreign intellectual property rights and may not be able to protect our intellectual property rights throughout the world.

We have limited intellectual property rights outside the U.S. Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the U.S. can be less extensive than those in the U.S. In addition, the laws of some foreign countries do not protect intellectual property to the same extent as federal and state laws in the U.S. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the U.S., or from selling or importing products made using our inventions in and into the U.S. or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patents to develop their own products and further, may export otherwise infringing products to territories where we have patents, but enforcement is not as strong as that in the U.S. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property in foreign jurisdictions. The legal systems of certain countries, particularly China and certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property, particularly those relating to biopharmaceutical products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. To date, we have not sought to enforce any issued patents in these foreign jurisdictions. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. The requirements for patentability may differ in certain countries, particularly developing countries. Furthermore, generic drug manufacturers or other competitors may challenge the scope, validity or enforceability of our or our licensors' patents, requiring us or our licensors to engage in complex, lengthy and costly litigation or other proceedings. Certain countries in Europe and developing countries, including China and India, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, we and our licensors may have limited remedies if patents are infringed or if we or our licensors are compelled to grant a license to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Risks Related to Our Common Stock

The issuance or sale of shares in the future to raise money or for strategic purposes could reduce the market price of our common stock.

In the future, we may issue securities to raise cash for operations, to pay down then existing indebtedness, as consideration for the acquisition of assets, as consideration for receipt of goods or services, to pay for the development of our CAR-T cancer therapeutics, to pay for the development of our breast cancer vaccine, to pay for the development of our ovarian cancer vaccine and for acquisitions of companies. We have an at-the-market equity offering under which, as of January 16, 2024 we may issue up to approximately $98 million of common stock, which is currently effective, and which may remain available to us in the future. We also have, and in the future may, issue securities convertible into our common stock. Any of these events may dilute stockholders' ownership interests in our company and have an adverse impact on the price of our common stock.

In addition, sales of a substantial amount of our common stock in the public market, or the perception that these sales may occur, could reduce the market price of our common stock. This could also impair our ability to raise additional capital through the sale of our securities.

Any actual or anticipated sales of shares by our stockholders may cause the trading price of our common stock to decline. The sale of a substantial number of shares of our common stock by our stockholders, or anticipation of such sales, could make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect sales.

We may fail to meet market expectations because of fluctuations in quarterly operating results, which could cause the price of our common stock to decline.

Our reported revenues and operating results have fluctuated in the past and may continue to fluctuate significantly from quarter to quarter in the future, specifically as we continue to devote our resources towards our CAR-T cancer therapeutics and our breast and ovarian cancer vaccines. It is possible that in future periods, we will have no revenue or, in any event, revenues could fall below or expenses could rise above the expectations of securities analysts or investors, which could cause the market price of our common stock to decline. The following are among the factors that could cause our operating results to fluctuate significantly from period to period:

- patient enrollment rates for our clinical trials;
- delays with respect to our clinical trials;
- clinical trial results relating to our CAR-T cancer therapeutics;
- clinical trial results relating to our breast cancer vaccine;
- results of pre-clinical studies relating to our ovarian cancer vaccine;
- progress with regulatory authorities towards the certification/approval of our CAR-T cancer therapeutics, our breast cancer vaccine or our ovarian cancer vaccine; and
- costs related to acquisitions, alliances and licenses.

Biotechnology company stock prices are especially volatile, and this volatility may depress the price of our common stock.

The stock market has experienced significant price and volume fluctuations, and the market prices of biotechnology companies have been highly volatile. We believe that various factors may cause the market price of our common stock to fluctuate, perhaps substantially, including, among others, the following:

- announcements of developments in the fields of CAR-T therapeutics or cancer vaccines;
- developments in relationships with third party vendors and laboratories;
- developments or disputes concerning our patents and other intellectual property;
- our or our competitors' technological innovations;
- variations in our quarterly operating results;
- our failure to meet or exceed securities analysts' expectations of our financial results;
- a change in financial estimates or securities analysts' recommendations;
- changes in management's or securities analysts' estimates of our financial performance;
- announcements by us or our competitors of significant contracts, acquisitions, strategic partnerships, joint ventures, capital commitments, new technologies, or patents; and
- the timing of or our failure to complete significant transactions.

In addition, we believe that fluctuations in our stock price during applicable periods can also be impacted by changes in governmental regulations in the drug development industry and/or court rulings and/or other developments in our remaining patent licensing and enforcement actions.

In the past, companies that have experienced volatility in the market price of their stock have been the objects of securities class action litigation. If our common stock was the object of securities class action litigation due to volatility in the market price of our stock, it could result in substantial costs and a diversion of management's attention and resources, which could materially harm our business and financial results.

Our common stock is currently listed on NASDAQ Capital Market, however if our common stock is delisted for any reason, it will become subject to the SEC's penny stock rules which may make our shares more difficult to sell.

If our common stock is delisted from NASDAQ Capital Market, our common stock will then fit the definition of a penny stock and therefore would be subject to the rules adopted by the SEC regulating broker-dealer practices in connection with transactions in penny stocks. The SEC rules may have the effect of reducing trading activity in our common stock making it more difficult for investors to sell their shares. The SEC's rules require a broker or dealer proposing to effect a transaction in a penny stock to deliver the customer a risk disclosure document that provides certain information prescribed by the SEC, including, but not limited to, the nature and level of risks in the penny stock market. The broker or dealer must also disclose the aggregate amount of any compensation received or receivable by him in connection with such transaction prior to consummating the transaction. In addition, the SEC's rules also require a broker or dealer to make a special written determination that the penny stock is a suitable investment for the purchaser and receive the purchaser's written agreement to the transaction before completion of the transaction. The existence of the SEC's rules may result in a lower trading volume of our common stock and lower trading prices.

We have issued a significant number of securities pursuant to our incentive plans and may continue to do so in the future. The vesting and, if applicable, exercise of these securities and the sale of the shares of common stock issuable thereunder may dilute stockholders' percentage ownership interest and may also result in downward pressure on the price of our common stock.

As of the date of this Report, we have issued and outstanding options to purchase 12,735,000 shares of our common stock with a weighted average exercise price of $3.68. Further, as of the date of this Report, our Board of Directors and Compensation Committee have the authority to issue awards totaling an additional 665,000 shares of our common stock which is replenished on a yearly basis in accordance with the provisions of our plan. Additionally, we have registered for resale all of the shares of common stock issuable under our incentive plans. Because the market for our common stock is thinly traded, the sales and/or the perception that those sales may occur, could adversely affect the market price of our common stock. Furthermore, the mere existence of a significant number of shares of common stock issuable upon vesting and, if applicable, exercise of these securities may be perceived by the market as having a potential dilutive effect, which could lead to a decrease in the price of our common stock.

We are a smaller reporting company and the reduced reporting requirements applicable to smaller reporting companies may make our common stock less attractive to investors.

We are a smaller reporting company ("SRC") and a non-accelerated filer, which allows us to take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not SRCs or non-accelerated filers, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended, reduced disclosure obligations regarding executive compensation in our Annual Report and our periodic reports and proxy statements and providing only two years of audited financial statements in our Annual Report and our periodic reports. We will remain an SRC until (a) the aggregate market value of our outstanding common stock held by non-affiliates as of the last business day our most recently completed second fiscal quarter exceeds $250 million or (b) (1) we have over $100 million in annual revenues and (2) the aggregate market value of our outstanding common stock held by non-affiliates as of the last business day our most recently completed second fiscal quarter exceeds $700 million. We cannot predict whether investors will find our common stock less attractive if we rely on certain or all of these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile and may decline.

We do not anticipate declaring any cash dividends on our common stock which may adversely impact the market price of our stock.

We have never declared or paid cash dividends on our common stock and do not plan to pay any cash dividends in the near future. Our current policy is to retain all funds and any earnings for use in the operation and expansion of our business. If we do not pay dividends, our stock may be less valuable to you because a return on your investment will only occur if our stock price appreciates.

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity.

We will provide the disclosure required under this Item 1C in our annual report for the year ended October 31, 2024 which is the first annual report for a fiscal year ending on or after December 15, 2023, the date on which disclosure under Item 106 of Regulation S-K is required.

Item 2. Properties.

We lease approximately 2,000 square feet of office space at 3150 Almaden Expressway, San Jose, California (our principal executive offices) from an unrelated party pursuant to a lease that expires September 30, 2024. Our base rent is approximately $5,000 per month and the lease provides for annual increases of approximately 3% and an escalation clause for increases in certain operating costs.

Item 3. Legal Proceedings.

Other than lawsuits we bring to enforce our patent rights, we are not a party to any material pending legal proceedings, nor are we aware of any pending litigation or legal proceeding against us that would have a material adverse effect on our financial position or results of operations.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for the Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information

Our common stock trades on the NASDAQ Capital Market under the symbol "ANIX".

Holders

As of January 12, 2024, the approximate number of record holders of our common stock was 312 and the closing price of our common stock was $4.39 per share.

Securities Authorized for Issuance Under Equity Compensation Plans

The following is information as of October 31, 2023 about shares of our common stock that may be issued upon the exercise of options, warrants and rights under all equity compensation plans in effect as of that date, including our 2010 Share Incentive Plan and our 2018 Share Incentive Plan. See Note 4 to our Consolidated Financial Statements for more information on these plans.

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
Equity compensation plans not approved by security holders (1)	1,189,000	$ 2.94	-
Equity compensation plans approved by security holders (2)	10,241,000	$ 3.67	750,000

(1) On July 14, 2010, the Board adopted the 2010 Share Incentive Plan. Officers, key employees and non-employee directors of, and consultants to, the Company or any of its subsidiaries and affiliates were eligible to participate in the 2010 Share Incentive Plan. The 2010 Share Incentive Plan provided for the grant of stock options, stock appreciation rights, stock awards, and performance awards and stock units. The 2010 Share Incentive Plan terminated with respect to additional grants on July 14, 2020.

(2) The 2018 Share Incentive Plan was adopted by the Board on January 25, 2018 and approved by our shareholders on March 29, 2018. Officers, key employees and non-employee directors of, and consultants to, the Company or any of its subsidiaries and affiliates are eligible to participate in the 2018 Share Incentive Plan. The 2018 Share Incentive Plan provides for the grant of incentive stock options, nonqualified stock options, stock appreciation rights, stock awards, performance awards and stock units (the "2018 Benefits"). The maximum number of shares of common stock available for issuance under the 2018 Share Incentive Plan was initially 5,000,000 shares. Additionally, commencing on the first business day in January 2019 and on the first business day of each calendar year thereafter, the maximum aggregate number of shares available for issuance shall be replenished such that, as of such first business day, the maximum aggregate number of shares available for issuance shall be 2,000,000 shares. The 2018 Share Incentive Plan is administered by the Compensation Committee, which determines the option price, term and provisions of the 2018 Benefits. The 2018 Share Incentive Plan terminates with respect to additional grants on March 28, 2028. The Board may amend, suspend or terminate the 2018 Share Incentive Plan at any time, subject in certain respects to obtaining shareholder approval.

Dividend Policy

No cash dividends have been paid on our common stock since our inception. We have no present intention to pay any cash dividends in the foreseeable future.

Recent Sales of Unregistered Securities

During the three months ended October 31, 2023, the Company issued an aggregate of 6,756 unregistered shares of our common stock to a company in payment of investor relations services. The common stock was issued in reliance on an exemption from registration under Section 4(a)(2) of the Securities Act as they were issued in a private transaction to investors, without a view to distribution, and were not issued through any general solicitation or advertisement.

Item 6. [Reserved]

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

General

In reviewing Management's Discussion and Analysis of Financial Condition and Results of Operations, you should refer to our Consolidated Financial Statements and the notes related thereto.

Results of Operations

Fiscal Year ended October 31, 2023 compared with Fiscal Year ended October 31, 2022

Revenue

In fiscal year 2023, we recorded revenue of approximately $210,000 from one license agreement related to our encrypted audio/video conference calling technology. The license agreement provided for a one-time, non-recurring, lump sum payment in exchange for a non-exclusive retroactive and future license, and covenant not to sue. Pursuant to the terms of the agreement, we have no further obligations with respect to the granted intellectual property rights, including no obligation to maintain or upgrade the technology, or provide future support or services. Accordingly, the performance obligations from the license were satisfied and 100% of the revenue was recognized upon execution of the license agreement. We did not have any revenue in fiscal year 2022.

Over the past several years, our revenue, if any, was derived from technology licensing and the sale of patented technologies, including revenue from the settlement of litigation. As part of our legacy operations, the Company remains engaged in limited patent licensing activities in the area of encrypted audio/video conference calling. We do not expect these activities to be a significant part of the Company's ongoing operations, nor do we expect these activities to require material financial resources or attention of senior management.

We have not generated any revenue to date from our therapeutics or vaccine programs. In addition, while we pursue our therapeutics and vaccine programs, we may also make investments in and form new companies to develop additional emerging technologies. We do not expect to begin generating revenue with respect to any of our current therapy or vaccine programs in the near term. We hope to achieve a profitable outcome by eventually licensing our technologies to large pharmaceutical companies that have the resources and infrastructure in place to manufacture, market and sell our technologies as therapeutics or vaccines. The eventual licensing of any of our technologies may take several years, if it is to occur at all, and may depend on positive results from human clinical trials.

Inventor Royalties, Contingent Legal Fees, Litigation and Licensing Expenses Related to Patent Assertion

In fiscal year 2023, inventor royalties, contingent legal fees, litigation and licensing expenses related to patent assertion activities were approximately $161,000. Inventor royalties and contingent legal fees are expensed in the period that the related revenues are recognized. Litigation and licensing expenses related to patent assertion, other than contingent legal fees, are expensed in the period incurred.

We did not have any inventor royalties, contingent legal fees, litigation and licensing expenses related to patent assertion activities in fiscal year 2022.

Research and Development Expenses

Research and development expenses incurred in fiscal year 2023 associated with each of our development programs consisted of approximately $1,839,000 for CAR-T therapeutics, approximately $2,682,000 for cancer vaccines, and approximately $248,000 for anti-viral therapeutics.

