

**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, 2020
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

(State or Other Jurisdiction of
Incorporation or Organization)

11-2622630

(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:

Common Stock, \$.01 par value

Trading Symbol:

ANIX

Name of Each Exchange on Which Registered:

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.

| | |
|---|---|
| Accelerated filer <input type="checkbox"/> | Large accelerated filer <input type="checkbox"/> |
| Smaller reporting company <input checked="" type="checkbox"/> | Non-accelerated filer <input checked="" type="checkbox"/> |
| | Emerging growth company <input type="checkbox"/> |

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, 2020 (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 (\$1.89): \$35,235,950

On January 7, 2021, the registrant had outstanding 26,076,819 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., 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 technology, a novel form of chimeric antigen receptor T-cell (“CAR-T”) technology, initially focused on treating ovarian cancer, and the discovery and ultimately development of anti-viral drug candidates for the treatment of COVID-19 focused on inhibiting certain viral protein functions of the virus. Our vaccine programs include the development of a vaccine against triple negative breast cancer (“TNBC”), the most lethal form of breast cancer, and a vaccine against ovarian cancer.

Our subsidiary, Certainty Therapeutics, Inc. (“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 future 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. Certainty is working with researchers at Moffitt to complete and submit an Investigational New Drug (“IND”) application with the U.S. Food and Drug Administration (“FDA”) and to perform human clinical trials. In collaboration with researchers at Moffitt, Certainty is currently performing tests on the clinical materials and assuming successful and timely completion of those tests, we anticipate an IND application will be submitted with the FDA during the first calendar quarter of 2021.

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 identifying over 30 potentially effective compounds that could disrupt either the function of a viral enzyme called an endoribonuclease, known as Non-Structural Protein-15 (“NSP-15”), or the main protease (“M^{Pro}”) of the virus. Our *in silico* molecular modeling indicates that any of the NSP-15 or M^{Pro} inhibitors might disrupt the virus’ ability to replicate in humans. Several of the most promising compounds have been synthesized and *in vitro* biological assays of the compounds are ongoing. If the biological activity of any of these compounds is verified, they will be tested in animal studies to further evaluate their candidacy as COVID-19 therapeutics.

While a number of preventative vaccines have recently been or will soon be approved for emergency use by the FDA, 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 may limit 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 long-term safety. Furthermore, all current treatments require administration in a hospital setting, thus potentially continuing to overburden the healthcare system, while we anticipate our treatment to use an oral formulation and to be available at pharmacies.

We hold an exclusive worldwide, royalty-bearing license to use certain intellectual property owned or controlled by The Cleveland Clinic Foundation (“Cleveland Clinic”) relating to certain breast cancer vaccine technology developed at Cleveland Clinic. This technology pertains to the use of vaccines for the treatment or prevention of TNBC and other breast cancers which express the α -lactalbumin protein. The α -lactalbumin protein is only expressed during lactation in healthy women, but may also be expressed in individuals with certain breast cancers, most notably TNBC.

Working with researchers at Cleveland Clinic, in November 2020, we submitted an IND application with the FDA to begin human clinical trials of the vaccine. In December 2020, we received authorization from the FDA to commence enrollment and treatment of patients in a Phase 1a clinical trial. We have commenced activities necessary to prepare for treatment of patients in the Phase 1a trial, and we anticipate being prepared to treat the first enrolled patient in the spring of 2021.

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.

On July 2, 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 are working with researchers at Moffitt to complete studies necessary to submit an IND application with the FDA. We then anticipate taking this therapy into human clinical testing 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 have performed numerous studies in preparation for an 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.

In October 2018, we attended a pre-IND meeting with the FDA to discuss numerous aspects of the planned clinical trial of our CAR-T therapy for ovarian cancer. The FDA answered a number of questions, providing a good understanding of the design for the clinical trial in our IND application.

We have completed the manufacturing of the clinical grade vector and are in the process of testing the materials and completing the IND application. We anticipate filing the IND in the first calendar quarter of 2021. The IND application, after review and approval by the FDA, will enable us to begin testing our therapy in ovarian cancer patients. Assuming the FDA approves our IND application, we anticipate beginning the human clinical trial as early as mid-2021.

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 2.4% 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 2020, 22,000 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 48%. However, ovarian cancer survival varies substantially by age, with the overall five-year survival rate for women 65 and older of only 31%.

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 no proven broadly effective treatments. Further, all treatments that are currently being employed require administration in a hospital setting, thus continuing to overburden the healthcare system. In addition, nearly all treatments currently 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 for the purpose of discovering and ultimately developing anti-viral drug candidates for COVID-19. Our collaboration has focused on two specific proteins of the coronavirus. The first protein is the 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 will attempt to identify 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.

The second target is an endoribonuclease, Non-Structural Protein-15 (“NSP-15”), which plays a role in breaking up the ribonucleic acid, or the genetic content, of the virus. Recent studies have demonstrated that the endoribonuclease of many viruses, including the SARS virus of 2003 and, it is believed the SARS-CoV-2, binds to a human host protein. This protein-protein interaction appears to dramatically increase the infectivity of the virus. Because this interaction between a viral protein and a human protein appears to be common to many viruses, compounds that are able to effectively disrupt this interaction, could function as broad spectrum anti-virals in addition to addressing COVID-19.

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} or NSP-15 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.

We selected the ten most promising compounds for synthesis and biological analysis. Biological testing of these compounds requires use of live virus, which limits the laboratories qualified to perform the necessary assays to Biosafety Level 3 (“BSL-3”) or Biosafety Level 4 labs. While availability of these labs is limited, we successfully established a relationship with a BSL-3 government lab in Europe, where biological assays, including binding assays, cellular assays, and viral activity assays, are currently being performed. Further, this lab has animal facilities and upon completion of the biological testing, will be prepared to test the compounds in animals to determine which compound may be appropriate for clinical evaluation.

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 over 20 million cases of COVID-19 and over 350,000 deaths. According to World Health Organization (“WHO”) data, globally, there have been over 85 million cases and approximately 1.9 million people have died. Furthermore, over the last three months, infections and deaths have increased.

Currently, there are no broadly effective treatments for COVID-19. Further, the 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. 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.

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The market for an orally delivered COVID-19 treatment that would dramatically reduce hospitalization rates would be significant given the current infection rates. The most recent CDC predictions indicate that in the U.S. alone new infections will remain at over 1.3 million cases per week and deaths will be nearly 20,000 per week through January 2021.

Competition

Competition in the COVID-19 treatment and prevention market is fierce, with hundreds of therapies and vaccines currently in development. Recently, a number of preventative vaccines have received regulatory approvals in the U.S. and Europe. There are still many questions about these vaccines, such as persistence and viral escape, and it will take time before it is known how well and for how long they will provide protection from infection. 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.

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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 nearly all cases of ovarian epithelial 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*.

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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.

We have been working with researchers at Cleveland Clinic to advance the breast cancer vaccine technology toward human clinical testing, and recently submitted an IND application to the FDA. In December 2020, we received authorization from the FDA to commence enrollment and treatment of patients in a Phase 1a clinical trial.

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 2020, 276,000 new cases of breast cancer will be diagnosed in the U.S. and 42,000 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., 276,000 women are estimated to be diagnosed with breast cancer this year, there are approximately 80 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 2.4% 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 2020, 22,000 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 48%. However, ovarian cancer survival varies substantially by age, with the overall five-year survival rate for women 65 and older of only 31%.

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., 22,000 women are estimated to be diagnosed with ovarian cancer this year, there are approximately 40 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.

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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, 2020, we had four employees, three full-time and one part time, working for our Company and subsidiaries.

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

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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 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, including through our current ATM program, 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.

Other

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.

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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, 2020, our accumulated deficit was approximately \$191,836,000. As of October 31, 2020, we had approximately \$9,057,000 in cash, cash equivalents and short-term investments, and working capital of approximately \$8,180,000. In fiscal year 2020, we incurred losses of approximately \$10,092,000 and we experienced negative cash flows from operations of approximately \$6,176,000. 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 7, 2021, we believe that our existing cash, cash equivalents, short-term investments and expected cash flows 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, 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 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, 2020, the Company only had approximately \$9,057,000 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.

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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.

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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 complete testing of clinical materials necessary to submit an IND application to the FDA for our CAR-T ovarian cancer therapeutic;
- obtain FDA approval to commence human clinical trials of our CAR-T ovarian cancer therapeutic;
- 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. We may not be able to reach such achievements, which would have a material adverse effect on our Company.

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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 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.

We do not currently carry product liability insurance, but intend to obtain such coverage prior to commencement of our clinical trials. Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the 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.

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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, in the pre-clinical stage of developing our CAR-T therapeutic technology and about to enter 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 safety benefits, as well as the challenges, of incorporating our product candidates into their treatment regimens;
- establishing sales and marketing capabilities upon obtaining any regulatory approval to gain market acceptance of a novel therapy; and
- the availability of coverage and adequate reimbursement from third-party payors for our novel and personalized therapy.

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

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

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

While our CAR-T technology has shown favorable results from in-vitro and in-vivo testing, including in large numbers of animals under the Good Laboratory Practice ("GLP") conditions necessary for inclusion in an IND application, we cannot guarantee that these results will be sufficient for the FDA to allow us to commence human clinical trials.

While studies on our CAR-T ovarian cancer therapeutic have generated promising results in large numbers of mice under GLP conditions, and toxicity studies have been performed and have had favorable results, there can be no assurance that the FDA will find these results sufficient to allow us to commence testing of our ovarian cancer therapy in human patients. If we are unable to commence human clinical trials for our product candidate, or if commencement of such trial is significantly delayed, we may be required to expend significant additional resources, which may not be available to us, and our business, prospects, financial condition and results of operations may be adversely affected.

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

On April 14, 2020, we entered into a collaboration agreement with OntoChem 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 are in the process of performing biological assays, 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 we will have the only effective treatment for COVID-19 or that we will be able to get our treatment to market prior to our competitors.

A successful preventative vaccine will likely limit the market for a COVID-19 treatment.

A number of preventative vaccines have recently been approved for use in human populations by regulatory agencies in the U.S. and Europe. The anticipated

effectiveness of these vaccines will likely limit the spread of COVID-19 and potentially reduce the market size for a COVID-19 treatment.

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 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.

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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 OntoChem, 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.

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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.

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

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

In particular, our 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 cells.

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;

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- 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;

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- 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.

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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.

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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 an at-the-market equity offering under which, as of January 7, 2021 we may issue up to approximately \$35 million of common stock, which is currently effective and under which we commenced selling shares in November 2019, and which may remain available to us in the future. 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 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;
- 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;
- 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 8,641,254 shares of our common stock with a weighted average exercise price of \$3.16 and 1,500,000 restricted stock awards (including options to purchase 1,500,000 shares of our common stock and a restricted stock award of 1,500,000 shares of our common stock that vest based upon achievement of certain stock price based milestones issued to Dr. Kumar in May 2018). 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. 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 global COVID-19 pandemic.

COVID-19 has spread globally and the World Health Organization (WHO) has declared it a pandemic. While still evolving, the COVID-19 pandemic has caused significant worldwide economic and financial turmoil, and has fueled concerns that it will lead to a global recession. On March 13, 2020, the United States declared a national emergency with respect to COVID-19 and the majority of states and U.S. territories, including the State of California, have since issued orders requiring the closure of non-essential businesses and/or requiring residents to stay at home. As the pandemic has evolved since March 2020, some restrictions have eased, however, with the recent surge of infection and hospitalization rates, more severe restrictions are being implemented by local government agencies. The Company is following the recommendations of local health authorities to minimize exposure risk for its team members and visitors, including requiring its employees to work from home. The continued and prolonged implementation of restrictions by federal, state and local authorities to slow the spread of COVID-19 have disrupted and, we expect, will continue to disrupt, our business and operations.

Specifically, 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; 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.

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, 2021. 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 6, 2021, the approximate number of record holders of our common stock was 334 and the closing price of our common stock was \$3.36 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, 2020.

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, 2020 compared with Fiscal Year ended October 31, 2019*****Revenue***

We did not have any revenue in fiscal year 2020. In fiscal year 2019, we recorded revenue of \$250,000 from one license agreement. 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. As discussed in Note 1 to our Consolidated Financial Statements, as part of our legacy operations, the Company remains engaged in limited patent licensing activities which we do not expect to be a significant part of our ongoing operations or revenue.

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

We did not have any inventor royalties, contingent legal fees, litigation and licensing expenses related to patent assertion activities in fiscal year 2020. In fiscal year 2019 inventor royalties, contingent legal fees, litigation and licensing expenses related to patent assertion activities were approximately \$166,000. 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.

Amortization of Patents

Amortization of patents was \$-0- in fiscal year 2020 compared to approximately \$419,000 in fiscal year 2019. We capitalize patent and patent rights acquisition costs and amortize the cost over the estimated economic useful life. The carrying value of capitalized patents was reduced to \$-0- as of October 31, 2019. During fiscal year 2020, we did not capitalize any patents or patent rights.

Research and Development Expenses

Research and development expenses are related to the development of our cancer diagnostics and therapeutics programs and our anti-viral drug program, and decreased by approximately \$1,092,000 to approximately \$4,381,000 in fiscal year 2020, from approximately \$5,473,000 in fiscal year 2019. The decrease in research and development expenses was primarily due to a decrease in employee stock award compensation expense of approximately \$1,251,000 and a decrease in Certainty's outside research and development expenses related to development of CAR-T therapeutics of approximately \$547,000, offset by an increase in Anixa Diagnostics Corporation's outside research and development expense to develop the Cchek™ artificial intelligence driven platform of non-invasive blood tests for the early detection of cancer of approximately \$561,000 and an increase in outside research and development to develop anti-viral drug candidates against COVID-19 of approximately \$141,000.

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Research and development expenses incurred in fiscal year 2020 associated with each of our development programs consisted of approximately \$2,455,000 for our suspended as of July 2020 cancer diagnostics program, approximately \$1,048,000 for CAR-T therapeutics, approximately \$510,000 for anti-viral therapeutics, and approximately \$368,000 for cancer vaccines.

General and Administrative Expenses

General and administrative expenses decreased by approximately \$66,000 to approximately \$5,597,000 in fiscal year 2020, from approximately \$5,663,000 in fiscal year 2019. The decrease in general and administrative expenses was principally due to a decrease in employee stock award compensation expense of approximately \$704,000, a decrease in legal and accounting fees of approximately \$423,000 in fiscal year 2020 primarily related to fees incurred in fiscal year 2019 in connection with a putative shareholder derivative complaint which was settled in August 2019, a decrease in expense 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, a decrease in patent expense of approximately \$144,000 primarily related to a patent expense reimbursement to Cleveland Clinic in fiscal year 2019, a decrease in investor and public relations expense of approximately \$107,000, offset by an increase in employee compensation and related costs, other than equity-based compensation, of approximately \$748,000, an increase in employee and director stock option expense of approximately \$460,000, an increase in corporate insurance expense of approximately \$230,000 primarily due to an increase in our directors and officers insurance premium, an increase in consultant expense related to our Cchek™ program of approximately \$120,000 and an increase in consultant stock option expense of approximately \$94,000.

Impairment in Carrying Amount of Patent Assets

The impairment in carrying amount of patent assets related to our legacy patent licensing activities recorded in fiscal year 2020 was \$-0- compared to approximately \$419,000 in the fiscal year 2019. The impairment recorded in fiscal year 2019 resulted from the write down of the value of our patent assets to the estimated undiscounted future cash flows we anticipated receiving from the patent assets. The estimated undiscounted future cash flows was based on our assessment of the market for potential licensees, as well as the status of ongoing negotiations with potential licensees.

Loss on Disposal of Property and Equipment

Other expense was \$148,000 in fiscal year 2020 compared to \$-0- in fiscal year 2019. The other expense recorded in fiscal year 2020 represents loss on disposal of property and equipment as a result of suspension of development of our Cchek™ program.

Interest Income

Interest income decreased to approximately \$34,000 in fiscal year 2020 compared to approximately \$71,000 in fiscal year 2019, due to a decrease in interest rates.

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Net Loss Attributable to Noncontrolling Interest

The net loss attributable to noncontrolling interest, representing Wistar's 5% ownership interest in Certainty's net loss, decreased by approximately \$98,000 to approximately \$74,000 in fiscal year 2020, from approximately \$172,000 in fiscal year 2019, as Certainty's net loss decreased. The decrease in Certainty's net loss was primarily due to a decrease in employee stock option and stock award compensation expense of approximately \$1,315,000 and a decrease in research and development expense of approximately \$547,000.

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 7, 2021, we believe that our existing cash, cash equivalents, short-term investments and expected cash flows will be sufficient to fund our activities for 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 2020, we raised approximately \$9,266,000, net of expenses, through at-the-market equity offerings of 3,854,305 shares of common stock. This included approximately \$427,000, net of expenses, through the sale of 112,238 shares of common stock in an at-the market equity offering which expired in November 2019 and approximately \$8,839,000, net of expenses, through the sale of 3,742,067 shares of common stock in an at-the-market equity offering under which we may issue up to \$50 million of common stock. Under our current at-the-market equity program which is currently effective and may remain available for us to use in the future, as of October 31, 2020, we may sell an additional approximately \$40,811,000 of common stock. We may seek to obtain working capital during our fiscal year 2021 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 could 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, 2020, cash used in operating activities was approximately \$6,176,000. Cash used in investing activities was approximately \$306,000, resulting from the purchases of certificates of deposit totaling \$5,010,000 and the purchase of property and equipment of approximately \$16,000, which was offset by the proceeds on maturities of certificates of deposit totaling \$4,720,000. Cash provided by financing activities was approximately \$9,407,000, resulting from the sale of 3,854,305 shares of common stock in at-the-market equity offerings of approximately \$9,266,000, the proceeds from exercise of stock options of approximately \$122,000 and the proceeds from the sale of common stock pursuant to employee stock purchase plan of approximately \$18,000. As a result, our cash, cash equivalents, and short-term

investments at October 31, 2020 increased approximately \$3,215,000 to approximately \$9,057,000 from approximately \$5,842,000 at the end of fiscal year 2019.

Off-Balance Sheet Arrangements

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

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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.

On November 1, 2018 we adopted Accounting Standards Update 2014-09 ("ASU 2014-09"), "Revenue from Contracts with Customers" using the modified retrospective method. Upon adoption of ASU 2014-09 we are required 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 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.

