# 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, 2021

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, $.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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. □

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 □
Non-accelerated filer ☒
Emerging growth company □
Accelerated filer □
Smaller reporting 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 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 30, 2021 (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 ($4.88): $139,830,036

On January 4, 2022, the registrant had outstanding 30,132,319 shares of common stock, par value $.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 therapies and vaccines that are focused on critical unmet needs in oncology and infectious disease. 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) the discovery and ultimately development of anti-viral drug candidates for the treatment of COVID-19 focused on inhibiting certain protein functions of the virus. 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) a preventative vaccine against ovarian cancer.

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 National Cancer Institute 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.

Certainty, in collaboration with the H. Lee Moffitt Cancer Center and Research Institute, Inc. ("Moffitt"), is advancing toward human clinical testing the CAR-T technology licensed by Certainty from Wistar aimed initially at treating ovarian cancer. We submitted an Investigational New Drug ("IND") application to the U.S. Food and Drug Administration ("FDA") in March 2021 and in August 2021, we received authorization from the FDA to commence enrollment and treatment of patients in a Phase 1 clinical trial. We are performing the activities necessary to prepare for treatment of patients in the Phase 1 clinical trial, and we anticipate treating the first enrolled patient in the first calendar quarter of 2022. This study is a dose-escalation trial with two arms based on injection 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 and the rate of patient recruitment.

In April 2020, we entered into a collaboration with OntoChem GmbH ("OntoChem") to discover and ultimately develop anti-viral drug candidates against COVID-19. Through this collaboration, we utilized advanced computational methods, machine learning, and molecular modeling techniques to perform *in silico* screening of over 1.2 billion compounds in chemical libraries (including publicly available compounds and OntoChem's proprietary libraries) to evaluate if any of these compounds could disrupt one of two key enzymes of SARS-CoV-2, the virus that causes the disease COVID-19.

The screening process resulted in the identification of multiple compounds that could potentially disrupt critical enzymes of the virus. Several of these compounds were synthesized and tested in *in vitro* biological assays. Upon completion of these biological assays, we identified two of the most promising compounds and tested them in animal models. In these animal studies, the two compounds were compared to Remdesivir, which at the time the assays were performed was the only anti-viral drug authorized by the FDA for COVID-19. The data showed that administration of the drugs to infected hamsters did not cause any noticeable adverse effects, and monitoring of weight and general animal behavior demonstrated comparable efficacy between each of our compounds and Remdesivir. Based on this promising data in the animal study, we directed our team to proceed to the next stage of drug development and we selected one of the compounds around which our team are performing combinatorial synthetic medicinal chemistry to evaluate whether potency can be increased and pharmacokinetics optimized.

In May 2021, after completion of the aforementioned animal studies, OntoChem assigned its rights and obligations related to this collaboration to MolGenie GmbH ("MolGenie"), a company spun-out from OntoChem focused on drug discovery and development. As a result of the MolGenie spin-out, there was no change in the personnel working on our project, and the assignment caused no interruptions to the program's development.

While use of preventative vaccines is widespread throughout much of the developed world, we believe that there is and will continue to be a need for effective treatments for COVID-19. There are a number of factors that have limited the effectiveness, both in the near and long term, of the vaccines currently in use, including, but not limited to, vaccine persistence, viral escape and perceptions of long-term safety resulting in vaccine resistance. Furthermore, there are currently two new anti-viral treatments, Pfizer's Paxlovid, which is a combination therapy consisting of the protease-inhibitor nirmatrelvir and the antiretroviral ritonavir and Merck's polymerase-inhibitor molnupiravir, that have recently been authorized for emergency use in the U.S. These treatments use oral formulations, while all other currently authorized or approved treatments require administration in a hospital setting. As the main component of Pfizer's treatment is a protease-inhibitor, it is most similar to our compounds, and we therefore anticipate similar or better efficacy with our compounds. Whereas Pfizer's nirmatrelvir was based on research done on rhinoviruses and not designed specifically for SARS-CoV-2, our compounds were designed specifically against the main protease of SARS-CoV-2 and at the current time we do not anticipate the need for a combination therapy.

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 a certain breast cancer vaccine technology developed at Cleveland Clinic. Utilizing this technology, we are working in collaboration with Cleveland Clinic to develop a method to vaccinate women against contracting breast cancer, focused specifically 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.

Following submission of an IND application with the FDA in November 2020, and the FDA's subsequent authorization to proceed with clinical trials in December 2020, in October 2021, we commenced dosing patients in a Phase 1 clinical trial of our breast cancer vaccine. Funded by a U.S. Department of Defense grant, this study is a multiple-ascending dose Phase 1 trial to determine the maximum tolerated dose 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 and 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. During the course of the study, participants will receive three vaccinations, each two weeks apart, and will be closely monitored for side effects and immune response. The study is estimated to be completed in the third calendar quarter of 2022.

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. 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 after 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. We entered into a joint development agreement with Cleveland Clinic to advance this vaccine toward human clinical testing.

In May 2021, Cleveland Clinic was granted an award for our ovarian cancer vaccine technology by the National Cancer Institute's ("NCI") PREVENT program. The NCI is a part of the National Institutes of Health. The PREVENT program is a peer-reviewed agent development program designed to support preclinical development of innovative interventions and biomarkers for cancer prevention and interception towards clinical trials. The scientific and financial resources of the PREVENT program will be used for our ovarian cancer vaccine technology to perform virtually all pre-clinical research and development, manufacturing and IND-enabling studies. This work will be 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 to the Company's assets.

In July 2020, we implemented a strategic realignment of our business and redirected resources to exclusively focus on the development of therapeutics and vaccines. Accordingly, we suspended operations of our subsidiary, Anixa Diagnostics Corporation, and the development of the Cchek™ artificial intelligence driven platform of non-invasive blood tests for the early detection of cancer.

Over the next several quarters, we expect the development of our breast and ovarian cancer vaccines, our COVID-19 therapeutic discovery program and Certainty's CAR-T technology to be the primary focus of the Company. As part of our legacy operations, the Company remains engaged in limited patent licensing activities regarding the Cchek™ liquid biopsy platform, as well as 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.

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. 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.

***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 commence clinical trials of this technology against ovarian cancer.

We have been working with researchers at Moffitt to complete the steps necessary to commence human clinical testing of our CAR-T therapy for patients suffering from ovarian cancer. 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 the IND application. 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.

We anticipate beginning the human clinical trials in the first calendar quarter of 2022. This study is a dose-escalation trial with two arms based on injection 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 and the rate of patient recruitment.

**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 5% of cancer deaths in women due to the disease's low survival rate. It is estimated that in 2021, approximately 21,000 new cases of ovarian cancer will be diagnosed and 14,000 American women will 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 49%. 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.

***COVID-19 therapeutics***

Coronavirus disease 2019 ("COVID-19") is an infectious disease caused by the severe acute respiratory syndrome coronavirus 2 ("SARS-CoV-2"). The disease was first identified in December 2019 in Wuhan, the capital of China's Hubei province, and has since spread globally, resulting in the ongoing coronavirus pandemic. SARS-CoV-2 is highly infectious, and while in the majority of cases results in mild symptoms, in many cases the symptoms progress to viral pneumonia and multi-organ failure.

There are currently few broadly available effective treatments. Further, most treatments that are currently being employed require administration in a hospital setting, thus continuing to overburden the healthcare system, and the orally-available treatments developed by Pfizer and Merck have only recently received authorization by the FDA. In addition, nearly all treatments currently in use or in clinical trials were originally developed for other indications, and were not designed specifically against SARS-CoV-2, and therefore may have limited effectiveness. We believe that newly designed drugs that are purposefully developed to specifically target SARS-CoV-2, enabled by recent studies of the molecular biology of the virus, will have the potential to be far more effective than repurposing existing drugs.

In April 2020, we entered into a collaboration agreement with OntoChem, who subsequently assigned its rights and obligations under the collaboration agreement to MolGenie, for the purpose of discovering and ultimately developing anti-viral drug candidates for COVID-19. Our collaboration has primarily focused on the virus' main protease ("$M^{pro}$"), which is an enzyme of the virus that severs a large poly-peptide into functional proteins that enable the virus to replicate in a human host. Our program has focused on identifying molecules that inhibit the function of this enzyme, and potentially stop or slow the virus' ability to replicate and cause disease. Since this protease does not have human analogs, potential inhibitors may not affect any human proteins and therefore toxic side effects may be minimized.

Through our collaboration, we utilized advanced computational methods, machine learning and molecular modeling techniques to perform *in silico* screening of over 1.2 billion compounds in OntoChem's chemistry and gene ontology database (including publicly available compounds and OntoChem's proprietary libraries) to evaluate if any of these compounds could disrupt $M^{pro}$ and to evaluate the molecules' potential side effects, as well as their drug-like characteristics. This screening process resulted in identifying a large number of compounds that could potentially be safe and effective against COVID-19.

The screening process resulted in the identification of multiple compounds that could potentially disrupt critical enzymes of the virus. Several of these compounds were synthesized and tested in *in vitro* biological assays. Upon completion of these biological assays, we identified two of the most promising compounds and tested them in animal models. In these animal studies, the two compounds were compared to Remdesivir, which at the time the assays were performed was the only anti-viral drug authorized by the FDA for COVID-19. The data showed that administration of the drugs to infected hamsters did not cause any noticeable adverse effects, and monitoring of weight and general animal behavior demonstrated comparable efficacy between each of our compounds and Remdesivir. Based on this promising data in the animal study, we directed our team at OntoChem to proceed to the next stage of drug development and we selected one of the compounds around which OntoChem and other third-party service providers are performing combinatorial synthetic medicinal chemistry to evaluate whether potency can be increased and pharmacokinetics optimized.

As SARS-CoV-2 has continued to mutate over the course of the pandemic, we have performed genomic variant analysis to determine whether our compounds may be effective against new variants as they have arisen. To date, the results of such analyses have shown that either no significant mutations have been found in or near the active site of the $M^{pro}$ enzyme or any known mutations do not change the function of the enzyme, and therefore we believe that our compounds should be effective against the Delta variant, as well as the newly identified Omicron variant, which has become the most common form of the virus circulating in the U.S., though there is no assurance that this will be the case.

**The Market**

According to U.S. Centers for Disease Control and Prevention ("CDC") data, as of the date of this Report, in the U.S., there have been nearly 54 million cases of COVID-19 and over 820,000 deaths. According to World Health Organization ("WHO") data, globally, there have been over 280 million cases and over 5.4 million people have died.

Currently, there are few broadly available effective treatments for COVID-19. Further, the most common treatments that are currently being employed, such as Remdesivir and various steroid and antibody treatments, are all in-patient therapeutics and require hospitalization, adding to the burden on the healthcare system. We believe that a better approach, which we are employing, would be a therapeutic that can be formulated as a pill and taken as soon as there is a positive test for COVID-19. While two orally-available anti-viral treatments developed by Pfizer and Merck have recently been authorized for emergency use by the FDA, both have limitations as Pfizer's treatment requires a combination therapy with an antiretroviral drug commonly used to treat HIV and the Merck treatment has shown limited efficacy.

The market for orally delivered COVID-19 treatments that would dramatically reduce hospitalization rates would be significant, especially if such treatments were effective against multiple variants of the virus.

**Competition**

Competition in the COVID-19 treatment and prevention market is fierce, with hundreds of therapies and vaccines currently in development. There are currently a number of preventative vaccines that have received regulatory approvals globally. While these vaccines have been effective in reducing the spread of COVID-19, there remain challenges regarding persistence and viral escape as well as the resistance to vaccination by a significant portion of the population and also the difficulty in vaccinating and boosting the world population. Further, there are currently two new orally-available anti-viral treatments, the combination protease-inhibitor-antiretroviral Paxlovid developed by Pfizer and the polymerase-inhibitor molnupiravir developed by Merck, that have recently been authorized for emergency use in the U.S. Any product candidates that we successfully develop and commercialize will have to compete with existing therapies and vaccines and new therapies and vaccines that may become available in the future. While we believe that our proprietary compounds for treating COVID-19 and scientific expertise in the field of synthetic chemistry 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.

***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.

During 2021, we worked with researchers at Cleveland Clinic to advance the breast cancer vaccine technology toward human clinical testing, and in October 2021, began treating patients in a Phase 1 clinical trial. In addition, in May 2021, we and our partners at Cleveland Clinic began working with the NCI who will perform all 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 30% of all female cancer cases, and 15% of cancer deaths in women. It is estimated that in 2021, 282,000 new cases of breast cancer will be diagnosed in the U.S. and 44,000 women will die from this disease. Despite continuous advances made in the field of cancer research every year, there has been little change in breast cancer incidence rate over the last ten 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., 282,000 women are estimated to be diagnosed with breast cancer this year, there are approximately 75 million women over the age of 40—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 5% of cancer deaths in women due to the disease's low survival rate. It is estimated that in 2021, 21,000 new cases of ovarian cancer will be diagnosed and 14,000 American women will 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 49%. 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., 21,000 women are estimated to be diagnosed with ovarian cancer this year, there are approximately 30 million women over the age of 60—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.

**Employees**

As of October 31, 2021, 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, Cleveland Clinic, and MolGenie, as well as their 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 of our product candidates has been positive, we may experience unfavorable results and unforeseen delays once we commence 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 we may be subjected to future litigation.

**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.

- 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 your percentage ownership interest and may also result in downward pressure on the price of our common stock.

**Risks Related to the COVID-19 Pandemic**

- Our business activities, including our clinical trials, are expected to be delayed or otherwise adversely affected by the ongoing COVID-19 pandemic.

**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, 2021, our accumulated deficit was approximately $204,790,000. As of October 31, 2021, we had approximately $35,728,000 in cash, cash equivalents and short-term investments, and working capital of approximately $34,733,000. In fiscal year 2021, we incurred losses of approximately $13,128,000 and we experienced negative cash flows from operations of approximately $4,937,000. 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 4, 2022, we believe that our existing cash, cash equivalents and short-term investments will be sufficient to fund our activities for 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 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, 2021, the Company had approximately $35,728,000 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, our breast and ovarian cancer vaccines and our COVID-19 therapy. We do not expect to generate significant revenues for the foreseeable future, and we may not be able to raise funds in the 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 cancer diagnostic and therapeutics 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 will 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, cancer vaccines and anti-viral therapeutics. Our CAR-T ovarian cancer therapeutic, our breast and ovarian cancer vaccines and our COVID-19 treatment 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 no operating history will face. In particular, shareholders should consider that there is a significant risk that we will not be able to:

- complete studies that successfully identify one or more clinical candidates to treat COVID-19;
- successfully complete animal studies necessary to submit an IND application to the FDA for our COVID-19 treatment;
- 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, or that our current business plan is sound;
- raise sufficient funds in the capital markets or otherwise to fully effectuate our business plan;
- maintain our management team, including the members of our scientific advisory board;
- 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 transition from a company with a research and development focus 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 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 discovery stage of developing our COVID-19 treatment and our ovarian cancer vaccine technology, about to enter the clinical stage of developing our CAR-T therapeutic technology and in the clinical stage 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.

***There is no guarantee that our collaboration with MolGenie will produce a successful anti-viral drug for COVID-19.***

In April 2020, we entered into a collaboration agreement with OntoChem, such agreement subsequently assigned to MolGenie, for the purpose of discovering and ultimately developing anti-viral drug candidates for COVID-19. Through this collaboration, we utilized advanced computational methods, machine learning and molecular modeling techniques to perform *in silico* screening of over 1.2 billion compounds in OntoChem's chemistry and gene ontology database (including publicly available compounds and OntoChem's proprietary libraries) to evaluate if any of these compounds could disrupt one of two key enzymes of COVID-19. While, to date, we have synthesized several potential COVID-19 compounds and have performed *in vitro* and *in vivo* analyses of such compounds, there is no guarantee that any of these compounds (or any other future compounds that we may identify) will demonstrate sufficient potency as predicted by the molecular modeling algorithms. Further, even if these compounds do demonstrate sufficient potency, there is no guarantee that the compounds will be effective in animal or human testing and that they will ultimately be effective anti-viral drugs for COVID-19. In addition, based on the current stage of development, while considering the streamlined regulatory processes for COVID-19 therapies, it may take up to two or more years before we could obtain Emergency Use Authorization from the FDA.