Research and development expenses are related to the development of our cancer therapeutic and vaccine programs, and our anti-viral drug program, and decreased by approximately $1,934,000 to approximately $4,769,000 in fiscal year 2023, from approximately $6,703,000 in fiscal year 2022. The decrease in research and development expenses was primarily due to a decrease in employee stock option compensation expense of approximately $1,386,000, a decrease in research and development expenses related to our COVID-19 development program of approximately $485,000 as a result of the suspension of that program in March 2023, a decrease in license fees of approximately $225,000, a decrease in consultant stock option expense of approximately $213,000, a decrease in research and development expenses related to our CAR-T development program of approximately $156,000, and a decrease in research and development expenses related to our ovarian cancer vaccine development program of approximately $130,000, offset by an increase in research and development expenses related to our breast cancer vaccine development program of approximately $563,000 and an increase in employee compensation and related costs, other than stock option compensation expense, of approximately $147,000.

General and Administrative Expenses

General and administrative expenses decreased by approximately $881,000 to approximately $6,291,000 in fiscal year 2023, from approximately $7,172,000 in fiscal year 2022. The decrease in general and administrative expenses was principally due to a decrease in employee stock option compensation expense of approximately $309,000, a decrease in professional fees of approximately $239,000, a decrease in consultant warrant expense of approximately $221,000, a decrease in employee compensation and related costs, other than stock option compensation expense, of approximately $214,000, and a decrease in patent expenses of approximately $152,000, offset by an increase in director compensation expense, other than stock option compensation expense, of approximately $121,000 and an increase in director stock option compensation expense of approximately $116,000.

Interest Income

Interest income increased to approximately $1,081,000 in fiscal year 2023 compared to approximately $104,000 in fiscal year 2022, due to an increase in interest rates and the increased dollar amount held in short-term investments.

Net Loss Attributable to Noncontrolling Interest

The net loss attributable to noncontrolling interest, representing Wistar's ownership interest in Certainty's net loss, decreased by approximately $57,000 to approximately $119,000 in fiscal year 2023, from approximately $176,000 in fiscal year 2022, as Certainty's net loss decreased.

Liquidity and Capital Resources

Our primary sources of liquidity are cash, cash equivalents and short-term investments.

Based on currently available information as of January 16, 2024, we believe that our existing cash, cash equivalents, short-term investments and expected cash flows will be sufficient to fund our activities for at least the next twelve months. We have implemented a business model that conserves funds by collaborating with third parties to develop our technologies. However, our projections of future cash needs and cash flows may differ from actual results. If current cash on hand, cash equivalents, short-term investments and cash that may be generated from our business operations are insufficient to continue to operate our business, or if we elect to invest in or acquire a company or companies or new technology or technologies that are synergistic with or complementary to our technologies, we may be required to obtain more working capital. Under our at-the-market equity program, which is currently effective and may remain available for us to use in the future, as of October 31, 2023, we may sell up to $100 million of common stock. We did not sell any shares under our at-the-market equity program during the fiscal year ended October 31, 2023. We may seek to obtain working capital during our fiscal year 2024 or thereafter through sales of our equity securities or through bank credit facilities or public or private debt from various financial institutions where possible. We cannot be certain that additional funding will be available on acceptable terms, or at all. If we do identify sources for additional funding, the sale of additional equity securities or convertible debt will result in dilution to our stockholders. We can give no assurance that we will generate sufficient cash flows in the future to satisfy our liquidity requirements or sustain future operations, or that other sources of funding, such as sales of equity or debt, would be available or would be approved by our security holders, if needed, on favorable terms or at all. If we fail to obtain additional working capital as and when needed, such failure could have a material adverse impact on our business, results of operations and financial condition. Furthermore, such lack of funds may inhibit our ability to respond to competitive pressures or unanticipated capital needs, or may force us to reduce operating expenses, which would significantly harm the business and development of operations.

During the fiscal year ended October 31, 2023, cash used in operating activities was approximately $6,209,000. Cash used in investing activities was approximately $5,602,000, resulting from the purchase of short-term investments of approximately $44,411,000, which was offset by the proceeds on maturities of short-term investments of approximately $38,809,000. Cash provided by financing activities was approximately $366,000, resulting from proceeds from the exercise of stock options of approximately $353,000 and proceeds from the sale of common stock pursuant to an employee stock purchase plan of approximately $13,000. As a result, our cash, cash equivalents, and short-term investments at October 31, 2023 decreased approximately $5,843,000 to approximately $23,844,000 from approximately $29,687,000 at the end of fiscal year 2022.

We have expected future cash obligations related to the lease of our offices through 2026, estimated at approximately $202,000.

Off-Balance Sheet Arrangements

We have no variable interest entities or other significant off-balance sheet obligation arrangements.

Critical Accounting Policies

The Company's consolidated financial statements are prepared in conformity with accounting principles generally accepted in the United States of America. In preparing these financial statements, we make assumptions, judgments and estimates that can have a significant impact on amounts reported in our consolidated financial statements. We base our assumptions, judgments and estimates on historical experience and various other factors that we believe to be reasonable under the circumstances. Actual results could differ materially from these estimates under different assumptions or conditions. On a regular basis, we evaluate our assumptions, judgments and estimates and make changes accordingly.

We believe that, of the significant accounting policies discussed in Note 2 to our Consolidated Financial Statements, the following accounting policies require our most difficult, subjective, or complex judgments:

- Revenue Recognition;
- Stock-Based Compensation; and
- Research and Development Expense.

Revenue Recognition

Our revenue has been derived solely from technology licensing and the sale of patented technologies. Revenue is recognized upon transfer of control of intellectual property rights and satisfaction of other contractual performance obligations to licensees in an amount that reflects the consideration we expect to receive.

Our revenue recognition policy requires us to make certain judgments and estimates in connection with the accounting for revenue. Such areas may include determining the existence of a contract and identifying each party's rights and obligations to transfer goods and services, identifying the performance obligations in the contract, determining the transaction price and allocating the transaction price to separate performance obligations, estimating the timing of satisfaction of performance obligations, determining whether a promise to grant a license is distinct from other promised goods or services and evaluating whether a license transfers to a customer at a point in time or over time.

Our revenue arrangements provide for the payment, within 30 days of execution of the agreement, of contractually determined, one-time, paid-up license fees in settlement of litigation and in consideration for the grant of certain intellectual property rights for patented technologies owned or controlled by the Company. These arrangements typically include some combination of the following: (i) the grant of a non-exclusive, retroactive and future license to manufacture and/or sell products covered by patented technologies owned or controlled by the Company, (ii) a covenant-not-to-sue, (iii) the release of the licensee from certain claims, and (iv) the dismissal of any pending litigation. In such instances, the intellectual property rights granted have been perpetual in nature, extending until the expiration of the related patents. Pursuant to the terms of these agreements, we have no further obligations with respect to the granted intellectual property rights, including no obligation to maintain or upgrade the technology, or provide future support or services. Licensees obtained control of the intellectual property rights they have acquired upon execution of the agreement. Accordingly, the performance obligations from these agreements were satisfied and 100% of the revenue was recognized upon the execution of the agreements.

Stock-Based Compensation

The compensation cost for service-based stock options granted to employees, directors and consultants is measured at the grant date, based on the fair value of the award using the Black-Scholes pricing model, and is recognized as an expense on a straight-line basis over the requisite service period (the vesting period of the stock option) which is one to four years. For employee options vesting if the trading price of the Company's common stock exceeds certain price targets, we use a Monte Carlo Simulation in estimating the fair value at grant date and recognize compensation cost over the implied service period. For stock-based awards that vest upon the achievement of a performance metric, the Company recognizes the estimated fair value of the award when achievement becomes probable.

For stock awards granted to employees and directors that vest at date of grant, we recognize expense based on the grant date market price of the underlying common stock. For restricted stock awards vesting upon achievement of a price target of our common stock, we use a Monte Carlo Simulation in estimating the fair value at grant date and recognize compensation cost over the implied service period (median time to vest).

The Black-Scholes pricing model and the Monte Carlo Simulation we use to estimate fair value requires valuation assumptions of expected term, expected volatility, risk-free interest rates and expected dividend yield. The expected term of stock options represents the weighted average period the stock options are expected to remain outstanding. For employees, we use the simplified method, which is a weighted average of the vesting term and contractual term, to determine expected term. The simplified method was adopted since we do not believe that historical experience is representative of future performance because of the impact of the changes in our operations and the change in terms from historical options. For consultants we use the contract term for expected term. Under the Black-Scholes pricing model, we estimated the expected volatility of our shares of common stock based upon the historical volatility of our share price over a period of time equal to the expected term of the grants. We estimated the risk-free interest rate based on the implied yield available on the applicable grant date of a U.S. Treasury note with a term equal to the expected term of the underlying grants. We made the dividend yield assumption based on our history of not paying dividends and our expectation not to pay dividends in the future.

We will reconsider use of the Black-Scholes pricing model and the Monte Carlo Simulation if additional information becomes available in the future that indicates another model would be more appropriate. If factors change and we employ different assumptions in future periods, the compensation expense that we record may differ significantly from what we have recorded in the current period.

Research and Development Expense

We recognize research and development expenses as incurred. Advance payments for future research and development activities are deferred and expensed as the services are performed. We recognize our preclinical studies and clinical trial expenses based on the services performed pursuant to contracts with research institutions, clinical research organizations ("CROs"), clinical manufacturing organizations ("CMOs"), and other parties that conduct and manage various stages of research and development activities on our behalf. Fees for such services are recognized based on management's estimates after considering the activities and tasks completed by each service provider in a given period, the time period over which services are expected to be performed, and the level of effort expended in each reporting period.

At each balance sheet date, management estimates prepaid and accrued research and development costs by discussing progress or stage of completion of activities with internal personnel and external service providers, and comparing this information to payments made, invoices received, and the agreed-upon contractual fee to be paid for such services in the applicable contract or statements of work.

In addition, we allocate certain internal compensation costs to research and development expenses based on management's estimates of each employee's time and effort expended.

Effect of Recent Accounting Pronouncements

We discuss the effect of recently issued pronouncements in Note 2 to the Consolidated Financial Statements.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

Not required for a smaller reporting company.

Item 8. Financial Statements and Supplementary Data.

See accompanying "Index to Consolidated Financial Statements."

Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Disclosure Controls and Procedures

We maintain disclosure controls and procedures, as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act. Under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, we evaluated the effectiveness of the design and operation of our disclosure controls and procedures pursuant to Rule 13a-15 and 15d-15 of the Exchange Act. Based upon that evaluation, our Chief Executive Officer and our Chief Financial Officer concluded that our disclosure controls and procedures were effective as of the end of fiscal year 2023.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as such term is defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act. Our management, including the principal executive officer and principal financial officer, does not expect that our internal controls over financial reporting will prevent all errors and all fraud. A control system, no matter how well designed and operated, cannot provide full assurance that the objectives of the control system are met, and no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within a company have been detected. Our internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external purposes in accordance with generally accepted accounting principles.

Under the supervision and with the participation of our management, including the principal executive officer and principal financial officer, we conducted an evaluation as to the effectiveness of our internal control over financial reporting as of October 31, 2023. In making this assessment, our management used the criteria for effective internal control set forth by the Committee of Sponsoring Organizations of the Treadway Commission in the *2013 Internal Control – Integrated Framework*. Based on this assessment, our management concluded that our internal control over financial reporting was effective as of October 31, 2023.

This Annual Report on Form 10-K does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by the Company's independent registered public accounting firm pursuant to an exemption of the Commission that permits smaller reporting companies and non-accelerated filers, such as the Company, to provide only management's report in this Annual Report on Form 10-K. Accordingly, our management's assessment of the effectiveness of our internal control over financial reporting as of October 31, 2023 has not been audited by our auditors, Haskell & White LLP.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting during the fourth quarter of fiscal year 2023 that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

Item 9B. Other Information.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this Item will be set forth in our Proxy Statement for the 2024 Annual Meeting of Stockholders scheduled for March 21, 2024 which such Proxy Statement will be filed with the SEC within 120 days of October 31, 2023, and will be incorporated into this Annual Report on Form 10-K by reference.

Item 11. Executive Compensation.

The information required by this Item will be set forth in our Proxy Statement for the 2024 Annual Meeting of Stockholders scheduled for March 21, 2024 which such Proxy Statement will be filed with the SEC within 120 days of October 31, 2023, and will be incorporated into this Annual Report on Form 10-K by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by this Item will be set forth in our Proxy Statement for the 2024 Annual Meeting of Stockholders scheduled for March 21, 2024 which such Proxy Statement will be filed with the SEC within 120 days of October 31, 2023, and will be incorporated into this Annual Report on Form 10-K by reference.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required by this Item will be set forth in our Proxy Statement for the 2024 Annual Meeting of Stockholders scheduled for March 21, 2024 which such Proxy Statement will be filed with the SEC within 120 days of October 31, 2023, and will be incorporated into this Annual Report on Form 10-K by reference.

Item 14. Principal Accounting Fees and Services.

The information required by this Item will be set forth in our Proxy Statement for the 2024 Annual Meeting of Stockholders scheduled for March 21, 2024 which such Proxy Statement will be filed with the SEC within 120 days of October 31, 2023, and will be incorporated into this Annual Report on Form 10-K by reference.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a)(1)(2) Financial Statement Schedules

See accompanying "Index to Consolidated Financial Statements."