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Stock-Based Compensation

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

On November 1, 2018 we adopted Accounting Standards Update 2018-07 ("ASU 2018-07") for stock-based compensation to non-employees. Upon adoption of ASU 2018-07 we estimated the fair value of unvested awards at the date of adoption, using the Black-Scholes pricing model. Future grants to consultants will be measured at the grant date, based on the fair value of the award using the Black-Scholes pricing model, consistent with our policy for grants to employees and directors.

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 and the change in terms from historical options. 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.”

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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 2020.

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, 2020. 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, 2020.

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, 2020 has not been audited by our auditors, Haskell & White LLP.

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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 2020 that has materially affected, or is reasonably likely to materially affect, the Company’s internal control over financial reporting.

Item 9B. Other Information.

On January 7, 2021, the Board of Directors of the Company confirmed its intention to hold the Company’s 2021 Annual Meeting of Shareholders (the “2021 Annual Meeting”) on Friday, May 21, 2021. The time and location of the 2021 Annual Meeting, and the matters to be considered, will be as set forth in the Company’s definitive proxy statement for the 2021 Annual Meeting to be filed in due course with the SEC.

Since the date of the 2021 Annual Meeting has been changed by more than 30 days from the anniversary date of the Company’s last annual meeting of shareholders, the Company is informing shareholders of this change and the updated deadline for shareholders to submit nominations for director or proposals for consideration at the 2021 Annual Meeting in accordance with the rules and regulations of the SEC and the Company’s By-laws. Accordingly, shareholders wishing to nominate a candidate for director or to propose other business at the 2021 Annual Meeting must ensure proper notice is received by the Company at its offices no later than March 17, 2021. The notice must include all of the information required by the Company’s By-laws.

PART III**Item 10. Directors, Executive Officers and Corporate Governance.****Our Directors and Executive Officers**

The following table sets forth certain information with respect to all of our directors and executive officers:

| Name | Position with the Company and Principal Occupation | Age | Director and/or Executive Officer Since |
|-------------------------|--|-----|---|
| Dr. Amit Kumar | Chairman of the Board, President and Chief Executive Officer | 56 | 2012 |
| Lewis H. Titterton, Jr. | Lead Independent Director | 76 | 2017 |
| Dr. Arnold Baskies | Director | 71 | 2018 |
| David Cavalier | Director | 51 | 2018 |
| Emily Gottschalk | Director | 60 | 2019 |
| Dr. John Monahan | Director | 74 | 2016 |
| Michael J. Catelani | Chief Operating Officer and Chief Financial Officer | 54 | 2016 |

We believe that our Board represents a desirable mix of backgrounds, skills, and experiences. The principal occupation and business experience during the last five years for our executive officers and directors and some of the specific experiences, qualifications, attributes or skills that led to the conclusion that each person should serve as one of our directors in light of our business and structure is as follows:

Amit Kumar, Ph.D., 56, Chairman of the Board, President and Chief Executive Officer. Dr. Kumar has served as our President and Chief Executive Officer since July 2017, as a director of the Company since November 2012 and as Chairman of the Board since August 2016. From June 2015 until August 2016, he served as Vice Chairman of the Board. Dr. Kumar served as a strategic advisor to the Company from September 2012 until July 2017. He has been Executive Chairman of the board of directors of Anixa Diagnostics Corporation, a wholly-owned subsidiary of the Company since June 2015. Upon his appointment as Executive Chairman of Anixa Diagnostics, Dr. Kumar resigned from his position as the CEO of Geo Fossil Fuels LLC, an energy company, which he had held since December 2010. From September 2001 to June 2010, he was President and CEO of CombiMatrix Corporation, a NASDAQ listed biotechnology company and also served as director from September 2000 to June 2012. He was Vice President of Life Sciences of Acacia Research Corporation, a publicly traded investment company, from July 2000 to August 2007 and also served as a director from January 2003 to August 2007. Dr. Kumar has served as Chairman of the board of directors of Ascent Solar Technologies, Inc., a publicly-held solar energy company, since June 2007. He served as a director of Aeolus Pharmaceuticals, Inc., a publicly traded biotechnology company, from June 2004 to June 2018. Dr. Kumar is Chairman of Actym Therapeutics, a private biotechnology company. Dr. Kumar has served on the board of the American Cancer Society since 2016. Dr. Kumar holds an A.B. in Chemistry from Occidental College. After graduate studies at Stanford University and Caltech, he received his Ph.D. from Caltech and completed his post-doctoral training at Harvard University. He has experience in technology driven startups, both at the board of directors and operating levels, in a broad variety of areas including finance, acquisitions, research and development, and marketing, and, as described above, has served as a director and/or officer of various publicly traded companies.

Lewis H. Titterton, Jr., 76, Director. Mr. Titterton has served as a director since July 2017, and as Lead Independent Director since July 2018. He previously served as a director of the Company from August 2010 through August 2016, as the Chairman of the Board from July 2012 through August 2016, and interim Chief Executive Officer from August 2012 until September 2012. He served on the board of directors of ParkerVision, Inc., a publicly traded wireless technology company, from September 2018 to April 2019. His background is in high technology with an emphasis on health care and he was the Chairman of the Board of Directors of NYMED, Inc., a diversified health services company, from 1989 until October 2018. Mr. Titterton founded MedE America, Inc. in 1986 and was Chief Executive Officer of Management and Planning Services, Inc. from 1978 to 1986. Mr. Titterton also served as one of our Directors from July 1999 to January 2003. He holds an MBA from the State University of New York at Albany, and a B.A. degree from Cornell University. Mr. Titterton has been involved with our Company as a director or investor for over twenty years. Mr. Titterton also has substantial experience with advising on the strategic development of technology companies and over forty years of experience in various aspects of the technology industry.

Arnold Baskies, MD, FACS, 71, Director. Dr. Baskies has served on our Board since September 2018. He previously served as a director of the Company from August 2016 until September 2017. Dr. Baskies is a surgical oncologist affiliated with Virtua Health Systems in southern New Jersey, where he specializes in surgical oncology and general surgery, and is Clinical Professor of Surgery at Rowan School of Medicine. He trained at Boston University Medical Center and the Surgery Branch of the National Cancer Institute where his early research involved immunotherapy. He has extensive experience in all facets of general surgical and surgical oncologic problems, with special interests in the treatment of breast cancer, gastrointestinal cancers, thyroid cancer, melanoma, and parathyroid disease, and is a co-investigator in several national studies dealing with breast cancer prevention. Dr. Baskies has served as a director of Baudax Bio, Inc., a publicly-held biotechnology company, since August 2020. He served as chairman of the New Jersey Governor's Task Force on Early Detection, Prevention and Treatment of Cancer, having created and chaired the cancer control plan for the state from 2000-2016, and is a member of numerous societies, including the Society of Surgical Oncology, the American Society of Breast Surgeons, and the American College of Surgeons. Dr. Baskies has been involved with the American Cancer Society for 40 years. He was awarded the Society's Silver Chalice Award in 1998 and the Society's St. George National Award in 2009. He has held leadership positions at many levels of the organization, including service as the first board scientific officer for the American Cancer Society Board of Directors in 2015, and was the chief medical officer and Chairman of the Board of Directors of the former Eastern Division of the American Cancer Society. In 2017, he served as the Chairman of the National Board of Directors of the American Cancer Society. He helped develop the current guidelines for breast cancer screening and colon cancer screening which are used on a daily basis in the United States and internationally. He chairs the Global Cancer Control Advisory Council for the society and the St. Baldrick's Foundation/ACS Alliance. He has helped set the standards for cancer care accreditation through his involvement with the Commission on Cancer. He received a medical degree from Boston University School of Medicine in 1975 and a bachelor of arts degree from Boston University College of Liberal Arts in 1971.

David Cavalier, 51, Director. Mr. Cavalier has served on our Board since September 2018. He is a seasoned executive and investor with over 20 years of experience in the biotechnology sector. He is currently the Chief Operating Officer of Mab & Stoke, Inc., a direct-to-consumer health and wellness company. He was the Chairman, from 2004 to 2018, and Chief Financial Officer, from 2013 to 2018, of Aeolus Pharmaceuticals, Inc., a biotechnology company where in 2011 he was instrumental in winning and managing a \$118 million advanced research and development contract from the U.S. Government. Prior to Aeolus, Mr. Cavalier was the founder, portfolio manager and Chief Operating Officer of Xmark Opportunity Partners, a biotechnology investment firm. Xmark was an activist fund, focused on creating positive change at the board and management level for portfolio companies. He began his biotech investment career at Brown Simpson Asset Management, where he co-managed the life sciences investment group. Mr. Cavalier previously worked for Tiger Real Estate, a private investment fund sponsored by Tiger Management Corporation. He began his career in the Investment Banking Division of Goldman, Sachs & Co. working on debt and equity offerings for public and private real estate companies. Mr. Cavalier currently serves as the Chairman of the New York Advisory Board for Enterprise Community Partners, a non-profit focused on policy, program and capital solutions for affordable housing. He received his B.A. from Yale University and his M.Phil. from Oxford University.

Emily Gottschalk, 60, Director. Ms. Gottschalk has served on our Board since October 2019. She is an experienced marketer with over 30 years of developing products for the consumer marketplace. She has been the CEO of The Garr Group, Inc. since 1997, a diverse entertainment and new product development company that she founded that sells entertainment and general merchandise to the mass, specialty and on-line market. Ms. Gottschalk co-founded IdeationUSA, LLC in 2017, a product development company focused on bringing innovative electronics to the consumer market. IdeationUSA identifies "white space" opportunities in the marketplace and defines and develops products that uniquely touch consumers lives. Ideation is equally focused on brick and mortar, on-line and emerging distribution channels. Previously, she was Marketing Director of Zany Brainy, a children's educational toy store that she launched. Since 1997, Ms. Gottschalk's companies have produced over 150 million CD's/DVD's to the US retail market, developed a proprietary Android tablet called "RealPad, by AARP" with Intel and has created private label brands across the home and craft market. She is a graduate of Cornell University's School of Hotel Administration and serves on the board of several philanthropic organizations.

John Monahan, Ph.D., 74, Director. Dr. Monahan has served on our Board since August 2016. He is an experienced executive and has served on a number of biotechnology company boards over the years. He is currently a director of Synthetic Biologics, Inc., a publicly traded biotechnology company, and from 2010 through 2015 he was the Senior Executive Vice President of Research & Development at Synthetic Biologics, Inc. He is also a director of Heat Biologics, Inc., a publicly traded biotechnology company, a position that he has held since 2011. In 1992 he founded Avigen, Inc., a biotechnology company that pioneered the development of gene medicines based on adeno-associated virus vectors, now an industry standard. Over a 12-year period as its Chief Executive Officer, Dr. Monahan took Avigen public through an initial public offering raising over \$235 million and led the company through several IND applications. Prior to Avigen, Dr. Monahan served as Vice President - Research and Development at Somatix Therapy Corp., and Director of Molecular & Cell Biology at Triton Biosciences, Inc. He was also previously Research Group Chief, Department of Molecular Genetics at Hoffmann-LaRoche Inc., and Adjunct Assistant Professor, Department of Cell Biology at New York University. Dr. Monahan earned a Ph.D. in Biochemistry from McMaster University, Hamilton, Canada, and a B.S. in Science from University College, Dublin, Ireland. Dr. Monahan has over 50 publications in scientific literature and has made hundreds of presentations and public TV appearances, to scientific groups, investors and the general public over the years.

Michael J. Catelani, 54, Chief Operating Officer and Chief Financial Officer. Mr. Catelani has served as our Chief Operating Officer since July 2017 and as Chief Financial Officer since November 2016. Mr. Catelani is a seasoned executive with over 30 years of experience in finance and operations. From October 2012 to July 2017, he served as a contract Chief Financial Officer to a number of established privately held businesses in the biotechnology field. In July 2006, he co-founded Tacere Therapeutics, Inc., a privately held biotechnology company, and served as its Chairman, President and Chief Financial Officer until its sale in October 2012. While at Tacere, Mr. Catelani

was instrumental in establishing and managing a \$150 million drug development collaboration with Pfizer, Inc. Prior to Tacere, he served on the Board of Directors and was the Chief Financial Officer of Benitec Biopharma Limited, an Australian Stock Exchange-listed biotechnology company. Prior to Benitec, Mr. Catelani served as Vice President and Chief Financial Officer at Axon Instruments, Inc., a U.S. corporation publicly traded on the Australian Stock Exchange that was a leading designer and manufacturer of instrumentation and software systems for biotechnology and diagnostics research. Previously, he served as the Vice President of Finance for Media Arts Group, Inc., an NYSE-listed company. Mr. Catelani has also worked with several early stage start-up companies in a variety of industries, including biotechnology, cleantech and retail, in both advisory and management roles. Mr. Catelani began his professional career at Ernst & Young and is a CPA (Inactive). He holds a B.S. degree in Business Administration, with a concentration in Accountancy, from Sacramento State University and an MBA from the University of California, Davis.

Of our current directors and executive officers, Drs. Kumar, Baskies and Monahan and Messrs. Titterton and Cavalier have served as a director of another public company within the past five years.

Our Significant Employees

We have no significant employees other than our executive management team.

Family Relationships

There are no family relationships between or among the directors, executive officers or persons nominated or chosen by the Company to become directors or executive officers.

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Involvement of Certain Legal Proceedings

To the best of our knowledge, during the past ten years, none of the following occurred with respect to a present or former director or executive officer of the Company: (1) any bankruptcy petition filed by or against any business of which such person was a general partner or executive officer either at the time of the bankruptcy or within two years prior to that time; (2) any conviction in a criminal proceeding or being subject to a pending criminal proceeding (excluding traffic violations and other minor offenses); (3) being subject to any order, judgment or decree, not subsequently reversed, suspended or vacated, of any court of competent jurisdiction, permanently or temporarily enjoining, barring, suspending or otherwise limiting his or her involvement in any type of business, securities or banking activities; (4) being found by a court of competent jurisdiction (in a civil action), the Commission or the Commodities Futures Trading Commission to have violated a federal or state securities or commodities law, and the judgment has not been reversed, suspended or vacated; (5) being subject of, or a party to, any Federal or State judicial or administrative order, judgment, decree or finding relating to an alleged violation of the federal or state securities, commodities, banking or insurance laws or regulations or any settlement thereof or involvement in mail or wire fraud in connection with any business entity not subsequently reversed, suspended or vacated and (6) being subject of, or a party to, any disciplinary sanctions or orders imposed by a stock, commodities or derivatives exchange or other self-regulatory organization.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Exchange Act requires our directors, executive officers and ten percent stockholders to file initial reports of ownership and reports of changes in ownership of our common stock with the Commission. Directors, executive officers and ten percent stockholders are also required to furnish us with copies of all Section 16(a) forms that they file. Based upon a review of these filings, we believe that all required Section 16(a) reports were made on a timely basis during fiscal year 2020.

Code of Ethics

We have adopted a formal code of ethics that applies to our principal executive officer, principal financial officer, principal accounting officer or controller or persons performing similar functions. We will provide a copy of our code of ethics to any person without charge, upon request. For a copy of our code of ethics write to Secretary, Anixa Biosciences, Inc., 3150 Almaden Expressway, Suite 250, San Jose, California 95118. A current copy of our code of ethics is also available on our website at <http://ir.anixa.com/governance-docs>.

Nomination Procedures

On July 9, 2015, the Board established a nominating and corporate governance committee (the "Nominating Committee"). The Nominating Committee has a charter which will be reviewed on an annual basis by members of the committee and will be at all times composed of exclusively independent directors. The principal duties and responsibilities of the Nominating Committee are to identify qualified individuals to become board members, recommend to the Board individuals to be designated as nominees for election as directors at the annual meetings of stockholders, and develop and recommend to the Board the Company's corporate governance guidelines. In selecting directors, the Nominating Committee will consider candidates that possess qualifications and expertise that will enhance the composition of the Board, including the considerations set forth below. The considerations set forth below are not meant as minimum qualifications, but rather as guidelines in weighing all of a candidate's qualifications and expertise.

- Candidates should be individuals of personal integrity and ethical character.
- Candidates should have background, achievements, and experience that will enhance our Board. This may come from experience in areas important to our business, substantial accomplishments or prior or current associations with institutions noted for their excellence.
- Candidates should have demonstrated leadership ability, the intelligence and ability to make independent analytical inquiries and the ability to exercise sound business judgment.

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- Candidates should be free from conflicts that would impair their ability to discharge the fiduciary duties owed as a director to Anixa and its stockholders, and we will consider directors' independence from our management and stockholders.
- Candidates should have, and be prepared to devote, adequate time and energy to the Board and its committees to ensure the diligent performance of their duties, including by attending meetings of the Board and its committees.
- Due consideration will be given to the Board's overall balance of diversity of perspectives, backgrounds and experiences, as well as age, gender and ethnicity.
- Consideration will also be given to relevant legal and regulatory requirements.

We are of the view that the continuing service of qualified incumbents promotes stability and continuity in the board room, contributing to the Board's ability to work as a collective body, while giving us the benefit of the familiarity and insight into our affairs that our directors accumulate during their tenure. Accordingly, the process of the Nominating Committee for identifying nominees for directors will reflect our practice of generally re-nominating incumbent directors who continue to satisfy the Board's criteria for membership on the Board, whom the Nominating Committee believes continue to make important contributions and who consent to continue their service on the Board. If the Nominating Committee determines that an incumbent director consenting to re-nomination continues to be qualified and has satisfactorily performed his or her duties as director during the preceding term, and that there exist no reasons, including considerations relating to the composition and functional needs of the Board as a whole, why in the Nominating Committee's view the incumbent should not be re-nominated, the Nominating Committee will, absent special circumstances, generally propose the incumbent director for re-election. Although we do not have a formal policy regarding the consideration of diversity in identifying and evaluating potential director candidates,

the Nominating Committee will take into account the personal characteristics (gender, ethnicity and age), skills and experience, qualifications and background of current and prospective directors' diversity as one factor in identifying and evaluating potential director candidates, so that the Board, as a whole, will possess what the nominating and corporate governance committee believes are appropriate skills, talent, expertise and backgrounds necessary to oversee our Company's business.