***There is significant competition in the search for a treatment for COVID-19.***

There is significant competition, including from other companies and governmental organizations, to find treatments for COVID-19. Many of these entities have substantially greater resources (including capital and personnel) than we do and many of these entities are much further ahead in pursuit of a treatment than we are. Even if we are successful in identifying a compound that may act as an effective treatment for COVID-19, there is no guarantee that our treatment will be successful against competitors.

***While pre-clinical testing of our product candidates have been positive, we may experience unfavorable results once we commence human clinical trials.***

We have not initiated clinical trials for any of our product candidates other than our breast cancer vaccine, for which we do not yet have any human clinical data, and we may not be able to commence clinical trials on the time frames we expect. As these product candidates have only been tested in animals, we face significant uncertainty regarding how effective and safe they will be in human patients and the results from preclinical studies may not be indicative of the results of clinical trials. Preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical 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 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, Cleveland Clinic for our breast and ovarian cancer vaccines and MolGenie, as well as other European partners, for our COVID-19 therapy to conduct our preclinical 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 preclinical, 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;
- competing clinical trials and approved therapies available for patients; and
- the impact of the ongoing COVID-19 pandemic.

In particular, our CAR-T ovarian cancer clinical trial will look to enroll patients with late stage ovarian cancer who have failed conventional treatment, and are willing and able to be treated at Moffitt. Our first breast cancer vaccine clinical trial will look to enroll patients who have undergone standard of care treatment for TNBC. Our second breast cancer vaccine clinical trial will look to enroll healthy women who, as a result of testing positive for the BRCA1 gene mutation which is a leading predictor of future incidence of breast cancer, have elected to have prophylactic mastectomies. These potential trial participants have to 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 future 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.

Additionally, due to the design of our breast cancer vaccine trials it is unlikely that any of the trial participants will experience a positive therapeutic effect which may further reduce the number of patients who may enroll in our trials.

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 INDs 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 planned breast cancer vaccine clinical trials, we will treat healthy women who, as a result of testing positive for the BRCA1 gene mutation, 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 manufacture 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 a FDA inspection or medical crisis, 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 preclinical 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 GCPs, 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, our COVID-19 therapeutic 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.

***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, our COVID-19 treatment 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, our COVID-19 treatment 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, our COVID-19 treatment 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 agreement imposes, 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 other 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, to pay for the development of our COVID-19 therapeutic and for acquisitions of companies. We 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, our breast and ovarian cancer vaccines and our COVID-19 therapeutic. 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;
- results of pre-clinical studies relating to our COVID-19 therapeutic;
- progress with regulatory authorities towards the certification/approval of our CAR-T cancer therapeutics, our breast cancer vaccine, our ovarian cancer vaccine or our COVID-19 therapeutic; 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, cancer vaccines or COVID-19 treatments;
- 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 your 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 10,700,626 shares of our common stock with a weighted average exercise price of $3.38. Further, as of the date of this Report, our Board of Directors and Compensation Committee have the authority to issue awards totaling an additional 2,000,000 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.

***Changes in accounting rules, assumptions and/or judgments could materially and adversely affect us.***

Accounting rules and interpretations for certain aspects of our operations are highly complex and involve significant assumptions and judgment. These complexities could lead to a delay in the preparation and dissemination of our financial statements. Furthermore, changes in accounting rules and interpretations or in our accounting assumptions and/or judgments, such as asset impairments, could significantly impact our financial statements. In some cases, we could be required to apply a new or revised standard retroactively, resulting in restating prior period financial statements. Any of these circumstances could have a material adverse effect on our business, prospects, liquidity, financial condition and results of operations.

***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.

**Risks related to the COVID-19 pandemic**

***Our business activities are expected to be adversely affected by the ongoing COVID-19 pandemic.***

The pandemic has caused periodic shutdowns of the laboratories and other service providers that we rely on to develop our programs, and those laboratories and service providers that have been operating or that have begun operating recently have been doing so with limited capacity due to social distancing requirements. As a result, our progress has been slowed and there is no assurance that we will be able to meet our previously announced timelines regarding the development of our programs.

The extent to which the COVID-19 pandemic impacts our business, operations and financial results will depend on numerous evolving factors that we may not be able to accurately predict, including: the duration and scope of the pandemic; governmental, business and individuals' actions that have been and continue to be taken in response to the pandemic; the impact of the pandemic on economic activity and actions taken in response; our ability to continue daily operations, including as a result of travel restrictions and people working from home; the effect the pandemic may have on the ability to recruit patients to participate in our clinical trials; and any closures of our and our business partners' offices and facilities.

While the Company is currently implementing solutions designed to reduce the potential impact of COVID-19, there can be no assurance that our efforts will adequately mitigate the risks of business disruptions and interruptions. Further, events such as natural disasters and public health emergencies divert our attention away from normal operations and limited resources. Our inability to timely resume normal operations following the pandemic disruption could adversely affect our business, financial condition or results of operations in a material manner.

Any of these events could materially adversely affect our business, financial condition, results of operations and/or stock price.

**Item 1B. Unresolved Staff Comments.**

None.

**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 3, 2022, the approximate number of record holders of our common stock was 322 and the closing price of our common stock was $3.02 per share.

**Securities Authorized for Issuance Under Equity Compensation Plans**

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

**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**

The Company did not issue any unregistered securities during the three months ended October 31, 2021.

**Item 6. Selected Financial Data.**

Not required for a smaller reporting company.

**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, 2021 compared with Fiscal Year ended October 31, 2020**

***Revenue***

In fiscal year 2021, we recorded revenue of approximately $513,000 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 2020.

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 regarding the Cchek™ liquid biopsy platform, as well as 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 2021 inventor royalties, contingent legal fees, litigation and licensing expenses related to patent assertion activities were approximately $385,000. 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 2020.

***Research and Development Expenses***

Research and development expenses incurred in fiscal year 2021 associated with each of our development programs consisted of approximately $2,634,000 for CAR-T therapeutics, approximately $2,231,000 for cancer vaccines, approximately $1,323,000 for anti-viral therapeutics and approximately $2,000 for cancer diagnostics.

Research and development expenses are related to the development of our cancer therapeutics, vaccine and diagnostics programs and our anti-viral drug program, and increased by approximately $1,809,000 to approximately $6,190,000 in fiscal year 2021, from approximately $4,381,000 in fiscal year 2020. The increase in research and development expenses was primarily due to an increase in employee stock option expense of approximately $2,440,000, an increase in outside research and development related to our development programs, other than our cancer diagnostics program, of approximately $772,000, an increase in consultant stock option expense of approximately $241,000 and an increase in legal fees primarily related to collaborative and license agreements of approximately $30,000, offset by a decrease in outside research and development expense related to our cancer diagnostics program of approximately $1,112,000, a decrease in employee compensation and related costs, other than stock option compensation expense, of approximately $515,000 and a decrease in depreciation expense of approximately $35,000, all such decreases primarily due to suspension of development of our cancer diagnostics program in July 2020.

***General and Administrative Expenses***

General and administrative expenses increased by approximately $1,476,000 to approximately $7,073,000 in fiscal year 2021, from approximately $5,597,000 in fiscal year 2020. The increase in general and administrative expenses was principally due to an increase in employee stock option expense of approximately $1,108,000, non-recurring income in the prior year period resulting from the discharge in January 2020 of a disputed liability of approximately $337,000 upon the expiration of the vendor's statutory right to pursue collection of the disputed liability, an increase in patent expense of approximately $336,000, an increase in directors compensation of approximately $209,000, an increase in warrant expense of approximately $96,000, an increase in corporate insurance expense of approximately $59,000 primarily due to an increase in our directors and officers insurance premium and an increase in investor and public relations expense of approximately $52,000, offset by a decrease in employee compensation and related costs, other than stock option expense, of approximately $584,000 and a decrease in consulting expense, other than warrant expense, of approximately $133,000.

***Gain (Loss) on Disposal of Property and Equipment***

Gain (loss) on disposal of property and equipment was a gain of approximately $5,000 in fiscal year 2021 compared to a loss of approximately $148,000 in fiscal year 2020. The disposal of property and equipment was in connection with the suspension of development of our cancer diagnostics program.

***Interest Income***

Interest income decreased to approximately $2,000 in fiscal year 2021 compared to approximately $34,000 in fiscal year 2020, due to a decrease in interest rates.

***Net Loss Attributable to Noncontrolling Interest***

The net loss attributable to noncontrolling interest, representing Wistar's 5% ownership interest in Certainty's net loss, increased by approximately $100,000 to approximately $174,000 in fiscal year 2021, from approximately $74,000 in fiscal year 2020, as Certainty's net loss increased. The increase in Certainty's net loss was primarily due to an increase in employee stock option expense of approximately $1,422,000, an increase in outside research and development of approximately $407,000 and an increase in patent expense of approximately $178,000.

**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 4, 2022, 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. During fiscal year 2021, we raised approximately $20,292,000, net of expenses, through a public offering in which we sold an aggregate of 4,285,715 shares of common stock and approximately $10,834,000, net of expenses, through an at-the-market equity program in which we sold an aggregate of 2,806,410 shares of common stock. Our at-the-market equity program was terminated on June 16, 2021. We may seek to obtain working capital during our fiscal year 2022 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 year ended October 31, 2021, cash used in operating activities was approximately $4,937,000. Cash used in investing activities was approximately $3,918,000, resulting from the purchase of short-term investments of approximately $16,499,000, which was offset by the proceeds on maturities of short-term investments of approximately $12,539,000, the proceeds from the sale of equipment of approximately $35,000 and proceeds received on sale of common stock by ZQX Advisors, LLC of approximately $6,000. Cash provided by financing activities was approximately $31,566,000, resulting from net proceeds of approximately $20,292,000 from a public offering of 4,285,715 shares of common stock, the sale of 2,806,410 shares of common stock in an at-the-market equity offering of approximately $10,834,000, proceeds from exercise of stock options of approximately $434,000 and proceeds from the sale of common stock pursuant to employee stock purchase plan of approximately $6,000. As a result, our cash, cash equivalents, and short-term investments at October 31, 2021 increased approximately $26,671,000 to approximately $35,728,000 from approximately $9,057,000 at the end of fiscal year 2020.

We have a future cash obligation related to the lease of our offices through 2026, estimated at approximately $331,000.

**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; and
- Stock-Based Compensation.

**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 expensed on a straight-line basis over the requisite service period (the vesting period of the stock option). 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 awards granted to employees, directors and consultants 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 values 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. For consultants we use the contract term for expected term. We estimate 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 estimate 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 Monte Carlo Simulation if additional information becomes available in the future that indicates other models 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. See Note 2 to the Consolidated Financial Statements for additional information.

**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 President and Chief Executive Officer and our Chief Operating Officer and 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 President and Chief Executive Officer and our Chief Operating Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of the end of fiscal year 2021.

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, 2021. 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, 2021.

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 a permanent exemption of the Commission that permits 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, 2021 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 2021 that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

**Item 9B. Other Information.**

Reference is made to that certain consulting agreement, dated September 19, 2012, between the Company and Dr. Amit Kumar. The consulting agreement, which has been inoperative since June 2015, was formally terminated on December 30, 2021. The termination of this consulting agreement has no impact on Dr. Kumar's employment with the Company as Dr. Kumar remains the Chief Executive Officer and President of the Company on an at-will basis.

## 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 2022 Annual Meeting of Stockholders scheduled for March 10, 2022 which such Proxy Statement will be filed with the SEC within 120 days of October 31, 2021, 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 2022 Annual Meeting of Stockholders scheduled for March 10, 2022 which such Proxy Statement will be filed with the SEC within 120 days of October 31, 2021, 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 2022 Annual Meeting of Stockholders scheduled for March 10, 2022 which such Proxy Statement will be filed with the SEC within 120 days of October 31, 2021, 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 2022 Annual Meeting of Stockholders scheduled for March 10, 2022 which such Proxy Statement will be filed with the SEC within 120 days of October 31, 2021, 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 2022 Annual Meeting of Stockholders scheduled for March 10, 2022 which such Proxy Statement will be filed with the SEC within 120 days of October 31, 2021, 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**

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| 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 | Form of Warrant issued to Acorn Management Partners LLC. (Filed herewith.) |
| 4.3 | 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.) |

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| 10.8 | Amended and Restated Collaboration Agreement, dated November 1, 2021, between Certainty Therapeutics, Inc. and H. Lee Moffitt Cancer Center and Research Institute, Inc. (Filed herewith.) |
| 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 | Collaboration Agreement, dated April 14, 2020, between the Company and OntoChem GmbH. (Incorporated by reference to Exhibit 10.1 to our Form 10-Q for the fiscal quarter ended April 30, 2020.) (Certain information has been redacted in the marked portions of the exhibit.) |
| 10.11 | Amendment to Collaboration Agreement between the Company and OntoChem GmbH. (Incorporated by reference to Exhibit 10.13 to our Form 10-K, for the fiscal year ended October 31, 2020.) |
| 10.12 | Assignment Agreement dated May 1, 2021, between the Company, OntoChem GmbH and MolGenie GmbH. (Incorporated by reference to Exhibit 10.1 to our Form 10-Q for the fiscal quarter ended April 30, 2021.) |
| 10.13 | Amendment 2 to the Collaboration Agreement between the Company and MolGenie GmbH. (Incorporated by reference to Exhibit 10.2 to our Form 10-Q for the fiscal quarter ended April 30, 2021.) (Certain information has been redacted in the marked portions of the exhibit.) |
| 10.14 | 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.) |
| 10.15 | Joint Development and Option Agreement, dated January 26, 2021, between the Company and The Cleveland Clinic Foundation. (Incorporated by reference to Exhibit 10.2 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.) |
| 14 | Code of Conduct (Incorporated by reference to Exhibit 14 to our Form 10-K, for the fiscal year ended October 31, 2020.) |
| 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 4, 2022. (Filed herewith.) |
| 31.2 | Certification of Chief Financial Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, dated January 4, 2022. (Filed herewith.) |
| 32.1 | Statement of Chief Executive Officer, pursuant to Section 1350 of Title 18 of the United States Code, dated January 4, 2022. (Filed herewith.) |
| 32.2 | Statement of Chief Financial Officer, pursuant to Section 1350 of Title 18 of the United States Code, dated January 4, 2022. (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, President and
January 4, 2022 Chief Executive Officer

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, President and
Chief Executive Officer
January 4, 2022 (Principal Executive Officer)

By: */s/ Michael J. Catelani*
Michael J. Catelani
Chief Operating Officer and
Chief Financial Officer
January 4, 2022 (Principal Financial and Accounting Officer)

By: */s/ Lewis H. Titterton, Jr.*
Lewis H. Titterton, Jr.
January 4, 2022 Director

By: */s/ Arnold Baskies*
Dr. Arnold Baskies
January 4, 2022 Director

By: */s/ Emily Gottschalk*
Emily Gottschalk
January 4, 2022 Director

**ANIXA BIOSCIENCES, INC. AND SUBSIDIARIES**

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS OCTOBER 31, 2021



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, 2021 and 2020, and the related consolidated statements of operations, equity, and cash flows for each of the two years in the period ended October 31, 2021, 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, 2021 and 2020, and the consolidated results of its operations and its cash flows for each of the years in the two year period ended October 31, 2021, 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.