(b) Exhibits

3.1	Certificate of Incorporation, as amended. (Incorporated by reference to Form 10-Q for the fiscal quarter ended July 31, 1992 and Form S-3, dated February 11, 2014.)
3.2	Amendment to the Certificate of Incorporation. (Incorporated by reference to Exhibit 3.2 to our Form 10-K for the fiscal year ended October 31, 2013.)
3.3	Certificate of Amendment to the Certificate of Incorporation. (Incorporated by reference to Exhibit 3.1 to our Form 8-K, dated September 4, 2014.)
3.4	Certificate of Designations, Preferences and Rights of Series A Convertible Preferred Stock. (Incorporated by reference to Exhibit 3.1 to our Form 8-K, dated September 10, 2014.)
3.5	Certificate of Amendment to the Certificate of Incorporation. (Incorporated by reference to Exhibit 3.1 to our Form 8-K, dated June 25, 2015.)
3.6	Certificate of Amendment to the Certificate of Incorporation. (Incorporated by reference to Exhibit 3.1 to our Form 10-Q for the fiscal quarter ended April 30, 2018.)
3.7	Certificate of Amendment to the Certificate of Incorporation. (Incorporated by reference to Exhibit 3.1 to our Form 8-K, dated October 1, 2018.)
3.8	Certificate of Amendment to the Certificate of Incorporation. (Incorporated by reference to Exhibit 3.1 to our Form 8-K, dated August 13, 2020.)
3.9	Amended and Restated By-laws. (Incorporated by reference to Exhibit 3.8 to our Form 10-K for the fiscal year ended October 31, 2019.)
3.10	Amendment to the Amended and Restated Bylaws of the Company. (Incorporated by reference to our Form 8-K, dated April 2, 2021.)
4.1	Form of Underwriter Warrants. (Incorporated by reference to Exhibit 4.1 to our Form 8-K, dated March 24, 2021.)
4.2	Description of the Company's Securities Registered under Section 12 of the Exchange Act (Incorporated by reference to the description of our common stock contained in our Current Report on Form 8-K filed on March 31, 2014.)
10.1	2010 Share Incentive Plan. (Incorporated by reference to Exhibit 10.1 to our Form 8-K, dated July 20, 2010.)
10.2	Amendment No. 1 to the 2010 Share Incentive Plan. (Incorporated by reference to Exhibit 10.1 to our Form 8-K, dated July 7, 2011.)

10.3	Amendment No. 2 to the 2010 Share Incentive Plan. (Incorporated by reference to Exhibit 10.1 to our Form 8-K, dated September 5, 2012.)
10.4	Amendment No. 3 to the 2010 Share Incentive Plan. (Incorporated by reference to Exhibit 10.1 to our Form 10-Q for the fiscal quarter ended January 31, 2014.)
10.5	2018 Share Incentive Plan. (Incorporated by reference to Exhibit 4.13 to our Form S-8 dated October 1, 2018.)
10.6	License Agreement, dated November 13, 2017, between Certainty Therapeutics, Inc. and The Wistar Institute of Anatomy and Biology. (Incorporated by reference to Exhibit 10.14 to our Form 10-K, dated January 9, 2018.) (Portions of this exhibit have been redacted pursuant to a request for confidential treatment. The redacted portions have been separately filed with the Securities and Exchange Commission.)
10.7	Amendment to License Agreement between Certainty Therapeutics, Inc. and The Wistar Institute of Anatomy and Biology. (Incorporated by reference to Exhibit 10.1 to our Form 10-Q for the fiscal quarter ended January 31, 2021.) (Certain information has been redacted in the marked portions of the exhibit.)
10.8	Amended and Restated Master Collaboration Agreement, dated November 1, 2021, between Certainty Therapeutics, Inc. and H. Lee Moffitt Cancer Center and Research Institute, Inc. (Incorporated by reference to Exhibit 10.8 to our Form 10-K for the fiscal year ended October 31, 2021.)
10.9	Exclusive License Agreement, dated July 8, 2019, between the Company and The Cleveland Clinic Foundation. (Incorporated by reference to Exhibit 10.1 to our Form 10-Q for the fiscal quarter ended July 31, 2019.) (Certain information has been redacted in the marked portions of the exhibit.)
10.10	Amendment to Exclusive License Agreement between the Company and The Cleveland Clinic Foundation. (Filed herewith.)
10.11	Exclusive License Agreement, dated October 20, 2020, between the Company and The Cleveland Clinic Foundation. (Incorporated by reference to Exhibit 10.14 to our Form 10-K, for the fiscal year ended October 31, 2020.) (Certain information has been redacted in the marked portions of the exhibit.)
10.12	Amendment No. 1 to Exclusive License Agreement between the Company and The Cleveland Clinic Foundation. (Incorporated by reference to Exhibit 10.1 to our Form 10-Q for the fiscal quarter ended July 31, 2022.) (Certain information has been redacted in the marked portions of the exhibit.)
10.13	Form of Controlled Equity Offering^{SM} Sales Agreement (Incorporated by reference to Exhibit 10.1 to our Form S-3 dated September 9, 2022)
14	Code of Conduct (Incorporated by reference to Exhibit 14 to our Form 10-K, for the fiscal year ended October 31, 2020.)
19	Insider Trading Policy (Filed herewith.)
21	Subsidiaries of Anixa Biosciences, Inc. (Incorporated by reference to Exhibit 21 to our Form 10-K, for the fiscal year ended October 31, 2020.)
23.1	Consent of Haskell & White LLP. (Filed herewith.)
31.1	Certification of Chief Executive Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, dated January 16, 2024. (Filed herewith.)
31.2	Certification of Chief Financial Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, dated January 16, 2024. (Filed herewith.)
32.1	Statement of Chief Executive Officer, pursuant to Section 1350 of Title 18 of the United States Code, dated January 16, 2024. (Filed herewith.)
32.2	Statement of Chief Financial Officer, pursuant to Section 1350 of Title 18 of the United States Code, dated January 16, 2024. (Filed herewith.)
99.1	Clawback Policy (Filed herewith.)

Item 16. Form 10-K Summary.

The Company has elected not to include a summary pursuant to this Item 16.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Anixa Biosciences, Inc.

By: */s/ Amit Kumar*
Dr. Amit Kumar
Chairman of the Board and
Chief Executive Officer
January 16, 2024

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the date indicated.

By: */s/ Amit Kumar*
Dr. Amit Kumar
Chairman of the Board and
Chief Executive Officer
January 16, 2024 (Principal Executive Officer)

By: */s/ Michael J. Catelani*
Michael J. Catelani
President, Chief Operating Officer and
Chief Financial Officer
January 16, 2024 (Principal Financial and Accounting Officer)

By: */s/ Lewis H. Titterton, Jr.*
Lewis H. Titterton, Jr.
January 16, 2024 Director

By: */s/ Arnold Baskies*
Dr. Arnold Baskies
January 16, 2024 Director

By: */s/ Emily Gottschalk*
Emily Gottschalk
January 16, 2024 Director

ANIXA BIOSCIENCES, INC. AND SUBSIDIARIES

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS
OCTOBER 31, 2023

Additional information required by schedules called for under Regulation S-X is either not applicable or is included in the consolidated financial statements or notes thereto.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders
Anixa Biosciences, Inc.

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Anixa Biosciences, Inc. (the "Company") as of October 31, 2023 and 2022, and the related consolidated statements of operations, equity, and cash flows for each of the two years in the period ended October 31, 2023, and the related notes (collectively, the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the consolidated financial position of the Company as of October 31, 2023 and 2022, and the consolidated results of its operations and its cash flows for each of the years in the two year period ended October 31, 2023, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence supporting the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing separate opinions on the critical audit matter or on the accounts or disclosures to which it relates.

Research and Development Expenses – Refer to Note 2 of the Consolidated Financial Statements

Critical Audit Matter Description:

The Company recognizes research and development expenses as incurred. Advance payments for future research and development activities are deferred and expensed as the services are performed. The Company recognizes its preclinical studies and clinical trial expenses based on the services performed pursuant to contracts with research institutions, clinical research organizations ("CROs"), clinical manufacturing organizations ("CMOs"), and other parties that conduct and manage various stages of research and development activities on the Company's behalf. Fees for such services are recognized based on management's estimates after considering the activities and tasks completed by each service provider in a given period, the time period over which services are expected to be performed, and the level of effort expended in each reporting period.

At each balance sheet date, management estimates prepaid and accrued research and development costs by discussing progress or stage of completion of activities with internal personnel and external service providers, and comparing this information to payments made, invoices received, and the agreed-upon contractual fee to be paid for such services in the applicable contract or statements of work.

In addition, the Company allocates certain internal compensation costs to research and development expenses based on management's estimates of each employee's time and effort expended.

How the Critical Matter was Addressed in the Audit:

The primary procedures we performed to address this critical audit matter included the following:

- We obtained an understanding, and evaluated the design and implementation, of controls relating to research and development costs, including controls over the review of third-party contracts, the process of gathering information from external and internal sources and management's review thereof, and the determination of prepaid positions, period-end accruals, and expense allocations.

- For the Company's significant third-party contracts, we performed the following procedures:

    - We obtained and read related master service agreements, statements of work, or other supporting agreements with the research institution, CRO, or CMO.
    - We performed corroborating inquiries with management personnel responsible for the oversight of the activities regarding the nature and status of work performed.
    - We evaluated evidence of services provided by third parties including invoices regarding activities completed, and we inspected evidence supporting payments made by the Company.
    - We compared the data and evidence obtained from internal and external sources to the amounts recorded by management and recalculated the related research and development expense and prepaid research and development expense.

- For the Company's internal compensation allocations, we performed the following procedures:

    - We performed corroborating inquiries with management personnel responsible for the oversight of the activities regarding the nature of employee services performed.

- We evaluated the reasonableness of allocations estimated by management by comparisons with prior periods and evaluating the reasonableness of significant changes made by management.
- We obtained written representations from management regarding the appropriateness of allocation estimates.

HASKELL & WHITE LLP

We have served as the Company's auditor since 2013

Irvine, California
January 16, 2024

ANIXA BIOSCIENCES, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
(in thousands, except share and per share data)

	October 31, 2023	October 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 915	$ 12,360
Short–term investments	22,929	17,327
Receivables	270	46
Prepaid expenses and other current assets	1,242	467
Total current assets	25,356	30,200
Operating lease right-of-use asset	166	212
Total assets	$ 25,522	$ 30,412
LIABILITIES AND EQUITY		
Current liabilities:		
Accounts payable	$ 206	$ 265
Accrued expenses	1,770	1,726
Operating lease liability	52	46
Total current liabilities	2,028	2,037
Operating lease liability, non-current	123	175
Total liabilities	2,151	2,212
Commitments and contingencies (Note 6)		
Equity:		
Shareholders' equity:		
Preferred stock, par value $100 per share; 19,860 shares authorized; no shares issued or outstanding	-	-
Series A convertible preferred stock, par value $100 per share; 140 shares authorized; no shares issued or outstanding	-	-
Common stock, par value $.01 per share; 100,000,000 shares authorized; 31,145,219 and 30,913,902 shares issued and outstanding as of October 31, 2023 and 2022, respectively	311	309
Additional paid-in capital	252,222	247,123
Accumulated deficit	(228,196)	(218,385)
Total shareholders' equity	24,337	29,047
Noncontrolling interest (Note 2)	(966)	(847)
Total equity	23,371	28,200
Total liabilities and equity	$ 25,522	$ 30,412

The accompanying notes are an integral part of these statements.

ANIXA BIOSCIENCES, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except per share data)

	For the years ended October 31,	
	2023	2022
Revenue	$ 210	$ -
Operating costs and expenses:		
Inventor royalties, contingent legal fees, litigation and licensing expenses	161	-
Research and development expenses (including non-cash share based compensation expenses of $2,037 and $3,635, respectively)	4,769	6,703
General and administrative expenses (including non-cash share based compensation expenses of $2,698 and $3,117, respectively)	6,291	7,172
Total operating costs and expenses	11,221	13,875
Loss from operations	(11,011)	(13,875)
Interest income	1,081	104
Net loss	(9,930)	(13,771)
Less: Net loss attributable to noncontrolling interest	(119)	(176)
Net loss attributable to common stockholders	$ (9,811)	$ (13,595)
Net loss per share:		
Basic and diluted	$ (0.32)	$ (0.45)
Weighted average common shares outstanding:		
Basic and diluted	30,980	30,374

The accompanying notes are an integral part of these statements.

ANIXA BIOSCIENCES, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF EQUITY
FOR THE YEARS ENDED OCTOBER 31, 2023 AND 2022
(in thousands, except share data)

	Common Stock		Additional Paid-in	Accumulated	Total Shareholders'	Non-controlling	Total
	Shares	Par Value	Capital	Deficit	Equity	Interest	Equity
BALANCE, October 31, 2021	30,050,894	$ 301	$ 239,927	$ (204,790)	$ 35,438	$ (671)	$ 34,767
Stock option compensation to employees and directors	-	-	6,000	-	6,000	-	6,000
Stock options and warrants issued to consultants	-	-	655	-	655	-	655
Common stock issued upon exercise of stock options and warrants	827,619	8	431	-	439	-	439
Common stock issued to consultants	30,648	-	97	-	97	-	97
Common stock issued pursuant to employee stock purchase plan	4,741	-	13	-	13	-	13
Net loss	-	-	-	(13,595)	(13,595)	(176)	(13,771)
BALANCE, October 31, 2022	30,913,902	$ 309	$ 247,123	$ (218,385)	$ 29,047	$ (847)	$ 28,200
Stock option compensation to employees and directors	-	-	4,422	-	4,422	-	4,422
Stock options issued to consultants	-	-	221	-	221	-	221
Common stock issued upon exercise of stock options	202,647	2	351	-	353	-	353
Common stock issued to consultants	24,310	-	92	-	92	-	92
Common stock issued pursuant to employee stock purchase plan	4,360	-	13	-	13	-	13
Net loss	-	-	-	(9,811)	(9,811)	(119)	(9,930)
BALANCE, October 31, 2023	31,145,219	$ 311	$ 252,222	$ (228,196)	$ 24,337	$ (966)	$ 23,371

The accompanying notes are an integral part of these statements.

ANIXA BIOSCIENCES, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	For the years ended October 31,	
	2023	2022
Cash flows from operating activities:		
Reconciliation of net loss to net cash used in operating activities:		
Net loss	$ (9,930)	$ (13,771)
Stock option compensation to employees and directors	4,422	6,000
Stock options and warrants issued to consultants	221	655
Common stock issued to consultants	92	97
Amortization of operating lease right-of-use asset	46	42
Change in operating assets and liabilities:		
Receivables	(224)	(29)
Prepaid expenses and other current assets	(775)	(208)
Accounts payable	(59)	129
Accrued expenses	44	631
Operating lease liability	(46)	(38)
Net cash used in operating activities	(6,209)	(6,492)
Cash flows from investing activities:		
Disbursements to acquire short-term investments	(44,411)	(22,486)
Proceeds from maturities of short-term investments	38,809	11,758
Net cash used in investing activities	(5,602)	(10,728)
Cash flows from financing activities:		
Proceeds from sale of common stock pursuant to employee stock purchase plan	13	13
Proceeds from exercise of stock options and warrants	353	439
Net cash provided by financing activities	366	452
Net decrease in cash and cash equivalents	(11,445)	(16,768)
Cash and cash equivalents at beginning of year	12,360	29,128
Cash and cash equivalents at end of year	$ 915	$ 12,360
Supplemental cash flow information:		
Cash proceeds from interest income	$ 838	$ 23

The accompanying notes are an integral part of these statements.