If the incumbent directors are not nominated for re-election or if there is otherwise a vacancy on the Board, the Nominating Committee may solicit recommendations for nominees from persons that the Nominating Committee believes are likely to be familiar with qualified candidates, including from members of the Board and management. While the Nominating Committee may also engage a professional search firm to assist in identifying qualified candidates, the Nominating Committee did not engage any third party to identify or evaluate or assist in identifying or evaluating the Director Nominees. We do not have a policy with regard to the consideration of director candidates recommended by stockholders. Due to the size of our Company and Board, the Nominating Committee does not believe that such a policy is necessary.

Depending on its level of familiarity with the candidates, the Nominating Committee may choose to interview certain candidates that it believes may possess qualifications and expertise required for membership on the Board. It may also gather such other information it deems appropriate to develop a well-rounded view of the candidate. Based on reports from those interviews or from Board members with personal knowledge and experience with a candidate, and on all other available information and relevant considerations, the Nominating Committee will select and nominate candidates who, in its view, are most suited for membership on the Board.

The members of the nominating committee are Dr. Arnold Baskies (Chairman), Dr. John Monahan and Lewis H. Titterton, Jr.

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Audit Committee and Audit Committee Financial Expert

On July 9, 2015, the Board established a separately-designated standing audit committee (the "Audit Committee") established in accordance with Section 3(a)(58)(A) of the Exchange Act, and Nasdaq Listing Rules. The Audit Committee has a charter which will be reviewed on an annual basis by members of the committee and will be at all times composed of exclusively independent directors who are "financially literate," meaning they are able to read and understand fundamental financial statements, including the Company's balance sheet, income statement and cash flow statement. In addition, the committee will have at least one member who qualifies as an "audit committee financial expert" as defined in rules and regulations of the SEC.

The principal duties and responsibilities of the Company's Audit Committee are to appoint the Company's independent auditors, oversee the quality and integrity of the Company's financial reporting and the audit of the Company's financial statements by its independent auditors and in fulfilling its obligations, the Company's Audit Committee will review with the Company's management and independent auditors the scope and result of the annual audit, the auditors' independence and the Company's accounting policies.

The Audit Committee will be required to report regularly to the Board to discuss any issues that arise with respect to the quality or integrity of the Company's financial statements, its compliance with legal or regulatory requirements and the performance and independence of the Company's independent auditors.

The members of the Audit Committee are David Cavalier (Chairman), Lewis H. Titterton, Jr. and Dr. John Monahan. Our Board has determined that Mr. Cavalier qualifies as an Audit Committee financial expert as defined by SEC rules, based on his education, experience and background. Please see Mr. Cavalier's biographical information above for a description of his relevant experience.

Item 11. Executive Compensation.

The following table sets forth certain information for the fiscal years ended October 31, 2020 and 2019, with respect to compensation awarded to, earned by or paid to our Chairman of the Board, President and Chief Executive Officer and our Chief Operating Officer and Chief Financial Officer (the "Named Executive Officers"). No other executive officer received total compensation in excess of \$100,000 during fiscal year 2020.

SUMMARY COMPENSATION TABLE

| Name and Principal Position | Year | Salary (\$) | Bonus (\$) | Option Awards (\$ (1)) | All Other Compensation (\$ (2)) | Total Compensation (\$) |
|---|------|-------------|------------|------------------------|---------------------------------|-------------------------|
| Dr. Amit Kumar | | | | | | |
| Chairman of the Board, | 2020 | \$ 521,625 | \$ 160,000 | \$ 1,674,400 | \$ 39,240 | \$ 2,395,265 |
| President and Chief Executive Officer | 2019 | \$ 476,250 | \$ 150,000 | \$ - | \$ 39,240 | \$ 665,490 |
| Michael J. Catelani | 2020 | \$ 287,219 | \$ 50,000 | \$ 322,000 | \$ - | \$ 659,219 |
| Chief Operating Officer and Chief Financial Officer | 2019 | \$ 263,021 | \$ 50,000 | \$ - | \$ - | \$ 313,021 |

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- (1) These amounts have been calculated in accordance with Accounting Standards Codification ("ASC") 718. A discussion of assumptions used in valuation of option awards may be found in Note 2 to our Consolidated Financial Statements for fiscal year ended October 31, 2020, included elsewhere in this Annual Report on Form 10-K. These amounts reflect our accounting expense for these stock options and restricted stock awards and do not correspond to the actual value that may be recognized by our Named Executive Officers.
- (2) These amounts reflect the sum of the incremental cost to us of all perquisites and personal benefits, which consisted of compensation for use of a home office and reimbursement of medical insurance benefits for Dr. Kumar.

Employment Agreements

Consulting Agreement with Dr. Amit Kumar

On September 19, 2012, the Company entered into a Consulting Agreement with Dr. Amit Kumar (the "Kumar Agreement") pursuant to which Dr. Kumar agreed to provide business consulting services for an initial annual consulting fee of \$120,000. On June 15, 2015, Dr. Kumar was appointed Vice Chairman of the Company and Executive Chairman of Anixa Diagnostics. As a result of this appointment, Dr. Kumar's annual cash compensation was increased to \$300,000 by the Board. On August 23, 2016, Dr. Kumar was appointed Executive Chairman of the Company, and on July 6, 2017, Dr. Kumar was appointed President and Chief Executive Officer of the Company. As of the beginning of each subsequent calendar year, Dr. Kumar's salary has been reviewed and adjusted by the Board's Compensation Committee. On January 1, 2021, Dr. Kumar's annual salary was \$582,085.

If Dr. Kumar's services are terminated by the Company or he terminates his services for any reason or no reason, the Company shall be obligated to pay to Dr. Kumar only any earned compensation and/or bonus due under the Kumar Agreement and any earned and unused paid time off and any unpaid reasonable and necessary expenses, due to him through the date of termination. All such payments shall be made in a lump sum immediately following termination.

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Stock Options

Outstanding Stock Option Awards

The following table sets forth certain information with respect to unexercised stock options held by the Named Executive Officers outstanding on October 31, 2020:

| OUTSTANDING OPTION AWARDS | | | | | |
|---------------------------|---|--|----------------------------|-------|------------------------|
| Name | Number of Securities Underlying Unexercised Options (#) Exercisable | Number of Securities Underlying Unexercised Options (#) Un-Exercisable | Option Exercise Price (\$) | | Option Expiration Date |
| | Time-based Option Awards | | | | |
| Dr. Amit Kumar | 320,000 | | \$ | 2.575 | 9/19/2022 |
| | 106,667 | | \$ | 2.575 | 9/19/2022 |
| | 213,333 | | \$ | 2.575 | 9/19/2022 |
| | 40,000 | | \$ | 2.575 | 11/8/2023 |
| | 200,000 | | \$ | 2.92 | 2/18/2026 |
| | 500,000(1) | 100,000(1) | \$ | 3.70 | 5/8/2028 |
| Michael J. Catelani | 158,889(2) | 361,111(2) | \$ | 3.84 | 12/12/29 |
| | 50,000 | | \$ | 4.85 | 11/15/2026 |
| | 162,500(3) | 37,500(3) | \$ | 0.96 | 7/6/2027 |
| | 416,667(1) | 83,333(1) | \$ | 3.70 | 5/8/2028 |
| | 30,556(2) | 69,444(2) | \$ | 3.84 | 12/12/29 |
| | Performance-based Option Awards | | | | |
| Dr. Amit Kumar | 500,000(4) | 1,000,000(4) | \$ | 3.70 | 5/8/2028 |

- (1) Options vest and become exercisable in 36 consecutive monthly installments, beginning May 31, 2018 and continuing through April 30, 2021.
- (2) Options vest and become exercisable in 36 consecutive monthly installments, beginning December 31, 2019 and continuing through November 30, 2022.
- (3) Options vest and become exercisable in one installment of 50,000 on July 6, 2018 and the remainder in twelve consecutive quarterly installments, beginning October 31, 2018 and continuing through July 31, 2021.
- (4) Options shall vest as follows: (i) 500,000 shares vest if during any 20 trading day period on or before May 31, 2021, the average closing stock price of the Company's Common Stock is at least \$5.00, (ii) 500,000 shares vest if during any 20 trading day period on or before May 31, 2021, the average closing stock price of the Company's Common Stock is at least \$7.00, and (iii) 500,000 shares vest if during any 20 trading day period on or before May 31, 2021, the average closing stock price of the Company's Common Stock is at least \$8.00.

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Stock Option Grants

The following table summarizes stock option grants during fiscal year 2020.

| GRANTS OF OPTION AWARDS | | | | |
|-------------------------|------------|---|--------------------------------------|-------------------------------|
| Name | Grant Date | Number of Securities Underlying Options (#) | Exercise Price of Option Awards (\$) | Grant Date Fair Value (\$)(1) |
| Amit Kumar | 12/12/19 | 520,000 | \$ 3.84 | \$ 1,674,400 |
| Michael J. Catelani | 12/12/19 | 100,000 | \$ 3.84 | \$ 322,000 |

- (1) These amounts have been calculated in accordance with ASC 718. A discussion of assumptions used in valuation of option awards may be found in Note 2 to our Consolidated Financial Statements for fiscal year ended October 31, 2020, included elsewhere in this Annual Report on Form 10-K. These amounts reflect our accounting expense for these stock options and restricted stock awards and do not correspond to the actual value that may be recognized by our Named Executive Officers.

Stock Option Exercises

During the year ended October 31, 2020, no stock options were exercised by Named Executive Officers.

Stock Awards

On May 8, 2018, a restricted stock award of 1,500,000 shares of common stock was granted under our 2018 Share Incentive Plan to Dr. Kumar. The restricted stock award vests in its entirety if during any 20 trading day period on or before May 31, 2021, the average closing stock price of the Company's Common Stock is at least \$11.00. The grant date fair value of this restricted stock award was \$4,814,265.

Potential Payments upon Termination or Change in Control

Dr. Amit Kumar

The time-based and performance-based options granted Dr. Kumar on May 8, 2018 provide for the vesting of the unvested portion of his options to be accelerated and such accelerated options to become immediately exercisable upon a change in control as defined below. The intrinsic value of options granted on May 8, 2018 would be \$-0-, which was calculated by multiplying (a) 1,100,000 options (being the number of options granted to him on May 8, 2018 that would be accelerated) by (b) an amount equal to the excess of (x) our closing share price on October 31, 2020 of \$2.06 and (y) the options' exercise price of \$3.70 per share.

Options granted Dr. Kumar on December 12, 2019 provide for the vesting of the unvested portion of his options to be accelerated and such accelerated options to become immediately exercisable upon a change in control as defined below. The intrinsic value of options granted on December 12, 2019 would be \$-0-, which was calculated by multiplying (a) 361,111 options (being the number of options granted to him on December 12, 2019 that would be accelerated) by (b) an amount equal to the excess of (x) our closing share price on October 31, 2020 of \$2.06 and (y) the options' exercise price of \$3.84 per share.

Michael J. Catelani

Options granted Mr. Catelani on July 6, 2017 provide for the vesting of the unvested portion of his options to be accelerated and such accelerated options to become immediately exercisable if Mr. Catelani is terminated without cause or upon a change in control as defined below. The intrinsic value of options granted on July 6, 2017 would be \$41,250, which was calculated by multiplying (a) 37,500 options (being the number of options granted to him on July 6, 2017 that would be accelerated) by (b) an amount equal to the excess of (x) our closing share price on October 31, 2019 of \$2.06 and (y) the options' exercise price of \$0.96 per share.

Options granted Mr. Catelani on May 8, 2018 provide for the vesting of the unvested portion of his options to be accelerated and such accelerated options to become immediately exercisable upon a change in control as defined below. The intrinsic value of options granted on May 8, 2018 would be \$-0-, which was calculated by multiplying (a) 83,333 options (being the number of options granted to him on May 8, 2018 that would be accelerated) by (b) an amount equal to the excess of (x) our closing share price on October 31, 2020 of \$2.06 and (y) the options' exercise price of \$3.70 per share.

Options granted Mr. Catelani on December 12, 2019 provide for the vesting of the unvested portion of his options to be accelerated and such accelerated options to become immediately exercisable upon a change in control as defined below. The intrinsic value of options granted on December 12, 2019 would be \$-0-, which was calculated by multiplying (a) 69,411 options (being the number of options granted to him on December 12, 2019 that would be accelerated) by (b) an amount equal to the excess of (x) our closing share price on October 31, 2020 of \$2.06 and (y) the options' exercise price of \$3.84 per share.

Change in Control

Under our 2010 Share Incentive Plan and our 2018 Share Incentive Plan, "change in control" means:

- **Change in Ownership:** A change in ownership of the Company occurs on the date that any one person, or more than one person acting as a group, acquires ownership of stock of the Company that, together with stock held by such person or group, constitutes more than 50% of the total fair market value or total voting power of the stock of the Company, excluding the acquisition of additional stock by a person or more than one person acting as a group who is considered to own more than 50% of the total fair market value or total voting power of the stock of the Company.
- **Change in Effective Control:** A change in effective control of the Company occurs on the date that either:
 - any one person, or more than one person acting as a group, acquires (or has acquired during the 12-month period ending on the date of the most recent acquisition by such person or persons) ownership of stock of the Company possessing 30% or more of the total voting power of the stock of the Company; or
 - a majority of the members of the Board is replaced during any 12-month period by directors whose appointment or election is not endorsed by a majority of the members of the Board before the date of the appointment or election; provided, that this paragraph will apply only to the Company if no other corporation is a majority shareholder.
- **Change in Ownership of Substantial Assets:** A change in the ownership of a substantial portion of the Company's assets occurs on the date that any one person, or more than one person acting as a group, acquires (or has acquired during the 12-month period ending on the date of the most recent acquisition by such person or persons) assets from the Company that have a total gross fair market value equal to or more than 40% of the total gross fair market value of the assets of the Company immediately before such acquisition or acquisitions. For this purpose, "gross fair market value" means the value of the assets of the Company, or the value of the assets being disposed of, determined without regard to any liabilities associated with such assets.

It is the intent that this definition be construed consistent with the definition of "Change of Control" as defined under Code Section 409A and the applicable treasury regulations, as amended from time to time.

Director Compensation

On August 13, 2020, after a review of non-employee director compensation at comparable companies, the Board approved cash and equity compensation of directors. Each non-employee director shall receive cash compensation of \$50,000 paid in four quarterly installments, and the grant of a 10 year nonqualified stock option to purchase 30,000 shares of common stock exercisable at \$2.68, such option vesting monthly over a one year period. Our employee director, Dr. Amit Kumar, did not receive any additional compensation for services provided as a director during fiscal year 2020.

The 2010 Share Incentive Plan provides that on January 1st of each year, each non-employee director (a "Director Participant") of the Company at that time shall automatically be granted a 10 year nonqualified stock option to purchase 12,000 shares of common stock (or 16,000 in the case of the Chairman of the Board to the extent he qualifies as a Director Participant), with an exercise price equal to the closing price on the date of grant, that will vest in four equal quarterly installments in the year of grant (the "Annual Grant"). Effective January 1, 2018 through the expiration of the 2010 Share Incentive Plan, each Director Participant waived their right to receive the Annual Grant.

The following table sets forth compensation of Lewis H. Titterton, Jr., Dr. Arnold Baskies, David Cavalier, Emily Gottschalk and Dr. John Monahan, our non-employee directors, for fiscal year 2020:

DIRECTORS' COMPENSATION

| Name | Cash (\$) | Option Awards (\$)(1)(2) | Total Compensation (\$) |
|-------------------------|--------------|-----------------------------|-------------------------------|
| Lewis H. Titterton, Jr. | \$ 12,500 | \$ 64,320 | \$ 76,820 |
| Dr. Arnold Baskies | \$ 12,500 | \$ 64,320 | \$ 76,820 |
| David Cavalier | \$ 12,500 | \$ 64,320 | \$ 76,820 |
| Emily Gottschalk | \$ 12,500 | \$ 64,320 | \$ 76,820 |
| Dr. John Monahan | \$ 12,500 | \$ 64,320 | \$ 76,820 |

- (1) These amounts have been calculated in accordance with ASC 718. A discussion of assumptions used in valuation of option awards may be found in Note 2 to our Consolidated Financial Statements for fiscal year ended October 31, 2020, included elsewhere in this Annual Report on Form 10-K. These amounts reflect our accounting expense for these stock options and do not correspond to the actual value that may be recognized by our directors.
- (2) At October 31, 2020, Mr. Titterton, Dr. Baskies, Mr. Cavalier, Ms. Gottschalk and Dr. Monahan held unexercised stock options to purchase 685,000, 158,000, 120,000, 75,000 and 188,000 shares respectively, of our common stock.

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

The following table sets forth certain information with respect to our common stock beneficially owned as of January 7, 2021 (or exercisable within 60 days of such date) by (a) each person who is known by our management to be the beneficial owner of more than 5% of our outstanding common stock, (b) each of our directors and executive officers, and (c) all directors and executive officers as a group:

| Name and Address of Beneficial Owner | Amount and Nature of Beneficial Ownership | | | Percent of Class (6) |
|---|---|-----|-----------|----------------------|
| | (1) | (2) | (3)(4)(5) | |
| <i>Directors and Officers of the Company</i> | | | | |
| Dr. Amit Kumar 3150 Almaden Expressway, Suite 250 San Jose, CA 95118 | | | 4,008,667 | 14.2% |
| Lewis H. Titterton, Jr. 3150 Almaden Expressway, Suite 250 San Jose, CA 95118 | | | 1,642,826 | 6.2% |
| Michael J. Catelani 3150 Almaden Expressway, Suite 250 San Jose, CA 95118 | | | 754,971 | 2.8% |
| Dr. John Monahan 3150 Almaden Expressway, Suite 250 San Jose, CA 95118 | | | 226,400 | *% |
| Dr. Arnold Baskies 3150 Almaden Expressway, Suite 250 San Jose, CA 95118 | | | 186,500 | *% |
| David Cavalier 3150 Almaden Expressway, Suite 250 San Jose, CA 95118 | | | 109,500 | *% |
| Emily Gottschalk 3150 Almaden Expressway, Suite 250 San Jose, CA 95118 | | | 62,500 | *% |
| All Directors and Executive Officers as a Group (7 persons) | | | 6,991,364 | 23.2% |

* Less than 1%.