Fair Value of Stock Options – Refer to Note 5 to the Consolidated Financial Statements

*Critical Audit Matter Description:*

The Company uses the Black-Scholes option-pricing model to estimate the fair value of its time-based stock options. The Black-Scholes option-pricing model involves the use of significant estimates, including the following:

- Expected dividend yield;
- Risk-free interest rate;
- Expected share price volatility; and
- Expected life of the award.

Additionally, the Company uses the Monte-Carlo simulation option-pricing model to estimate the fair value of its market condition stock options. The Monte Carlo simulation option-pricing model calculates multiple potential outcomes for an award and establishes a fair value based on the most likely outcome. Key assumptions for the Monte-Carlo simulation option-pricing model include:

- Risk-free interest rate;
- Expected share price volatility;
- Expected dividends; and
- Cost of equity.

Given the significant estimates involved in estimating the fair value of stock options, the related audit effort in evaluating management's estimates in determining the inputs to fair value stock option models was extensive and required a high degree of auditor judgment.

*How the Critical Audit Matter was Addressed in the Audit:*

We obtained an understanding over management's process to estimate the fair value of stock options, including how each of the estimates required are developed to utilize the Black-Scholes and Monte-Carlo simulation option-pricing models. We applied the following audit procedures related to testing management's estimates utilized in the option-pricing models:

- We performed a look-back at the Company's previously issued dividends, noting there were none. We inquired with management who informed us that no future dividends were currently anticipated.
- We compared the Company's risk-free interest rate used to the comparable United States treasury yield for a term comparable to the stock options' expected term.
- We recalculated the Company's historical share price volatility for a term comparable to the stock options' expected term.
- We recalculated the expected term of stock options granted to employees and non-employee directors using the simplified method, whereby, the expected term equals the average of the vesting term and the original contractual term of the option.
- We performed inquiries with the independent third-party valuation specialist assisting the Company with the Monte-Carlo simulation to ensure the inputs used in the calculation, the fair value of the awards, and the expected vesting periods, were reasonable.

HASKELL & WHITE LLP

We have served as the Company's auditor since 2013

Irvine, California
January 4, 2022

**ANIXA BIOSCIENCES, INC. AND SUBSIDIARIES**

CONSOLIDATED BALANCE SHEETS

| | October 31, 2021 | October 31, 2020 |
|---|---|---|
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | $ 29,128,298 | $ 6,417,061 |
| Short–term investments | 6,599,595 | 2,640,000 |
| Prepaid expenses and other current assets | 275,556 | 311,563 |
| Total current assets | 36,003,449 | 9,368,624 |
| | | |
| Operating lease right-of-use asset | 253,955 | 54,340 |
| Other assets | - | 30,000 |
| | | |
| Total assets | $ 36,257,404 | $ 9,452,964 |
| | | |
| LIABILITIES AND EQUITY | | |
| Current liabilities: | | |
| Accounts payable | $ 136,196 | $ 232,368 |
| Accrued expenses | 1,094,935 | 901,025 |
| Operating lease liability | 39,397 | 55,198 |
| Total current liabilities | 1,270,528 | 1,188,591 |
| | | |
| Operating lease liability, non-current | 220,082 | - |
| Total liabilities | 1,490,610 | 1,188,591 |
| | | |
| Commitments and contingencies (Note 7) | | |
| 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; 30,050,894 and 24,248,695 shares issued and outstanding, respectively | 300,509 | 242,486 |
| Additional paid-in capital | 239,926,809 | 200,354,488 |
| Accumulated deficit | (204,790,018) | (191,835,618) |
| Total shareholders' equity | 35,437,300 | 8,761,356 |
| Noncontrolling interest (Note 2) | (670,506) | (496,983) |
| Total equity | 34,766,794 | 8,264,373 |
| | | |
| Total liabilities and equity | $ 36,257,404 | $ 9,452,964 |

The accompanying notes are an integral part of these statements.

**ANIXA BIOSCIENCES, INC. AND SUBSIDIARIES**

CONSOLIDATED STATEMENTS OF OPERATIONS

| | For the years ended October 31, | |
|---|---|---|
| | 2021 | 2020 |
| Revenue | $ 512,500 | $ - |
| Operating costs and expenses: | | |
| Inventor royalties, contingent legal fees, litigation and licensing expenses | 385,002 | - |
| Research and development expenses (including non-cash share based compensation expenses of $4,165,668 and $1,484,545, respectively) | 6,189,692 | 4,381,205 |
| General and administrative expenses (including non-cash share based compensation expenses of $3,892,410 and $2,652,915, respectively) | 7,073,498 | 5,596,997 |
| Total operating costs and expenses | 13,648,192 | 9,978,202 |
| Loss from operations | (13,135,692) | (9,978,202) |
| Gain (loss) on disposal of property and equipment | 5,447 | (148,084) |
| Interest income | 2,322 | 33,923 |
| Net loss | (13,127,923) | (10,092,363) |
| Less: Net loss attributable to noncontrolling interest | (173,523) | (74,008) |
| Net loss attributable to common stockholders | $ (12,954,400) | $ (10,018,355) |
| Net loss per share: | | |
| Basic and diluted | $ (0.45) | $ (0.45) |
| Weighted average common shares outstanding: | | |
| Basic and diluted | 28,578,892 | 22,229,042 |

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, 2021 AND 2020

| | Common Stock | | Additional Paid-in | Accumulated | Total Shareholders' | Non-controlling | Total |
|---|---|---|---|---|---|---|---|
| | Shares | Par Value | Capital | Deficit | Equity | Interest | Equity |
| BALANCE, October 31, 2019 | 20,331,754 | $ 203,317 | $ 186,849,299 | $ (181,817,263) | $ 5,235,353 | $ (422,975) | $ 4,812,378 |
| Stock option compensation to employees and directors | - | - | 3,922,719 | - | 3,922,719 | - | 3,922,719 |
| Stock options issued to consultants | - | - | 214,741 | | 214,741 | - | 214,741 |
| Common stock issued upon exercise of stock options | 51,100 | 511 | 121,759 | - | 122,270 | - | 122,270 |
| Common stock issued pursuant to employee stock purchase plan | 11,536 | 115 | 18,336 | - | 18,451 | - | 18,451 |
| Common stock issued in an at-the-market offering, net of offering expenses of $362,918 | 3,854,305 | 38,543 | 9,227,634 | - | 9,266,177 | - | 9,266,177 |
| Net Loss | - | - | - | (10,018,355) | (10,018,355) | (74,008) | (10,092,363) |
| BALANCE, October 31, 2020 | 24,248,695 | $ 242,486 | $ 200,354,488 | $ (191,835,618) | $ 8,761,356 | $ (496,983) | $ 8,264,373 |
| Stock option compensation to employees and directors | - | - | 7,503,037 | - | 7,503,037 | - | 7,503,037 |
| Expired restricted stock award to employee | (1,500,000) | (15,000) | 15,000 | - | - | - | - |
| Stock options and warrants issued to consultants | - | - | 555,041 | - | 555,041 | - | 555,041 |
| Common stock issued upon exercise of stock options | 207,697 | 2,077 | 432,147 | - | 434,224 | - | 434,224 |
| Common stock issued pursuant to employee stock purchase plan | 2,377 | 24 | 5,976 | - | 6,000 | - | 6,000 |
| Common stock issued in a public offering, net of offering expenses of $2,208,150 | 4,285,715 | 42,858 | 20,248,996 | - | 20,291,854 | - | 20,291,854 |
| Common stock issued in an at-the-market offering, net of offering expenses of $340,775 | 2,806,410 | 28,064 | 10,805,651 | - | 10,833,715 | - | 10,833,715 |
| Proceeds received on sale of common stock held by ZQX Advisors, LLC | - | - | 6,473 | - | 6,473 | - | 6,473 |
| Net Loss | - | - | - | (12,954,400) | (12,954,400) | (173,523) | (13,127,923) |
| BALANCE, October 31, 2021 | 30,050,894 | $ 300,509 | $ 239,926,809 | $ (204,790,018) | $ 35,437,300 | $ (670,506) | $ 34,766,794 |

The accompanying notes are an integral part of these statements.

**ANIXA BIOSCIENCES, INC. AND SUBSIDIARIES**

CONSOLIDATED STATEMENTS OF CASH FLOWS

| | For the years ended October 31, | |
|---|---|---|
| | 2021 | 2020 |
| Cash flows from operating activities: | | |
| Reconciliation of net loss to net cash used in operating activities: | | |
| Net loss | $ (13,127,923) | $ (10,092,363) |
| Stock option compensation to employees and directors | 7,503,037 | 3,922,719 |
| Stock options and warrants issued to consultants | 555,041 | 214,741 |
| Depreciation of property and equipment | - | 38,276 |
| (Gain) loss on disposal of property and equipment | (5,447) | 148,084 |
| Amortization of operating lease right-of-use asset | 59,864 | 51,881 |
| Change in operating assets and liabilities: | | |
| Receivables | - | 64,296 |
| Prepaid expenses and other current assets | 36,007 | (124,360) |
| Accounts payable | (96,172) | (353,449) |
| Accrued expenses | 193,910 | 5,527 |
| Operating lease liability | (55,198) | (51,023) |
| Net cash used in operating activities | (4,936,881) | (6,175,671) |
| | | |
| Cash flows from investing activities: | | |
| Disbursements to acquire short-term investments | (16,498,895) | (5,010,000) |
| Proceeds from maturities of short-term investments | 12,539,300 | 4,720,000 |
| Proceeds from sale of equipment | 35,447 | - |
| Proceeds received on sale of common stock by ZQX Advisors, LLC | 6,473 | - |
| Purchase of property and equipment | - | (15,791) |
| Net cash used in investing activities | (3,917,675) | (305,791) |
| | | |
| Cash flows from financing activities: | | |
| Proceeds from sale of common stock in a public offering, net of expenses | 20,291,854 | - |
| Proceeds from sale of common stock in an at-the-market offering, net of expenses | 10,833,715 | 9,266,177 |
| Proceeds from sale of common stock pursuant to employee stock purchase plan | 6,000 | 18,451 |
| Proceeds from exercise of stock options | 434,224 | 122,270 |
| Net cash provided by financing activities | 31,565,793 | 9,406,898 |
| | | |
| Net increase in cash and cash equivalents | 22,711,237 | 2,925,436 |
| Cash and cash equivalents at beginning of year | 6,417,061 | 3,491,625 |
| Cash and cash equivalents at end of year | $ 29,128,298 | $ 6,417,061 |
| | | |
| Supplemental cash flow information: | | |
| Cash proceeds from interest income | $ 1,824 | $ 39,890 |
| | | |
| Supplemental disclosure of non-cash investing activity: | | |
| Operating lease right-of-use asset | $ (259,479) | $ - |
| | | |
| Supplemental disclosure of non-cash financing activities: | | |
| Operating lease liability | $ 259,479 | $ - |
| Fair value of warrants issued in connection with public offering | $ 1,040,700 | $ - |

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., incorporated on November 5, 1982 under the laws of the State of Delaware, is a biotechnology company developing therapies and vaccines that are focused on critical unmet needs in oncology and infectious disease. Our therapeutics programs include 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 we are developing through a subsidiary, Certainty Therapeutics, Inc. ("Certainty"), and discovery and ultimately development of anti-viral drug candidates for the treatment of COVID-19 focused on inhibiting certain protein functions of the virus. Our vaccine programs include the development of a preventative vaccine against triple negative breast cancer ("TNBC"), the most lethal form of breast cancer, as well as other forms of breast cancer, and a preventative vaccine against ovarian cancer.

In September 2017 we formed Certainty to develop 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") relating to Wistar's CAR-T technology. 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. In addition, in November 2017, we entered into a collaboration with the H. Lee Moffitt Cancer Center and Research Institute, Inc. ("Moffitt") to advance our CAR-T therapy toward human clinical trials.

In April 2020, we entered into a collaboration with OntoChem GmbH ("OntoChem"), which subsequently assigned its rights and obligations under the collaboration to MolGenie GmbH ("MolGenie"), a company spun-out from OntoChem focused on drug discovery and development, to discover and develop anti-viral drug candidates against COVID-19. In July 2019, we entered into 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, and we are working in collaboration with Cleveland Clinic to develop a method to vaccinate women against contracting breast cancer, focused specifically on TNBC. Further, in October 2020, we executed a license agreement with Cleveland Clinic pursuant to which we were 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.

In July 2020, we suspended operations of our subsidiary, Anixa Diagnostics Corporation, and the development of the Cchek™ artificial intelligence driven platform of non-invasive blood tests for the early detection of cancer.

Over the next several quarters, we expect the development of our breast and ovarian cancer vaccines, our COVID-19 therapeutic program and Certainty's CAR-T technology to be the primary focus of the Company. As part of our legacy operations, the Company remains engaged in limited patent licensing activities regarding the Cchek™ liquid biopsy platform, as well as 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.

In the 2021 fiscal year as well as 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. 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.

Funding and Management's Plans

Based on currently available information as of January 4, 2022, 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. During fiscal year 2021, we raised approximately $20,292,000, net of expenses, through a public offering in which we sold an aggregate of 4,285,715 shares of common stock and approximately $10,834,000, net of expenses, through an at-the-market equity program in which we sold an aggregate of 2,806,410 shares of common stock. Our at-the-market equity program was terminated on June 16, 2021. We may seek to obtain working capital during our fiscal year 2022 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, 2021:

| | | |
|---|---|---|
| Balance October 31, 2019 | $ | (422,975) |
| Net loss attributable to noncontrolling interest | | (74,008) |
| Balance October 31, 2020 | | (496,983) |
| Net loss attributable to noncontrolling interest | | (173,523) |
| Balance October 31, 2021 | $ | (670,506) |

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 generally 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, consisting primarily of employee compensation, payments to third parties for research and development activities and other direct costs associated with developing immuno-therapy drugs against cancer, developing anti-viral drug candidates for COVID-19, developing our breast cancer vaccine, developing our ovarian cancer vaccine, and developing a platform for non-invasive blood tests for early cancer detection (such development having been suspended in fiscal year 2020), are expensed in the consolidated financial statements in the year incurred.

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, 2021:

| | Level 1 | Level 2 | Level 3 | Total |
|---|---|---|---|---|
| Money market funds: | | | | |
| Cash and cash equivalents | $ 28,948,976 | $ - | $ - | $ 28,948,976 |
| Certificates of deposit: | | | | |
| Short term investments | - | 2,000,000 | - | 2,000,000 |
| U. S. treasury bills: | | | | |
| Short term investments | - | 4,599,595 | - | 4,599,595 |
| Total financial assets | $ 28,948,976 | $ 6,599,599 | $ - | $ 35,548,571 |

The following table presents the hierarchy for our financial assets measured at fair value on a recurring basis as of October 31, 2020:

| | Level 1 | Level 2 | Level 3 | Total |
|---|---|---|---|---|
| Money market funds: | | | | |
| Cash and cash equivalents | $ 3,902,292 | $ - | $ - | $ 3,902,292 |
| Certificates of deposit: | | | | |
| Cash and cash equivalents | 2,250,000 | | - | 2,250,000 |
| Short term investments | - | 2,640,000 | - | 2,640,000 |
| Total financial assets | $ 6,152,292 | $ 2,640,000 | $ - | $ 8,792,292 |

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 and cash equivalents are stated at carrying value which approximates fair value.

Cash and Cash Equivalents

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

Short-term Investments

At October 31, 2021 and 2020, we had certificates of deposit and United States treasury bills with maturities greater than 90 days and less than 12 months when acquired of $6,599,595 and $2,640,000, respectively, that were classified as short-term investments and reported at fair value.