ANIXA BIOSCIENCES, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. BUSINESS AND FUNDING

Description of Business

As used herein, "we," "us," "our," the "Company" or "Anixa" means Anixa Biosciences, Inc. and its consolidated subsidiaries.

Anixa Biosciences, Inc. is a biotechnology company developing vaccines and therapies that are focused on critical unmet needs in oncology. Our vaccine programs include (i) the development of a preventative vaccine against triple negative breast cancer ("TNBC"), the most lethal form of breast cancer, as well other forms of breast cancer and (ii) the development of a preventative vaccine against ovarian cancer. Our therapeutics programs include (i) the development of a chimeric endocrine receptor T cell therapy, a novel form of chimeric antigen receptor T cell ("CAR-T") technology, initially focused on treating ovarian cancer, which is being developed at our subsidiary, Certainty Therapeutics, Inc. ("Certainty"), and (ii) until March 2023, the development of anti-viral drug candidates for the treatment of COVID-19 focused on inhibiting certain protein functions of the virus.

We hold an exclusive worldwide, royalty-bearing license to use certain intellectual property owned or controlled by The Cleveland Clinic Foundation ("Cleveland Clinic") relating to certain breast cancer vaccine technology developed at Cleveland Clinic. The license agreement requires us to make certain cash payments to Cleveland Clinic upon achievement of specific development milestones. Utilizing this technology, we are working in collaboration with Cleveland Clinic to develop a method to vaccinate women against contracting breast cancer, focused initially on TNBC. The focus of this vaccine is a specific protein, α-lactalbumin, that is only expressed during lactation in a healthy mother's mammary tissue. This protein disappears when the mother is no longer lactating, but reappears in many forms of breast cancer, especially TNBC. Studies have shown that vaccinating against this protein prevents breast cancer in mice.

In October 2021, following the U.S. Food and Drug Administration's ("FDA") authorization to proceed, we commenced dosing patients in a Phase 1 clinical trial of our breast cancer vaccine. This study, which is being funded by a U.S. Department of Defense grant to Cleveland Clinic, is a multiple-ascending dose Phase 1 trial to determine the maximum tolerated dose ("MTD") of the vaccine in patients with early-stage, triple-negative breast cancer as well as monitor immune response. The study is being conducted at Cleveland Clinic. The first segment of the study, Phase 1a, will consist of 18 to 24 patients who have completed treatment for early-stage, triple-negative breast cancer within the past three years and are currently tumor-free but at high risk for recurrence. Studies show that 42% of TNBC patients will have a recurrence of their cancer, with most of the recurrences occurring in the first two to three years after standard of care treatment. During the course of the Phase 1a study, participants will receive three vaccinations, each two weeks apart, and will be closely monitored for side effects and immune response. In January 2023, the number of participants in each dose cohort was expanded, and as of August 2023, we had completed vaccinating all patients in these expanded cohorts. In December 2023, we presented the immunological data collected to date at the San Antonio Breast Cancer Symposium. The data presented show that in the vaccinated women who had been tested to date, various levels of antigen-specific T cell responses were observed at all dose levels. We have begun vaccinating participants in up to three additional dose cohorts at dose levels higher than the currently determined MTD and lower than the highest dose where we observed dose limiting toxicity. Further, we have commenced vaccination of participants in the second segment of the trial, Phase 1b, that includes participants who have never had cancer, but carry certain genetic mutations such as BRCA1, BRCA2 or PALB2, that indicate a greater risk of developing TNBC in the future, and have elected to have a prophylactic mastectomy. Finally, we are currently enrolling participants in the third segment of the trial, Phase 1c, that includes post-operative TNBC patients that have residual disease following neoadjuvant chemo-immunotherapy and are currently undergoing treatment with pembrolizumab (Keytruda®).

In November 2020, we executed a license agreement with Cleveland Clinic pursuant to which the Company was granted an exclusive worldwide, royalty-bearing license to use certain intellectual property owned or controlled by Cleveland Clinic relating to certain ovarian cancer vaccine technology. The license agreement requires us to make certain cash payments to Cleveland Clinic upon achievement of specific development milestones. This technology pertains to among other things, the use of vaccines for the treatment or prevention of ovarian cancers which express the anti-Mullerian hormone receptor 2 protein containing an extracellular domain ("AMHR2-ED"). In healthy tissue, this protein regulates growth and development of egg-containing follicles in the ovary. While expression of AMHR2-ED naturally and markedly declines during menopause, this protein is expressed at high levels in the ovaries of postmenopausal women with ovarian cancer. Researchers at Cleveland Clinic believe that a vaccine targeting AMHR2-ED could prevent the occurrence of ovarian cancer.

In May 2021, Cleveland Clinic was granted acceptance for our ovarian cancer vaccine technology into the National Cancer Institute's ("NCI") PREVENT program. The NCI is a part of the National Institutes of Health ("NIH"). The PREVENT program is a peer-reviewed agent development program designed to support pre-clinical development of innovative interventions and biomarkers for cancer prevention and interception towards clinical trials. The scientific and financial resources of the PREVENT program are being used for our ovarian cancer vaccine technology to perform virtually all pre-clinical research and development, manufacturing and Investigational New Drug ("IND") application enabling studies. This work is being performed at NCI facilities, by NCI scientific staff and with NCI financial resources and will require no material financial expenditures by the Company, nor the transfer of any rights of the Company's assets.

Our subsidiary, Certainty, is developing immuno-therapy drugs against cancer. Certainty holds an exclusive worldwide, royalty-bearing license to use certain intellectual property owned or controlled by The Wistar Institute ("Wistar"), the nation's first independent biomedical research institute and a leading NCI designated cancer research center, relating to Wistar's chimeric endocrine receptor targeted therapy technology. We have initially focused on the development of a treatment for ovarian cancer, but we also may pursue applications of the technology for the development of treatments for additional solid tumors. The license agreement requires Certainty to make certain cash and equity payments to Wistar upon achievement of specific development milestones. With respect to Certainty's equity obligations to Wistar, Certainty issued to Wistar shares of its common stock equal to five percent (5%) of the common stock of Certainty, such equity stake subject to dilution by further funding of Certainty's activities by the Company. Due to such Company funding, Wistar's equity stake in Certainty was 4.6% as of October 31, 2023.

Certainty, in collaboration with the H. Lee Moffitt Cancer Center and Research Institute, Inc. ("Moffitt"), has begun human clinical testing of the CAR-T technology licensed by Certainty from Wistar aimed initially at treating ovarian cancer. After receiving authorization from the FDA, we commenced enrollment of patients in a Phase 1 clinical trial and treated the first patient in August 2022. Further, in May 2023 and August 2023, we treated the second and third patients in the trial, respectively, at the same dose level as the first patient, and the treatment appears to have been well-tolerated by all patients treated to date. We anticipate that we will begin enrolling the successive patient cohort, that we expect to give a three-times higher dose of cells, in the first calendar quarter of 2024. This study is a dose-escalation trial with two arms based on delivery method—intraperitoneal or intravenous—to determine the maximum tolerated dose in patients with recurrent epithelial ovarian cancer and to assess persistence, expansion and efficacy of the modified T cells. The study is being conducted at Moffitt and will consist of 24 to 48 patients who have received at least two prior lines of chemotherapy. The study is estimated to be completed in two to four years depending on multiple factors including when maximum tolerated dose is reached, the rate of patient enrollment, and how long we maintain the two different delivery methods.

In April 2020, we entered into a collaboration with OntoChem GmbH ("OntoChem") which was later assigned to MolGenie GmbH, a company spun-out from OntoChem focused on drug discovery and development, to discover and ultimately develop anti-viral drug candidates against COVID-19. Through this collaboration, we identified compounds that appeared to be effective in disrupting the main protease of SARS-CoV-2, the virus that causes the disease COVID-19. While our compounds have shown promise as an effective treatment, results of animal studies indicate that there is not sufficient oral bioavailability, and it is unclear whether an orally delivered treatment may be developed. We do not currently believe that there is a viable market for an injectable treatment given the current oral treatments available. Furthermore, we believe the needed additional investment in research for alternative delivery methods would divert resources from more promising projects. Therefore, in March 2023, we decided to pause further development of our COVID-19 therapeutic. We continue to prosecute our U.S. patent applications of this technology and may decide to restart development at some time in the future.

Over the next several quarters, we expect the development of our vaccines and therapeutics to be the primary focus of the Company. As part of our legacy operations, the Company remains engaged in limited patent licensing activities of its various patent portfolios. We do not expect these activities to be a significant part of the Company's ongoing operations nor do we expect these activities to require material financial resources or attention of senior management.

Over the past several years, our revenue was derived from technology licensing and the sale of patented technologies, including revenue from the settlement of litigation (during the year ended October 31, 2023, we derived approximately $210,000 of revenue from these activities). We have not generated any revenue to date from our vaccine or therapeutics programs. In addition, while we pursue our vaccine and therapeutics programs, we may also make investments in and form new companies to develop additional emerging technologies. We do not expect to begin generating revenue with respect to any of our current vaccine or therapy programs in the near term. We hope to achieve a profitable outcome by eventually licensing our technologies to large pharmaceutical companies that have the resources and infrastructure in place to manufacture, market and sell our technologies as vaccines or therapeutics. The eventual licensing of any of our technologies may take several years, if it is to occur at all, and may depend on positive results from human clinical trials.

Funding and Management's Plans

Based on currently available information as of January 16, 2024, we believe that our existing cash, cash equivalents, short-term investments and expected cash flows will be sufficient to fund our activities for at least the next twelve months. We have implemented a business model that conserves funds by collaborating with third parties to develop our technologies. However, our projections of future cash needs and cash flows may differ from actual results. If current cash on hand, cash equivalents, short-term investments and cash that may be generated from our business operations are insufficient to continue to operate our business, or if we elect to invest in or acquire a company or companies or new technology or technologies that are synergistic with or complementary to our technologies, we may be required to obtain more working capital. Under our at-the-market equity program which is currently effective and may remain available for us to use in the future, as of October 31, 2023, we may sell up to $100 million of common stock. We did not sell any shares under our at-the-market equity program during the fiscal year ended October 31, 2023. We may seek to obtain working capital during our fiscal year 2024 or thereafter through sales of our equity securities or through bank credit facilities or public or private debt from various financial institutions where possible. We cannot be certain that additional funding will be available on acceptable terms, or at all. If we do identify sources for additional funding, the sale of additional equity securities or convertible debt will result in dilution to our stockholders. We can give no assurance that we will generate sufficient cash flows in the future to satisfy our liquidity requirements or sustain future operations, or that other sources of funding, such as sales of equity or debt, would be available or would be approved by our security holders, if needed, on favorable terms or at all. If we fail to obtain additional working capital as and when needed, such failure could have a material adverse impact on our business, results of operations and financial condition. Furthermore, such lack of funds may inhibit our ability to respond to competitive pressures or unanticipated capital needs, or may force us to reduce operating expenses, which would significantly harm the business and development of operations.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The consolidated financial statements include the accounts of Anixa Biosciences, Inc. and its wholly and majority owned subsidiaries. All intercompany transactions have been eliminated.

Noncontrolling Interest

Noncontrolling interest represents Wistar's equity ownership in Certainty and is presented as a component of equity. The following table sets forth the changes in noncontrolling interest for the two years ended October 31, 2023 (in thousands):

Balance October 31, 2021	$	(671)
Net loss attributable to noncontrolling interest		(176)
Balance October 31, 2022		(847)
Net loss attributable to noncontrolling interest		(119)
Balance October 31, 2023	$	(966)

Revenue Recognition

Our revenue has been derived solely from technology licensing and the sale of patented technologies. Revenue is recognized upon transfer of control of intellectual property rights and satisfaction of other contractual performance obligations to licensees in an amount that reflects the consideration we expect to receive.

Our revenue recognition policy requires us to make certain judgments and estimates in connection with the accounting for revenue. Such areas may include determining the existence of a contract and identifying each party's rights and obligations to transfer goods and services, identifying the performance obligations in the contract, determining the transaction price and allocating the transaction price to separate performance obligations, estimating the timing of satisfaction of performance obligations, determining whether a promise to grant a license is distinct from other promised goods or services and evaluating whether a license transfers to a customer at a point in time or over time.

Our revenue arrangements provide for the payment, within 30 days of execution of the agreement, of contractually determined, one-time, paid-up license fees in settlement of litigation and in consideration for the grant of certain intellectual property rights for patented technologies owned or controlled by the Company. These arrangements typically include some combination of the following: (i) the grant of a non-exclusive, retroactive and future license to manufacture and/or sell products covered by patented technologies owned or controlled by the Company, (ii) a covenant-not-to-sue, (iii) the release of the licensee from certain claims, and (iv) the dismissal of any pending litigation. In such instances, the intellectual property rights granted have been perpetual in nature, extending until the expiration of the related patents. Pursuant to the terms of these agreements, we have no further obligations with respect to the granted intellectual property rights, including no obligation to maintain or upgrade the technology, or provide future support or services. Licensees obtained control of the intellectual property rights they have acquired upon execution of the agreement. Accordingly, the performance obligations from these agreements were satisfied and 100% of the revenue was recognized upon the execution of the agreements.

Cost of Revenues

Cost of revenues include the costs and expenses incurred in connection with our patent licensing and enforcement activities, including inventor royalties paid to original patent owners, contingent legal fees paid to external counsel, other patent-related legal expenses paid to external counsel, licensing and enforcement related research and consulting and other expenses paid to third-parties. These costs are included under the caption "Operating costs and expenses" in the accompanying consolidated statements of operations.