- (1) A beneficial owner of a security includes any person who directly or indirectly has or shares voting power and/or investment power with respect to such security or has the right to obtain such voting power and/or investment power within sixty (60) days. Except as otherwise noted, each designated beneficial owner in this Annual Report on Form 10-K has sole voting power and investment power with respect to the shares of common stock beneficially owned by such person.
- (2) Includes 240,000 shares, 474,000 shares, 225,000 shares, 113,000 shares, 83,000 shares, 45,000 shares and 1,180,000 shares which Dr. Amit Kumar, Lewis H. Titterton, Jr., Michael J. Catelani, Dr. John Monahan, Dr. Arnold Baskies, David Cavalier and all directors and executive officers as a group, respectively, have the right to acquire within 60 days upon exercise of options granted pursuant to the 2010 Share Incentive Plan.
- (3) Includes 1,366,667 shares, 62,500 shares, 522,222 shares, 62,500 shares, 62,500 shares, 62,500 shares, 62,500 shares and 2,201,389 shares which Dr. Amit Kumar, Lewis H. Titterton, Jr., Michael J. Catelani, Dr. John Monahan, Dr. Arnold Baskies, David Cavalier, Emily Gottschalk and all directors and executive officers as a group, respectively, have the right to acquire within 60 days upon exercise of options granted pursuant to the 2018 Share Incentive Plan.

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- (4) Includes 640,000 shares, 86,000 shares and 726,000 shares which Dr. Amit Kumar, Lewis H. Titterton, Jr. and all directors and executive officers as a group, respectively, have the right to acquire within 60 days pursuant to option agreements with the Company.
- (5) Includes 1,500,000 restricted shares of common stock awarded to Dr. Amit Kumar pursuant to the 2018 Share Incentive Plan for which Dr. Kumar has voting rights but that vest only if during any twenty (20) trading day period on or before May 31, 2021 in which Dr. Kumar is employed by Anixa, the average closing stock price of the Company's common stock is at least \$11.00.
- (6) Based on 26,076,819 shares of common stock outstanding as of January 7, 2020.

Change in Control

We are not aware of any arrangement that might result in a change in control of the Company in the future.

Equity Compensation Plan Information

The following is information as of October 31, 2020 about shares of our common stock that may be issued upon the exercise of options, warrants and rights under all equity compensation plans in effect as of that date, including our 2010 Share Incentive Plan and our 2018 Share Incentive Plan. See Note 4 to our Consolidated Financial Statements for more information on these plans.

| Plan category | Number of securities to be issued upon exercise of outstanding options, warrants and rights (a) | Weighted average exercise price of outstanding options, warrants and rights | Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) |
|--|---|---|---|
| Equity compensation plans not approved by security holders (1) | 3,605,534 | \$ 2.70 | - |
| Equity compensation plans approved by security holders (2) | 4,346,661 | \$ 3.69 | 2,388,339 |

- (1) On July 14, 2010 the Board adopted the 2010 Share Incentive Plan. Officers, key employees and non-employee directors of, and consultants to, the Company or any of its subsidiaries and affiliates are eligible to participate in the 2010 Share Incentive Plan. The 2010 Share Incentive Plan provides for the grant of stock options, stock appreciation rights, stock awards, and performance awards and stock units (the “2010 Benefits”). The maximum number of shares of common stock available for issuance under the 2010 Share Incentive Plan was initially 600,000 shares. On July 6, 2011 and August 29, 2012, the 2010 Share Incentive Plan was amended by our Board to increase the maximum number of shares of common stock that may be granted to 1,080,000 and 1,200,000 shares, respectively. On November 8, 2013, the Board approved an amendment to provide that effective and following November 8, 2013, the maximum aggregate number of shares available for issuance will be 800,000 shares. Additionally, commencing on the first business day in 2014 and on the first business day of each calendar year thereafter, the maximum aggregate number of shares available for issuance shall be replenished such that, as of such first business day, the maximum aggregate number of shares available for issuance shall be 800,000 shares. Current and future non-employee directors are automatically granted a 10 year nonqualified stock option to purchase 12,000 shares of Common Stock (or 16,000 in the case of the Chairman of the Board) on January 1st of each year that will vest in four equal quarterly installments. The 2010 Share Incentive Plan was administered by the Stock Option Committee through August 2012, from August 2012 through November 2012, by the Executive Committee of the Board of Directors, from November 2012 through July 2015, by the Board of Directors and since July 2015, by the Compensation Committee, which determines the option price, term and provisions of the 2010 Benefits. The 2010 Share Incentive Plan terminated with respect to additional grants on July 14, 2020.

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

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

Transactions with Related Persons

Aside from compensation arrangements with executive officers described above, there are no other transactions entered into by the Company with related persons.

Related Person Transaction Approval Policy

While we have no written policy regarding approval of transactions between us and a related person, our Board, as matter of appropriate corporate governance, reviews and approves all such transactions, to the extent required by applicable rules and regulations. Generally, management would present to the Board for approval at the next regularly scheduled Board meeting any related person transactions proposed to be entered into by us. The Board may approve the transaction if it is deemed to be in the best interests of our stockholders and the Company.

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Director Independence

Our Board oversees the activities of our management in the handling of the business and affairs of our company. Our common stock trades on the NASDAQ Capital Market and we are subject to listing requirements which include the requirement that our Board be comprised of a majority of “independent” directors. Lewis H. Titterton, Jr., Dr. Arnold Baskies, David Cavalier, Emily Gottschalk and Dr. John Monahan currently meet the definition of “independent” as defined by the SEC. Dr. Amit Kumar is an employee of the Company and as such does not qualify as an “independent” director. The Board of Directors has separately designated audit, nominating and compensation committees.

Item 14. Principal Accounting Fees and Services.

The following table describes fees for professional audit services rendered and billed by Haskell & White LLP, our present independent registered public accounting firm and principal accountant, for the audit of our consolidated financial statements and for other services during fiscal years 2020 and 2019.

| Type of Fee | 2020 | 2019 |
|------------------------|------------|------------|
| Audit Fees (1) | \$ 79,650 | \$ 79,850 |
| Audit Related Fees (2) | 1,000 | 6,500 |
| Tax Fees (3) | 28,000 | 33,000 |
| All Other Fees (4) | 7,500 | 8,150 |
| Total | \$ 116,150 | \$ 127,500 |

- (1) Audit fees for fiscal years 2020 and 2019 represent fees billed for services rendered by Haskell & White LLP for the audit of our consolidated financial statements and review of our quarterly reports on Form 10-Q.
- (2) Audit related fees for fiscal years 2020 and 2019 represent fees billed for services rendered by Haskell & White LLP in connection with our Registration Statements filed during fiscal years 2020 and 2019.
- (3) Tax Fees for fiscal years 2020 and 2019 represent fees billed for services rendered by Haskell & White LLP for the preparation of Federal and State income tax returns.
- (4) All other fees for fiscal years 2020 and 2019 represent fees billed for services rendered by Haskell & White LLP in connection with the preparation of comfort letters and research of various tax subjects.

Procedures For Board of Directors Pre-Approval of Audit and Permissible Non-Audit Services of Independent Auditor

Our Board is ultimately responsible for reviewing and approving, in advance, any audit and any permissible non-audit engagement or relationship between us and our independent registered public accounting firm. On July 9, 2015, the Board established an Audit Committee which was authorized to assume these responsibilities. Haskell & White LLP’s engagement to conduct all audit and permissible non-audit related activities incurred during fiscal years 2020 and 2019 were approved by our audit committee in accordance with these procedures.

Item 15. Exhibits, Financial Statement Schedules.

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

See accompanying "Index to Consolidated Financial Statements."

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(b) Exhibits

- 3.1 [Certificate of Incorporation, as amended. \(Incorporated by reference to Form 10-Q for the fiscal quarter ended July 31, 1992 and Form S-3, dated February 11, 2014.\)](#)
- 3.2 [Amendment to the Certificate of Incorporation. \(Incorporated by reference to Exhibit 3.2 to our Form 10-K for the fiscal year ended October 31, 2013.\)](#)
- 3.3 [Certificate of Amendment to the Certificate of Incorporation. \(Incorporated by reference to Exhibit 3.1 to our Form 8-K, dated September 4, 2014.\)](#)
- 3.4 [Certificate of Designations, Preferences and Rights of Series A Convertible Preferred Stock. \(Incorporated by reference to Exhibit 3.1 to our Form 8-K, dated September 10, 2014.\)](#)
- 3.5 [Certificate of Amendment to the Certificate of Incorporation. \(Incorporated by reference to Exhibit 3.1 to our Form 8-K, dated June 25, 2015.\)](#)
- 3.6 [Certificate of Amendment to the Certificate of Incorporation. \(Incorporated by reference to Exhibit 3.1 to our Form 10-Q for the fiscal quarter ended April 30, 2018.\)](#)
- 3.7 [Certificate of Amendment to the Certificate of Incorporation. \(Incorporated by reference to Exhibit 3.1 to our Form 8-K, dated October 1, 2018.\)](#)
- 3.8 [Certificate of Amendment to the Certificate of Incorporation. \(Incorporated by reference to Exhibit 3.1 to our Form 8-K, dated August 13, 2020.\)](#)
- 3.9 [Amended and Restated By-laws. \(Incorporated by reference to Exhibit 3.8 to our Form 10-K for the fiscal year ended October 31, 2019.\)](#)
- 4.1 [Form of Warrant issued to Adaptive Capital LLC. \(Incorporated by reference to Exhibit 4.2 to our Form 10-K, dated December 7, 2016.\)](#)
- 4.2 [Form of Warrant issued to Acorn Management Partners LLC. \(Filed herewith.\)](#)
- 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 [Consulting Agreement, dated as of September 19, 2012, between the Company and Amit Kumar. \(Incorporated by reference to Exhibit 10.37 to our Form 10-K for the fiscal year ended October 31, 2012.\) \(Portions of this exhibit have been redacted pursuant to a request for confidential treatment. The redacted portions have been separately filed with the Securities and Exchange Commission.\)](#)
- 10.7 [License Agreement, dated November 13, 2017, between Certainty Therapeutics, Inc. and The Wistar Institute of Anatomy and Biology. \(Incorporated by reference to Exhibit 10.14 to our Form 10-K, dated January 9, 2018.\) \(Portions of this exhibit have been redacted pursuant to a request for confidential treatment. The redacted portions have been separately filed with the Securities and Exchange Commission.\)](#)
- 10.8 [Collaboration Agreement, dated November 17, 2017, between Certainty Therapeutics, Inc. and H. Lee Moffitt Cancer Center and Research Institute, Inc. \(Incorporated by reference to Exhibit 10.15 to our Form 10-K, dated January 9, 2018.\) \(Portions of this exhibit have been redacted pursuant to a request for confidential treatment. The redacted portions have been separately filed with the Securities and Exchange Commission.\)](#)
- 10.9 [Amendment 1 to the Collaboration Agreement between Certainty Therapeutics, Inc. and H. Lee Moffitt Cancer Center and Research Institute, Inc. \(Incorporated by reference to Exhibit 10.2 to our Form 10-Q for the fiscal quarter ended July 31, 2019.\)](#)

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- 10.10 [Amendment 2 to the Collaboration Agreement between Certainty Therapeutics, Inc. and H. Lee Moffitt Cancer Center and Research Institute, Inc. \(Filed herewith.\) \(Certain information has been redacted in the marked portions of the exhibit.\)](#)
- 10.11 [Exclusive License Agreement, dated July 8, 2019, between the Company and The Cleveland Clinic Foundation. \(Incorporated by reference to Exhibit 10.1 to our Form 10-Q for the fiscal quarter ended July 31, 2019.\) \(Certain information has been redacted in the marked portions of the exhibit.\)](#)
- 10.12 [Collaboration Agreement, dated April 14, 2020, between the Company and OntoChem GmbH. \(Incorporated by reference to Exhibit 10.1 to our Form 10-Q for the fiscal quarter ended April 30, 2020.\) \(Certain information has been redacted in the marked portions of the exhibit.\)](#)
- 10.13 [Amendment to Collaboration Agreement between the Company and OntoChem GmbH. \(Filed herewith.\)](#)
- 10.14 [Exclusive License Agreement, dated October 20, 2020, between the Company and The Cleveland Clinic Foundation. \(Filed herewith.\) \(Certain information has been redacted in the marked portions of the exhibit.\)](#)
- 10.15 [At Market Issuance Sales Agreement, dated June 21, 2019, between the Company and B. Riley FBR, Inc. \(Incorporated by reference to Exhibit 10.1 to our Registration Statement of Form S-3 filed June 11, 2019.\)](#)
- 14 [Code of Conduct \(Filed herewith.\)](#)
- 21 [Subsidiaries of Anixa Biosciences, Inc. \(Filed herewith.\)](#)
- 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 7, 2021. \(Filed herewith.\)](#)
- 31.2 [Certification of Chief Financial Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, dated January 7, 2021. \(Filed herewith.\)](#)
- 32.1 [Statement of Chief Executive Officer, pursuant to Section 1350 of Title 18 of the United States Code, dated January 7, 2021. \(Filed herewith.\)](#)
- 32.2 [Statement of Chief Financial Officer, pursuant to Section 1350 of Title 18 of the United States Code, dated January 7, 2021. \(Filed herewith.\)](#)

Item 16. Form 10-K Summary.

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

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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 7, 2021

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
(Principal Executive Officer)

January 7, 2021

By: /s/ Michael J. Catelani

Michael J. Catelani
Chief Operating Officer and
Chief Financial Officer
(Principal Financial and Accounting Officer)

January 7, 2021

By: /s/ Lewis H. Titterton, Jr.

Lewis H. Titterton, Jr.
Director

January 7, 2021

By: /s/ Arnold Baskies

Dr. Arnold Baskies
Director

January 7, 2021

By: /s/ David Cavalier

David Cavalier
Director

January 7, 2021

By: /s/ Emily Gottschalk

Emily Gottschalk
Director

January 7, 2021

By: /s/ John Monahan

Dr. John Monahan
Director

January 7, 2021

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ANIXA BIOSCIENCES, INC. AND SUBSIDIARIES

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OCTOBER 31, 2020

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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, 2020 and 2019, and the related consolidated statements of operations, shareholders' equity, and cash flows for each of the two years in the period ended October 31, 2020, 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, 2020 and 2019, and the consolidated results of its operations and its cash flows for each of the two years in the period ended October 31, 2020, in conformity with accounting principles generally accepted in the United States.

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 audit, 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.

/s/ Haskell & White LLP
HASKELL & WHITE LLP

We have served as the Company's auditor since 2013.

Irvine, California
January 7, 2021

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ANIXA BIOSCIENCES, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

| | October 31, 2020 | October 31, 2019 |
|--|---------------------|---------------------|
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 6,417,061 | \$ 3,491,625 |
| Short-term investments in certificates of deposit | 2,640,000 | 2,350,000 |
| Receivables | 2,231 | 66,527 |
| Prepaid expenses and other current assets | 309,332 | 184,972 |
| Total current assets | <u>9,368,624</u> | <u>6,093,124</u> |
| Property and equipment, net of accumulated depreciation of \$-0- and \$95,015, respectively | - | 200,569 |
| Operating lease right-of-use asset | 54,340 | - |
| Other assets | 30,000 | - |
| Total assets | <u>\$ 9,452,964</u> | <u>\$ 6,293,693</u> |
| LIABILITIES AND EQUITY | | |
| Current liabilities: | | |
| Accounts payable | \$ 232,368 | \$ 585,817 |
| Accrued expenses | 901,025 | 895,498 |
| Operating lease liability | 55,198 | - |
| Total current liabilities | <u>1,188,591</u> | <u>1,481,315</u> |
| Commitments and contingencies (Note 6) | | |
| Equity: | | |
| Shareholders' equity: | | |
| Preferred stock, par value \$100 per share; 19,860 shares authorized; no shares issued or outstanding | - | - |
| Series A convertible preferred stock, par value \$100 per share; 140 shares authorized; no shares issued or outstanding | - | - |
| Common stock, par value \$.01 per share; 100,000,000 and 48,000,000 shares authorized, respectively; 24,248,695 and 20,331,754 shares issued and outstanding, respectively | 242,486 | 203,317 |
| Additional paid-in capital | 200,354,488 | 186,849,299 |
| Accumulated deficit | (191,835,618) | (181,817,263) |
| Total shareholders' equity | <u>8,761,356</u> | <u>5,235,353</u> |
| Noncontrolling interest (Note 2) | (496,983) | (422,975) |
| Total equity | <u>8,264,373</u> | <u>4,812,378</u> |
| Total liabilities and equity | <u>\$ 9,452,964</u> | <u>\$ 6,293,693</u> |

The accompanying notes are an integral part of these statements.

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ANIXA BIOSCIENCES, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS

| | For the years ended October 31, | |
|---|---------------------------------|------------|
| | 2020 | 2019 |
| Revenue | \$ - | \$ 250,000 |
| Operating costs and expenses: | | |
| Inventor royalties, contingent legal fees, litigation and licensing expenses | - | 166,250 |
| Amortization of patents | - | 418,750 |
| Research and development expenses (including non-cash share based compensation expenses of \$1,484,545 and \$2,825,630, respectively) | 4,381,205 | 5,473,427 |

| | | |
|---|------------------------|------------------------|
| General and administrative expenses (including non-cash share based compensation expenses of \$2,652,915 and \$2,888,115, respectively) | 5,596,997 | 5,662,828 |
| Impairment in carrying amount of patent assets (Note 2) | - | 418,750 |
| Total operating costs and expenses | 9,978,202 | 12,140,005 |
| Loss from operations | (9,978,202) | (11,890,005) |
| Loss on disposal of property and equipment | (148,084) | - |
| Interest income | 33,923 | 71,353 |
| Net loss | (10,092,363) | (11,818,652) |
| Less: Net loss attributable to noncontrolling interest | (74,008) | (171,598) |
| Net loss attributable to common stockholders | <u>\$ (10,018,355)</u> | <u>\$ (11,647,054)</u> |
| Net loss per share: | | |
| Basic and diluted | <u>\$ (0.45)</u> | <u>\$ (0.59)</u> |
| Weighted average common shares outstanding: | | |
| Basic and diluted | <u>22,229,042</u> | <u>19,789,795</u> |

The accompanying notes are an integral part of these statements.