Property and equipment

As a result of the suspension of operations of our subsidiary, Anixa Diagnostics Corporation, as discussed in Note 1, we recorded a gain of approximately $5,000 during the year ended October 31, 2021 and a loss of approximately $148,000 during the year ended October 31, 2020, on disposal of property and equipment

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.

Stock-Based Compensation

We maintain stock equity incentive plans under which we may grant non-qualified stock options, incentive stock options, stock appreciation rights, stock awards, performance awards and stock units to employees, non-employee 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 $3,531,000 and $3,923,000, during the years ended October 31, 2021 and 2020, respectively. Included in stock-based compensation cost for service-based options granted to employees and directors during the years ended October 31, 2021 and 2020 was approximately $1,841,000 and $3,011,000, respectively, related to the amortization of compensation cost for stock options granted in prior periods but not yet vested. As of October 31, 2021, there was unrecognized compensation cost related to non-vested service-based stock options granted to employees and directors of approximately $5,490,000, which will be recognized over a weighted-average period of 2.2 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 May 8, 2018, we issued market condition stock options to purchase 1,500,000 shares of common stock, to our Chairman, President and Chief Executive Officer, vesting at target trading prices of $5.00 to $8.00 per share before May 31, 2021, with implied service periods of three to seven months. The assumptions used in the Monte Carlo Simulation for the May 18, 2018 grant were stock price on date of grant and exercise price of $3.70, contract term of 10 years, expected volatility of 119.6% and risk-free interest rate of 2.97%. In October 2018, the first tranche of 500,000 shares of market condition options became exercisable upon achieving an average closing price above $5.00 per share for twenty consecutive trading days. The remaining tranches did not vest as of May 31, 2021 and expired.

On June 1, 2021, our Chairman, 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, 2021, 500,000 shares and 25,000 shares granted to our Chairman, President and Chief Executive Officer and our Chief Operating Officer and Chief Financial Officer, respectively, have vested.

We recorded stock-based compensation expense related to market condition stock options granted to employees of approximately $3,972,000 during the year ended October 31, 2021, which amount did not include any expense related to the amortization of compensation cost for stock options granted in prior periods. We did not record any compensation expense related to market condition stock options during the year ended October 31, 2020. As of October 31, 2021, there was unrecognized compensation cost related to market condition stock options granted to employees of approximately $2,537,000, which will be recognized over a weighted-average period of 0.62 years

We recorded consulting expense, related to service-based stock options granted to consultants, during the years ended October 31, 2021 and 2020 of approximately $460,000 and $215,000, respectively. Included in stock-based consulting expense for the years ended October 31, 2021 and 2020 was approximately $103,000 and $123,000, respectively, related to compensation cost for stock options granted in prior periods but not yet vested. As of October 31, 2021, there was unrecognized consulting expense related to non-vested service-based stock options granted to consultants of approximately $900,000, which will be recognized over a weighted-average period of 2.1 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, 2021 and 2020 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, 2021 and 2020:

| | For the Year Ended October 31, | |
|---|---|---|
| | 2021 | 2020 |
| Weighted average fair value at grant date | $ 2.93 | $ 2.97 |
| Valuation assumptions: | | |
| Expected life (years) | 5.66 | 5.86 |
| Expected volatility | 109.02% | 114.22% |
| Risk-free interest rate | 0.69% | 1.45% |
| 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. 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 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.

Stock Award Compensation Expense

We account for stock awards granted to employees, directors and consultants in accordance with ASC 718. On May 8, 2018, a restricted stock award of 1,500,000 shares of common stock was granted to our Chairman, President and Chief Executive Officer. The restricted stock award was to vest in its entirety upon achievement of a target trading price of $11.00 per share of the Company's common stock before May 31, 2021. The restricted stock award did not vest as of May 31, 2021 and expired. 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 assumptions used in the Monte Carlo Simulation were stock price on date of grant of $3.70, contract term of 3.06 years, expected volatility of 128.8% and risk-free interest rate of 2.66%. We did not record any compensation expense related to the restricted stock award during the years ended October 31, 2021 and 2020. We did not issue any stock awards during the years ended October 31, 2021 and 2020. As of October 31, 2021, there was no unrecognized compensation cost related to the restricted stock awards.

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, 2021 and 2020 we recorded consulting expense, based on the fair value, of approximately $96,000 and $-0-, 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, 2021 and 2020 were options to purchase 10,770,626 shares and 7,952,195 shares, respectively, and warrants to purchase 860,000 shares and 560,000 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 January 2020, the FASB issued Accounting Standards Update 2020-01 ("ASU 2020-01") Investments-Equity Securities (Topic 321), Investments-Equity Method and Joint Ventures (Topic 323), and Derivatives and Hedging (Topic 815). The amendments in ASU 2020-01 clarify certain interactions between the guidance to account for certain equity securities under Topic 321, the guidance to account for investments under the equity method of accounting in Topic 323, and the guidance in Topic 815, which could change how an entity accounts for an equity security under the measurement alternative or a forward contract or purchased option to purchase securities that, upon settlement of the forward contract or exercise of the purchased option, would be accounted for under the equity method of accounting or the fair value option in accordance with Topic 825, Financial Instruments. These amendments improve current GAAP by reducing diversity in practice and increasing comparability of the accounting for these interactions. The amendments in this update are effective for fiscal years beginning after December 15, 2020, and interim periods within those fiscal years. The adoption of this standard will not have a material impact on our consolidated financial statements and related disclosures.

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. We do not expect the adoption of this standard to have a material impact on our consolidated financial statements and related disclosures.

In May 2021, the FASB issued Accounting Standards Update 2021-04 ("ASU No. 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. We do not expect the adoption of this standard to have a material impact on our consolidated financial statements and related disclosures.

In October 2021, the FASB issued Accounting Standards Update 2021-08 ("ASU No. 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 2021.

## 3. PUBLIC OFFERING

On March 25, 2021, the Company completed a public offering in which we sold an aggregate of 4,285,715 shares of its common stock, which represented 15.8% of the Company's outstanding shares at the time of the offering, at a public offering price of $5.25 per share. The Company realized net proceeds of approximately $20,292,000 from the public offering, after deducting underwriting discounts and deal expenses. In connection with the public offering, the Company issued to certain designees of the underwriter, as compensation, warrants expiring on March 22, 2026, to purchase 300,000 shares of common stock exercisable for $6.5625 per share.

4. ACCRUED EXPENSES

Accrued liabilities consist of the following as of:

| | October 31, | |
|---|---|---|
| | 2021 | 2020 |
| Payroll and related expenses | 491,950 | 415,331 |
| Accrued royalty and contingent legal fees | 577,190 | 449,691 |
| Accrued collaborative research and license expense | - | 30,000 |
| Accrued other | 25,795 | 6,003 |
| | $ 1,094,935 | $ 901,025 |

5. SHAREHOLDERS' EQUITY

Stock Option Plans

During the year ended October 31, 2021, 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. Further, we had an additional stock option plan, the Anixa Biosciences, Inc. 2003 Share Incentive Plan (the "2003 Share Plan"), under which all outstanding options expired during the year ended October 31, 2020.

During the years ended October 31, 2021 and 2020, stock options to purchase 207,697 shares, net of 60,691 shares withheld on cashless exercises, and 51,100 shares of common stock, respectively, were exercised with aggregate proceeds of approximately $434,000 and $122,000, respectively.

*2003 Share Plan*

The 2003 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. The exercise price with respect to all of the options granted under the 2003 Share Plan since its inception was equal to the fair market value of the underlying common stock at the grant date. In accordance with the provisions of the 2003 Share Plan, the plan terminated with respect to the grant of future options on April 21, 2013. Information regarding the 2003 Share Plan for the year ended October 31, 2020 is as follows:

| | Shares | Weighted Average Exercise Price Per Share |
|---|---|---|
| Options Outstanding at October 31, 2019 | 400 | $ 17.00 |
| Expired | (400) | $ 17.00 |
| Options Outstanding and Exercisable at October 31, 2020 | - | |

*2010 Share Plan*

The 2010 Share Plan provides 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 is replenished such that 800,000 shares are 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. In accordance with the provisions of the 2010 Share Plan, the plan terminated with respect to the grant of future options on July 14, 2020. Information regarding the 2010 Share Plan for the two years ended October 31, 2021 is as follows:

| | Shares | Weighted Average Exercise Price Per Share | Aggregate Intrinsic Value |
|---|---|---|---|
| Options Outstanding at October 31, 2019 | 1,998,668 | $ 2.80 | |
| Exercised | (51,100) | $ 2.39 | |
| Forfeited | (40,034) | $ 3.34 | |
| Options Outstanding at October 31, 2020 | 1,907,534 | $ 2.82 | |
| Exercised | (178,500) | $ 2.75 | |
| Expired | (10,400) | $ 4.57 | |
| Options Outstanding and Exercisable at October 31, 2021 | 1,718,634 | $ 2.82 | $ 4,839,591 |

The following table summarizes information about stock options outstanding under the 2010 Share Plan as of October 31, 2021:

| Range of Exercise Prices | Number Outstanding and Exercisable | Weighted Average Remaining Contractual Life (in years) | Weighted Average Exercise Price |
|---|---|---|---|
| $0.67 - $2.30 | 527,500 | 4.55 | $ 1.54 |
| $2.58 - $3.13 | 677,000 | 2.79 | $ 2.79 |
| $3.46 - $5.30 | 514,134 | 6.49 | $ 4.16 |

*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, 2021, the 2018 Share Plan had 1,147,937 shares available for future grants. Information regarding the 2018 Share Plan for the two years ended October 31, 2021 is as follows:

| | Shares | Weighted Average Exercise Price Per Share | Aggregate Intrinsic Value |
|---|---|---|---|
| Options Outstanding at October 31, 2019 | 3,935,000 | $ 3.74 | |
| Granted | 1,045,000 | $ 3.56 | |
| Forfeited | (633,339) | $ 3.83 | |
| Options Outstanding at October 31, 2020 | 4,346,661 | $ 3.69 | |
| Granted | 4,490,000 | $ 3.82 | |
| Exercised | (33,888) | $ 3.81 | |
| Expired | (1,392,781) | $ 3.70 | |
| Options Outstanding at October 31, 2021 | 7,409,992 | $ 3.76 | $ 27,893,269 |
| Options Exercisable at October 31, 2021 | 3,718,334 | $ 3.69 | $ 13,715,371 |

The following table summarizes information about stock options outstanding under the 2018 Share Plan as of October 31, 2021:

| | 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 | 3,939,992 | 7.69 | $ 3.42 | 2,872,223 | 7.27 | $ 3.55 |
| $ 3.96 - $5.30 | 3,470,000 | 8.98 | $ 4.16 | 846,111 | 8.23 | $ 4.16 |

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, 2021 is as follows:

| | Shares | Weighted Average Exercise Price Per Share | Aggregate Intrinsic Value |
|---|---|---|---|
| Options Outstanding at October 31, 2019 and 2020 | 1,698,000 | $ 2.58 | |
| Exercised | (56,000) | $ 2.58 | |
| Options Outstanding and Exercisable at October 31, 2021 | 1,642,000 | $ 2.58 | $ 3,604,190 |

The following table summarizes information about outstanding and exercisable Non-Plan Options as of October 31, 2021:

| Range of Exercise Prices | Number Outstanding and Exercisable | Weighted Average Remaining Contractual Life (in years) | Weighted Average Exercise Price |
|---|---|---|---|
| $ 2.58 | 1,642,000 | 0.82 | $ 2.58 |

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, 2021 and 2020, employees purchased 2,377 and 11,536 shares, respectively, with aggregate proceeds of approximately $6,000 and $18,000, respectively.

Common Stock Purchase Warrants

On November 1, 2019 an outstanding warrant, expiring on November 1, 2023, to purchase 25,000 shares of common stock at $4.04 per share, was exchanged for a stock option with the same terms as the warrant.

On October 30, 2020 we issued a warrant, expiring on October 30, 2025, to purchase 60,000 shares of common stock at $2.06 per share, vesting over five months, to a consultant for investor relations services. We recorded consulting expense of approximately $96,000 during the year ended October 31, 2021, based on the fair value of the warrant recognized on a straight-line basis over the vesting period.

As discussed in Note 3, in connection with the March 25, 2021 public offering, 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, 2021 is as follows:

| | Shares | Weighted Average Exercise Price Per Share | Aggregate Intrinsic Value |
|---|---|---|---|
| Warrants Outstanding at October 31, 2019 | 525,000 | $ 4.98 | |
| Issued | 60,000 | $ 2.06 | |
| Exchanged | (25,000) | $ 4.04 | |
| Warrants Outstanding at October 31, 2020 | 560,000 | $ 4.71 | |
| Issued | 300,000 | $ 6.56 | |
| Warrants Outstanding and Exercisable at October 31, 2021 | 860,000 | $ 5.36 | $ 162,600 |

The following table summarizes information about the Company's outstanding and exercisable warrants as of October 31**,** 2021:

| Range of Exercise Prices | Number Outstanding and Exercisable | Weighted Average Remaining Contractual Life (in years) | Weighted Average Exercise Price |
|---|---|---|---|
| $ 2.06 - $6.56 | 860,000 | 1.83 | $ 5.36 |

ZQX Advisors, LLC

ZQX Advisors, LLC ("ZQX") was an inactive joint venture in which we held a 19.5% interest, and which was dissolved during fiscal year 2021. The only assets of ZQX were shares of our common stock which were sold during fiscal year 2021, for which we received proceeds of approximately $6,000.

6. 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 was set to expire on September 30, 2021. Effective August 17, 2021, the lease was amended to extend the expiration date to 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 amendment to the lease resulted in a right-of-use asset and lease liability of approximately $260,000 with a discount rate of 10%. Rent expense was approximately $64,000 and $64,000, respectively, for the years ended October 31, 2021 and 2020.

On November 1, 2019, the Company adopted ASC 842, which increases transparency and comparability by recognizing a lessee's rights and obligations resulting from leases by recording them on the balance sheet as lease assets and lease liabilities. The new guidance requires the recognition of the right-of-use ("ROU") assets and related operating lease liabilities on the balance sheet. The Company adopted the new guidance using the modified retrospective approach on November 1, 2019. The Company elected the package of practical expedients permitted within the standard, which allow an entity to forgo reassessing (i) whether a contract contains a lease, (ii) classification of leases, and (iii) whether capitalized costs associated with a lease meet the definition of initial direct costs. Also, the Company elected the expedient allowing an entity to use hindsight to determine the lease term and impairment of ROU assets and the expedient to allow the Company to not have to separate lease and non-lease components. The Company has also elected the short-term lease accounting policy under which Anixa would not recognize a lease liability or ROU asset for any lease that at the commencement date has a lease term of twelve months or less and does not include a purchase option that Anixa is more than reasonably certain to exercise.

For operating leases, the lease liability is initially and subsequently measured at the present value of the unpaid lease payments. The remaining 59-month lease term as of October 31, 2021 for the Company's lease includes the noncancelable period of the lease and the additional two-year option period that the Company expects to exercise. All ROU assets are reviewed for impairment.

Balance sheet information related to the Company's lease is presented below:

| | Balance Sheet Location | October 31, 2021 | October 31, 2020 |
|---|---|---|---|
| Operating Lease: | | | |
| Right-of-use asset | Operating lease right- of-use asset | 253,955 | 54,340 |
| Right-of-use liability, current | Operating lease liability | 39,397 | 55,198 |
| Right-of-use liability, long-term | Operating lease liability, non-current | 220,082 | - |

As of October 31, 2021, the annual minimum lease payments of our operating lease liability were as follows:

| For Years Ending October 31, | Operating Leases |
|---|---|
| 2022 | $ 63,579 |
| 2023 | 65,491 |
| 2024 | 67,452 |
| 2025 | 69,473 |
| 2026 | 65,428 |
| Total future minimum lease payments, undiscounted | 331,423 |
| Less: Imputed interest | 71,944 |
| Present value of future minimum lease payments | $ 259,479 |

## 7. 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.

### Collaborative Research and License Commitments

As of October 31, 2021, our commitments under the collaborative and license agreements with Moffitt, Wistar, Cleveland Clinic and MolGenie for the year ending October 31, 2022 were approximately $345,000.