Research and Development Expenses

Research and development expenses consist primarily of payments to third parties for research and development activities, including expenses related to clinical trials, employee compensation, and other direct costs associated with developing our therapeutics and vaccines.

We recognize research and development expenses as incurred. Advance payments for future research and development activities are deferred and expensed as the services are performed. We recognize our preclinical studies and clinical trial expenses based on the services performed pursuant to contracts with research institutions, clinical research organizations ("CROs"), clinical manufacturing organizations ("CMOs"), and other parties that conduct and manage various stages of research and development activities on our behalf. Fees for such services are recognized based on management's estimates after considering the activities and tasks completed by each service provider in a given period, the time period over which services are expected to be performed, and the level of effort expended in each reporting period.

At each balance sheet date, management estimates prepaid and accrued research and development costs by discussing progress or stage of completion of activities with internal personnel and external service providers, and comparing this information to payments made, invoices received, and the agreed-upon contractual fee to be paid for such services in the applicable contract or statements of work.

In addition, we allocate certain internal compensation costs to research and development expenses based on management's estimates of each employee's time and effort expended.

Fair Value Measurements

Accounting Standards Codification ("ASC") 820, Fair Value Measurements and Disclosures ("ASC 820"), defines fair value, establishes a framework for measuring fair value under U.S. generally accepted accounting principles (GAAP), and expands disclosures about fair value measurements. In accordance with ASC 820, we have categorized our financial assets and liabilities, based on the priority of the inputs to the valuation technique, into a three-level fair value hierarchy as set forth below. If the inputs used to measure the financial instruments fall within different levels of the hierarchy, the categorization is based on the lowest level input that is significant to the fair value measurement of the instrument.

Financial assets and liabilities recorded in the accompanying consolidated balance sheets are categorized based on the inputs to the valuation techniques as follows:

Level 1 – Financial instruments whose values are based on unadjusted quoted prices for identical assets or liabilities in an active market which we have the ability to access at the measurement date.

Level 2 – Financial instruments whose values are based on quoted market prices in markets where trading occurs infrequently or whose values are based on quoted prices of instruments with similar attributes in active markets.

Level 3 – Financial instruments whose values are based on prices or valuation techniques that require inputs that are both unobservable and significant to the overall fair value measurement. These inputs reflect management's own assumptions about the assumptions a market participant would use in pricing the instrument.

The following table presents the hierarchy for our financial assets measured at fair value on a recurring basis as of October 31, 2023 (in thousands):

	Level 1	Level 2	Level 3	Total
Money market funds:				
Cash equivalents	$ 778	$ -	$ -	$ 778
Certificates of deposit:				
Short term investments	-	720	-	720
U. S. treasury bills:				
Short term investments	-	22,209	-	22,209
Total financial assets	$ 778	$ 22,929	$ -	$ 23,707

The following table presents the hierarchy for our financial assets measured at fair value on a recurring basis as of October 31, 2022 (in thousands):

	Level 1	Level 2	Level 3	Total
Money market funds:				
Cash equivalents	$ 11,175	$ -	$ -	$ 11,175
Certificates of deposit:				
Cash equivalents		1,000		1,000
Short term investments	-	13,700	-	13,700
U. S. treasury bills:				
Short term investments	-	3,627	-	3,627
Total financial assets	$ 11,175	$ 18,327	$ -	$ 29,502

Our non-financial assets that are measured on a non-recurring basis are property and equipment and other assets which are measured using fair value techniques whenever events or changes in circumstances indicate a condition of impairment exists. The estimated fair value of prepaid expenses and other current assets, accounts payable and accrued expenses approximates their individual carrying amounts due to the short-term nature of these measurements. Cash equivalents are stated at carrying value which approximates fair value.

Cash Equivalents

Cash equivalents consist of highly liquid, short-term investments with original maturities of three months or less when purchased.

Short-term Investments

At October 31, 2023 and 2022, we had certificates of deposit and United States treasury bills with maturities greater than 90 days and less than 12 months when acquired of approximately $22,929,000 and $17,327,000, respectively, that were classified as short-term investments and reported at fair value.

Income Taxes

We recognize deferred tax assets and liabilities for the estimated future tax effects of events that have been recognized in our financial statements or tax returns. Under this method, deferred tax assets and liabilities are determined based on the difference between the financial statement and tax bases of assets and liabilities using enacted tax rates in effect in the years in which the differences are expected to reverse. A valuation allowance is established, when necessary, to reduce deferred tax assets to the amount expected to be realized.

Share-Based Compensation

We maintain equity incentive plans under which we may grant incentive stock options, non-qualified stock options, stock appreciation rights, stock awards, performance awards, or stock units to employees, directors and consultants.

Stock Option Compensation Expense

We account for stock options granted to employees, directors and consultants using the accounting guidance in ASC 718, Stock Compensation ("ASC 718"). We estimate the fair value of service-based stock options on the date of grant, using the Black-Scholes pricing model, and recognize compensation expense over the requisite service period of the grant.

We recorded stock-based compensation expense, related to service-based stock options granted to employees and directors, of approximately $4,422,000 and $3,463,000, during the years ended October 31, 2023 and 2022, respectively. Included in stock-based compensation cost for service-based options granted to employees and directors during the years ended October 31, 2023 and 2022 was approximately $3,023,000 and $2,788,000, respectively, related to the amortization of compensation cost for stock options granted in prior periods but not yet vested. As of October 31, 2023, there was unrecognized compensation cost related to non-vested service-based stock options granted to employees and directors of approximately $5,194,000, which will be recognized over a weighted-average period of 1.7 years.

For stock options that vest based on market conditions, such as the trading price of the Company's common stock exceeding certain price targets, we use a Monte Carlo Simulation in estimating the fair value at grant date and recognize compensation expense over the implied service period (median time to vest). On June 1, 2021, our Chairman, then-President and Chief Executive Officer and our Chief Operating Officer and Chief Financial Officer were awarded market condition stock options for 2,000,000 shares and 100,000 shares of common stock, respectively, that vest in four equal installments upon the Company's share price achieving targets ranging from $5.00 to $8.00 per share, with implied service periods of three to fifteen months. The assumptions used in the Monte Carlo Simulation for the June 1, 2021 grants were stock price on date of grant and exercise price of $4.02, contract term of 10 years, expected volatility of 75% and risk-free interest rate of 1.62%. As of October 31, 2023, 500,000 options and 25,000 options granted to our Chairman, then-President and Chief Executive Officer and our Chief Operating Officer and Chief Financial Officer, respectively, have vested.

During the year ended October 31, 2023, we recorded no stock-based compensation expense related to market condition stock options granted to employees. We recorded stock-based compensation expense related to market condition stock options granted to employees of approximately $2,537,000 during the year ended October 31, 2022, which amount represented expense related to the amortization of compensation cost for stock options granted during the year ended October 31, 2021. As of October 31, 2023, there was no unrecognized compensation cost related to market condition stock options granted to employees.

We recorded consulting expense, related to service-based stock options granted to consultants, during the years ended October 31, 2023 and 2022 of approximately $221,000 and $434,000, respectively. Included in stock-based consulting expense for the years ended October 31, 2023 and 2022 was approximately $209,000 and $434,000, respectively, related to compensation cost for stock options granted in prior periods but not yet vested. As of October 31, 2023, there was unrecognized consulting expense related to non-vested service-based stock options granted to consultants of approximately $281,000, which will be recognized over a weighted-average period of 2.5 years.

Fair Value Determination

We use the Black-Scholes pricing model in estimating the fair value of stock options granted to employees, directors and consultants which vest over a specific period of time. The stock options we granted during each of the years ended October 31, 2023 and 2022 consisted of awards with 5-year and 10-year terms that vest over 12 to 36 months.

The following weighted average assumptions were used in estimating the fair value of stock options granted during the years ended October 31, 2023 and 2022:

	For the Year Ended October 31,	
	2023	2022
Weighted average fair value at grant date	$ 3.29	$ 2.18
Valuation assumptions:		
Expected life (years)	5.47	5.76
Expected volatility	100.27%	102.72%
Risk-free interest rate	3.87%	1.99%
Expected dividend yield	0%	0%

The expected term of stock options represents the weighted average period the stock options are expected to remain outstanding. For employees and directors, we use the simplified method, which is a weighted average of the vesting term and contractual term, to determine expected term. The simplified method was adopted since we do not believe that historical experience is representative of future performance because of the impact of the changes in our operations and the change in terms from historical operations. For consultants, we use the contract term for expected term. Under the Black-Scholes pricing model, we estimated the expected volatility of our shares of common stock based upon the historical volatility of our share price over a period of time equal to the expected term of the options. We estimated the risk-free interest rate based on the implied yield available on the applicable grant date of a U.S. Treasury note with a term equal to the expected term of the underlying grants. We made the dividend yield assumption based on our history of not paying cash dividends and our expectation not to pay dividends in the future.

Under ASC 718, the amount of stock-based compensation expense recognized is based on the portion of the awards that are ultimately expected to vest. Accordingly, if deemed necessary, we reduce the fair value of the stock option awards for expected forfeitures, which are forfeitures of the unvested portion of surrendered options. Based on our historical experience and future expectations, we have not reduced the amount of stock-based compensation expenses for anticipated forfeitures.

We will reconsider use of the Black-Scholes pricing model if additional information becomes available in the future that indicates another model would be more appropriate. If factors change and we employ different assumptions in the application of ASC 718 in future periods, the compensation expense that we record under ASC 718 may differ significantly from what we have recorded in the current period.

Warrants

For warrants granted to consultants for services rendered, we estimate the fair value using the Black-Scholes pricing model on the date of grant. During the years ended October 31, 2023 and 2022 we recorded consulting expense, based on the fair value, of $0 and approximately $221,000, respectively, for warrants granted to consultants.

Net Loss Per Share of Common Stock

In accordance with ASC 260, Earnings Per Share, basic net loss per common share ("Basic EPS") is computed by dividing net loss by the weighted average number of common shares outstanding. Diluted net loss per common share ("Diluted EPS") is computed by dividing net loss by the weighted average number of common shares and dilutive common share equivalents and convertible securities then outstanding. Diluted EPS for all years presented is the same as Basic EPS, as the inclusion of the effect of common share equivalents then outstanding would be anti-dilutive. For this reason, excluded from the calculation of Diluted EPS for the years ended October 31, 2023 and 2022 were options to purchase 11,430,000 shares and 10,318,872 shares, respectively, and warrants to purchase 300,000 shares and 300,000 shares, respectively.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Estimates and assumptions are used for, but not limited to, determining stock-based compensation, asset impairment evaluations, tax assets and liabilities, license fee revenue, the allowance for doubtful accounts, depreciation lives and other contingencies. Actual results could differ from those estimates.

Effect of Recently Issued Pronouncements

In August 2020, the FASB issued Accounting Standards Update 2020-06 ("ASU 2020-06"), Accounting for Convertible Instruments and Contracts in an Entity's Own Equity. The amendments in ASU 2020-06 include guidance on convertible instruments and the derivative scope exception for contracts in an entity's own equity and simplifies the accounting for convertible instruments which include beneficial conversion features or cash conversion features by removing certain separation models in Subtopic 470-20. Additionally, ASU 2020-06 will require entities to use the "if-converted" method when calculating diluted earnings per share for convertible instruments. The amendments in this update are effective for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. The adoption of this standard did not have a material impact on our consolidated financial statements and related disclosures.

In May 2021, the FASB issued Accounting Standards Update 2021-04 ("ASU 2021-04"), Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options. The guidance in ASU 2021-04 requires the issuer to treat a modification of an equity-classified written call option (the "option") that does not cause the option to become liability-classified as an exchange of the original option for a new option. This guidance applies whether the modification is structured as an amendment to the terms and conditions of the option or as termination of the original option and issuance of a new option. The amendments in this update are effective for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. The adoption of this standard did not have a material impact on our consolidated financial statements and related disclosures.

In October 2021, the FASB issued Accounting Standards Update 2021-08 ("ASU 2021-08"), Business Combinations (Topic 805): Accounting for Contract Assets and Contract Liabilities from Contracts with Customers, to require that an acquirer recognize and measure contract assets and contract liabilities acquired in a business combination in accordance with Topic 606, Revenue from Contracts with Customers. At the acquisition date, an acquirer should account for the related revenue contracts in accordance with Topic 606 as if it had originated the contracts. The amendments in this update should be applied prospectively and are effective for fiscal years beginning after December 15, 2022, including interim periods within those fiscal years. We do not expect the adoption of this standard to have a material impact on our consolidated financial statements and related disclosures.

Concentration of Credit Risks

Financial instruments that potentially subject us to concentrations of credit risk are cash equivalents, short-term investments and accounts receivable. Cash equivalents are primarily highly rated money market funds. Short-term investments are certificates of deposit within federally insured limits as well as U.S. treasury bills. Where applicable, management reviews our accounts receivable and other receivables for potential doubtful accounts and maintains an allowance for estimated uncollectible amounts. Our policy is to write-off uncollectable amounts at the time it is determined that collection will not occur. One licensee accounted for 100% of revenues from patent licensing activities during fiscal year 2023.

3. ACCRUED EXPENSES

Accrued liabilities consist of the following as of:

	October 31,	
	2023	2022
Payroll and related expenses	$ 1,114	$ 1,144
Accrued royalty and contingent legal fees	626	577
Accrued other	30	5
	$ 1,770	$ 1,726

4. SHAREHOLDERS' EQUITY

Stock Option Plans

During the year ended October 31, 2023, we had two stock option plans: the Anixa Biosciences, Inc. 2010 Share Incentive Plan (the "2010 Share Plan") and the Anixa Biosciences, Inc. 2018 Share Incentive Plan (the "2018 Share Plan") which were adopted by our Board of Directors on July 14, 2010 and January 25, 2018, respectively. The 2018 Share Plan was approved by our shareholders on March 29, 2018. In accordance with the provisions of the 2010 Share Plan, the plan terminated with respect to the grant of future securities on July 14, 2020.

During the years ended October 31, 2023 and 2022, stock options to purchase 157,761 and 387,739 shares of common stock, respectively, were exercised on a cash basis, with aggregate proceeds of approximately $353,000 and $439,000, respectively. During the years ended October 31, 2023 and 2022, stock options to purchase 161,111 shares of common stock, of which 116,225 shares were withheld, and 1,488,881 shares of common stock, of which 1,083,517 shares were withheld, were exercised on a cashless basis, respectively.