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ANIXA BIOSCIENCES, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF EQUITY FOR THE YEARS ENDED OCTOBER 31, 2020 and 2019

| | Common Stock | | Additional Paid-in Capital | Accumulated Deficit | Total Shareholders Equity | Non- controlling Interest | Total Equity |
|--|-------------------|-------------------|----------------------------------|-------------------------|---------------------------------|---------------------------------|---------------------|
| | Shares | Par Value | | | | | |
| BALANCE, October 31, 2018 | 18,908,632 | \$ 189,086 | \$ 175,415,931 | \$ (170,170,209) | \$ 5,434,808 | \$ (251,377) | \$ 5,183,431 |
| Stock option compensation to employees and directors | - | - | 3,560,883 | - | 3,560,883 | - | 3,560,883 |
| Stock options and warrants issued to consultants | - | - | 198,421 | - | 198,421 | - | 198,421 |
| Common stock issued upon exercise of stock options | 47,600 | 476 | 121,594 | - | 122,070 | - | 122,070 |
| Restricted stock award compensation to employee pursuant to stock incentive plan | - | - | 1,954,441 | - | 1,954,441 | - | 1,954,441 |
| Common stock issued pursuant to employee stock purchase plan | 11,650 | 116 | 38,970 | - | 39,086 | - | 39,086 |
| Common stock issued in at-the-market offering | 1,363,872 | 13,639 | 5,513,789 | - | 5,527,428 | - | 5,527,428 |
| Shareholder derivative complaint settlement | - | - | 45,270 | - | 45,270 | - | 45,270 |
| Net Loss | - | - | - | (11,647,054) | (11,647,054) | (171,598) | (11,818,652) |
| 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 at-the-market offering | 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 | <u>24,248,695</u> | <u>\$ 242,486</u> | <u>\$ 200,354,488</u> | <u>\$ (191,835,618)</u> | <u>\$ 8,761,356</u> | <u>\$ (496,983)</u> | <u>\$ 8,264,373</u> |

The accompanying notes are an integral part of these statements.

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ANIXA BIOSCIENCES, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS

| | For the years ended October 31, | |
|--|---------------------------------|---------------------|
| | 2020 | 2019 |
| Cash flows from operating activities: | | |
| Reconciliation of net loss to net cash used in operating activities: | | |
| Net loss | \$ (10,092,363) | \$ (11,818,652) |
| Stock option compensation to employees and directors | 3,922,719 | 3,560,883 |
| Stock options and warrants issued to consultants | 214,741 | 198,421 |
| Restricted stock award compensation to employee pursuant to stock incentive plan | - | 1,954,441 |
| Amortization of patents | - | 418,750 |
| Depreciation of property and equipment | 38,276 | 47,558 |
| Loss on disposal of property and equipment | 148,084 | - |
| Amortization of operating lease right-of-use asset | 51,881 | - |
| Impairment in carrying amount of patent assets | - | 418,750 |
| Change in operating assets and liabilities: | | |
| Receivables | 64,296 | 271,700 |
| Prepaid expenses and other current assets | (124,360) | (9,481) |
| Accounts payable | (353,449) | 3,805 |
| Accrued expenses | 5,527 | 212,399 |
| Operating lease liability | (51,023) | - |
| Net cash used in operating activities | <u>(6,175,671)</u> | <u>(4,741,426)</u> |
| Cash flows from investing activities: | | |
| Disbursements to acquire short-term investments in certificates of deposit | (5,010,000) | (3,850,000) |
| Proceeds from maturities of short-term investments in certificates of deposit | 4,720,000 | 3,500,000 |
| Purchase of property and equipment | (15,791) | (175,457) |
| Net cash used in investing activities | <u>(305,791)</u> | <u>(525,457)</u> |
| Cash flows from financing activities: | | |
| Proceeds from sale of common stock in at-the-market offering | 9,266,177 | 5,527,428 |
| Proceeds from sale of common stock pursuant to employee stock purchase plan | 18,451 | 39,086 |
| Proceeds from settlement of shareholder derivative complaint | - | 14,034 |
| Proceeds from exercise of stock options and warrants | 122,270 | 122,070 |
| Net cash provided by financing activities | <u>9,406,898</u> | <u>5,702,618</u> |
| Net increase in cash and cash equivalents | 2,925,436 | 435,735 |
| Cash and cash equivalents at beginning of year | 3,491,625 | 3,055,890 |
| Cash and cash equivalents at end of year | <u>\$ 6,417,061</u> | <u>\$ 3,491,625</u> |
| Supplemental cash flow information: | | |
| Cash proceeds from interest income | <u>\$ 39,890</u> | <u>\$ 55,729</u> |
| Supplemental disclosure of non-cash investing activity: | | |
| Disposal of fully depreciated property and equipment | <u>\$ -</u> | <u>\$ (6,343)</u> |
| Supplemental disclosure of non-cash financing activity: | | |
| Note receivable issued for settlement of shareholder derivative complaint | <u>\$ -</u> | <u>\$ 31,236</u> |

The accompanying notes are an integral part of these statements.

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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. Our primary operations involve 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 technology, a novel form of CAR-T technology, initially focused on treating ovarian cancer, and the discovery and ultimately development of anti-viral drug candidates for the treatment of COVID-19 focused on inhibiting certain viral protein functions of the virus. Our vaccine programs include the development of a vaccine against triple negative breast cancer (“TNBC”), the most lethal form of breast cancer, and a vaccine against ovarian cancer.

Our subsidiary, Certainty Therapeutics, Inc. (“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”) relating to Wistar’s CAR-T technology. We have initially focused on the development of a treatment for ovarian cancer, but we may also 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. 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 its CAR-T technology for treating ovarian cancer.

In April 2020, in collaboration with OntoChem GmbH (“OntoChem”), we commenced a project 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. We are working with researchers at OntoChem and other collaboration partners to advance the compounds discovered through this screening process toward human clinical testing.

We hold an exclusive worldwide, royalty-bearing license to use certain intellectual property owned or controlled by The Cleveland Clinic Foundation (“Cleveland Clinic”) relating to certain breast cancer vaccine technology developed at Cleveland Clinic. We are working in collaboration with Cleveland Clinic to develop a method to vaccinate women against contracting breast cancer, focused specifically on TNBC. A specific protein, alpha-lactalbumin, has been identified that is only present during lactation in healthy women, but reappears in many forms of breast cancer, especially TNBC. Studies have shown that vaccinating against this protein prevents breast cancer in mice. We are working with researchers and clinicians at Cleveland Clinic to prepare for treatment of patients in a Phase 1a clinical trial.

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 the use of vaccines for the treatment or prevention of ovarian cancers which express the extracellular domain of anti-Mullerian hormone receptor II (“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, AMHR2-ED is expressed at high levels in the ovaries of postmenopausal women with ovarian cancer. Researchers at Cleveland Clinic believe that a vaccination targeting AMHR2-ED could prevent the occurrence of ovarian cancer.

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ANIXA BIOSCIENCES, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

On July 2, 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, and may depend on positive results from human clinical trials.

Funding

Based on currently available information as of January 7, 2021, we believe that our existing cash, cash equivalents, short-term investments and expected cash flows will be sufficient to fund our activities for 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 2020, we raised approximately \$9,266,000, net of expenses, through at-the-market equity offerings of 3,854,305 shares of common stock. This included approximately \$427,000, net of expenses, through the sale of 112,238 shares of common stock in an at-the market equity offering which expired in November 2019 and approximately \$8,839,000, net of expenses, through the sale of 3,742,067 shares of common stock in an at-the-market equity offering under which we may issue up to \$50 million of common stock. Under our current at-the-market equity program which is currently effective and may remain available for us to use in the future, we may sell an additional approximately \$40,811,000 of common stock. We may seek to obtain working capital during our fiscal year 2021 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 could 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.

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ANIXA BIOSCIENCES, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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, 2020:

| | | |
|--|----|-----------|
| Balance October 31, 2018 | \$ | (251,377) |
| Net loss attributable to noncontrolling interest | | (171,598) |
| Balance October 31, 2019 | | (422,975) |
| Net loss attributable to noncontrolling interest | | (74,008) |
| Balance October 31, 2020 | \$ | (496,983) |

Revenue Recognition

Since fiscal 2016 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.

On November 1, 2018 we adopted Accounting Standards Update 2014-09 (“ASU 2014-09”), “Revenue from Contracts with Customers” using the modified retrospective method. Upon adoption of ASU 2014-09 we are required 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 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.

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ANIXA BIOSCIENCES, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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, consulting and other expenses paid to third-parties and the amortization of patent-related investment costs. 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 a platform for non-invasive blood tests for early detection of cancer, developing immuno-therapy drugs against cancer, development of our breast cancer vaccine, development of our ovarian cancer vaccine and development of anti-viral drug candidates for COVID-19, 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.

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ANIXA BIOSCIENCES, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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 |

The following table presents the hierarchy for our financial assets measured at fair value on a recurring basis as of October 31, 2019:

| | Level 1 | Level 2 | Level 3 | Total |
|---------------------------------|---------------------|---------------------|-------------|---------------------|
| Money market funds: | | | | |
| Cash and cash equivalents | \$ 2,706,944 | \$ - | \$ - | \$ 2,706,944 |
| Certificates of deposit: | | | | |
| Cash and cash equivalents | 500,000 | | - | 500,000 |
| Short term investments | - | 2,350,000 | - | 2,350,000 |
| Total financial assets | \$ 3,206,944 | \$ 2,350,000 | \$ - | \$ 5,556,944 |

Our non-financial assets that are measured on a non-recurring basis include our property and equipment which are measured using fair value techniques whenever events or changes in circumstances indicate a condition of impairment exists. The estimated fair value of accounts receivable, prepaid expenses, 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, 2020 and 2019, we had certificates of deposit with maturities greater than 90 days and less than 12 months when acquired of \$2,640,000 and \$2,350,000, respectively, that were classified as short-term investments and reported at fair value.

Patents

Our only identifiable intangible assets are patents and patent rights. We capitalize patent and patent rights acquisition costs and amortize the cost over the estimated economic useful life. No patent acquisition costs were capitalized during the years ended October 31, 2020 and 2019. We recorded patent amortization expense of \$0- and approximately \$419,000, respectively, during the years ended October 31, 2020 and 2019.

In evaluating the carrying amount of capitalized patents at January 31, 2019, we determined that a write-down of the carrying amount of approximately \$419,000, to a carrying value of approximately \$168,000, should be recorded as of January 31, 2019. The write-down was based on estimated undiscounted future cash flows of the capitalized patents compared to the carrying value.

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ANIXA BIOSCIENCES, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Our estimates of future cash flows was based on our most recent assessment of the market for potential licensees, as well as the status of ongoing negotiations with potential licensees. While we may be able to generate future cash flows from this patent portfolio, as of October 31, 2020 and 2019, we could not reasonably determine an estimate of any such future cash flows. The carrying value of capitalized patents is \$0- as of October 31, 2020 and 2019.

Property and equipment

We capitalized computers and test equipment used in our cancer diagnostics and therapeutics programs and charged depreciation on a straight-line basis over 60 months. Equipment purchases during the years ended October 31, 2020 and 2019 were approximately \$16,000 and \$175,000, respectively. We recorded depreciation expense of approximately \$38,000 and 48,000, respectively, during the years ended October 31, 2020 and 2019. As a result of the suspension of operations of our subsidiary, Anixa Diagnostics Corporation, as discussed in Note 1, we recorded a loss on disposal of property and equipment of approximately \$148,000 during the year ended October 31, 2020.

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 and directors using the accounting guidance in ASC 718 "Stock Compensation" ("ASC 718"). In accordance with ASC 718, we estimate the fair value of service-based options on the date of grant, using the Black-Scholes pricing model. We recognize compensation expense for stock option awards over the requisite or implied service period of the grant. We recorded stock-based compensation expense, related to service-based stock options granted to employees and directors, of approximately \$3,923,000 and \$3,185,000, during the years ended October 31, 2020 and 2019, respectively.

Included in stock-based compensation cost for service-based options granted to employees and directors during the years ended October 31, 2020 and 2019 was approximately \$3,011,000 and \$3,166,000, respectively, related to the amortization of compensation cost for stock options granted in prior periods but not yet vested. As of October 31, 2020, there was unrecognized compensation cost related to non-vested service-based stock options granted to employees and directors of approximately \$2,605,000, which will be recognized over a weighted-average period of 1.5 years.

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ANIXA BIOSCIENCES, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

For stock options granted to employees 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 cost over the implied service period (median time to vest). On May 8, 2018, we issued market condition 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 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%. We recorded stock-based compensation expense related to market condition stock options granted to employees of \$-0- and approximately \$376,000 during the years ended October 31, 2020 and 2019, respectively, which included \$-0- and approximately \$376,000, respectively, of expense related to the amortization of compensation cost for stock options granted in prior periods but not yet vested. As of October 31, 2020, there was no unrecognized compensation cost related to market condition stock options.

On November 1, 2018 we adopted Accounting Standards Update 2018-07 (“ASU 2018-07”) for stock options granted to consultants. Upon adoption of ASU 2018-07 we estimated the fair value of unvested service-based and performance-based stock options at the date of adoption, using the Black-Scholes pricing model. Subsequent to adoption of ASU 2018-07, future grants to consultants are measured at the grant date, based on the fair value of the award using the Black-Scholes pricing model, consistent with our policy for grants to employees and directors. In prior periods, in accordance with U.S. GAAP, we estimated the fair value of service-based and performance-based stock options granted to consultants at each reporting period using the Black-Scholes pricing model. We recognize the fair value of stock options granted to consultants as consulting expense over the requisite or implied service period of the grant.

We recorded consulting expense, related to service based and performance-based stock options granted to consultants, during the years ended October 31, 2020 and 2019 of approximately \$215,000 and \$113,000, respectively. Included in stock-based consulting expense for the years ended October 31, 2020 and 2019 was approximately \$123,000 and \$99,000, respectively, related to compensation cost for stock options granted in prior periods but not yet vested. As of October 31, 2020, there was unrecognized consulting expense related to non-vested stock options granted to consultants, related to service-based options of approximately \$340,000, which will be recognized over a weighted-average period of ~1.9 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, 2020 and 2019 consisted of awards with 5-year and 10-year terms that vest over 12 to 36 months.

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ANIXA BIOSCIENCES, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

The following weighted average assumptions were used in estimating the fair value of stock options granted during the years ended October 31, 2020 and 2019:

| | For the Year Ended October 31, | |
|---|-----------------------------------|---------|
| | 2020 | 2019 |
| Weighted average fair value at grant date | \$ 2.97 | \$ 3.87 |
| Valuation assumptions: | | |
| Expected life (years) | 5.86 | 5.47 |
| Expected volatility | 114.22% | 116.72% |
| Risk-free interest rate | 1.45% | 1.61% |
| Expected dividend yield | 0% | 0% |

The expected term of stock options represents the weighted average period the stock options are expected to remain outstanding. For employees and directors, we use the simplified method, which is a weighted average of the vesting term and contractual term, to determine expected term. The simplified method was adopted since we do not believe that historical experience is representative of future performance because of the impact of the changes in our operations and the change in terms from historical options which vested immediately to terms including vesting periods of up to three years. 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 and directors 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 vests 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. 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%. During the years ended October 31, 2020 and 2019 we recorded compensation expense related to the restricted stock award of \$-0- and approximately \$1,954,000, respectively. We did not issue any stock awards during the years ended October 31, 2020 and 2019. As of October 31, 2020, there was no unrecognized compensation cost related to the restricted stock awards.

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ANIXA BIOSCIENCES, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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, 2020 and 2019 we recorded consulting expense, based on the fair value, of \$-0- and approximately \$85,000, respectively, for warrants granted to consultants.

Net Loss Per Share of Common Stock

In accordance with ASC 260, "Earnings Per Share", basic net loss per common share ("Basic EPS") is computed by dividing net loss by the weighted average number of common shares outstanding. Diluted net loss per common share ("Diluted EPS") is computed by dividing net loss by the weighted average number of common shares and dilutive common share equivalents and convertible securities then outstanding. Diluted EPS for all years presented is the same as Basic EPS, as the inclusion of the effect of common share equivalents then outstanding would be anti-dilutive. For this reason, excluded from the calculation of Diluted EPS for the years ended October 31, 2020 and 2019 were options to purchase 7,952,195 and 7,632,068 shares, respectively, and warrants to purchase 560,000 shares and 525,000 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 February 2016, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update 2016-02 ("ASU 2016-02") Accounting Standards Codification Topic 842, Leases ("ASC 842"), which supersedes Topic 840, Leases, and which requires lessees to recognize most leases on the balance sheet. The new lease standard does not substantially change lessor accounting. For public companies, the standard was effective for the first interim reporting period within annual periods beginning after December 15, 2018, although early adoption was permitted. Lessees and lessors were required to apply the new standard at the beginning of the earliest period presented in the financial statements in which they first apply the new guidance. In July 2018, FASB issued ASU 2018-11, Leases, which provides an additional transition option for an entity to apply the provisions of ASC 842 by recognizing a cumulative effect adjustment at the effective date of adoption without adjusting the prior comparative periods presented. The requirements of this standard include a significant increase in required disclosures. The Company adopted ASU 2016-02 on November 1, 2019. The adoption of this standard did not have a material impact on our consolidated financial statements. See Note 5 regarding the accounting and disclosures related to our office lease.

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. 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 uncollectible 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 2019.

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ANIXA BIOSCIENCES, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

3. ACCRUED EXPENSES

Accrued liabilities consist of the following as of:

| | <u>October 31,</u> | |
|--|--------------------|-------------------|
| | <u>2020</u> | <u>2019</u> |
| Payroll and related expenses | 415,331 | 72,850 |
| Accrued royalty and contingent legal fees | 449,691 | 449,691 |
| Accrued collaborative research and license expense | 30,000 | 371,710 |
| Accrued other | 6,003 | 1,247 |
| | <u>\$ 901,025</u> | <u>\$ 895,498</u> |

4. SHAREHOLDERS' EQUITY

Stock Option Plans

During the year ended October 31, 2020, we had three stock option plans: the Anixa Biosciences, Inc. 2003 Share Incentive Plan (the "2003 Share Plan"), 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 April 21, 2003, July 14, 2010 and January 25, 2018, respectively. The 2018 Share Plan was approved by our shareholders on March 29, 2018

During the years ended October 31, 2020 and 2019, stock options to purchase 51,100 and 47,600 shares of common stock, respectively, were exercised with aggregate proceeds of approximately \$122,000 and \$122,000, respectively.