### Impact of Coronavirus Pandemic

The ongoing global outbreak of COVID-19 has resulted in significant governmental measures being implemented to control the spread of the virus and while the Company cannot predict their scope or the severity of the outbreak, these developments and measures could materially and adversely affect the Company's business, the operations of the Company's collaboration partners, and the Company's results of operations and financial condition. The Company is closely monitoring the impact of the COVID-19 pandemic on all aspects of its business and has taken steps to minimize its impact on the Company's business. Although COVID-19 has not had a material adverse impact on the Company's operations and its clinical and preclinical programs, the extent to which COVID-19 ultimately impacts the Company's business, results of operations or financial condition will depend on future developments which are highly uncertain and cannot be predicted with confidence, such as the duration of the outbreak, the occurrence of new mutations of the SARS-CoV-2 virus, new information that may emerge concerning the severity of COVID-19 or the effectiveness of actions taken to contain the pandemic or mitigate its impact, among others. Certain of the Company's collaboration partners have experienced shutdowns or other business disruptions. As a result, the Company's ability to conduct its business in the manner and on the timelines presently planned could be materially or negatively affected, which could have a material adverse impact on the Company's business, results of operations and financial condition.

8. INCOME TAXES

Income tax provision (benefit) consists of the following:

| | Year Ended October 31, | |
|---|---|---|
| | 2021 | 2020 |
| Federal: | | |
| Current | $ - | $ - |
| Deferred | 604,000 | 404,000 |
| State: | | |
| Current | - | - |
| Deferred | (129,000) | (800,000) |
| Adjustment to valuation allowance related to net deferred tax assets | (475,000) | 396,000 |
| | $ - | $ - |

The tax effects of temporary differences that give rise to significant portions of the deferred tax asset, net, at October 31, 2021 and 2020, are as follows:

| | October 31, | |
|---|---|---|
| | 2021 | 2020 |
| Long-term deferred tax assets: | | |
| Federal and state NOL and tax credit carryforwards | $ 20,230,000 | $ 19,727,000 |
| Deferred compensation | 7,502,000 | 8,009,000 |
| Intangibles | 330,000 | 828,000 |
| Other | 219,000 | 192,000 |
| Subtotal | 28,281,000 | 28,756,000 |
| Less: valuation allowance | (28,281,000) | (28,756,000) |
| Deferred tax asset, net | $ - | $ - |

As of October 31, 2021, we had tax net operating loss and tax credit carryforwards of approximately $82,393,000 and $1,597,000, respectively, available within statutory limits (expiring at various dates between 2022 and 2041), to offset any future regular Federal corporate taxable income and taxes payable. 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, 2021, management has not determined the extent of any such limitations, if any.

We had California tax net operating loss carryforwards of approximately $32,714,000 as of October 31, 2021, available within statutory limits (expiring at various dates between 2022 and 2041), to offset future corporate taxable income and taxes payable, if any, under certain computations of such taxes.

We have provided a 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, | | | |
|---|---|---|---|---|
| | 2021 | | 2020 | |
| Income tax benefit at U.S. Federal statutory income tax rate | $ (2,757,000) | (21.00)% | $ (2,119,000) | (21.00)% |
| State income taxes | (917,000) | (6.98)% | (705,000) | (6.98)% |
| Permanent differences | 23,000 | 0.17% | 32,000 | 0.32% |
| Expiring net operating losses, credits and other | 4,126,000 | 31.43% | 2,396,000 | 23.74% |
| Change in valuation allowance | (475,000) | (3.62)% | 396,000 | 3.92% |
| Income tax provision | $ - | 0.00% | $ - | 0.00% |

During the two fiscal years ended October 31, 2021, we incurred no Federal and no State income taxes. We have no unrecognized tax benefits as of October 31, 2021 and 2020 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.

## 9. 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 five reportable segments, each with different operating and potential revenue generating characteristics: (i) CAR-T Therapeutics, (ii) Cancer Vaccines, (iii) Anti-Viral Therapeutics, (iv) our legacy Cancer Diagnostics activities and (v) our legacy Patent Licensing activities. The following represents selected financial information for our segments for the years ended October 31, 2021 and 2020:

| | Year Ended October 31, | |
|---|---|---|
| | 2021 | 2020 |
| Net income/(loss): | | |
| CAR-T Therapeutics | $ (5,672,622) | $ (2,241,443) |
| Cancer Vaccines | (4,558,811) | (828,136) |
| Anti-Viral Therapeutics | (2,927,979) | (1,168,969) |
| Cancer Diagnostics | (78,067) | (5,836,594) |
| Patent Licensing | 109,556 | (17,221) |
| Total | $ (13,127,923) | $ (10,092,363) |
| | | |
| Total operating costs and expenses | $ 13,648,192 | $ 9,978,202 |
| Less non-cash share-based compensation | (8,058,078) | (4,137,460) |
| Operating costs and expenses excluding non-cash share-based compensation | $ 5,590,114 | $ 5,840,742 |
| | | |
| Operating costs and expenses excluding non-cash share based compensation: | | |
| CAR-T Therapeutics | $ 2,421,487 | $ 1,141,542 |
| Cancer Vaccines | 1,641,977 | 365,681 |
| Anti-Viral Therapeutics | 1,080,279 | 739,140 |
| Cancer Diagnostics | 49,170 | 3,581,377 |
| Patent Licensing | 397,201 | 13,002 |
| Total | $ 5,590,114 | $ 5,840,742 |

| | October 31, | |
|---|---|---|
| | 2021 | 2020 |
| Total assets: | | |
| CAR-T Therapeutics | $ 15,067,933 | $ 2,988,124 |
| Cancer Vaccines | 13,276,518 | 946,923 |
| Anti-Viral Therapeutics | 7,368,214 | 2,464,361 |
| Cancer Diagnostics | 391,618 | 2,869,529 |
| Patent Licensing | 153,121 | 184,027 |
| Total | $ 36,257,404 | $ 9,452,964 |

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 $512,500 and inventor royalties, contingent legal fees, litigation and licensing expense of $385,002, for the year ended October 31, 2021 were solely related to our patent licensing segment. All our revenue is generated domestically (United States) based on the country in which the licensee is located.

**Exhibit 4.2**

**NEITHER THIS SECURITY NOR THE SECURITIES ISSUABLE UPON EXERCISE HEREOF HAS BEEN REGISTERED UNDER THE UNITED STATES SECURITIES ACT OF 1933, AS AMENDED (THE "ACT"), OR ANY STATE SECURITIES OR "BLUE SKY LAWS," AND MAY NOT BE OFFERED, SOLD, TRANSFERRED, ASSIGNED, PLEDGED OR HYPOTHECATED ABSENT AN EFFECTIVE REGISTRATION THEREOF UNDER SUCH ACT OR COMPLIANCE WITH RULE 144 PROMULGATED UNDER SUCH ACT, OR UNLESS THE COMPANY HAS RECEIVED AN OPINION OF COUNSEL, REASONABLY SATISFACTORY TO THE COMPANY AND ITS COUNSEL, THAT SUCH REGISTRATION IS NOT REQUIRED.**

Warrant No. _____

Void after 5:00 p.m. Eastern Time on October 30, 2026 (subject to Section 2 herein, the "***Expiration Date***")

November 1, 2021

ANIXA BIOSCIENCES, INC.

WARRANT TO PURCHASE SHARES OF COMMON STOCK

This Warrant is issued to ACORN MANAGEMENT PARTNERS, L.L.C. (the "***Holder***") by ANIXA BIOSCIENCES, INC., a Delaware corporation (the "***Company***"), pursuant to the terms of that certain Professional Relations and Consulting Agreement, dated as of November 1, 2021, by and among the Company and the Holder (the "***Agreement***").

1. Purchase of Shares. Subject to the terms and conditions hereinafter set forth, the Holder of this Warrant is entitled, upon surrender of this Warrant at the principal office of the Company (or at such other place as the Company shall notify the Holder hereof in writing), to purchase from the Company up to SIXTY THOUSAND (60,000) shares of the Company's Common Stock (the "***Common Stock***") at the Exercise Price.

2. Exercise Period. This Warrant shall vest and become exercisable such that TEN THOUSAND (10,000) shares underlying the Warrant shall vest and become exercisable on the first day of each month beginning on November 1, 2021 through April 1, 2022. The vested and exercisable portion of this Warrant may be exercised at any time on or prior to the Expiration Date. Notwithstanding the foregoing, if the Agreement is terminated for any reason, the vesting of this Warrant pursuant to this Section 2 shall immediately cease, the unvested portion of this Warrant shall immediately expire unexercised and the Termination Date of this Warrant shall be accelerated such that this Warrant shall terminate thirty (30) calendar days after the termination of the Agreement. For the avoidance of any doubt, by way of example, if the Agreement is terminated on December 15, 2021, this Warrant shall be exercisable for 20,000 shares of Common Stock and shall expire on January 14, 2022.

3. Exercise Price. The initial Exercise Price of this Warrant shall be $4.77 per share as adjusted for stock splits, stock dividends, combinations and the like.

4. Method of Exercise. While this Warrant remains outstanding and is exercisable in accordance with Section 2 above, the Holder may exercise, in whole or in part, the purchase rights evidenced hereby. Such exercise shall be effected by:

(a) the surrender of the Warrant, together with a notice of exercise to the Secretary of the Company at its principal offices during normal business hours on any business day prior to the Expiration Date; and

(b) the payment to the Company of an amount equal to the aggregate Exercise Price for the number of shares of Common Stock being purchased in the form of cash or certified or bank check payable to the order of the Company.

The Company agrees that the shares of Common Stock issuable upon exercise of the Warrants shall be deemed to be issued to the Holder as the record holder of such shares as of the close of business on the date on which this Warrant shall have been surrendered and payment made for such shares as aforesaid. Notwithstanding the foregoing, no such surrender shall be effective to constitute the person or entity entitled to receive such shares as the record holder thereof while the transfer books of the Company for the Common Stock are closed for any purpose (but not for any period in excess of five (5) days); but any such surrender of this Warrant for exercise during any period while such books are so closed shall become effective for exercise immediately upon the reopening of such books, as if the exercise had been made on the date this Warrant was surrendered and for the number of shares of Common Stock and at the Exercise Price in effect at the date of such surrender. This Warrant and all rights and options hereunder shall expire on the Expiration Date, and shall be wholly null and void and of no value to the extent this Warrant is not exercised before it expires.

5. Cashless Exercise. In lieu of exercising this Warrant in cash as described in Section 4, this Warrant may also be exercised, in whole or in part, at such time by means of a "cashless exercise" in which the Holder, upon exercise, shall be entitled to receive a number of shares of Common Stock equal to the quotient obtained by dividing [(A-B) (X)] by (A), where:

(A) = the five (5) day VWAP on the trading day immediately preceding the date on which Holder elects to exercise this Warrant by means of a "cashless exercise," as set forth in the notice of exercise;
`

(B) = the Exercise Price of this Warrant, as adjusted hereunder; and

(X) = the number of shares of Common Stock that would be issuable upon exercise of this Warrant in accordance with the terms of this Warrant if such exercise were by means of a cash exercise rather than a cashless exercise.

Upon a cashless exercise, the Holder shall receive shares in accordance with the terms of Section 4 above, provided that no cash payment will be required with the surrendered Warrant and notice of exercise. For purposes of this Section 5, "***VWAP***" means, for any date, the price determined by the first of the following clauses that applies: (a) if the Common Stock is then listed or quoted on a "national securities exchange," the daily volume weighted average price of the Common Stock for such date (or the nearest preceding date) on the trading market on which the Common Stock is then listed or quoted as reported by Bloomberg L.P. (based on a trading day from 9:30 a.m. (New York City time) to 4:02 p.m. (New York City time)), (b) if the Common Stock is then quoted on the OTCQB or OTCQX, the volume weighted average price of the Common Stock for such date (or the nearest preceding date) on OTCQB or OTCQX as applicable, (c) if the Common Stock is not then listed or quoted for trading on OTCQB or OTCQX and if prices for the Common Stock are then reported in the "Pink Sheets" published by OTC Markets, Inc. (or a similar organization or agency succeeding to its functions of reporting prices), the most recent bid price per share of the Common Stock so reported, or (d) in all other cases, the fair market value of a share of Common Stock as determined by an independent appraiser selected in good faith by the Holder and reasonably acceptable to the Company, the fees and expenses of which shall be paid by the Company.

6. Certificates for Common Stock. Upon the exercise of the purchase rights evidenced by this Warrant, one or more certificates for the number of shares of Common Stock so purchased shall be issued as soon as practicable thereafter, and in any event within five (5) days of the delivery of the exercise notice and other deliverables required herein. Notwithstanding the foregoing, the Company, at its sole discretion, may elect to issue the shares of Common Stock so exercised in uncertificated, book entry form on the books and records of the Company.

7. Issuance of Common Stock. The Company covenants that the shares of Common Stock, when issued pursuant to the exercise of this Warrant, will be duly and validly issued, fully paid and nonassessable and free from all taxes, liens and charges with respect to the issuance thereof; provided, however, that the Holder shall be required to pay any and all taxes that may be payable in respect of any transfer involved in the issuance and delivery of any certificate in a name other than that of the then Holder as reflected upon the books of the Company.

8. Adjustment of Exercise Price and Number of Shares of Common Stock. The number of and kind of securities purchasable upon exercise of this Warrant and the Exercise Price shall be subject to adjustment from time to time as follows:

(a) Stock Dividends and Splits. If the Company, at any time while this Warrant is outstanding: (i) pays a stock dividend or otherwise makes a distribution or distributions on shares of its Common Stock or any other equity or equity equivalent securities payable in shares of Common Stock (which, for avoidance of doubt, shall not include any shares of Common Stock issued by the Company upon exercise of this Warrant), (ii) subdivides outstanding shares of Common Stock into a larger number of shares, (iii) combines (including by way of reverse stock split) outstanding shares of Common Stock into a smaller number of shares or (iv) issues by reclassification of shares of the Common Stock any shares of capital stock of the Company, then in each case the Exercise Price shall be multiplied by a fraction of which the numerator shall be the number of shares of Common Stock outstanding immediately before such event and of which the denominator shall be the number of shares of Common Stock outstanding immediately after such event, and the number of shares issuable upon exercise of this Warrant shall be proportionately adjusted such that the aggregate Exercise Price of this Warrant shall remain unchanged. Any adjustment made pursuant to this Section 8(a) shall become effective immediately after the record date for the determination of stockholders entitled to receive such dividend or distribution and shall become effective immediately after the effective date in the case of a subdivision, combination or re-classification.

(b) Reclassification, Reorganization and Consolidation. In case of any reclassification, capital reorganization or change in the capital stock of the Company (other than as a result of a subdivision, combination or stock dividend provided for in Section 8(a) above), then the Company shall make appropriate provision so that the Holder of this Warrant shall have the right at any time prior to the expiration of this Warrant to purchase, at a total price equal to that payable upon the exercise of this Warrant, the kind and amount of shares of stock and other securities and property receivable in connection with such reclassification, reorganization or change by a Holder of the same number of shares of Common Stock as were purchasable by the Holder of this Warrant immediately prior to such reclassification, reorganization or change. In any such case appropriate provisions shall be made with respect to the rights and interest of the Holder of this Warrant so that the provisions hereof shall thereafter be applicable with respect to any shares of stock or other securities and property deliverable upon exercise hereof, and appropriate adjustments shall be made to the purchase price per share payable hereunder, provided the aggregate purchase price shall remain the same.