2010 Share Plan

The 2010 Share Plan provided for the grant of nonqualified stock options, stock appreciation rights, stock awards, performance awards and stock units to employees, directors and consultants. On the first business day of each calendar year the aggregate number of shares available for future issuance was replenished such that 800,000 shares were available. The exercise price with respect to all of the options granted under the 2010 Share Plan was equal to the fair market value of the underlying common stock at the grant date. Information regarding the 2010 Share Plan for the two years ended October 31, 2023 is as follows:

	Shares	Weighted Average Exercise Price Per Share	Aggregate Intrinsic Value
Options Outstanding at October 31, 2021	1,718,634	$ 2.82	
Exercised	(212,000)	$ 2.68	
Expired	(5,134)	$ 3.63	
Options Outstanding at October 31, 2022	1,501,500	$ 2.83	
Exercised	(312,500)	$ 2.41	
Options Outstanding and Exercisable at October 31, 2023	1,189,000	$ 2.94	$ 770,800

The following table summarizes information about stock options outstanding under the 2010 Share Plan as of October 31, 2023:

Range of Exercise Prices	Number Outstanding and Exercisable	Weighted Average Remaining Contractual Life (in years)	Weighted Average Exercise Price
$0.67 - $2.27	366,000	3.59	$ 1.27
$2.58 - $3.13	314,000	2.21	$ 2.91
$3.46 - $5.30	509,000	4.54	$ 4.17

2018 Share Plan

The 2018 Share Plan provides for the grant of incentive stock options, nonqualified stock options, stock appreciation rights, stock awards, performance awards and stock units to employees, directors and consultants. On the first business day of each calendar year the maximum aggregate number of shares available for future issuance is replenished such that 2,000,000 shares are available. The exercise price with respect to all of the options granted under the 2018 Share Plan was equal to the fair market value of the underlying common stock at the grant date. As of October 31, 2023, the 2018 Share Plan had 750,000 shares available for future grants. Information regarding the 2018 Share Plan for the two years ended October 31, 2023 is as follows:

	Shares	Weighted Average Exercise Price Per Share	Aggregate Intrinsic Value
Options Outstanding at October 31, 2021	7,409,992	$ 3.76	
Granted	1,430,000	$ 2.74	
Exercised	(22,620)	$ 3.15	
Options Outstanding at October 31, 2022	8,817,372	$ 3.60	
Granted	1,640,000	$ 3.97	
Exercised	(6,372)	$ 2.89	
Forfeited/Expired	(210,000)	$ 5.10	
Options Outstanding at October 31, 2023	10,241,000	$ 3.67	$ 1,112,030
Options Exercisable at October 31, 2023	6,721,970	$ 3.50	$ 884,783

The following table summarizes information about stock options outstanding under the 2018 Share Plan as of October 31, 2023:

	Options Outstanding			Options Exercisable		
Range of Exercise Prices	Number Outstanding	Weighted Average Remaining Contractual Life (in years)	Weighted Average Exercise Price	Number Exercisable	Weighted Average Remaining Contractual Life (in years)	Weighted Average Exercise Price
$ 2.09 - $3.87	5,476,000	6.50	$ 3.24	4,828,361	6.22	$ 3.29
$ 3.96 - $5.30	4,765,000	7.70	$ 4.16	1,893,609	7.20	$ 4.02

Non-Plan Options

In addition to options granted under stock option plans, during the years ended October 31, 2012 and 2013, the Board of Directors approved the grant of stock options to certain employees and directors (the “Non-Plan Options”).

Information regarding the Non-Plan Options for the two years ended October 31, 2023 is as follows:

	Shares	Weighted Average Exercise Price Per Share
Options Outstanding October 31, 2021	1,642,000	$ 2.58
Exercised	(1,642,000)	$ 2.58
Options Outstanding and Exercisable at October 31, 2022	-	

Employee Stock Purchase Plan

The Company maintains the Anixa Biosciences, Inc. Employee Stock Purchase Plan which permits eligible employees to purchase shares at not less than 85% of the market value of the Company's common stock on the offering date or the purchase date of the applicable offering period, whichever is lower. The plan was adopted by our Board of Directors on August 13, 2018 and approved by our shareholders on September 27, 2018. During the years ended October 31, 2023 and 2022, employees purchased 4,360 and 4,741 shares, respectively, with aggregate proceeds of approximately $13,000 and $13,000, respectively.

Common Stock Purchase Warrants

On November 1, 2021 we issued a warrant, expiring on October 30, 2026, to purchase 60,000 shares of common stock at $4.77 per share, vesting over five months, to a consultant for investor relations services. We recorded consulting expense of approximately $221,000 during the year ended October 31, 2022, based on the fair value of the warrant recognized on a straight-line basis over the vesting period. The warrant terminated in May 2022 upon termination of the consulting agreement.

In connection with a public offering in March 2021, we issued to certain designees of the underwriter, as compensation, warrants to purchase 300,000 shares of common stock at $6.5625 per share, expiring on March 22, 2026.

Information regarding the Company's warrants for the two years ended October 31, 2023 is as follows:

	Shares	Weighted Average Exercise Price Per Share	Aggregate Intrinsic Value
Warrants Outstanding at October 31, 2021	860,000	$ 5.36	
Issued	60,000	$ 4.77	
Exercised	(60,000)	$ 2.06	
Expired	(560,000)	$ 4.71	
Warrants Outstanding and Exercisable at October 31, 2022 and October 31, 2023	300,000	$ 6.56	$ 0

The following table summarizes information about the Company's outstanding and exercisable warrants as of October 31, 2023:

Exercise Price	Number Outstanding and Exercisable	Weighted Average Remaining Contractual Life (in years)	Weighted Average Exercise Price
$ 6.56	300,000	2.39	$ 6.56

5. LEASES

We lease approximately 2,000 square feet of office space at 3150 Almaden Expressway, San Jose, California (our principal executive offices) from an unrelated party pursuant to an operating lease that, as amended, will expire on September 30, 2024, with an option to extend the lease an additional two years. Our base rent is approximately $5,000 per month and the lease provides for annual increases of approximately 3% and an escalation clause for increases in certain operating costs. The lease, as amended, resulted in a right-of-use asset and lease liability of approximately $260,000 with a discount rate of 10%. Rent expense was approximately $66,000 for each of the years ended October 31, 2023 and 2022.

For operating leases, the lease liability is initially and subsequently measured at the present value of the unpaid lease payments. The remaining 35-month lease term as of October 31, 2023 for the Company's lease includes the noncancelable period of the lease and the additional two-year option period that the Company believes it is reasonably certain to exercise. All right-of-use assets are reviewed for impairment when indications of impairment are present.

As of October 31, 2023, the annual minimum lease payments of our operating lease liability were as follows (in thousands):

For Years Ending October 31,	Operating Leases
2024	$ 67
2025	70
2026	65
Total future minimum lease payments, undiscounted	202
Less: Imputed interest	27
Present value of future minimum lease payments	$ 175

6. COMMITMENTS AND CONTINGENCIES

Litigation Matters

Other than lawsuits we bring to enforce our patent rights, we are not involved in any litigation or other legal proceedings and management is not aware of any pending litigation or legal proceeding against us that would have a material adverse effect upon our results of operations or financial condition.

License Commitments

As of October 31, 2023, our commitments under the license agreements with Wistar and Cleveland Clinic for the year ending October 31, 2024 were approximately $70,000.

Research & Development Agreements

We have entered into certain research and development agreements with various third-party vendors related to the manufacturing of materials necessary for the expected Phase 2 clinical trial of our breast cancer vaccine. As of October 31, 2023, future payments the Company may make under these agreements may be approximately $3.5 million and such payments may be made over up to a five-year period.

7. INCOME TAXES

Income tax provision (benefit) consists of the following:

	Year Ended October 31,	
	2023	2022
Federal:		
Current	$ -	$ -
Deferred	(1,739,000)	(1,021,000)
State:		
Current	-	-
Deferred	(583,000)	(350,000)
Adjustment to valuation allowance related to net deferred tax assets	1,322,000	1,371,000
	$ -	$ -

The tax effects of temporary differences that give rise to significant portions of the deferred tax asset, net, at October 31, 2023 and 2022, are as follows:

	October 31,	
	2023	2022
Long-term deferred tax assets:		
Federal and state NOL and tax credit carryforwards	$ 26,532,000	$ 22,196,000
Deferred compensation	7,752,000	6,851,000
Intangibles	218,000	274,000
Other	-	281,000
Subtotal	34,502,000	29,602,000
Less: valuation allowance	(34,502,000)	(29,602,000)
Deferred tax asset, net	$ -	$ -

As of October 31, 2023, we had Federal tax net operating loss and tax credit carryforwards of approximately $95,752,000 and $1,870,000, respectively. At the federal level, businesses can carry forward their net operating losses indefinitely, but the deductions are limited to 80 percent of taxable income. Prior to the Tax Cuts and Jobs Act (TCJA) of 2017, businesses could carry losses forward for 20 years (without a deductibility limit). If the tax benefits relating to deductions of option holders' income are ultimately realized, those benefits will be credited directly to additional paid-in capital. Certain changes in stock ownership can result in a limitation on the amount of net operating loss and tax credit carryovers that can be utilized each year. As of October 31, 2023, management has not determined the extent of any such limitations, if any.

We had California tax net operating loss carryforwards of approximately $51,065,000 as of October 31, 2023, available within statutory limits (expiring at various dates between 2024 and 2043), to offset future corporate taxable income and taxes payable, if any, under certain computations of such taxes.

We have provided a 100% valuation allowance against our deferred tax asset due to our current and historical pre-tax losses and the uncertainty regarding their realizability. The primary differences from the Federal statutory rate of 21% and the effective rate of 0% is attributable to expiring net operating losses and a change in the valuation allowance. The following is a reconciliation of income taxes at the Federal statutory tax rate to income tax expense (benefit):

	Year Ended October 31,			
	2023		2022	
Income tax benefit at U.S. Federal statutory income tax rate	(2,085,000)	(21.00)%	$ (2,892,000)	(21.00)%
State income taxes	(693,000)	(6.98)%	(962,000)	(6.98)%
Permanent differences	20,000	0.20%	14,000	0.10%
Expiring net operating losses, credits and other	1,436,000	14.46%	2,469,000	17.93%
Change in valuation allowance	1,322,000	13.32%	1,371,000	9.95%
Income tax provision	$ -	0.00%	$ -	0.00%

During the two fiscal years ended October 31, 2023, we incurred no Federal and no State income taxes. We have no unrecognized tax benefits as of October 31, 2023 and 2022 and we account for interest and penalties related to income tax matters in general and administrative expenses. Tax years to which our net operating losses relate remain open to examination by Federal and California authorities to the extent which the net operating losses have yet to be utilized.

8. SEGMENT INFORMATION

We follow the accounting guidance of ASC 280, Segment Reporting ("ASC 280"). Reportable operating segments are determined based on the management approach. The management approach, as defined by ASC 280, is based on the way that the chief operating decision-maker organizes the segments within an enterprise for making operating decisions and assessing performance. While our results of operations are primarily reviewed on a consolidated basis, the chief operating decision-maker manages the enterprise in four reportable segments, each with different operating and potential revenue generating characteristics: (i) CAR-T Therapeutics, (ii) Cancer Vaccines, (iii) Anti-Viral Therapeutics and (iv) Other. The following represents selected financial information for our segments for the years ended October 31, 2023 and 2022:

	Year Ended October 31,	
	2023	2022
Net income (loss):		
CAR-T Therapeutics	$ (3,879)	$ (5,776)
Cancer Vaccines	(5,111)	(4,889)
Anti-Viral Therapeutics	(945)	(3,075)
Other	5	(31)
Total	$ (9,930)	$ (13,771)
Total operating costs and expenses	$ 11,221	$ 13,875
Less non-cash share-based compensation	(4,735)	(6,655)
Operating costs and expenses excluding non-cash share-based compensation	$ 6,486	$ 7,220
Operating costs and expenses excluding non-cash share based compensation:		
CAR-T Therapeutics	$ 2,467	$ 3,206
Cancer Vaccines	3,265	2,355
Anti-Viral Therapeutics	553	1,634
Other	201	25
Total	$ 6,486	$ 7,220

	October 31,	
	2023	2022
Total assets:		
CAR-T Therapeutics	$ 7,523	$ 16,921
Cancer Vaccines	17,215	9,442
Anti-Viral Therapeutics	700	3,811
Other	84	238
Total	$ 25,522	$ 30,412

Operating costs and expenses excluding non-cash share-based compensation is the measurement the chief operating decision-maker uses in managing the enterprise.

The Company's consolidated revenue of $210,000 and inventor royalties, contingent legal fees, litigation and licensing expense of $161,000, for the year ended October 31, 2023 were solely related to our other segment. All our revenue is generated domestically (United States) based on the country in which the licensee is located.

AMENDMENT TO EXCLUSIVE LICENSE AGREEMENT

This Amendment ("Amendment") is made as of September 18, 2023 ("Amendment Effective Date") by and between **The Cleveland Clinic Foundation** ("Licensor"), an Ohio non-profit nonprofit corporation located at 9500 Euclid Avenue, Cleveland, Ohio 44195, and **Anixa Biosciences, Inc.** a Delaware corporation ("**Licensee**") located at 3150 Almaden Expy, Suite 250, San Jose, CA 95118.