2003 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 two years ended October 31, 2020 is as follows:

| | <u>Shares</u> | <u>Weighted Average Exercise Price Per Share</u> | <u>Aggregate Intrinsic Value</u> |
|---|---------------|--|--|
| Options Outstanding at October 31, 2018 | 12,000 | \$ 2.77 | |
| Exercised | (11,600) | \$ 2.94 | |
| Options Outstanding at October 31, 2019 | 400 | \$ 17.00 | |
| Forfeited/Expired | (400) | \$ 17.00 | |

ANIXA BIOSCIENCES, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

2010 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 maximum 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, 2020 is as follows:

| | Shares | Weighted Average Exercise Price Per Share | Aggregate Intrinsic Value |
|---|-----------|---|------------------------------|
| Options Outstanding at October 31, 2018 | 2,131,868 | \$ 2.11 | |
| Granted | 10,000 | \$ 3.64 | |
| Exercised | (32,000) | \$ 2.27 | |
| Forfeited | (111,200) | \$ 3.89 | |
| Options Outstanding at October 31, 2019 | 1,998,668 | \$ 2.80 | |
| Exercised | (51,100) | \$ 2.39 | |
| Forfeited/Expired | (40,034) | \$ 2.34 | |
| Options Outstanding at October 31, 2020 | 1,907,534 | \$ 2.82 | \$ 327,340 |
| Options Exercisable at October 31, 2020 | 1,791,284 | \$ 2.84 | \$ 280,878 |

The following table summarizes information about stock options outstanding under the 2010 Share Plan as of October 31, 2020:

| Range of Exercise Prices | Options Outstanding | | | Options Exercisable | | |
|-----------------------------|-----------------------|--|---------------------------------------|-----------------------|--|---------------------------------------|
| | 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 |
| \$ 0.67 - \$2.30 | 549,000 | 5.45 | \$ 1.57 | 507,750 | 5.35 | \$ 1.62 |
| \$ 2.58 - \$3.13 | 834,000 | 2.84 | \$ 2.79 | 834,000 | 3.13 | \$ 2.79 |
| \$ 3.46 - \$5.75 | 524,534 | 7.25 | \$ 4.17 | 449,534 | 7.17 | \$ 4.49 |

ANIXA BIOSCIENCES, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

2018 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, 2020, the 2018 Share Plan had 2,388,339 shares available for future grants. Information regarding the 2018 Share Plan for the two years ended October 31, 2020 is as follows:

| | Shares | Weighted Average Exercise Price Per Share | Aggregate Intrinsic Value |
|---|-----------|---|------------------------------|
| Options Outstanding at October 31, 2018 | 3,482,000 | \$ 3.73 | |
| Granted | 465,000 | \$ 3.87 | |
| Exercised | (4,000) | \$ 3.84 | |
| Forfeited/Expired | (8,000) | \$ 3.84 | |
| Options Outstanding at October 31, 2019 | 3,935,000 | \$ 3.74 | |
| Granted | 1,045,000 | \$ 3.56 | |
| Forfeited/Expired | (633,339) | \$ 3.83 | |
| Options Outstanding at October 31, 2020 | 4,346,661 | \$ 3.69 | \$ -0- |
| Options Exercisable at October 31, 2020 | 2,456,109 | \$ 3.74 | \$ -0- |

The following table summarizes information about stock options outstanding under the 2018 Share Plan as of October 31, 2020:

| Range of Exercise Prices | Options Outstanding | | | Options Exercisable | | |
|--------------------------------|-----------------------|--|---------------------------------------|-----------------------|--|---------------------------------------|
| | 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 - \$3.70 | 3,247,781 | 7.70 | \$ | 3.62 | 1,861,948 | 7.58 | \$ | 3.68 |
| \$ | 3.84 - \$4.61 | 1,098,880 | 8.49 | \$ | 3.90 | 594,161 | 8.25 | \$ | 3.92 |

Non-Plan Options

In addition to options granted under the 2003 Share Plan, the 2010 Share Plan and the 2018 Share Plan, 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, 2020 is as follows:

| | Shares | Weighted Average Exercise Price Per Share | Aggregate Intrinsic Value |
|--|-----------|---|---------------------------|
| Options Outstanding at October 31, 2018 | 1,780,000 | \$ 1.58 | |
| Forfeited | (82,000) | \$ 5.32 | |
| Options Outstanding and Exercisable at October 31, 2019 and 2020 | 1,698,000 | \$ 2.58 | \$ -0- |

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ANIXA BIOSCIENCES, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

The following table summarizes information about outstanding and exercisable Non-Plan Options as of October 31, 2020:

| Range of Exercise Prices | Number Outstanding and Exercisable | Weighted Average Remaining Contractual Life (in years) | Weighted Average Exercise Price |
|--------------------------|------------------------------------|--|---------------------------------|
| \$ 2.58 | 1,698,000 | 1.75 | \$ 2.58 |

Re-Priced Stock Options

On August 21, 2019, the Company entered into a settlement agreement in connection with a putative shareholder derivative complaint filed in the Court of Chancery of the State of Delaware on November 5, 2018. Pursuant to the settlement agreement the Company agreed, among other things, to reprice certain stock options that were repriced on September 6, 2017 to \$0.67 to the option price immediately prior to that repricing. Accordingly, 4,000 stock options in the 2003 Share Plan with exercise prices of \$2.58, 878,400 stock options in the 2010 Share Plan with exercise prices ranging from \$0.96 to \$5.30 and 1,046,000 Non-Plan Options with exercise prices of \$2.58, were re-priced to the option price immediately prior to the September 6, 2017 repricing. In addition, certain individual defendants in the derivative complaint who had exercised stock options that were re-priced in the 2017 re-pricing and sold the underlying shares paid approximately \$45,000 to the Company representing a portion of the amount received for those shares.

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, 2020 and 2019, employees purchased 11,536 and 11,650 shares, respectively, with aggregate proceeds of approximately \$18,000 and \$39,000, respectively.

Common Stock Purchase Warrants

During the year ended October 31, 2019 we issued a warrant, expiring on November 1, 2023, to purchase 25,000 shares of common stock at \$4.04 per share, vesting over 12 months, to a consultant for investor relations services. On November 1, 2019 the warrant was exchanged for a stock option with the same terms as the warrant. We recorded consulting expense of approximately \$85,000 during the year ended October 31, 2019, based on the fair value of the warrant recognized on a straight-line basis over the vesting period.

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.

Information regarding the Company's warrants for the two years ended October 31, 2020 is as follows:

| | Shares | Weighted Average Exercise Price Per Share |
|--|-----------|---|
| Warrants Outstanding at October 31, 2018 | 829,400 | \$ 7.04 |
| Issued | 25,000 | \$ 4.04 |
| Expired | (329,400) | \$ 10.09 |
| 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 |
| Warrants Exercisable at October 31, 2020 | 510,000 | \$ 4.97 |

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ANIXA BIOSCIENCES, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

5. LEASES

We lease approximately 2,000 square feet of office space at 3150 Almaden Expressway, San Jose, California (our principal executive offices) from an unrelated party pursuant to an operating lease that expires September 30, 2021. 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. Under an operating lease that expired on May 31, 2019 we also leased approximately 3,000 square feet of office space at 12100 Wilshire Boulevard, Los Angeles, California (our former executive offices) from an unrelated party. As of August 1, 2018, we had subleased these facilities. Rent expense was approximately \$64,000 and \$60,000, respectively, for the years ended October 31, 2020 and 2019.

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. As a result, the consolidated balance sheet as of October 31, 2019 was not restated and is not comparative.

The adoption of ASC 842 resulted in the recognition of ROU assets of \$106,221, and lease liabilities for operating leases of \$106,299 on the Company's consolidated balance sheet as of November 1, 2019. The difference between the ROU assets and the operating lease liability represents the difference between the lease cost and the amount of rent paid in October 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 11-month lease term as of October 31, 2020 for the Company's lease includes the noncancelable period of the lease. The lease does not contain a Company option to extend the lease or an option to extend the lease controlled by the lessor. All ROU assets are reviewed for impairment.

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

| | Balance Sheet Location | October 31, 2020 | November 1, 2019 | October 31, 2019 |
|-----------------------------------|-------------------------------------|------------------|------------------|------------------|
| Operating Lease: | | | | |
| Right-of-use asset | Operating lease right- of-use asset | \$ 54,340 | \$ 106,221 | \$ - |
| Right-of-use liability, current | Operating lease liability | 55,198 | 51,101 | - |
| Right-of-use liability, long-term | Not presented | - | 55,198 | - |

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ANIXA BIOSCIENCES, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

As of October 31, 2020, the annual minimum lease payments of our operating lease liability were as follows:

| | Operating Leases |
|--|------------------|
| Fiscal year 2021 future minimum payments, undiscounted | \$ 59,136 |
| Less: Imputed interest | 3,938 |
| Present value of future minimum lease payments | \$ 55,198 |

6. COMMITMENTS AND CONTINGENCIES

Litigation Matters

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

Collaborative Research and License Commitments

As of October 31, 2020, our commitments under the collaborative and license agreements with Moffitt, Wistar, Cleveland Clinic and OntoChem for the year ending October 31, 2021 were approximately \$188,000.

7. INCOME TAXES

Income tax provision (benefit) consists of the following:

| | Year Ended October 31, | |
|--|------------------------|-------------|
| | 2020 | 2019 |
| Federal: | | |
| Current | \$ - | \$ - |
| Deferred | 404,000 | (948,000) |
| State: | | |
| Current | - | - |
| Deferred | (800,000) | (995,000) |
| Adjustment to valuation allowance related to net deferred tax assets | 396,000 | 1,943,000 |
| | <u>\$ -</u> | <u>\$ -</u> |

The tax effects of temporary differences that give rise to significant portions of the deferred tax asset, net, at October 31, 2020 and 2019, are as follows:

October 31,

| | 2020 | 2019 |
|--|---------------|---------------|
| Long-term deferred tax assets: | | |
| Federal and state NOL and tax credit carryforwards | \$ 19,727,000 | \$ 19,593,000 |
| Deferred compensation | 8,009,000 | 7,619,000 |
| Intangibles | 828,000 | 943,000 |
| Other | 192,000 | 205,000 |
| Subtotal | 28,756,000 | 28,360,000 |
| Less: valuation allowance | (28,756,000) | (28,360,000) |
| Deferred tax asset, net | \$ - | \$ - |

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ANIXA BIOSCIENCES, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

As of October 31, 2020, we had tax net operating loss and tax credit carryforwards of approximately \$81,316,000 and \$1,545,000, respectively, available within statutory limits (expiring at various dates between 2021 and 2040), 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, 2020, management has not determined the extent of any such limitations, if any.

We had California tax net operating loss carryforwards of approximately \$26,671,000 as of October 31, 2020, available within statutory limits (expiring at various dates between 2021 and 2040), 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, | | | |
|--|------------------------|--------------|----------------|--------------|
| | 2020 | | 2019 | |
| Income tax benefit at U.S. Federal statutory income tax rate | \$ (2,119,000) | (21.00)% | \$ (2,482,000) | (21.00)% |
| State income taxes | (705,000) | (6.98)% | (1,045,000) | (8.84)% |
| Permanent differences | 32,000 | 0.32% | 30,000 | 0.25% |
| Expiring net operating losses, credits and other | 2,396,000 | 23.74% | 1,554,000 | 13.15% |
| Change in valuation allowance | 396,000 | 3.92% | 1,943,000 | 16.44% |
| Income tax provision | <u>\$ -</u> | <u>0.00%</u> | <u>\$ -</u> | <u>0.00%</u> |

During the two fiscal years ended October 31, 2020, we incurred no Federal and no State income taxes. We have no unrecognized tax benefits as of October 31, 2020 and 2019 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.

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ANIXA BIOSCIENCES, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

8. SEGMENT INFORMATION

We follow the accounting guidance of ASC 280 "Segment Reporting" ("ASC 280"). Reportable operating segments are determined based on the management approach. The management approach, as defined by ASC 280, is based on the way that the chief operating decision-maker organizes the segments within an enterprise for making operating decisions and assessing performance. While our results of operations are primarily reviewed on a consolidated basis, the chief operating decision-maker manages the enterprise in five reportable segments, each with different operating and potential revenue generating characteristics: (i) CAR-T Therapeutics, (ii) Cancer Vaccines, (iii) Anti-Viral Therapeutics, (iv) Cancer Diagnostics and (v) our legacy Patent Licensing activities. The following represents selected financial information for our segments for the years ended October 31, 2020 and 2019:

| | Year Ended October 31, | |
|---|------------------------|------------------------|
| | 2020 | 2019 |
| Net loss: | | |
| CAR-T Therapeutics | \$ (2,241,443) | \$ (5,074,868) |
| Cancer Vaccines | (828,136) | (677,450) |
| Anti-Viral Therapeutics | (1,168,969) | - |
| Cancer Diagnostics | (5,836,594) | (5,196,471) |
| Patent Licensing | (17,221) | (869,863) |
| Total | <u>\$ (10,092,363)</u> | <u>\$ (11,818,652)</u> |
| Total operating costs and expenses | \$ 9,978,202 | \$ 12,140,005 |
| Less non-cash share-based compensation | (4,137,460) | (5,713,746) |
| Operating costs and expenses excluding non-cash share-based compensation | <u>\$ 5,840,742</u> | <u>\$ 6,426,259</u> |
| Operating costs and expenses excluding non-cash share based compensation: | | |
| CAR-T Therapeutics | \$ 1,141,542 | \$ 2,212,090 |
| Cancer Vaccines | 365,681 | 458,392 |
| Anti-Viral Therapeutics | 739,140 | - |
| Cancer Diagnostics | 3,581,377 | 2,689,761 |
| Patent Licensing | <u>13,002</u> | <u>1,066,016</u> |

| | | | | |
|-------------------------|----|-------------|----|-----------|
| Total | \$ | 5,840,742 | \$ | 6,426,259 |
| | | October 31, | | |
| | | 2020 | | 2019 |
| Total assets: | | | | |
| CAR-T Therapeutics | \$ | 2,988,124 | \$ | 2,382,460 |
| Cancer Vaccines | | 946,923 | | 489,881 |
| Anti-Viral Therapeutics | | 2,464,361 | | - |
| Cancer Diagnostics | | 2,869,529 | | 2,921,784 |
| Patent Licensing | | 184,027 | | 499,568 |
| Total | \$ | 9,452,964 | \$ | 6,293,693 |

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 \$250,000, inventor royalties, contingent legal fees, litigation and licensing expense of \$166,250, amortization of patents of \$418,750 and impairment in carrying amount of patent assets of \$418,750 for the year ended October 31, 2019 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.

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ANIXA BIOSCIENCES, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

9. IMPACT OF CORONAVIRUS PANDEMIC

On March 10, 2020, the World Health Organization declared the COVID-19 outbreak a pandemic. The virus and actions taken to mitigate its spread have had and are expected to continue to have a broad adverse impact on the economies and financial markets of many countries, including the geographical areas in which the Company operates and conducts its business and which the Company's partners operate and conduct their business. We are currently following the recommendations of local health authorities to minimize exposure risk for our team members and visitors. However, the scale and scope of this pandemic is unknown and the duration of the business disruption and related financial impact cannot be reasonably estimated at this time. While we have implemented specific business continuity plans to reduce the potential impact of COVID-19, there is no guarantee that our continuity plans will be successful.

We have already experienced certain disruptions to our business such as temporary closure of our offices and similar disruptions have occurred for our partners. Specifically, the outbreak has caused 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 more 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 advancement of our programs.

The extent to which COVID-19 or any other health epidemic may impact our results will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of COVID-19 and the actions to contain COVID-19 or treat its impact, among others. Accordingly, COVID-19 could have a material adverse effect on our business, results of operations, financial condition and prospects.

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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 [], [2025]
(subject to Section 2 herein, the "*Expiration Date*")

October [], 2020

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 October [], 2020, 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 last day of each month beginning on October 31, 2020 through March 31, 2021. 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, 2020, this Warrant shall be exercisable for 20,000 shares of Common Stock and shall expire on January 14, 2021.

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3. Exercise Price. The initial Exercise Price of this Warrant shall be \$[] 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.

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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 reclassification.

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(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.”

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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 _____, 2020

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:

Redactions with respect to certain portions hereof denoted with “****”

AMENDMENT 2 TO THE COLLABORATION AGREEMENT

BETWEEN

CERTAINTY THERAPEUTICS, INC.

AND

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

Moffitt Agreement Identifier: Anixa-CERTainty Contract (Conejo-Garcia) 17-0173
Project Title: Development of CAR-T/CER-T Therapies for Ovarian and Prostate Cancer
Moffitt Principal Investigator: Dr. Jose Conejo-Garcia

The “Agreement” described above was previously entered into on November 17, 2017 (hereinafter “Effective Date”) and duly amended on July 24, 2019 (“Amendment 1 Effective Date”) 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”). Moffitt and Company are hereinafter referred to individually as “Party” and collectively as “Parties.”

WHEREAS, Moffitt requests an extension of the Agreement end date from November 17, 2020 to November 17, 2021; and

WHEREAS, Moffitt requests Company to provide additional funds to cover Moffitt’s management of services provided by a third-party vendor to carry out Third Party Materials production as part of the Development Plan; and

WHEREAS, Company agrees to Moffitt’s extended participation in the investigation set forth in the Research Plan attached as Exhibit B to the original Agreement; and

WHEREAS, Company agrees to provide additional funds to Moffitt as defined herein as Exhibit C-1 in this Amendment 2; and

WHEREAS, Moffitt and Company agree to these modifications as set forth by procedures described in Section 13.9 of the original Agreement.

NOW, THEREFORE, in consideration of the foregoing recitals, which are incorporated herein as covenants, and the mutual promises herein made and exchanged, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Company and Moffitt agree to the following:

1. **Terms.** Capitalized terms in this Amendment 2 shall have the same meaning as those in the Agreement, unless specifically defined in the Amendment 2. All section and paragraph references refer to sections or paragraphs, as applicable, in the Agreement.

Redactions with respect to certain portions hereof denoted with “****”

2. Amendments.

2.1 ARTICLE 7 Term and Termination shall hereby be deleted and replaced with the following:

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”).