(c) Notice of Adjustment. When any adjustment is required to be made in the number or kind of shares purchasable upon exercise of the Warrant, or in the Exercise Price, the Company shall promptly notify the Holder of such event and of the number of shares of Common Stock or other securities or property thereafter purchasable upon exercise of this Warrant.

(d) No Fractional Shares or Scrip. If as a result of any adjustment pursuant to this Section 8, the Holder would be entitled to receive a fractional interest in a share of Common Stock, the Company will, upon exercise, round down to the nearest whole number of shares of Common Stock issuable to the Holder.

9. Restrictive Legend. The shares of Common Stock received upon exercise of this Warrant (unless registered under the Act) shall be stamped or imprinted with a legend in substantially the following form:

> "THE SHARES REPRESENTED BY THIS CERTIFICATE HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "ACT"), AND HAVE BEEN ACQUIRED FOR INVESTMENT AND NOT WITH A VIEW TO, OR IN CONNECTION WITH, THE SALE OR DISTRIBUTION THEREOF. NO TRANSFER OF THESE SHARES OR ANY INTEREST THEREIN MAY BE MADE EXCEPT: (I) PURSUANT TO AN EFFECTIVE REGISTRATION STATEMENT UNDER THE ACT; (II) PURSUANT TO AND IN ACCORDANCE WITH THE TERMS AND CONDITIONS OF RULE 144; OR (III) PURSUANT TO AN OPINION OF COUNSEL SATISFACTORY TO THE ISSUER THAT SUCH TRANSFER DOES NOT REQUIRE REGISTRATION UNDER THE ACT."

10. Transfer of Warrant.

(a) Limitation on Transfer. The Holder shall not, directly or indirectly, sell, give, assign, hypothecate, pledge, encumber, grant a security interest in or otherwise dispose of (whether by operation of law or otherwise) (each a "**Transfer**") this Warrant or any right, title or interest herein or hereto, except in accordance with the provisions of this Warrant. Any attempt to Transfer this Warrant, in whole or in part, or any rights hereunder in violation of the preceding sentence shall be null and void ab initio and the Company shall not register any such Transfer.

(b) Transfer Procedures. If the Holder wishes to Transfer this Warrant to a transferee (a "**Transferee**") under this Section 10, the Holder shall give notice to the Company through the use of the assignment form attached hereto as Exhibit B of its intention to make any Transfer permitted under this Section 10 not less than five (5) days prior to effecting such Transfer, which notice shall state the name and address of each Transferee to whom such Transfer is proposed. This Warrant may, in accordance with the terms hereof, be transferred in whole or in part. If this Warrant is transferred in whole, the assignee shall receive a new Warrant (registered in the name of such assignee or its nominee) which new Warrant shall cover the number of shares assigned. If this Warrant is transferred in part, the assignor and assignee shall each receive a new Warrant (which, in the case of the assignee, shall be registered in the name of the assignee or its nominee), each of which new Warrant shall cover the number of shares not so assigned and in respect of which no such exercise has been made in the case of the assignor and the number of shares so assigned, in the case of the assignee.

(c) Transfers in Compliance with Law; Substitution of Transferee. Notwithstanding any other provision of this Warrant, no Transfer may be made pursuant to this Section 10 unless (a) the Transferee has agreed in writing to be bound by the terms and conditions hereto, (b) the Transfer complies in all respects with the applicable provisions of this Warrant, and (c) the Transfer complies in all respects with applicable federal and state securities laws, including, without limitation, the Securities Act. If requested by the Company in its reasonable judgment, the transferring Holder shall supply to the Company (x) an opinion of counsel, at such transferring Holder's expense, to the effect that such Transfer complies with the applicable federal and state securities laws; and (y) a written statement to the Company, in such form as it may reasonably request, certifying that the Transferee is an "accredited investor" as defined in Rule 501(a) under the Securities Act.

11. Rights of Stockholders. Except as described elsewhere herein, no holder of this Warrant shall be entitled, as a Warrant holder, to vote or receive dividends or be deemed the holder of shares of Common Stock or any other securities of the Company which may at any time be issuable on the exercise hereof for any purpose, nor shall anything contained herein be construed to confer upon the holder of this Warrant, as such, any of the rights of a stockholder of the Company or any right to vote for the election of directors or upon any matter submitted to stockholders at any meeting thereof, or to give or withhold consent to any corporate action (whether upon any recapitalization, issuance of stock, reclassification of stock, change of par value, consolidation, merger, conveyance, or otherwise) or to receive notice of meetings, or to receive dividends or subscription rights or otherwise until the Warrant shall have been exercised and the shares of Common Stock purchasable upon the exercise hereof shall have become deliverable, as provided herein.

12. Loss, Theft, Destruction or Mutilation of Warrant. The Company covenants that upon receipt by the Company of evidence reasonably satisfactory to it of the loss, theft, destruction or mutilation of this Warrant or any stock certificate relating to the shares of Common Stock issuable upon exercise of this Warrant, and in case of loss, theft or destruction, of indemnity or security reasonably satisfactory to it (which, in the case of the Warrant, shall not include the posting of any bond), and upon surrender and cancellation of such Warrant or stock certificate, if mutilated, the Company will make and deliver a new Warrant or stock certificate of like tenor and dated as of such cancellation, in lieu of such Warrant or stock certificate.

13. Authorized Shares. The Company covenants that, during the period the Warrant is outstanding, it will reserve from its authorized and unissued Common Stock a sufficient number of shares to provide for the issuance of all of the shares issuable upon the exercise of any purchase rights under this Warrant.

14. Entire Agreement. This Warrant constitutes the entire agreement between the Company and the Holder with respect to the Warrant.

15. Notices. All notices and other communications required or permitted hereunder shall be in writing, shall be effective when given, and shall in any event be deemed to be given upon receipt or, if earlier, (a) five (5) days after deposit with the U.S. Postal Service or other applicable postal service, if delivered by first class mail, postage prepaid, (b) upon delivery, if delivered by hand, (c) one business day after the business day of deposit with Federal Express or similar overnight courier, freight prepaid, if such overnight delivery is requested, or (d) one business day after the business day of facsimile transmission, if delivered by facsimile transmission with copy by first class mail, postage prepaid, and shall be addressed (i) if to the Holder, at the Holder's address as set forth in the Agreement, and (ii) if to the Company, at the address as set forth in the Agreement, or at such other address as a party may designate by ten days advance written notice to the other party pursuant to the provisions above.

16. Governing Law. This Warrant and all actions arising out of or in connection with this Warrant shall be governed by and construed in accordance with the General Corporation Law of the State of Delaware as to matters within the scope thereof, and as to all other matters shall be governed by and construed in accordance with the internal laws of the State of Delaware, without regard to conflict of law principles that would result in the application of any law other than the law of the State of Delaware.

17. Remedies. The Holder, in addition to being entitled to exercise all rights granted by law, including recovery of damages, will be entitled to specific performance of its rights under this Warrant. The Company agrees that monetary damages would not be adequate compensation for any loss incurred by reason of a breach by it of the provisions of this Warrant.

18. Successors and Assigns. Subject to applicable securities laws, this Warrant and the rights evidenced hereby shall inure to the benefit of and be binding upon the successors and permitted assigns of the Company. The provisions of this Warrant are intended to be for the benefit of any Holder from time to time of this Warrant.

19. Amendment and Waiver. No provision of this Warrant shall be waived or modified without the written consent of the Company and the Holder.

20. Severability. Wherever possible, each provision of this Warrant shall be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Warrant shall be prohibited by or invalid under applicable law, such provision shall be ineffective to the extent of such prohibition or invalidity, without invalidating the remainder of such provisions or the remaining provisions of this Warrant.

**[**Signature Page Follows**]**

Issued this ___ day of _____, 2021

**ANIXA BIOSCIENCES, INC.**

By: _____

Name: _____

Title: _____

**ANIXA BIOSCIENCES, INC.**
**SIGNATURE PAGE TO WARRANT TO PURCHASE COMMON STOCK**

**EXHIBIT A TO WARRANT**

**NOTICE OF EXERCISE**

TO: Anixa Biosciences, Inc.
3150 Almaden Expressway, Suite 250
San Jose, CA 95118

Attention: Michael Catelani

1. The undersigned hereby elects to purchase _____ shares of Common Stock pursuant to the terms of the attached Warrant).

2. The undersigned elects to exercise the attached Warrant:

[ ] by means of a cash payment, and tenders herewith payment in full for the purchase price of the shares being purchased, together with all applicable transfer taxes, if any.

[ ] by the cancellation of such number of shares of Common Stock underlying the Warrant as is necessary, in accordance with the formula set forth in Section 5, to exercise this Warrant with respect to the maximum number of shares of Common Stock purchasable pursuant to the cashless exercise procedure set forth in Section 5.

3. Please issue a certificate or certificates representing said shares of Common Stock in the name of the undersigned or in such other name as is specified below:

_____
(Name)

_____

_____
(Address)

_____
(Signature)

_____
(Name)

_____ _____
(Date) (Title)

**EXHIBIT B TO WARRANT**

**FORM OF TRANSFER**

(To be signed only upon transfer of Warrant)

FOR VALUE RECEIVED, the undersigned hereby sells, assigns and transfers unto _____ the right represented by the attached Warrant to purchase _____ shares of Common Stock of Anixa Biosciences, Inc. to which the attached Warrant relates.

Dated: _____

_____

(Signature must conform in all respects to name of Holder as specified on the face of the Warrant)

Address: _____

_____

_____

Signed in the presence of:

_____

_____

DocuSign Envelope ID: 26A41C84-D037-489C-AD92-1E460086D544

EXECUTION COPY

**AMENDED AND RESTATED MASTER COLLABORATION AGREEMENT**

THIS AMENDED AND RESTATED MASTER COLLABORATION AGREEMENT (this "Agreement") by and between H. LEE MOFFITT CANCER CENTER AND RESEARCH INSTITUTE, INC. a non-profit Florida corporation organized pursuant to Section 1004.43, Florida Statutes, whose address is 12902 Magnolia Drive Tampa, Florida 33612 ("Moffitt") and CERTAINTY THERAPEUTICS, INC., a corporation duly organized under the laws of Delaware whose address is 3150 Almaden Expressway, Suite 250, San Jose, California 95118 (hereinafter "Company") will be effective as of November 1, 2021 (hereinafter "Effective Date"), and upon execution, will amend, restate, and supersede in its entirety that certain Collaboration Agreement between the Parties, dated November 17, 2017 (the "Original Effective Date"), as amended by Amendment 1 thereto dated July 24, 2019 and Amendment 2 thereto dated October 16, 2020 (as amended, the "Original Collaboration Agreement") in accordance with Section 13.9 of the Original Collaboration Agreement. Each of Moffitt and Company may be referred to herein as a "Party" or together as the "Parties".

WHEREAS, the Company has been formed to exploit certain intellectual property obtained in a license from The Wistar Institute of Anatomy and Biology pursuant to a License Agreement between The Wistar Institute of Anatomy and Biology ("Wistar") and Company, dated November 13, 2017; and

WHEREAS, Moffitt is a National Cancer Institute designated comprehensive cancer center, a statewide research institute, and a national resource for basic science, clinical research, and interdisciplinary approaches to research and patient treatment; and

WHEREAS, the Parties have successfully completed the first Research Plan outlined in the Original Collaboration Agreement, which was described in Exhibits A, B, and C in that Original Collaboration Agreement and shall hereto be combined and incorporated by reference into this Agreement as Exhibit A-1; and

WHEREAS, the Parties wish to amend and restate the Original Collaboration Agreement in its entirety on the terms and subject to the conditions set forth in this Agreement to augment the scope of the Original Collaboration Agreement to include additional Research Plans and revise certain other terms and conditions of the Original Collaboration Agreement.

NOW THEREFORE, in consideration of the foregoing and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereby agree as follows:

ARTICLE 1 DEFINITIONS.

1.1. The foregoing recitals are hereby incorporated herein by reference and acknowledged as true and correct. Unless specifically set forth to the contrary in this Agreement, the following terms, whether use in the singular or plural, shall have the respective meanings set forth below.

(a) "Anti-Corruption Laws" shall mean any anti-bribery and anti-corruption laws, rules, regulations applicable to a Party under this Agreement (each as amended from

time to time) including the Prevention of Corruption Act (cap.241) of Singapore, the U.S. Anti-Kickback Law, U.S. Foreign Corrupt Practices Act, the UK Bribery Act 2010 and the OECD Convention Against the Bribery of Foreign Government Officials in International Business Transactions, together with any applicable implementing legislation, including any applicable local law addressing bribery or corruption.

(b) "Confidential Information" shall mean all information and materials, including but not limited to invention disclosures, proprietary technologies, economic information, business or research strategies, trade secrets and material embodiments thereof, furnished by or on behalf of such Party under this Agreement or the Original Collaboration Agreement which would reasonably be considered to be proprietary or confidential, or that is marked "confidential" (or if provided in oral, visual or non-tangible form, made known at the time of disclosure to be confidential, but shall not include Data.

(c) "Data" shall mean Moffitt Data and Company Data.

(d) "Invention" shall mean any and all discoveries, developments, improvements, modifications, formulations, analogs or homologs, materials, compositions of matter, cell lines, processes, machines, manufactures and other inventions (whether or not patentable) conceived, discovered, or otherwise made under or arises from any Research Plan.

(e) "Joint Inventions" shall mean Inventions arising from any Research Plan and invented jointly on one hand by Company employees or persons obligated to assign Inventions to Company and on the other hand by Moffitt employees. Moffitt and Company shall jointly own all Joint Inventions.

(f) "Company Data" shall have the meaning set forth in Section 4.1.

(g) "Company Inventions" shall mean Inventions arising from any Research Plan and invented solely by Company employees or persons obligated to assign their Inventions to Company. Company retains all right, title, and interest in and to all Company Inventions.

(h) "Company Research Materials" shall mean (i) compound, cell line, mouse, vector, antibody, tissue, or any material transferred from Company to Moffitt while this Agreement is or the Original Collaboration Agreement was in full force and effect and (ii) is fully identified and described in a specific Research Plan, each of which is incorporated herein in its entirety, or the Original Collaboration Agreement. If Company Research Materials are not listed on or identified in such Research Plan or the Original Collaboration Agreement, then the Parties understand and agree that Company will not be providing any Company Research Materials under this Agreement.

(i) "Moffitt Data" shall have the meaning set forth in Section 4.1 of this Agreement.

(j) "Moffitt Inventions" shall mean Inventions arising from any Research Plan and invented solely by its employees, including from its employees use of Third Party Research Materials. Moffitt has the full right and authority to protect and commercialize Moffitt Inventions.

(k) "Moffitt Research Materials" shall mean (i) compound, cell line, mouse, vector, antibody, tissue, or any material generated or created under a specific Research Plan and transferred from Moffitt to Company while this Agreement is in full force and effect and (ii) is fully identified and described in such Research Plan. Moffitt Research Materials includes progeny and derivatives of Moffitt Research Materials. If Moffitt Research Materials are not listed on or identified in such Research Plan, then the Parties understand and agree that Moffitt will not be providing any Moffitt Research Materials under this Agreement.

(l) "Third Party Research Materials" shall mean any third party owned (i) compound, cell line, mouse, vector, antibody, tissue, or any material generated, created that Moffitt is required to use to conduct a Research Plan while this Agreement is in full force and effect and (ii) are identified and described in such Research Plan.

(m) "Option Period" shall have the meaning set forth in Section 6.5.

(n) "Negotiation Period" shall have the meaning set forth in Section 6.5.

(o) "Payments" shall mean, individually or collectively, all fees, payments, and/or other amounts payable by Company to Moffitt pursuant to this Agreement and one or more Research Plan(s).