WHEREAS, the parties entered into an Exclusive License Agreement ("Agreement") effective as of **July 8, 2019**;

WHEREAS, the parties desire to amend the Agreement in certain respects, including to add the following terms and conditions to the Agreement; and

NOW THEREFORE, in consideration of the mutual covenants stated herein and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto intending to be legally bound to such amendments, covenant and agree as follows:

1. Changes to Agreement.
   a. Article 8.4 is added to Article 8 of the Agreement:
      i. For avoidance of doubt, Anixa may disclose Confidential Information with third party vendors, subcontractors, and/or manufacturers under confidentiality terms substantially similar to those contained herein and as necessary to exercise its rights and perform its obligations under this Agreement

2. Miscellaneous.
   a. Except as modified in this Amendment, all other terms, conditions, and covenants of the Agreement shall remain in effect as written. This Amendment, together with the Agreement, constitutes the entire agreement between the parties with respect to the subject matter hereof, and supersedes all previous representations, agreements, understandings, and negotiations with respect thereto. In the event of a conflict between the foregoing, this Amendment shall control.
   b. Capitalized terms used in this Amendment but not defined herein shall have the meanings ascribed to them in the Agreement.
   c. This Amendment (i) may be executed in counterparts, each of which shall be deemed to be an original and all of which, taken together, shall constitute a single agreement binding on all parties, and (ii) will be considered executed by a party when the signature of such party is delivered physically or by email or facsimile transmission to the other party or parties, as appropriate. The parties agree that any signature delivered by email or facsimile transmission shall have the same force and effect as an original signature.

IN WITNESS WHEREOF, the parties hereby execute this Amendment through their authorized representations.

Anixa Biosciences Inc.

By: Michael J Catelani
Signature

Michael J. Catelani
Name

President, COO & CFO
Title

10/13/2023
Date

THE CLEVELAND CLINIC FOUNDATION

By: Timothy L Longville
Signature

Timothy L. Longville
Name

CAO / Controller
Title

10/13/2023
Date

APPROVED AS TO FORM
CCF – Law Department
DATE 9/13/2023 CMS# 4308204
By: Gordon Dowd

Exhibit 19

Anixa Biosciences, Inc.
POLICY ON INSIDER TRADING

Anixa Biosciences, Inc., a Delaware corporation (the "**Company**"), is committed to the highest standards of ethical business conduct. This Insider Trading Policy provides the standards of the Company on trading and causing the trading of the Company's securities or securities of other publicly-traded companies while in possession of confidential information of the Company. This policy is divided into two parts: the first part prohibits trading in certain circumstances and applies to all directors, officers and employees of the Company and its wholly-owned subsidiaries, and the second part imposes special additional trading restrictions and applies to all (i) directors of the Company, (ii) executive officers of the Company and its wholly-owned subsidiaries and (iii) all employees that are designated as Vice Presidents or whose main function is accounting or financial reporting (collectively, "**Covered Persons**" or "Insiders"). To the extent applicable, any reference hereinafter to the Company applies with equal force and effect to the Company's wholly-owned subsidiaries.

One of the principal purposes of the federal securities laws is to prohibit so-called "insider trading." Simply stated, insider trading occurs when a person uses material non-public information obtained through involvement with the Company to make decisions to purchase, sell, give away or otherwise trade the Company's securities or the securities of any other publicly-traded companies or to provide that information to others outside the Company. The prohibitions against insider trading apply to trades, tips and recommendations by virtually any person, including all persons associated with the Company, if the information involved is "material" and "non-public." These terms are defined in this Policy under Part I, Section 3 below. The prohibitions would apply to any director, officer or employee who buys or sells securities of the Company or the securities of any other publicly-traded companies in a related business (collectively, "Company securities") on the basis of material non-public information that he or she obtained about the Company, its customers, suppliers, or other companies with which the Company has contractual relationships or may be negotiating transactions.

Revised March 2023

PART I

1. Applicability

This Policy applies to all transactions in the Company's securities, including common stock, stock options and any other securities that the Company may issue, such as preferred stock, notes, bonds and convertible securities, as well as to derivative securities relating to any of the Company's securities, whether or not issued by the Company.

This Policy applies to all directors, officers and employees of the Company and its wholly-owned subsidiaries, as applicable.

Post-Termination Transactions. This Policy continues to apply to transactions in Company securities even after an employee, officer or director has resigned or terminated employment. If the person who resigns or separates from the Company is in possession of material non-public information at that time, he or she may not trade in Company securities until that information has become public or is no longer material.

2. General Policy: No Trading or Causing Trading While in Possession of Material Non-public Information

(a) No director, officer or employee may purchase or sell any Company security, whether or not issued by the Company, while in possession of material non-public information about the Company. (The terms "material" and "non-public" are defined in Part I, Section 3(a) and (b) below.)

(b) No director, officer or employee who knows of any material non-public information about the Company may communicate that information to any other person, including family and friends, except when such communication is part of their regular duties and is needed to further the business of the Company.

(c) In addition, no director, officer or employee may purchase or sell any security of any other company, whether or not issued by the Company, while in possession of material non-public information about that company that was obtained in the course of his or her involvement with the Company. No director, officer or employee who knows of any such material non-public information may communicate that information to any other person, including family and friends, except when such communication is part of their regular duties and is needed to further the business of the Company.

(d) For compliance purposes, you should never trade, tip or recommend securities (or otherwise cause the purchase or sale of securities) while in possession of information that you have reason to believe is material and non-public unless you first consult with, and obtain the advance approval of the Compliance Officer (defined in Part I, Section 3(c) below).

(e) Covered Persons must "pre-clear" all trading in securities of the Company in accordance with the procedures set forth in Part II, Section 3 below.

APPLICABILITY OF POLICY TO INSIDER INFORMATION REGARDING OTHER COMPANIES

This Policy and the guidelines described herein also apply to material non-public information relating to other companies, including the Company's customers, vendors or suppliers ("**business partners**"), when that information is obtained in the course of employment with, or other services performed on behalf of the Company. Civil and criminal penalties, as well as termination of employment, may result from trading on material non-public information regarding the Company's business partners. All Insiders should treat material non-public information about the Company's business partners with the same care as is required with respect to information relating directly to the Company.

3. Definitions

(a) Materiality. Insider trading restrictions come into play only if the information you possess is "material." Materiality, however, involves a relatively low threshold. The U.S. Supreme Court and other federal courts have ruled that information should be regarded as "material" if there is ***a substantial likelihood*** that a ***reasonable investor***:

(1) would consider the information important in making an investment decision; and

(2) would view the information as having significantly altered the "total mix" of available information about the Company.

Information dealing with the following subjects is reasonably likely to be found material in particular situations:

(i) significant changes in the Company's prospects;

(ii) significant write-downs in assets or increases in reserves;

(iii) developments regarding significant litigation or government agency investigations;

(iv) liquidity problems;

(v) changes in earnings estimates or unusual gains or losses in major operations;

(vi) major changes in management;

(vii) changes in dividends;

(viii) extraordinary borrowings;

(ix) award or loss of a significant contract;

(x) changes in debt ratings;

(xi) proposals, plans or agreements, even if preliminary in nature, involving mergers, acquisitions, divestitures, recapitalizations, strategic alliances, licensing arrangements, or purchases or sales of substantial assets;

(xii) public offerings;

(xiii) pending statistical reports;

(xiv) results of studies; and

(xv) potential licenses and joint ventures.

Material information is not limited to historical facts but may also include projections and forecasts. With respect to a future event, such as a merger, acquisition, licenses or introduction of a new business line, the point at which negotiations or business line development are determined to be material is determined by balancing the probability that the event will occur against the magnitude of the effect the event would have on the Company's operations or the market price of the Company's securities should it occur. Thus, information concerning an event that would have a large effect on the price of the Company's common stock, such as a merger, may be material even if the possibility that the event will occur is relatively small. When in doubt about whether particular non-public information is material, presume it is material. **If you are unsure whether information is material, you should consult with the Compliance Officer before making any decision to disclose such or to trade in or recommend securities to which that information relates.**

(b) Non-public Information. Insider trading prohibitions come into play only when you possess information that is material and "non-public." The fact that information has been disclosed to a few members of the public does not make it public for insider trading purposes. To be "public" the information must have been disseminated in a manner designed to reach investors generally, and sufficient time must have elapsed to permit the investors to absorb and evaluate the information. Even after public disclosure of information about the Company, you must wait until the close of business on the second trading day after the information was publicly disclosed before you can treat the information as public.

Non-public information may include:

(i) information available to a select group of analysts or brokers or institutional investors;

(ii) undisclosed facts that are the subject of rumors, even if the rumors are widely circulated; and

(iii) information that has been entrusted to the Company on a confidential basis until a public announcement of the information has been made and enough time has elapsed for the market to respond to a public announcement of the information (normally two or three days).

As with questions of materiality, if you are not sure whether information is considered public, you should either consult with the Compliance Officer or assume that the information is "non-public" and treat it as confidential.

(c) Compliance Officer. The Company has appointed its Chief Financial Officer as the Compliance Officer for this Policy. The duties of the Compliance Officer include, but are not limited to, the following:

(i) assisting with implementation of this Policy;

(ii) circulating this Policy to all employees and ensuring that this Policy is amended as necessary to remain up-to-date with insider trading laws;

(iii) pre-clearing all trading in securities of the Company by Covered Persons in accordance with the procedures set forth in Part II, Section 3 below; and

(iv) providing approval of any transactions under Part II, Section 4 below.

4. Violations of Insider Trading Laws

Penalties for trading on or communicating material non-public information can be severe, both for individuals involved in such unlawful conduct and their employers and supervisors, and may include jail terms, criminal fines, civil penalties and civil enforcement injunctions. Given the severity of the potential penalties, compliance with this Policy is absolutely mandatory.

(a) Legal Penalties. A person who violates insider trading laws by engaging in transactions in a company's securities when he or she has material non-public information can be sentenced to a substantial jail term and required to pay a penalty of several times the amount of profits gained or losses avoided.

In addition, a person who tips others may also be liable for transactions by the tippees to whom he or she has disclosed material non-public information. Tippers can be subject to the same penalties and sanctions as the tippees, and the SEC has imposed large penalties even when the tipper did not profit from the transaction.

Insiders may be subject to penalties of up to $5,000,000 for individuals (and $25,000,000 for a business entity) and up to twenty (20) years in prison for engaging in transactions in the Company's securities at a time when they possess material non-public information regarding the Company. In addition, the SEC has the authority to seek a civil monetary penalty of up to three times the amount of profit gained or loss avoided by illegal insider trading. "Profit gained" or "loss avoided" generally means the difference between the purchase or sale price of the Company's stock and its value as measured by the trading price of the stock a reasonable period after public dissemination of the material non-public information.

(b) Company-imposed Penalties. Employees who violate this Policy may be subject to disciplinary action by the Company, including dismissal for cause. Any exceptions to the Policy, if permitted, may only be granted by the Compliance Officer and must be provided before any activity contrary to the above requirements takes place.

PART II

1. Blackout Periods

All Covered Persons are prohibited from trading in the Company's securities during blackout periods.

(a) Quarterly Blackout Periods. Trading in the Company's securities is prohibited during the period beginning at the close of the market on the last day of each fiscal quarter and ending at the close of business on the second business day following the earlier of the Company's (i) issuance of a full earnings release for such quarter (containing substantially the material information that would be included in the subsequent report) or (ii) filing of the Form 10-Q or Form 10-K (the "**Standard Blackout Period**"). During these periods, Covered Persons generally possess or are presumed to possess material non-public information about the Company's financial results.

(b) Other Blackout Periods. From time to time, other types of material non-public information regarding the Company (such as negotiation of mergers, acquisitions, licenses or dispositions or new business line developments or study results) may be pending and not be publicly disclosed. While such material non-public information is pending, the Company may impose special blackout periods during which Covered Persons are prohibited from trading in the Company's securities. If the Company imposes a special blackout period, it will notify the Covered Persons affected.

(c) Exception. **Trading According to a Pre-established Plan (10b5-1) or by Delegation.** The SEC has adopted Rule 10b5-1 (which was amended in December 2022) under which insider trading liability can be avoided if Insiders follow very specific procedures. In general, such procedures involve trading according to pre-established instructions, plans or programs (a "**10b5-1 Plan**") after a required "cooling off" period described below. **10b5-1 Plans must:**

(i) **Be documented by a contract, written plan, or formal instruction which provides that the trade take place in the future.** For example, an Insider can contract to sell his or her shares on a specific date, or simply delegate such decisions to an investment manager, 401(k) plan administrator or similar third party. This documentation must be provided to the Company's Insider Trading Compliance Officer;

(ii) **Include in its documentation the specific amount, price and timing of the trade, or the formula for determining the amount, price and timing.** For example, the Insider can buy or sell shares in a specific amount and on a specific date each month, or according to a pre-established percentage (of the Insider's salary, for example) each time that the share price falls or rises to pre-established levels. In the case where trading decisions have been delegated (i.e., to a third party broker or money manager), the specific amount, price and timing need not be provided;

(iii) **Be implemented at a time when the Insider does not possess material non-public information.** As a practical matter, this means that the Insider may set up 10b5-1 Plans, or delegate trading discretion, only outside a Blackout Period (discussed in Part II, Section 1, above), assuming the Insider is not in possession of material non-public information;

(iv) **Remain beyond the scope of the Insider's influence after implementation.** In general, the Insider must allow the 10b5-1 Plan to be executed without changes to the accompanying instructions, and the Insider cannot later execute a hedge transaction that modifies the effect of the 10b5-1 Plan. Insiders should be aware that the termination or modification of a 10b5-1 Plan after trades have been undertaken under such plan could negate the 10b5-1 affirmative defense afforded by such program for all such prior trades. As such, termination or modification of a 10b-5 Plan should only be undertaken in consultation with your legal counsel. If the Insider has delegated decision-making authority to a third party, the Insider cannot subsequently influence the third party in any way and such third party must not possess material non-public information at the time of any of the trades;

(v) **Be subject to a "cooling off" period**. Effective February 27, 2023, Rule 10b5-1 contains a "cooling-off period" for directors and officers that prohibit such insiders from trading in a 10b5-1 Plan until the later of (i) 90 days following the plan's adoption or modification or (ii) two business days following the Company's disclosure (via a report filed with the SEC) of its financial results for the fiscal quarter in which the plan was adopted or modified; and

(vi) **Contain Insider certifications**. Effective February 27, 2023, directors and officers are required to include a certification in their 10b5-1 Plans to certify that at the time the plan is adopted or modified: (i) they are not aware of material non-public information about the Company or its securities and (ii) they are adopting the 10b5-1 Plan in good faith and not as part of a plan or scheme to evade the anti-fraud provisions of the Exchange Act.