2.2 Exhibit C-1 as outlined herein shall be incorporated into the Agreement as an addendum to Exhibit C of the Agreement. Exhibit C-1 describes the additional funding amount to be added to the Budget and the Payment Schedule for said funding amount.

3. **Interpretation.** Except as expressly modified herein, the Agreement shall remain in full force and effect in accordance with its terms. To the extent there are any inconsistencies or ambiguities between this Amendment 2 Amendment and the Agreement, the terms of this Amendment 2 shall supersede the Agreement.

IN WITNESS WHEREOF, the Parties have caused this Amendment 2 to the Agreement to be executed by their duly authorized representatives as of the date of last signature below (the “Amendment 2 Effective Date”).

CERTAINTY THERAPEUTICS, INC.

BY: /s/ Amit Kumar
Name: Amit Kumar
Title: Chief Executive Officer (CEO)
Date: October 13, 2020

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

BY: /s/ Margaret J. Fonner
Name: Margaret J. Fonner
Title: Director, Office of Sponsored Research
Date: 10/16/2020

Redactions with respect to certain portions hereof denoted with “****”

**EXHIBIT C-1
ADDENDUM TO BUDGET**

Principal Investigator: Conejo-Garcia, José

| BUDGET - YEAR 1 | | | | | YEAR 1 Salary and Fringe Benefits | TOTAL | |
|---|----------------------------|-----------------------------------|------------------------------------|--|--|---|------------|
| PERSONNEL | | | | | | | |
| NAME | ROLE ON PROJECT | Percent Effort Devoted | Calendar Months Devoted | | | | |
| KEY PERSONNEL (MCC A) | | | | | | | |
| Dr. Conejo-Garcia | PI | *** | *** | | | | |
| Dr. Abate-Daga | Co-I | *** | *** | | | | |
| | | *** | *** | | | | |
| TECHNICAL STAFF (MCC B) | | | | | | | |
| SUBTOTALS | | | | | → | \$ *** | \$ *** |
| Other Expenses | | | | | | | |
| Subawards/Consortium Contractual Costs | | | | | | \$ *** | |
| Alliance Management Fee | | | | | | \$ *** | |
| SUBTOTAL DIRECT COSTS | | | | | | \$ *** | \$ *** |
| FACILITIES AND ADMINISTRATIVE COSTS @ | | | | | | \$ *** | \$ *** |
| TOTAL COSTS FOR TOTAL PERIOD | | | | | | \$ 262,804 | \$ 262,804 |
| PAYMENT SCHEDULE | | | | | | \$150,000 upon execution of Agreement \$112,804 upon completed generation of viral vector for clinical trial | |

AMENDMENT TO COLLABORATION AGREEMENT

This AMENDMENT TO COLLABORATION AGREEMENT (the “**Amendment**”) is made as of October 19, 2020 (the “**Amendment Effective Date**”), by and between Anixa Biosciences, Inc., a Delaware corporation (“**Anixa**”), and OntoChem GmbH, a German limited liability company (“**OntoChem**”). Anixa and OntoChem are referred to herein individually as a “**Party**” and collectively as the “**Parties**.”

WHEREAS, the Parties entered into a Collaboration Agreement (the “**Agreement**”) on April 14, 2020;

WHEREAS, the Parties agree that more time is necessary to complete the activities set forth in the Research Plan attached as Exhibit A to the original Agreement; and

WHEREAS, Anixa agrees to provide additional funds to OntoChem to complete the Research Plan.

NOW, THEREFORE, in consideration of the foregoing recitals, and the mutual promises herein made and exchanged, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree to the following:

1. Terms. Capitalized terms in this Amendment shall have the same meaning as those in the Agreement, unless specifically defined in this Amendment.

2. Amendments.

2.1 Section 3.1(a) of the Agreement is hereby amended and restated to read in its entirety as follows:

3.1(a) pay OntoChem: (i) 16,667 Euros withing five (5) days after the Effective Date; (ii) five (5) installments in the amount of 16,667 Euros on each one-month anniversary of the Effective Date, except that the last such payment will be due on October 21, 2020; and (iii) three (3) installments in the amount of 8,334 Euros on each one-month anniversary of the Effective Date commencing on November 14, 2020; and

2.2 Section 3.1(b) of the Agreement is hereby amended and restated to read in its entirety as follows:

3.1(b) reimburse OntoChem for its out-of-pocket expenses incurred in performing the Research Plan on a pass-through basis without mark-up, within thirty (30) days after delivery of an invoice therefor (including reasonable supporting documentation), provided that Anixa has approved such expenses in advance and in writing (including in regard to the selection of specific Hit Compounds to be synthesized and analyzed in biological assays). It is estimated that OntoChem’s out-of-pocket expenses under the Research Plan will include 165,000 Euros payable to Tube Pharmaceuticals GmbH as a subcontractor of OntoChem, subject to Section 2.5.

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2.3 Section 4.6 of the Agreement is hereby amended and restated to read in its entirety as follows:

4.6 Survival. Expiration or termination of this Agreement will not affect the rights and obligations of the Parties that accrued prior to the effective date of such expiration or termination. The following provisions will remain in effect following expiration or termination of this Agreement and the Parties will continue to be bound thereby: Sections 2.4, 2.7, 2.8 (last sentence only), 3.2, 3.3, 3.4, 3.5, 4.5, 4.6, 5, 6, 8 and 9.

2. Interpretation. Except as expressly modified herein, the Agreement shall remain in full force and effect in accordance with its terms. To the extent there are any inconsistencies or ambiguities between this Amendment and the Agreement, the terms of this Amendment shall supersede the Agreement.

3. Governing Law. This Amendment and the rights and obligations of the Parties hereunder will be governed by the laws of the State of Delaware without regard to the conflict of laws provisions of any jurisdiction. The Parties agree that the 1980 United Nations Convention on Contracts for the International Sale of Goods shall not apply to this Amendment.

4. Counterparts. The Parties may execute this Amendment in multiple counterparts, all of which together will constitute one instrument. Signatures to this Amendment delivered by facsimile or other electronic transmission (e.g., portable document format (PDF)) will be deemed to be binding as original signatures.

IN WITNESS WHEREOF, the Parties have executed this Amendment as of the Amendment Effective Date.

ANIXA BIOSCIENCES, INC.

By: /s/ Amit Kumar
Amit Kumar, Ph.D.
President and CEO

ONTOCHEM GMBH

By: /s/ Lutz Weber
Lutz Weber, Ph.D.
CEO

-2-

Redactions with respect to certain portions hereof denoted with “****”

EXCLUSIVE LICENSE AGREEMENT

between

THE CLEVELAND CLINIC FOUNDATION

and

ANIXA BIOSCIENCES, INC.

dated as of

October 20, 2020

Redactions with respect to certain portions hereof denoted with “****”

EXCLUSIVE LICENSE AGREEMENT

This Exclusive License Agreement (this “**Agreement**”) is made and entered into effective as of October 20, 2020 (the “**Effective Date**”), by and between The Cleveland Clinic Foundation, a nonprofit Ohio corporation (“**Licensor**”), and Anixa Biosciences, Inc., a Delaware corporation (“**Licensee**”).

RECITALS:

WHEREAS, Licensor owns certain patents and/or patent applications pertaining to the use of vaccines for the treatment or prevention of Ovarian Cancer and other types of cancers, which express the Anti-Mullerian Hormone Receptor 2 (AMHR2) protein, including an Anti-Mullerian Hormone Receptor 2 containing an Extracellular Domain (AMHR2-ED) developed by Vincent K. Tuohy, Justin Johnson and Suparna Mazumder (who are “**Inventors**” as defined below) that it believes should be developed and commercialized for the greater public good; and

WHEREAS, Licensor desires to grant to Licensee an exclusive license under such patents and/or patent applications in order to develop and commercialize such technology, and Licensee desires such license and agrees to use commercially reasonable efforts to develop and commercialize such technology, in each case subject to the terms, conditions and other provisions contained herein.

NOW, THEREFORE, in consideration of the mutual covenants contained in this Agreement and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties agree as follows:

Article 1
DEFINITIONS

1.1 Defined Terms. In addition to such terms as are defined elsewhere in this Agreement, the capitalized terms in this Agreement shall have the following meanings:

“**Action**” has the meaning set forth in Section 10.1.1.

“**Affiliate**” as to any Person, means any other Person that, directly or indirectly through one or more intermediaries, is in control of, is controlled by, or is under common control with, such Person. For purposes of this definition, “control” of a Person means the power, directly or indirectly, either to (a) vote 50% or more of the securities having ordinary voting power for the election of directors (or persons performing similar functions) of such Person or (b) direct or cause the direction of the management and policies of such Person, whether by contract or otherwise.

“**Agent**” has the meaning set forth in Section 23.3.

“**Agreement**” has the meaning set forth in the Preamble.

“**Annual Update**” has the meaning set forth in Section 4.2(b).

“**Bankruptcy Code**” means Title 11 of the United States Code, as amended from time to time, or any similar federal or state law for the relief of debtors.

“**Change in Control**” of any Person means (a) a merger or consolidation of such Person, (b) a transaction or series of related transactions in which any Person or group of persons within the meaning of § 13(d)(3) of the Securities Exchange Act of 1934, becomes the beneficial owner, directly or indirectly, of fifty percent (50%) or more of the combined voting power of the outstanding securities of such Person, or (c) the sale or other transfer to a third party of all or substantially all of such Person’s assets related to the subject matter of this Agreement.

Redactions with respect to certain portions hereof denoted with “****”

“**Confidential Information**” means all non-public, confidential or proprietary information of a party, or its Affiliates or Representatives, that is disclosed directly or indirectly from or on behalf of the Disclosing Party to the Receiving Party, whether in oral, written, electronic or other form or media, whether or not such information is marked, designated or otherwise identified as “confidential” and that, due to the nature of its subject matter or circumstances surrounding its disclosure, would reasonably be understood to be confidential or proprietary, including, without limitation, the Licensed Know-how and the terms and existence of this Agreement.

Confidential Information does not include information that the Receiving Party can demonstrate by documentation or other evidence (i) was already known to the Receiving Party without restriction on use or disclosure prior to the receipt of such information directly or indirectly from or on behalf of the Disclosing Party; (ii) was independently developed by the Receiving Party without use of or reference to the Disclosing Party’s Confidential Information; (iii) is or becomes generally known to the public or otherwise becomes publicly available, other than through a breach of this Agreement by the Receiving Party; or (iv) is or was made available to the Receiving Party on a non-confidential basis by a third party having the lawful right to do so without breaching any obligation of confidentiality to the Disclosing Party.

“**Cure Period**” has the meaning set forth in Section 4.1(b).

“**Debarred**” has the meaning set forth in Section 23.3.

“**Debtor Relief Law**” means the Bankruptcy Code and all other liquidation, bankruptcy, assignment for the benefit of creditors, conservatorship, moratorium, receivership, insolvency, rearrangement, reorganization or similar debtor relief laws of the US or other applicable jurisdictions in effect from time to time.

“**Declaring Party**” has the meaning set forth in Section 9.2.2.

“**Default**” means any of the events specified in Section 7.2, Section 7.4, or anywhere else in this Agreement, which results in (a) Licensor having the right to terminate this Agreement or (b) automatic termination of this Agreement.

“**Development Plan**” means the initial plan to be attached hereto as Exhibit A pursuant to Section 5.7, setting forth the strategy and schedule for Licensee’s research, development and testing of Licensed Products, including the estimated dates of initiation and completion of material development activities (to be performed by or on behalf of Licensee or Licensor) leading to Regulatory Approval and commercial sale of Licensed Products, and thereafter any updates to the development plan as provided by Licensee pursuant to Section 4.2.

“**Development Report**” means a written account of Licensee’s progress under the Development Plan including the information specified in Exhibit C to this Agreement.

“**Disclosing Party**” has the meaning set forth in Section 8.1.

“**Dispute**” has the meaning set forth in Section 9.2.1.

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Redactions with respect to certain portions hereof denoted with “**”**

“**Earned Know-how Royalty**” has the meaning set forth in Section 3.2(b).

“**Earned Patent Royalty**” has the meaning set forth in Section 3.2(a).

“**Earned Royalties**” means, collectively, the Earned Patent Royalty and the Earned Know-how Royalty.

“**Effective Date**” has the meaning set forth in the Preamble.

The expression “**expiration**” and “**expire**”, when referring to a claim in a Licensed Patent means any expiration, revocation, invalidation or other termination of a Licensed Patent incorporating the pending, issued or enforceable claim.

“**FDA**” has the meaning set forth in the definition of Regulatory Authority.

“**Field 1**” means vaccines for the prevention of Ovarian Cancer and other cancers, which express the Anti-Mullerian Hormone Receptor 2 (AMHR2) protein, including an Anti-Mullerian Hormone Receptor 2 protein with an extracellular domain (AMHR2-ED).

“**Field 2**” means vaccines for the therapeutic treatment of Ovarian Cancer and other cancers, which express the Anti-Mullerian Hormone Receptor 2 (AMHR2) protein, including an Anti-Mullerian Hormone Receptor 2 protein with an extracellular domain (AMHR2-ED).

“**Fields**” means, collectively, Field 1 and Field 2.

“**First Commercial Sale**” means the first arms-length, non-clinical trial-related sale of a Licensed Product.

“**Force Majeure Event**” has the meaning set forth in Section 4.1(b).

“**GAAP**” means generally accepted accounting principles in the United States of America as in effect from time to time.

“**Governmental Authority**” means the government of any nation or any political subdivision thereof, whether at the national, state, territorial, provincial, municipal or any other level, and any agency, authority, instrumentality, regulatory body, court, central bank or other entity exercising executive, legislative, judicial, taxing, regulatory or administrative powers or functions of, or pertaining to, government.

“**Indemnitee**” has the meaning set forth in Section 10.1.1.

“**Infringement Notice**” has the meaning set forth in Section 6.4.1.

“**Inventors**” means each person listed as an inventor on any Licensed Patent.

“**Issue Fee**” has the meaning set forth in Section 3.1.

“**Law**” means any statute, law, ordinance, regulation, rule, code, order, constitution, treaty, common law, judgment, decree, other requirement or rule of law of any Governmental Authority or Regulatory Authority.

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Redactions with respect to certain portions hereof denoted with “**”**

“**Licensed Know-how**” means any unpatentable or unpatented developments, proprietary knowledge, ideas, specifications, prototypes, drawings, know-how, formulas, information, data, methods, processes, tools, designs, testing programs, expertise, concepts or techniques, and similar knowledge not known by Licensee prior to Licensor disclosing such knowledge to Licensee, solely to the extent that they are (a) pertinent to the Licensed Patents, (b) not subject to the exclusive rights of any third parties or research sponsor restrictions, (c) (i) in existence, and known to the Inventor or members of his laboratory(ies), as of the Effective Date or (ii) generated by or on behalf of Licensor (solely or jointly with others) during the Term through the exercise of Licensor’s retained rights under Section 2.4.1, including non-clinical and clinical data, and (d) applicable primarily within the Fields, further described in Appendix A.

“**Licensed Know-how Product**” means a product or part of a product in the Fields that is sold, transferred, or otherwise disposed of in a jurisdiction where (i) a Licensed Patent has expired; (ii) patent protection is not pursued, but the product or part of a product sold, transferred, or otherwise disposed of would be expected to infringe (with respect to Valid Claims of patent applications) any Valid Claim; or (iii) that was derived from, utilizes, uses, is used, or made through use of, embodies, contains, incorporates (in each case, in whole or in part), or uses any element of any of the Licensed Know-how.

“**Licensed Know-how Royalty Term**” means, with respect to a particular Licensed Product in a particular country, the period of time commencing on the First Commercial Sale of such Licensed Product in such country and ending on the **** of such First Commercial Sale.

“**Licensed Patents**” means the patents and patent applications listed on Appendix A, together with (a) all patents that issue therefrom, and (b) all corresponding foreign patents and patent applications thereof, together with all divisionals, continuations (but excluding continuations-in-part), reissues, reexaminations, extensions or renewals of any of the foregoing having the same priority date as the parent and listing at least one of the Inventors as inventors.

“**Licensed Patent Challenge**” has the meaning set forth in Section 6.5(a).

“**Licensed Patent Royalty Term**” means, with respect to a particular Licensed Product in a particular country, the period of time commencing on the First Commercial Sale of such Licensed Product in such country and continuing through the date of expiration of the last to expire Valid Claim of the Licensed Patents covering the sale of such Licensed Product in such country.

“**Licensed Patent Product**” means any product or part of a product in the Fields the making, use, sale, offer to sell, or import of which infringes or would be expected to infringe (with respect to Valid Claims of patent applications) a Valid Claim, but for the license granted in this Agreement.

“**Licensed Product**” means (i) a Licensed Patent Product; or (ii) a Licensed Know-how Product.

“**Licensed Technology**” means, collectively, the Licensed Patents and the Licensed Know-How.

“**Licensee**” has the meaning set forth in the Preamble.

“**Licensor**” has the meaning set forth in the Preamble.

“**Losses**” means all losses, damages, liabilities, deficiencies, claims, actions, judgments, settlements, interest, awards, penalties, fines, costs or expenses of whatever kind, including reasonable attorneys’ fees and the cost of enforcing any right to indemnification hereunder and the cost of pursuing any insurance providers.

4

Redactions with respect to certain portions hereof denoted with “**”**

“**Major Market**” has the meaning set forth in Section 4.1(a).

“**Net Sales**” means the total gross amount of monies or cash equivalent or other consideration paid or payable to Licensee or any Sublicensee for sales of Licensed Products less the sum of the following amounts, without duplication: ***.

For non-cash and partial-cash sales, the applicable Licensed Product shall be considered sold at the fair market value of the consideration received. For sales not at arms-length, Net Sales shall be equal to the fair market price of such Licensed Products as when transferred in comparable arms-length transactions.

In the event that Licensed Products are used by Licensee or Sublicensees for demonstration or marketing purposes rather than sold, the Parties shall agree upon an appropriate Net Sales price, if at all applicable based upon the nature and circumstance regarding the demonstration or marketing purposes, for each such use. Further, any transfer or use of a Licensed Product for clinical trials or compassionate use will not be deemed a sale for purposes of calculating Net Sales.

For the purposes of calculating Net Sales, all calculations of Net Sales shall be in accordance with GAAP and based on, or valued as if based on, bona fide arms’ length transactions and not on any bundled, loss-leading or other blended or artificial selling or transfer price.