(p) "Research Plan" shall mean a statement of work that is signed by the Parties and attached hereto as Exhibit A, which is incorporated herein in its entirety or later becomes attached through an amendment by the Parties. It is contemplated that each separate project under this Agreement shall have its own Research Plan and associated Payments. As each subsequent Research Plan and associated Payments are agreed to and signed by the Parties, each shall state that it is to be incorporated and made a part of this Agreement and shall be consecutively numbered as Exhibits A-1, A-2, A-3, etc., and utilize the template form for the Research Plan as outlined in Exhibit B. For clarity, the plural of "Research Plan" is "Research Plans". For further clarity, the first Research Plan outlined in the Original Collaboration Agreement, which was described in Exhibits A, B, and C in that Original Collaboration Agreement, shall be deemed Exhibit A-1 hereunder.

(q) "Term" shall have the meaning set forth in Section 7.1 of this Agreement.

## ARTICLE 2 SUPPLY OF RESEARCH MATERIALS.

2.1. Company agrees to provide Moffitt with the Company Research Materials to the extent set forth in a Research Plan. Company also may, at its discretion, provide Moffitt with certain information relating to the Company Research Materials. Moffitt agrees to provide Company with Moffitt Research Materials to the extent set forth in a Research Plan.

ARTICLE 3 RESEARCH ACTIVITIES.

3.1. Moffitt and Company shall and use commercially reasonable efforts to undertake the Research Plans under this Agreement. Any Research Plan may be modified, supplemented, or amended, but only as agreed to in writing by both Parties. The Parties acknowledge and agree that the performance of the Research Plan under Exhibit A-1 has been completed and that Moffitt has been fully compensated for such performance under the Original Collaboration Agreement.

3.2. Moffitt will use any Company Research Materials provided to Moffitt solely for research purposes in accordance with the applicable Research Plan. Moffitt will obtain written permission to use any Third Party Research Materials required to conduct the applicable Research Plan. Moffitt will not use Company Research Materials, Moffitt Research Materials, or Third Party Research Materials to conduct studies or trials in human subjects, in clinical trials, or for in vitro or in vivo diagnostic purposes involving human subjects without the prior written consent of Company. Moffitt will not transfer any Company Research Materials to a third party.

3.3. Company will use Moffitt Research Materials and Third Party Research Materials solely for research purposes in accordance with the applicable Research Plan. Company will not use Moffitt Research Materials or conduct studies or trials in human subjects, in clinical trials, or for in vitro or in vivo diagnostic purposes involving human subjects without the prior written consent of Moffitt. Company will not transfer Moffitt Research Materials to a third party. Company shall not use the Moffitt Research Material, Company Research Material, or Third Party Research Material to produce or manufacture products that will be sold, leased, licensed or transferred to any third party.

ARTICLE 4 DATA AND REPORTING.

4.1. "Moffitt Data" shall mean any data, results, analysis (including bioinformatic analysis), or other information generated by or in collaboration with Moffitt in its performance of any Research Plan or use of Company Research Materials or Third Party Research Materials. "Company Data" shall mean any data, results, analysis (including bioinformatic analysis), or other information generated by Company in its performance of any Research Plan or use of the Moffitt Research Materials. The Moffitt Data and Company Data shall be jointly owned by the Parties. Each Research Plan and all Moffitt Data and Company Data generated from conducting each Research Plan shall be conducted and recorded in accordance with Good Laboratory Practices (GLP) and in a manner to support an Investigational New Drug Application with the FDA. From time to time, the Company and its authorized agents, may monitor the conduct of any Research Plan, and generation of Moffitt Data in accordance with these requirements and may visit Moffitt and meet with the Moffitt principal investigator(s) responsible for the performance of the applicable Research Plan for the purpose of such monitoring. Any such monitoring or visits shall be scheduled with reasonable advance notice in coordination with Moffitt during normal business hours and under Moffitt's supervision. To the extent required by law, Moffitt shall also permit inspection by responsible legal and regulatory authorities with respect to any Research Plan and preclinical studies to be conducted in accordance with the applicable Research Plan or as otherwise reasonably necessary to satisfy the request of such authorities related to such

Research Plan. To the extent permitted by law and practicable, Moffitt shall notify Company of any such inspections. Throughout the Term, Moffitt shall maintain complete and accurate records of all Moffitt Data and provide Company a copy of such Moffitt Data at least quarterly and upon reasonable request by Company and its authorized agents at time intervals other than quarterly. Throughout the Term, Company shall maintain complete and accurate records of all Company Data and provide Moffitt a copy of such Company Data at least quarterly and upon reasonable request by Moffitt at time intervals other than quarterly. Within sixty days after the expiration or termination of this Agreement or completion of any applicable Research Plan, whichever is earlier, Moffitt shall promptly provide a written report, and copy, of any and all of the Moffitt Data to Company. Within sixty days after the expiration or termination of this Agreement or completion of any applicable Research Plan, whichever is earlier, Company shall promptly provide a written report, and copy, of any and all of the Company Data to Moffitt.

4.2. Company recognizes that Moffitt and any third party that may own rights in the Moffitt Data and may wish to publish the Data in scientific journals or present the Data at symposia or other academic meetings, and Company agrees that Moffitt (and any third party having rights in the Moffitt Data) will have the right to do so, solely in accordance with the following provisions. Moffitt will submit to Company any such proposed publication or presentation of the Data at least thirty (30) days prior to the submission for publication or presentation. If Company determines that the proposed publication or presentation contains patentable subject matter that requires protection, Company may require the delay of publication or presentation for an additional period of not more than thirty (30) days to permit the preparation and filing of a patent application. If Company, on its own, or after consultation with Wistar, determines that the proposed publication or presentation includes Company Confidential Information, it will so inform Moffitt, and Moffitt will delete such Company Confidential Information from any proposed disclosure as directed by Company. Notwithstanding the foregoing, once Company has reviewed a publication or presentation for written or oral disclosure and the additional period of 30 days to permit filing of a patent application has expired, Moffitt (and third parties) shall be allowed to freely disclose such publication or presentation in the future. If Moffitt makes any material changes to a publication or presentation, such publication or presentation must be re-submitted to Company for review in accordance with this Section 4.2.

4.3. The Parties may elect to collaborate together in writing a manuscript to be published in a respected scientific journal. For such jointly written manuscript, authorship shall be based on contributions to the applicable Research Plan, in accordance with academic standards and custom.

## ARTICLE 5 OWNERSHIP; NO IMPLIED LICENSE.

5.1. Moffitt acknowledges and agrees that, notwithstanding any other provisions of this Agreement, (i) Company holds all right, title, and interest in and to the Company Research Materials and Company Confidential Information, and (ii) Company has the right to use or permit others to use the Company Research Materials and Company Confidential Information at any time for any lawful purpose. No option, license, or conveyance of rights, express or implied, is granted by Company to Moffitt in connection with any Company Research Materials or Company Confidential Information, except the right to use the

Company Research Materials and Company Confidential Information in accordance with the terms of this Agreement.

5.2. Company acknowledges and agrees that, notwithstanding any other provisions of this Agreement, (i) Moffitt holds all right, title, and interest in and to the Moffitt Research Materials and Moffitt Confidential Information, and (ii) Moffitt has the right to use or permit others to use the Moffitt Research Materials and Moffitt Confidential Information at any time for any lawful purpose. No option, license, or conveyance of rights, express or implied, is granted by Moffitt to Company in connection with any Moffitt Research Materials or Moffitt Confidential Information, except the right to use the Moffitt Research Materials and Moffitt Confidential Information in accordance with the terms of this Agreement. For the avoidance of doubt, this does not affect the Company's joint ownership of the Moffitt Data as set forth in Section 4.1.

## ARTICLE 6 INVENTIONS.

6.1. Inventorship shall be determined by the patent laws of the United States and initial ownership shall follow inventorship. Each Party shall retain all of its right, title and interest in and to any and all inventions made prior to, or outside the activities of, this Agreement. Except as expressly set forth herein, no license, express or implied, is granted with respect to any patents, patent applications, know-how (whether patentable or unpatentable) or other intellectual property rights of the other Party.

6.2. Moffitt shall have the sole right to file, prosecute and maintain patent applications and patents with respect to Moffitt Inventions. Company shall have the sole right to file, prosecute and maintain patent applications and patents with respect to Company Inventions.

6.3. With respect to Joint Inventions, Company shall file, prosecute, and maintain patent applications on behalf of the Parties, at Company's sole expense. With respect to any Joint Invention, Company shall (a) consult with Moffitt and keep Moffitt fully informed of the progress of all patent applications and patents, including all issues relating to the preparation, filing, prosecution and maintenance of patent applications and patents that claim Joint Inventions, (b) consult with Moffitt and keep the Moffitt fully informed about Company's patent strategy with respect to patent applications that claim Joint Inventions, (c) provide to Moffitt advance copies of documents relevant to preparation, filing, prosecution and maintenance of the patent applications and patents that claim Joint Inventions sufficiently in advance of filing to allow Moffitt a reasonable opportunity to review and comment on such documents, (d) consider and implement all Moffitt comments on such patent filings, and (e) provide Moffitt with final copies of such documents.

6.4. Company hereby grants Moffitt a royalty free, non sublicensable, non transferable, perpetual, non exclusive license to use and practice any Company Invention for its internal non-commercial research purposes. Moffitt hereby grants Company a royalty free, non sublicensable, non transferable, perpetual, non exclusive license to use and practice any Moffitt Invention for its internal, non-commercial research purposes.

6.5. Moffitt hereby grants Company an option to a royalty-bearing, sublicensable, exclusive license in Moffitt Inventions and Moffitt's interest in Joint Inventions for such territories as Company may request. Company may exercise its option to such exclusive

license at any time within six (6) months after Moffitt notifies Company of a new Invention. ("Option Period"). In the event Company notifies Moffitt in writing that it wishes to exercise its option to an exclusive license during the Option Period, the Parties shall have six (6) months ("Negotiation Period") to agree on the terms of such license, which shall be negotiated in good faith under commercially reasonable terms. In the event that (a) Company fails to notify Moffitt of its desire to exercise its option to an exclusive license during the Option Period, or (b) Company notifies Moffitt that it does not wish to exercise its option to an exclusive license, or (c) the Parties are unable to agree on the terms of such license by the end of the Negotiation Period, then Moffitt shall have no further obligation to Company with respect to such Invention except that Company's internal research use license shall continue in effect.

6.6. Moffitt shall obtain all intellectual property rights in all data and intellectual property that any vendor or subcontractor Moffitt engages in performing any Research Plan. Any data that a vendor or subcontractor that Moffitt engages in performing any Research Plan generates or creates shall be treated as Moffitt Data jointly owned by Moffitt and the Company and any such subcontractor or vendor that Moffitt engages shall have no rights in and to such data, Moffitt also shall obtain all intellectual property rights in any new inventions that any vendor or subcontractor Moffitt engages develops in performing any Research Plan. To the extent that they are not Joint Inventions, any such inventions generated or created by a vendor or subcontractor that Moffitt engages in performing any Research Plan shall be treated as Moffitt Inventions, subject to Section 6.5. In the event that Moffitt engages a third party academic organization to perform any of the activities under any Research Plan, Moffitt shall use commercially reasonable efforts to obtain the greatest amount of data and intellectual property rights from such relationship. In any event, Moffitt shall ensure at a minimum, that any intellectual property that a third party academic organization creates or develops in the course of performing any Research Plan that is necessary for commercialization, shall be made available for license to Company on fair, reasonable, and non-discriminatory terms.

## ARTICLE 7 TERM AND TERMINATION.

7.1. This Agreement will commence as of the Effective Date set forth in the first paragraph of this Agreement and unless terminated otherwise as provided herein, this Agreement will expire forty-eight (48) months from such date, unless extended upon mutual written agreement of the Parties ("Term").

7.2. Either Party may terminate this Agreement (i) upon any breach by the other Party of the terms or conditions of this Agreement, which breach cannot be, or is not, cured within thirty (30) days after the breaching Party receives written notice by the non-breaching Party regarding such breach or (ii) upon the other Party becoming bankrupt or making an assignment for the benefit of its creditors, upon appointment of a trustee or receiver for the other Party of all or substantially all of its property, or upon the filing of a voluntary or involuntary petition by or against the other Party under any bankruptcy or insolvency law, the reorganization or rearrangement provisions of the United States Bankruptcy Code, or any similar law, (iii) or upon the termination, death, or other nonavailability of the Moffitt principal investigator(s) responsible for conducting the applicable Research Plan and the Parties cannot reach agreement on new principal investigators. The rights of termination

under this Section 7 will not be affected in any way by a Party's waiver or failure to take action with respect to any previous breach or other circumstance giving rise to the rights of termination hereunder.

7.3. Termination of this Agreement for any reason will be without prejudice to any rights that will have accrued to the benefit of either Party prior to such termination. Sections 3-6, 7.3, 8, 10, and 13 shall survive termination or expiration of this Agreement. Upon expiration or termination of this Agreement, Moffitt (i) will immediately terminate all Research Plans, including without limitation ceasing all uses of the Company Research Materials and Company Confidential Information, and (ii) will, at the direction of Company, within thirty days after termination, destroy or return (a) all Company Research Materials supplied to it and (b) all copies of the Company Confidential Information (except that Moffitt may retain one copy of the Company Confidential Information solely for archival purposes, subject to the obligations of Section 8 below). Upon expiration or termination of this Agreement, Company (i) will immediately terminate all Research Plans, including without limitation ceasing all uses of the Moffitt Research Materials and Moffitt Confidential Information, and (ii) will, at the direction of Moffitt, within thirty days after termination, destroy or return (a) all Moffitt Research Materials supplied to it and (b) all copies of the Moffitt Confidential Information (except that Company may retain one copy of the Moffitt Confidential Information solely for archival purposes, subject to the obligations of Section 8 below).

## ARTICLE 8 CONFIDENTIALITY AND USE.

8.1. To the extent permitted by law, the Parties shall safeguard the other Party's Confidential Information against disclosure to third parties with the same degree of care as it exercises with its own data of a similar nature. Moffitt and Company agree not to disclose Confidential Information to others (except to their employees, agents, independent contractors, consultants, or affiliates who are bound by a like obligation of confidentiality). The Parties shall use the Confidential Information of the other Party in furtherance of performing or carrying out their respective obligations and duties under this Agreement. Confidential Information does not include information which:

(a) is publicly available prior to the date of this Agreement or becomes publicly available thereafter through no wrongful act of the receiving Party;

(b) was known to the receiving Party prior to the date of disclosure or becomes known to the receiving Party thereafter from a third party having a bona fide right to disclose the information;

(c) the receiving Party can demonstrate, through written documentation, was in the receiving Party's rightful possession on a non-confidential basis prior to disclosure by the providing Party hereunder;

(d) the receiving Party can demonstrate, through written documentation, is disclosed to the receiving Party without restriction on further disclosure;

(e) the receiving Party can demonstrate, through written documentation, is independently developed without the use of the providing Party's Confidential Information;

(f) must reasonably be disclosed to regulatory authorities, provided that the receiving Party promptly notifies the providing Party to give the providing Party the opportunity to contest or limit the scope of such disclosure; or

(g) is obligated to produce pursuant to an order of a court of competent jurisdiction or a facially valid administrative, legislative or other subpoena or pursuant to applicable law, provided that the receiving Party promptly notifies the providing Party to give the providing Party the opportunity to contest or limit the scope of such order.

8.2. The obligations of confidentiality and non use under this Section 8 shall continue for five (5) years after the expiration or termination of this Agreement.

8.3. Use of Name; Publicity. The Parties may make the factual statement that Company has entered into this Agreement with Moffitt and may discuss the terms of this Agreement, any Research Plan, and progress and status of the completion of any Research Plan, in filings of the Company or Anixa Biosciences, Inc. made with the Securities Exchange Commission (SEC) and in investor or road show presentations.