Important: In addition, effective February 27, 2023: (i) Insiders are prohibited from having multiple overlapping 10b5-1 Plans or more than one plan in any given year, (ii) a modification relating to amount, price and timing of trades under a 10b5-1 Plan is deemed a plan termination and the adoption of a new 10b5-1 Plan which requires a new cooling off period, and (iii) whether a particular trade is undertaken pursuant to a 10b5-1 Plan will need to be disclosed (by checkoff box) on the applicable Forms 4 or 5 of the Insider.

Pre-Approval Required: Prior to implementing a 10b5-1 Plan, all officers and directors must receive the approval for such plan from (and provide the details of the plan to) the Company's Insider Trading Compliance Officer in accordance with the procedures set forth in Part II, Section 3.

2. Trading Window

Covered Persons are permitted to trade in the Company's securities when no blackout period is in effect. Generally, this means that Covered Persons can trade at any time outside of the Standard Blackout Period. However, even during this trading window, a Covered Person who is in possession of any material non-public information should not trade in the Company's securities until the information has been made publicly available or is no longer material. In addition, the Company may close this trading window if a special blackout period under Part II, Section 1(b) above is imposed and will re-open the trading window once the special blackout period has ended.

3. Pre-clearance of Securities Transactions

(a) Because Covered Persons are likely to obtain material non-public information on a regular basis, the Company requires all such persons to refrain from trading, even during a trading window under Part II, Section 2 above, without first pre-clearing all transactions in the Company's securities.

(b) Subject to the exemption in subsection (d) below, no Covered Person may, directly or indirectly, purchase or sell (or otherwise make any transfer, gift, pledge or loan of) any Company security at any time without first obtaining prior approval from the Compliance Officer. These procedures also apply to transactions by such person's spouse, other persons living in such person's household and minor children and to transactions by entities over which such person exercises control.

(c) The Compliance Officer shall record the date each request is received and the date and time each request is approved or disapproved. Unless revoked, a grant of permission will normally remain valid until the close of trading two business days following the day on which it was granted. If the transaction does not occur during the two-day period, pre-clearance of the transaction must be re-requested.

(d) Pre-clearance of trades after an Approved 10b5-1 Plan is properly entered into and followed is not required for purchases and sales of securities under an Approved 10b5-1 Plan. With respect to any purchase or sale under an Approved 10b5-1 Plan, the third party effecting transactions on behalf of the Covered Person should be instructed to send duplicate confirmations of all such transactions to the Compliance Officer.

4. Prohibited Transactions

(a) Directors and executive officers are prohibited from trading in the Company's equity securities during a blackout period imposed under an "individual account" retirement or pension plan of the Company, during which at least 50% of the plan participants are unable to purchase, sell or otherwise acquire or transfer an interest in equity securities of the Company, due to a temporary suspension of trading by the Company or the plan fiduciary.

(b) A Covered Person, including such person's spouse, other persons living in such person's household and minor children and entities over which such person exercises control, is prohibited from engaging in the following transactions in the Company's securities unless advance approval is obtained from the Compliance Officer:

(i) Short-term trading. Covered Persons who purchase Company securities may not sell any Company securities of the same class for at least six months after the purchase and a Covered Person who sells Company securities may not purchase any Company securities of the same class for at least six months after the sale (in each case, other than purchases of securities from the Company pursuant to the exercise of options that are exempt from Section 16(b) of the Securities Exchange Act of 1934 by reason of Rule 16b-3);

(ii) Short sales. Covered Persons may not sell the Company's securities short;

(iii) Options trading. Covered Persons may not buy or sell puts or calls or other derivative securities on the Company's securities; and

(iv) Hedging. Covered Persons may not enter into hedging or monetization transactions or similar arrangements with respect to Company securities.

5. Acknowledgment and Certification

All Covered Persons are required to sign the attached acknowledgment and certification.

ACKNOWLEDGMENT AND CERTIFICATION

The undersigned does hereby acknowledge receipt of the Company's Insider Trading Policy. The undersigned has read and understands (or has had explained) such Policy and agrees to be governed by such Policy at all times in connection with the purchase and sale of securities and the confidentiality of non-public information.

_____
(Signature)

_____
(Please print name)

Date: _____

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Post-Effective Amendment No. 2 to the Registration Statement on Form S-1 on Form S-3 (No. 333-193869), Registration Statements on Form S-3 (Nos. 333-267369, 333-217060 and 333-232067) and the Registration Statement on Form S-8 (No. 333-269118) of Anixa Biosciences, Inc. (the "Company") of our report dated January 16, 2024, relating to our audits of the Company's consolidated financial statements as of October 31, 2023 and 2022, and for each of the years in the two year period ended October 31, 2023, included in the Company's Annual Report on Form 10-K for the fiscal year ended October 31, 2023.

HASKELL & WHITE LLP

Irvine, California
January 16, 2024

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO SECURITIES EXCHANGE ACT RULES 13A-14(A) AND 15D-14(A)
AS ADOPTED PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Dr. Amit Kumar, Chairman of the Board and Chief Executive Officer of Anixa Biosciences, Inc., certify that:

1. I have reviewed this Annual Report on Form 10-K of Anixa Biosciences, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: January 16, 2024

/s/ Amit Kumar
Dr. Amit Kumar
Chairman of the Board and
Chief Executive Officer

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO SECURITIES EXCHANGE ACT RULES 13A-14(A) AND 15D-14(A)
AS ADOPTED PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Michael J. Catelani, President, Chief Operating Officer and Chief Financial Officer of Anixa Biosciences, Inc., certify that:

1. I have reviewed this Annual Report on Form 10-K of Anixa Biosciences, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: January 16, 2024

/s/ Michael J. Catelani
Michael J. Catelani
President, Chief Operating Officer and
Chief Financial Officer

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to Section 1350 of Title 18 of the United States Code, the undersigned, Dr. Amit Kumar, Chairman of the Board and Chief Executive Officer of Anixa Biosciences, Inc. (the "Company"), hereby certifies that:

1. The Company's Form 10-K Annual Report for the fiscal year ended October 31, 2023 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: January 16, 2024

/s/ Amit Kumar
Dr. Amit Kumar
Chairman of the Board and
Chief Executive Officer

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to Section 1350 of Title 18 of the United States Code, the undersigned, Michael J. Catelani, President, Chief Operating Officer and Chief Financial Officer of Anixa Biosciences, Inc. (the "Company"), hereby certifies that:

1. The Company's Form 10-K Annual Report for the fiscal year ended October 31, 2023 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: January 16, 2024

/s/ Michael J. Catelani

Michael J. Catelani
President, Chief Operating Officer and
Chief Financial Officer

Exhibit 99.1

ANIXA BIOSCIENCES, INC.

EXECUTIVE COMPENSATION CLAWBACK POLICY

Adopted as of November 17, 2023

The Board of Directors (the "**Board**") of Anixa Biosciences, Inc. (the "**Company**") has adopted the following executive compensation clawback policy (this "**Policy**"). This Policy shall supplement any other clawback or compensation recovery policy or policies adopted by the Company or included in any agreement between the Company, or any subsidiary of the Company, and a person covered by this Policy. If any such other policy or agreement provides that a greater amount of compensation shall be subject to clawback, such other policy or agreement shall apply to the amount in excess of the amount subject to clawback under this Policy.

This Policy shall be interpreted to comply with Securities and Exchange Commission ("**SEC**") Rule 10D-1 and Listing Rule 5608 (the "**Listing Rule**") of The Nasdaq Stock Market, LLC ("**Nasdaq**"), as may be amended or supplemented and interpreted from time to time by Nasdaq. To the extent this Policy is in any manner deemed inconsistent with the Listing Rule, this Policy shall be treated as having been amended to be compliant with the Listing Rule.

1. Definitions. Unless the context indicates otherwise the following definitions apply for purposes of this Policy:

(a) **Executive Officer**. An executive officer is the Company's chief executive officer and/or president, principal financial officer, principal accounting officer (or if there is no such accounting officer, the controller), any vice-president of the Company in charge of a principal business unit, division, or function (such as sales, administration, or finance), any other officer who performs a policy-making function, or any other person who performs similar policy-making functions for the Company. Executive officers of the Company's parent(s) or subsidiaries are deemed executive officers of the Company if they perform such policy making functions for the Company. Policy-making function is not intended to include policy-making functions that are not significant. Identification of an executive officer for purposes of the Listing Rule would include at a minimum executive officers identified in the Listing Rule.

(b) **Financial Reporting Measures**. Financial reporting measures are measures that are determined and presented in accordance with the accounting principles used in preparing the Company's financial statements, and any measures that are derived wholly or in part from such measures. Stock price and total shareholder return are also financial reporting measures. A financial reporting measure need not be presented within the financial statements or included in a filing with the SEC and may be such financial measures as may be determined by the Board or the Compensation Committee thereof (the "**Compensation Committee**").

(c) **Incentive-Based Compensation**. Incentive-based compensation is any compensation that is granted, earned or vested based wholly or in part upon the attainment of a financial reporting measure.

(d) **Received**. Incentive-based compensation is deemed "received" in the Company's fiscal period during which the financial reporting measure specified in the incentive-based compensation award is attained, even if the payment or grant of the incentive-based compensation occurs after the end of that period.

2. Application of this Policy. This recovery of Incentive-Based Compensation from an Executive Officer as provided for in this Policy shall apply only in the event that the Company is required to prepare an accounting restatement due to the material noncompliance of Company with any financial reporting requirement under the United States securities laws, including any required accounting restatement to correct an error in previously issued financial statements that is material to the previously issued financial statements, or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period. Questions as to "materiality" will be made by the Compensation Committee in coordination with the Audit Committee

3. Recovery Period.

(a) The Incentive-Based Compensation subject to recovery is the Incentive-Based Compensation Received during the three (3) completed fiscal years immediately preceding the date that the Company is required to prepare an accounting restatement as described in Section 2 above, provided that the person served as an Executive Officer at any time during the performance period applicable to the Incentive-Based Compensation in question. The date that the Company is required to prepare an accounting restatement shall be determined pursuant to the Listing Rule.

(b) Notwithstanding the foregoing, this Policy shall only apply if the Incentive-Based Compensation is Received (i) while the Company has a class of securities listed on Nasdaq and (ii) on or after October 2, 2023.

(c) The provisions of the Listing Rule shall apply with respect to Incentive-Based Compensation received during a transition period arising due to a change in the Company's fiscal year.

4. Erroneously Awarded Compensation. The amount of Incentive-Based Compensation subject to recovery from the applicable Executive Officers under this Policy ("**Erroneously Awarded Compensation**") shall be equal to the amount of Incentive-Based Compensation Received that exceeds the amount of Incentive Based-Compensation that otherwise would have been Received had it been determined based on the restated amounts and shall be computed without regard to any taxes paid. For Incentive-Based Compensation based on stock price or total shareholder return, where the amount of Erroneously Awarded Compensation is not subject to mathematical recalculation directly from the information in an accounting restatement: (a) the amount shall be based on a reasonable estimate by the Company's Chief Financial Officer (or principal accounting officer, if the office of Chief Financial Officer is not then filled) of the effect of the accounting restatement on the stock price or total shareholder return upon which the Incentive-Based Compensation was received, which estimate shall be subject to the review and approval of the Compensation Committee; and (b) the Company must maintain reasonable documentation of the determination of that reasonable estimate and provide such documentation to Nasdaq if requested. Notwithstanding the foregoing, if the proposed Incentive-Based Compensation recovery would affect compensation paid to the Company's Chief Financial Officer, the determination shall be made by the Compensation Committee.

5. Timing of Recovery. The Company shall recover any Erroneously Awarded Compensation reasonably promptly except to the extent that the conditions of paragraphs (a), (b), or (c) below apply. The Compensation Committee shall determine the repayment schedule for each amount of Erroneously Awarded Compensation in a manner that complies with this "reasonably promptly" requirement. Such determination shall be consistent with any applicable legal guidance by the SEC, Nasdaq, judicial opinion, or otherwise. The determination of "reasonably promptly" may vary from case to case and the Compensation Committee is authorized to adopt additional rules or policies to further describe what repayment schedules satisfy this requirement.

(a) Erroneously Awarded Compensation need not be recovered if the direct expense paid to a third party to assist in enforcing (or making determinations in connection with the enforcement of) this Policy would exceed the amount to be recovered and the Compensation Committee has made a determination that recovery would be impracticable. Before concluding that it would be impracticable to recover any amount of Erroneously Awarded Compensation based on expense of enforcement, the Company shall (i) make a reasonable attempt to recover such Erroneously Awarded Compensation, (ii) document such reasonable attempt or attempts to recover, and (iii) provide appropriate documentation to the Compensation Committee or Nasdaq, if requested.

(b) Erroneously Awarded Compensation need not be recovered if recovery would violate home country law where that law was adopted prior to November 28, 2022. Before concluding that it would be impracticable to recover any amount of Erroneously Awarded Compensation based on a violation of home country law, the Company shall obtain an opinion of home country counsel, in form and substance that would be reasonably acceptable to Nasdaq, that recovery would result in such a violation and shall provide such opinion to Nasdaq, if requested.

(c) Erroneously Awarded Compensation need not be recovered if recovery would likely cause an otherwise tax-qualified retirement plan, under which benefits are broadly available to employees of the Company, to fail to meet the requirements of 26 U.S.C. 401(a)(13) or 26 U.S.C. 411(a) and the regulations thereunder (as such provision may be amended, modified or supplemented).

6. Compensation Committee Decisions. Decisions of the Compensation Committee with respect to this Policy shall be final, conclusive and binding on all Executive Officers subject to this Policy.

7. No Indemnification. Notwithstanding anything to the contrary in any other policy of the Company or any agreement between the Company and an Executive Officer, no Executive Officer shall be indemnified by the Company against the loss arising from the recovery of any Erroneously Awarded Compensation.

8. Agreement to Policy by Executive Officers. The Company shall take reasonable steps to inform Executive Officers of this Policy and obtain their express agreement to this Policy, which steps may constitute the inclusion of this Policy as an attachment to any award that is accepted by an Executive Officer. This Policy shall be deemed to apply to each employment or grant agreement between the Company or any of its subsidiaries and any Executive Officer subject to this Policy.

# # #