## ARTICLE 9 NOTICES.

9.1. Any request, notice, report, payment, approval or other communication required or permitted under this Agreement will be in writing, and will be deemed delivered (i) on the date of delivery when delivered personally; (ii) on the date sent by confirmed facsimile (followed by the actual document sent by commercial express courier specifying next day delivery, with written verification of receipt); (iii) one business day after deposit with a commercial overnight courier specifying next day delivery, with written verification of receipt; or (iv) on the date received when sent by registered or certified mail, return receipt requested, postage prepaid; and (v) on the date received when sent by electronic mail. All communications will be sent to the address set forth below or such other address as either Party may designate from time to time in accordance with this Section 9.1.

To Company :
Certainty Therapeutics, Inc.
3150 Almaden Expressway,
Suite 250, San Jose, California 95118
Attn: Amit Kumar, Chief Executive Officer
Email: ak@anixa.com.com

To Moffitt:
H. Lee Moffitt Cancer Center and Research Institute, Inc.
Attention: Director, Office of Sponsored Research
12902 Magnolia Drive, MBC-OSR
Tampa, FL 33612
Fax: (813) 745-6804
awards@moffitt.org

With courtesy copies to:

H. Lee Moffitt Cancer Center and Research Institute, Inc.
Attention: Vice President for Research

DocuSign Envelope ID: 26A41C84-D037-489C-AD92-1E460086D544



Administration
12902 Magnolia Drive, SRB-3
Tampa, FL 33612
Fax: (813) 745-8709

H. Lee Moffitt Cancer Center and Research Institute, Inc.
Attn: L. David de la Parte, General Counsel
12902 Magnolia Drive
Tampa, Florida 33612-9497

ARTICLE 10 GOVERNING LAW.

10.1. This Agreement shall be governed by, and construed and interpreted in accordance with, the laws of the State of Florida without reference to conflict of laws principles or statutory rules of arbitration included therein. Any dispute or proceeding under this Agreement shall be subject to the exclusive jurisdiction and venue of the 13th Judicial Circuit in and for Hillsborough County, Florida and the Parties hereby consent to the exclusive personal jurisdiction and venue of these courts.

ARTICLE 11 WARRANTIES AND INDEMNIFICATION.

11.1. Moffitt accepts any Company Research Materials with the knowledge that they are experimental in nature and agree to comply with all laws and regulations for the shipping, handling and use thereof. COMPANY RESEARCH MATERIALS ARE BEING SUPPLIED "AS IS" WITH NO WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR WARRANTY AGAINST INFRINGEMENT. Company accepts the Moffitt Research Materials with the knowledge that they are experimental in nature and agree to comply with all laws and regulations for the shipping, handling and use thereof. MOFFITT RESEARCH MATERIALS ARE BEING SUPPLIED "AS IS" WITH NO WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR WARRANTY AGAINST INFRINGEMENT.

11.2. No indemnification for any loss, claim, damage, or liability is intended or provided by either Party under this Agreement. Each Party shall be liable for any loss, claim, damage or liability that said Party incurs as a result of said Party's activities under this Agreement.

ARTICLE 12 FINANCIAL TERMS.

12.1. Moffitt shall be compensated by Company for its conduct of each Research Plan in accordance with the firm fixed price amount as detailed in Section 4 of such Research Plan. The applicable Payments and Payment Schedules set forth the dollar amount and schedule for all payments owed to Moffitt for the performance of each Research Plan under this Agreement. Unless otherwise agreed in writing by the Parties, such payment amount is inclusive of any and all applicable fees, personnel costs, and overhead. For clarity, the Parties understand and agree that this is a firm fixed price contract and that there shall be no

allowances or reimbursement for any cost whatsoever except as otherwise explicitly provided in this Agreement or the applicable Research Plan.

The Parties certify that the funding amount of each Research Plan will be set in advance and consistent with fair market value in arms-length transactions. The Parties further certify that the Payments have not been determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the Parties for which payment may be made in whole or in part under Medicare, Medicaid, or other Federal health care programs. Each of Company and Moffitt acknowledge, represent, and agree that the financial consideration for the arrangements set forth in this Agreement and under any Research Plan issued pursuant to this Agreement shall be (i) consistent with the fair market value of the commitments, rights, goods, and services provided under such arrangement in arms-length transactions, and established through arms-length negotiations by Company and Moffitt; (ii) determined without reference to, or consideration of, in any manner, the formulary status, generation of business by one Party to another, clinical referrals, payment, or coverage of any Company or Company Affiliate pharmaceutical product on any health plan administered by Moffitt or any other payer Affiliate or division of Moffitt; and (iii) nothing contained in this Agreement or in a Research Plan shall be construed in any manner as an obligation or inducement for Moffitt or any of its staff involved in the research contemplated hereunder to refer patients or to order for patients any product manufactured or distributed by or on behalf of Company. Company and Moffitt agree to cooperate fully in any fair market value analysis conducted by the other Party or a third party engaged by the other Party to conduct such analysis.

## ARTICLE 13 MISCELLANEOUS.

13.1. The Parties shall have separate agreements with their employees whereby the employees are obligated to assign all right, title, and interest in any Invention generated in the course of any Research Plans to such Party.

13.2. Company shall perform any Research Plans and its other obligations hereunder, and use the Moffitt Research Materials in compliance with all applicable laws, regulations and legal requirements, including but not limited to those relating to biotechnological research, handling and containment of biohazardous materials, and use or disclosure of patient information or materials.

13.3. Moffitt shall perform any Research Plans and its other obligations hereunder, and use the Company Research Materials in compliance with all applicable laws, regulations and legal requirements, including but not limited to those relating to biotechnological research, handling and containment of biohazardous materials, and use or disclosure of patient information or materials.

13.4. Moffitt shall (a) comply with all applicable laws, rules and regulations pertaining to the development, testing, manufacture, marketing, import or export of any licensed products; and (b) not employ, contract with or retain any person directly or indirectly in the performance of any Research Plan if such person is: (i) excluded from a Federal health care program as outlined in Sections 1128 and 1156 of the Social Security Act (see the Office of Inspector General of the Department of Health and Human Services List of Excluded Individuals/Entities at http://www.oig.hhs.gov/fraud/exclusions/exclusions_list.asp), (ii)

debarred by any Health Authority, including (but not limited to) by the FDA under 21 U.S.C. 335a (see the FDA Office of Regulatory Affairs Debarment List at http://www.fda.gov/ICECI/EnforcementActions/FDADebarmentList/default.htm), or (iii) excluded from contracting with the federal government (see the Excluded Parties Listing System at www.sam.gov).

13.5. Moffitt acknowledges that the transfer and use by foreign nationals of certain commodities and technical data is subject to U.S. laws and regulations controlling the export and use by foreign nationals of such commodities and technical data, including the Arms Export Control Act, the International Traffic in Arms Regulations ("ITAR"), the Export Administration Regulations ("EAR") and the laws and regulations implemented by the Office of Foreign Assets Control, U.S. Department of the Treasury ("OFAC"). These laws and regulations, among other things, prohibit or require a license for the export or use by foreign nationals of certain types of technical data to specified countries. Moffitt shall comply with all such applicable U.S. laws and regulations in the performance of all Research Plans.

13.6. Moffitt agrees that it has not and will not, either directly or indirectly, engage in bribery, or offer, or promise, or authorize to pay or make any improper payment of any monies or financial or other advantage, including cash, loan, gift, travel, entertainment, hospitality, facilitation payment, kickback, political or philanthropic contribution, anything of value, or any other perceived benefit to improperly obtain or retain a business advantage in violation of any Anti-Corruption Laws and further, each Party hereunder agrees that it shall not take any action that would cause the other Party to be in violation of such Anti-Corruption Laws in the performance of all Research Plans.

13.7. The Parties represent and warrant that they have the right and authority to enter into this Agreement and perform its obligations and grant the rights granted hereunder and that no pre-existing or future obligation, through contract or otherwise, will substantially interfere with or prevent them from performing its obligations or substantially interfere with or prevent them from exercising its rights hereunder.

13.8. Each Party shall not assign or transfer any rights, obligations or duties under this Agreement without the prior written consent of the other Party.

13.9. This Agreement shall constitute the entire understanding between the Parties and supersedes any and all prior or contemporaneous representations, agreements and promises, written or oral, between the Parties regarding the subject matter of this Agreement. No modification, amendment, or waiver may be accomplished to the terms of the Agreement without the written consent of both Parties.

13.10. This Agreement may be executed in one or more counterpart copies (including by facsimile, pdf, or other electronic delivery), which when joined, shall together constitute one agreement.

13.11. In the event that any provision of this Agreement shall be found invalid, illegal or unenforceable, the validity, legality and enforceability of the remaining provisions shall not in any way be affected or impaired.

13.12. It is understood that this Agreement in no way alters any rights that the U.S. Government might have.

13.13. The headings preceding the text of each section of this Agreement are for convenience only and shall not be construed to define, modify, expand, limit, or affect the construction of or to be taken into account in interpreting the substance of this Agreement.

13.14. The failure of any Party hereto to enforce at any time, or for any period of time, any provision of this Agreement shall not be construed as a waiver of either such provision or of the right of such Party thereafter to enforce each and every provision of this Agreement.

13.15. Company shall comply with all applicable United States law and regulations controlling the export of certain commodities and technical data, including without limitation all Export Administration Regulations of the United States Department of Commerce. Among other things, these laws and regulations prohibit or require a license for the export of certain types of commodities and technical data to specified countries. Company hereby gives written assurance that it will comply with all applicable United States export control laws and regulations, that it bears sole responsibility for any violation of such laws and regulations by itself.

13.16. Anixa Biosciences, Inc. (formerly known as ITUS Corporation) hereby absolutely, unconditionally and irrevocably guarantees to Moffitt the Company's timely and faithful payment of all financial obligations to Moffitt as set forth in Section 12 and the Payment Schedules outlined in each Research Plan under this Agreement.

13.17. Moffitt is subject to requirements of Section 286.101, Florida Statues, which requires disclosure of aspects of contracts and grants with entities that are an agent, affiliate, or subsidiary of any legal entity, governmental or otherwise, created solely under the laws of the Russian Federation, the Republic of Iran, the People's Republic of China, the Democratic People's Republic of Korea, the Republic of Cuba, Bolivarian Republic of Venezuela, or the Syrian Arab Republic. Company represents that they are not an agent, affiliate, or subsidiary of a legal entity incorporated or formed as an entity in these listed nations. If Company is not able to truthfully make this representation, Company must provide Moffitt written notice contemporaneous with executing this Agreement describing Company's relationship with any of these listed nations. Company shall have a continuing obligation to provide timely notice to Moffitt in the event Company has become an agent, affiliate, or subsidiary of a legal entity incorporated or formed as an entity in these listed nations after execution of this Agreement. All notices to Moffitt required by this paragraph shall be made as provided in Section 9 of this Agreement.

For clarity, the Parties agree that the foregoing shall not be construed to prohibit disclosure by Moffitt of the identity of the Parties or the terms of this Agreement to the Florida Department of Financial Services or other state agencies, or political subdivisions in order to comply with the disclosure requirements of Florida Statute 286.101 and that any such disclosure shall not require notice to Company.

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their duly authorized representatives as of the Effective Date.

**CERTAINTY THERAPEUTICS, INC.**

By: _____

Name: Amit Kumar

Title: Chief Executive Officer (CEO)

**H. LEE MOFFITT CANCER CENTER AND RESEARCH INSTITUTE, INC.**

By: DocuSigned by: Lowell Smith EBD337A7261045D...

Name: Lowell Smith

Title: Sr. Director, Research Bus. Office

12/10/2021

**ANIXA BIOSCIENCES, INC.**

By: _____

Name: Michael Catelani

Title: Chief Operating Officer (COO)

EXECUTION COPY

EXHIBIT B

TEMPLATE FORM OF RESEARCH PLAN

**EXHIBIT A-#**

**RESEARCH PLAN AND PAYMENTS**

This Research Plan is entered into:

| | |
|---|---|
| Effective as of | [DATE] (the "**Research Plan Effective Date**") |
| by and between: | H. Lee Moffitt Cancer Center and Research Institute, Inc. (**"Moffitt"**)<br><br>and<br><br>[NAME OF COMPANY] ("**Company**") |
| Pursuant to:<br><br>The Amended and Restated Master Collaboration Agreement (the **"Agreement"**) effective as of:<br>[DATE OF AGREEMENT]<br><br>by and between Moffitt and Company | |

The terms and conditions of the Agreement are incorporated into this Research Plan by reference. In the event of a conflict between the Agreement and a Research Plan, the terms of the Agreement shall prevail. If there are terms in the Agreement that are not in this Research Plan, such silence does not constitute a conflict, discrepancy or inconsistency. All capitalized terms have the respective meanings given to them in the Agreement.

1. Research Plan Term.

   This Research Plan is effective as of the Research Plan Effective Date and continues in full force and effect until the earlier of (a) [DATE OF RESEARCH PLAN EXPIRATION ], or (b) mutually acceptable completion of the Research Plan, or (c) termination in accordance with the terms of the Agreement (the "**Research Plan Term**").

2. Description and Quantity of Moffitt Research Materials And Company Research Materials.

| **Company Research Material** | **Description of Material** | **Quantity(ies)** |
|---|---|---|
| | | |
| | | |

| **Moffitt Research Materials** | **Description of Material** | **Quantity(ies)** |
|---|---|---|

| | | |
|---|---|---|
| | | |
| | | |

3. Protocol; Description of Research.
[INSERT COPY OF THE RESEARCH PROPOSAL/PROTOCOL]

4. Payments and Invoicing.
   a. **Payments.** In consideration for the performance by Moffitt of its obligations under this Agreement and this Research Plan, Company agrees to pay Moffitt the following firm fixed price of _____dollars ($xxx,xxx) according to the terms contained herein and the Payment Schedule below.

| | |
|---|---|
| **Payment Schedule:** | $xx,xxx shall be due upon execution of this Research Plan |
| | |
| | |
| | |
| | |
| | |

   b. **Invoice Procedure.** Such amounts will be invoiced in United States Dollars to the attention of _____ at the following email address: _____. Moffitt's contact for invoicing questions will be listed on the invoice. Company will satisfy payment of all undisputed amounts as outlined in the Agreement to the account designated by Moffitt on the invoice with reference to this Agreement.

In order to demonstrate their agreement, the Parties have executed this Research Plan as of the Research Plan Effective Date.

| | |
|---|---|
| Agreed and Accepted: | Agreed and Accepted: |
| H. LEE MOFFITT CANCER CENTER AND RESEARCH INSTITUTE, INC. | COMPANY, INC. |
| By: _____ | By: _____ |
| Name: _____ | Name: _____ |
| Title: _____ | Title: _____ |

**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. 333-217060 and 333-232067) and Registration Statement on Form S-8 (No. 333-251942) of Anixa Biosciences, Inc. (the "Company") of our report dated January 4, 2022 relating to our audits of the Company's consolidated financial statements as of October 31, 2021 and 2020, and for each of the years then ended, included in the Company's Annual Report on Form 10-K for the year ended October 31, 2021.

HASKELL & WHITE LLP

Irvine, California
January 4, 2022

**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, President 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 4, 2022

*/s/ Amit Kumar*
Dr. Amit Kumar
Chairman of the Board, President 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, 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 4, 2022

*/s/ Michael J. Catelani*
Michael J. Catelani
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, President 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, 2021 (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 4, 2022

*/s/ Amit Kumar*

Dr. Amit Kumar
Chairman of the Board, President 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, 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, 2021 (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 4, 2022

*/s/ Michael J. Catelani*
Michael J. Catelani
Chief Operating Officer and
Chief Financial Officer