Net Sales shall not include Sublicensing Revenue.

Where Licensed Products are not sold, but are otherwise transferred or disposed of, the Net Sales amount of such Licensed Product for the purposes of computing the Earned Royalty shall be the average Net Sales price at which Licensed Products, sold in similar quantities and similar locations, are then currently being offered for sale by Licensee or its Sublicensees. Where such products are not then currently being offered for sale by Licensee or a Sublicensee, the Net Sales price of products otherwise disposed of, for the purpose of computing the Earned Patent Royalty and the Earned Know-how Royalty, shall be the average selling price at which products of similar kind and quality, sold in similar quantities and similar locations, are then currently being offered for sale by other manufacturers.

In the event that a Licensed Product is sold together with one or more products or services that are not Licensed Products for a single price (a **Combination**”), the gross amount invoiced for such Licensed Product for purposes of calculating Net Sales shall be calculated by multiplying the gross amount invoiced for such Combination by the fraction $A/(A+B)$, where “A” is the gross amount invoiced for such Licensed Product sold separately and “B” is the gross amount invoiced for such other product(s) or service(s) sold separately. In the event that such Licensed Product or such other product(s) or service(s) are not sold separately, the portion of the gross amount invoiced for such Combination that is attributable to Net Sales for purposes of royalty determination shall be mutually agreed by the Parties in good faith based upon the relative value of the Licensed Product and the other product(s) or service(s) included in the Combination.

The expression “**transferred or otherwise disposed of**” means (y) not sold but delivered, directly or indirectly, by Licensee or Sublicensees to others (including deliveries for export), regardless of any return or exchange consideration; or (z) exploited or otherwise used by Licensee or Sublicensees for any purpose other than routine testing of such Licensed Products.

“**Notice**” has the meaning set forth in Section 9.2.2.

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“**Patenting Costs**” means any and all reasonable, documented, out-of-pocket costs and expenses, including without limitation government fees and attorneys’ fees and costs, of preparing, filing, prosecuting, issuing and maintaining any of the Licensed Patents, including continuations, extensions, re-examinations, reissues and appeals.

“**Patent Reimbursement Amount**” has the meaning set forth in Section 6.2.1.

“**Person**” means any individual, partnership, trust, incorporated or unincorporated association, joint venture, limited liability company, or other legal entity of any kind, foreign or domestic.

“**Phase I Clinical Trial**” means an FDA (or other foreign regulatory authority) approved dose escalating safety study with respect to a Licensed Product.

“**Phase II Clinical Trial**” means a human clinical study of a Licensed Product, the principal purpose of which is a determination of safety and efficacy in the target patient population, as described in 21 C.F.R. 312.21(b), or a similar human clinical study prescribed by the Regulatory Authority in a country other than the United States. Phase II Clinical Trial also includes the portion of any human clinical study that meets the foregoing definition, as in the case of a study designated as a “Phase I/II” clinical trial.

“**Phase III Clinical Trial**” means a human clinical study of a Licensed Product, the design of which is acknowledged by the FDA to be sufficient for such clinical study to satisfy the requirements of 21 C.F.R. 312.21(c), or a similar human clinical study prescribed by the Regulatory Authority in a country other than the United States.

Phase III Clinical Trial also includes (a) the portion of any human clinical study that meets the foregoing definition, as in the case of a study designated as a “Phase II/III” clinical trial, and (b) any other human clinical study serving as a pivotal study from which the data are actually submitted to the applicable Regulatory Authority in connection with an application for Regulatory Approval, whether or not such study is expressly designated as a “Phase III” clinical trial.

“**Product Report**” has the meaning set forth in Section 5.3.

“**Quarterly Period**” means each three-month period commencing on January 1, April 1, July 1 and October 1.

“**Receiving Party**” has the meaning set forth in Section 8.1.

“**Regulatory Approval**” means any approvals (including supplements, amendments, pre- and post-approvals and price approvals), licenses, registrations or authorizations, howsoever called, of any Regulatory Authority, which are necessary for the distribution, importation, exportation, manufacture, production, use, storage, transport or clinical testing and/or sale of a Licensed Product in a regulatory jurisdiction.

“**Regulatory Authority**” means the United States Food and Drug Administration (“**FDA**”) or any counterpart of the FDA outside the United States, or other national, supra-national, regional, state or local regulatory agency, department, bureau, commission, council, ethics committee, review board or other entity with authority over the distribution, importation, exportation, manufacture, production, use, storage, transport or clinical testing and/or sale of a Licensed Product.

“**Regulatory Filings**” means any filings, and all data contained therein, as may be required by the FDA or equivalent foreign Regulatory Authorities for the development, manufacture or commercialization of a Licensed Product hereunder.

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“**Representatives**” means a party’s employees, officers, directors, consultants and legal advisors.

“**Reserved Interests**” has the meaning set forth in Section 2.7.

“**Responsible Officer**” with respect to any Person, means the chief executive officer, president or chief financial officer of such Person.

“**Review Period**” has the meaning set forth in Section 2.4.2.

The terms “**sale**”, “**sold**” and “**sell**” as used in this Agreement include without limitation sales, leases, licenses, rentals and other modes of distribution or transfer of a product or its beneficial use. Licensed Products will be considered sold when delivered or invoiced, whichever occurs first.

“**Sublicense**” shall mean an agreement in which Licensee (a) sublicenses any of the rights licensed to Licensee hereunder, (b) agrees not to assert such rights or to sue, prevent or seek a legal remedy for the practice of same, or (c) is under an obligation to grant, assign or transfer any such rights or non-assertion, or to forebear from granting or transferring such rights to any other entity. Agreements expressly considered Sublicenses includes without limitation licenses, option agreements, or similar agreements, to the extent that the rights granted therein relate to the rights licensed to Licensee hereunder.

“**Sublicense Fees**” has the meaning set forth in Section 3.4.

“**Sublicensee**” shall mean any non-Affiliate third party to whom Licensee has granted a Sublicense.

“**Sublicensing Revenue**” shall mean any and all consideration received by Licensee from sublicensing any of the rights granted to it under Section 2.1 of this Agreement, including without limitation cash and cash equivalents, license issue fees and other licensing fees, option fees, milestone payments, or other payments of any kind, but excluding royalties on sales of Licensed Products and minimum annual royalties.

“**Taxes**” means any and all present or future income, stamp or other taxes, levies, imposts, duties, deductions, charges, fees or withholdings imposed, levied, withheld or assessed by any Governmental Authority, together with any interest, additions to tax or penalties imposed thereon and with respect thereto.

“**Term**” has the meaning set forth in Section 7.1.

“**Territory**” means worldwide.

“**Valid Claim**” means any pending or issued claim of any Licensed Patent that has not been admitted by Licensor or otherwise caused to be invalid or unenforceable through reissue, disclaimer or otherwise, or held invalid or unenforceable by a Governmental Authority of competent jurisdiction from whose judgment no appeal is allowed or timely taken.

1.2 Interpretation.

(a) For purposes of this Agreement: (i) the words “include,” “includes” and “including” shall be deemed to be followed by the words “without limitation”; (ii) the word “or” is not exclusive; and (iii) the words “herein,” “hereof,” “hereby,” “hereto” and “hereunder” refer to this Agreement as a whole.

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(b) In the computation of periods of time from a specified date to a later specified date, the word “from” means “from and including;” the words “to” and “until” each mean “to but excluding;” and the word “through” means “to and including.”

(c) The definitions of terms herein shall apply equally to the singular and plural forms of the terms defined. Unless the context otherwise requires, references herein: (i) to Sections, Appendices and Exhibits refer to the Sections, Appendices and Exhibits attached to, this Agreement; (ii) to an agreement, instrument or other document means such agreement, instrument or other document as amended, supplemented and modified from time to time to the extent permitted by the provisions thereof; and (iii) to a statute means such statute as amended from time to time and includes any successor legislation thereto and any regulations promulgated thereunder. This Agreement shall be construed without regard to any presumption or rule requiring construction or interpretation against the party drafting an instrument or causing any instrument to be drafted. Any Appendices and Exhibits referred to herein shall be construed with, and as an integral part of, this Agreement to the same extent as if they were set forth verbatim herein.

(d) All accounting terms not specifically or completely defined herein shall be construed in conformity with, and all financial data required to be submitted pursuant to this Agreement shall be prepared in conformity with, GAAP as in effect from time to time.

2.1 License Grant.

(a) Subject to the terms and conditions of this Agreement, Licensor hereby grants to Licensee (i) the exclusive worldwide (as to the countries for which patent protection is sought) license, with the right to grant and authorize Sublicenses as set forth below, under the Licensed Patents to make, have made, use, offer to sell, sell and import Licensed Products in the Fields in the Territory, and (ii) a non-exclusive worldwide license, with the right to grant and authorize Sublicenses as set forth below, to use or practice the Licensed Know-How to make, have made, use, offer to sell, sell and import Licensed Products in the Fields in the Territory.

(b) Licensor shall, within *** after the Effective Date, disclose the Licensed Know-how to Licensee in accordance with Article 12. Licensee acknowledges and agrees that the Licensed Know-how is considered Confidential Information and has independent value and will provide Licensee with a competitive advantage and/or commercial value. Licensed Know-how includes *** and other information as described in Appendix A. In addition, Licensor shall (i) disclose to Licensee all Licensed Know-how generated during the Term, including non-clinical and clinical data, within *** after such Licensed Know-how is generated, in an electronic format reasonably acceptable to Licensee, and (ii) obtain such consents from third parties as may be necessary to make such disclosures to Licensee, including informed consents from subjects participating in clinical trials, as applicable. For clarity, clinical data delivered in accordance with the preceding sentence shall include raw data and case report forms.

2.2 Sublicensing.

(a) Licensee may sublicense the rights granted to it under Section 2.1, ***, so long as, ***, (w) ***, (x) this Agreement has not been terminated, (y) Licensee is not in breach of its obligations hereunder (or there is not otherwise a continuing Default), and (z) the following criteria are satisfied:

(i) the Sublicense is in writing;

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(ii) ***;

(iii) ***; and

(iv) ***.

(b) ***.

(c) ***.

(d) ***.

(e) Licensee will provide Licensor with (i) a fully signed, copy of each Sublicense granted by Licensee under this Agreement and any amendments thereto, including all exhibits, attachments and related documents, within *** of executing the same, (ii) a copy of all reports provided to Licensee by Sublicensees during the term of the Sublicense on a quarterly basis; and (iii) notification of the termination of any Sublicense, in each case, which information will be Licensee's Confidential Information. Notwithstanding any Sublicense, Licensee shall remain primarily liable to Licensor for all of Licensee's duties and obligations contained in this Agreement, including, without limitation, the payment of all Earned Royalties due hereunder. Any act or omission of a Sublicensee that would be a breach of this Agreement if committed or omitted by Licensee will be a breach by Licensee.

2.3 **Government Rights.** Notwithstanding anything herein to the contrary, any and all provisions contained herein, (including without limitation, the licenses and other rights granted hereunder and all representations and warranties of Licensor) are limited by and subject to the rights and requirements of the United States Government that may attach as a result of U.S. Government sponsorship, in any way, of research at Licensor in which one or more invention covered by the Licensed Patents was conceived or first actually reduced to practice, as set forth in 35 U.S.C. §§200-206, 37 C.F.R. Part 401 and in the relevant Government research contracts with Licensor, and as such rights and requirements may be amended or modified by Law. To the extent applicable, such rights and requirements include without limitation (i) the grant of a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the U.S. Government any of the Licensed Patents throughout the world (as set forth in 35 U.S.C. §202(c)(4)), and (ii) the requirement that Licensed Products used or sold in the United States will be manufactured substantially in the United States (as set forth in 35 U.S.C. §204) (provided that if Licensee seeks a waiver to manufacture Licensed Products outside of the United States, Licensor will reasonably cooperate at Licensee's cost and expense, where applicable).

2.4 Retained Rights; Requirements.

2.4.1 **Research Use Right.** Any and all licenses granted hereunder are subject to the right of Licensor, on behalf of itself and its investigators, to practice and use the Licensed Patents and the subject matter described and/or claimed therein, and to permit others at academic, government, and not-for-profit institutions to practice and use the Licensed Patents and the subject matter described and/or claimed therein, for its and their own research (including without limitation, pre-clinical, non-clinical and clinical research), testing, educational, internal or patient-care purposes. For avoidance of any doubt, any research previously performed, currently being performed, or performed in the future by Licensor, at Licensor's facilities or using Licensor's resources, or that Licensor or Inventor is in any way related to (whether as Principal Investigator, sponsor or otherwise) is subject to the retained rights in this Section 2.4.1 (the “Permitted Research”). Permitted Research includes, without limitation, any research activities of Licensor or Inventors (while an employee of Licensor) that are funded in whole or in part by any Governmental Authorities or any philanthropic or similar sources. For clarity, Licensor agrees and acknowledges that this Section 2.4.1 does not give Licensor the right to practice or use the Licensed Technology in connection with the commercial sale of any product or service.

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2.4.2 **Right to Publish.** Licensee recognizes and accepts the importance of communicating medical study and scientific data and the necessity of conveying such information in a timely manner, and, therefore, encourages their publication in reputable scientific journals and at seminars or conferences, even if such publication includes Licensed Know-how. Licensee further recognizes and accepts that under Licensor's mission as an academic medical center, Licensor and its investigators must have a meaningful right to publish without Licensee's approval or editorial control. Licensor shall submit to Licensee for its review a copy of any proposed manuscript *** prior to the estimated date of submission for publication. Within *** of receiving such manuscript (the “Review Period”), if Licensee reasonably determines that the proposed publication contains patentable subject matter which requires protection for Licensee, Licensee may require the delay of publication for a period of time not to exceed *** for the purpose of filing patent applications. Further, Licensor and its investigators agree to remove from the proposed publication anything that Licensee identifies within the Review Period as Licensee's Confidential Information. If no written response is received from Licensee within the Review Period, it may be conclusively presumed that publication may proceed without delay. For avoidance of any doubt, Licensor and Inventor (while an employee of Licensor) retain the right to publish any medical study or scientific data arising from the Permitted Research, subject to compliance with this Section 2.4.2.

2.5 Regulatory Affairs.

(a) Licensor hereby grants Licensee, and its Affiliates and Sublicensees, a “right of reference,” as that term is defined in 21 C.F.R. § 314.3(b), or a comparable right existing under the Laws of any other jurisdiction, to any Regulatory Filings owned or otherwise controlled by Licensor or its Affiliates to the extent relating to the research,

development, manufacture or commercialization of a Licensed Product in the Fields in the Territory, and, upon request, shall promptly provide a signed statement to such effect in accordance with 21 C.F.R. §314.50(g)(3) or the Laws of any other jurisdiction.

(b) Licensee shall have the right to audit any clinical data included in the Licensed Know-how (“**Licensed Clinical Data**”) for accuracy and completeness, upon at least *** prior written notice, at Licensee’s sole expense, including but not limited to any incidental costs incurred by Licensor as a result of any such audit. If a Regulatory Authority requests that Licensee provide additional information regarding any Licensed Clinical Data, then the parties shall discuss the scope of such request and, if the requested information is owned or otherwise controlled by Licensor, Licensor shall provide such information to Licensee in a reasonable amount of time and cooperate with Licensee in responding to such request.

(c) Licensor shall provide Licensee with prompt written notice of an impending inspection by a Regulatory Authority relating to the Licensed Clinical Data and the results of such inspection, including any FDA Form 483 notices (or similar notices of other Regulatory Authorities). Further, if a Regulatory Authority makes any finding that impacts or could reasonably be expected to impact the Licensed Clinical Data, then Licensor shall provide Licensee with prompt written notice thereof and solicit (and reasonably consider) Licensee’s feedback regarding any plan for remedial action.

(d) Licensor does not represent or warrant that any Licensed Clinical Data was created in accordance with or pursuant to any requirements under the C.F.R., or any comparable Laws of any jurisdiction. Furthermore, Licensor does not represent or warrant that any Licensed Clinical Data was created for submission to any Governmental Authority.

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2.6 No Grant of Other Technology or Patent Rights. Except as otherwise expressly provided in this Agreement, under no circumstances shall Licensee, as a result of this Agreement obtain any ownership interest or license in or other right to any technology, know-how, patents, patent applications, products, or materials of Licensor, including items owned, controlled or developed by Licensor, at any time pursuant to this Agreement. This Agreement does not create, and shall under no circumstances be construed or interpreted as creating, an obligation on the part of Licensor to grant any license to Licensee other than as expressly set forth herein. Any further contract or license agreement between the parties shall be in writing.

2.7 Reserved Rights. All rights and interests of Licensor not expressly granted to Licensee are reserved by Licensor (the “**Reserved Interests**”) for itself, its Affiliates and partners (other than Licensee) and other licensees and Sublicensees, including the rights to use and grant licenses under the Licensed Patents or any other technology owned or controlled by Licensor to make, have made, use, offer to sell, sell, have sold and import products (other than Licensed Products within the Fields for so long as Licensee has an exclusive license to Licensed Products within the Fields under this Agreement). It shall not be a breach of this Agreement for Licensor, acting directly or indirectly, to exploit its Reserved Interests in any manner anywhere in the Territory, whether or not such activity is competitive with the activities of Licensee, including the research, development and commercialization or licensing of others to research, develop and commercialize products (other than Licensed Products within the Fields for so long as Licensee has an exclusive license under the Licensed Patents to develop and commercialize products within the Fields under this Agreement), including products that potentially compete in the same product market as a Licensed Product); provided that the foregoing shall not be construed to be a grant of any license, implied or otherwise, by Licensee to Licensor or to permit Licensor to breach the confidentiality provisions of this Agreement.

Article 3

FINANCIAL CONSIDERATION

3.1 Issue Fee. In consideration of its license to the Licensed Technology hereunder, Licensee shall pay to Licensor a non-refundable, non-creditable license fee in an amount equal to *** dollars (\$***) (the “**Issue Fee**”), payable to Licensor ***.

3.2 Earned Royalties.

(a) In consideration of its license to the Licensed Patents hereunder, Licensee shall pay to Licensor a quarterly royalty equal to *** of the Net Sales (the “**Earned Patent Royalty**”) of a particular Licensed Product sold, transferred or otherwise disposed of in a particular country where a Valid Claim exists covering the sale of such Licensed Product in such Country during the Licensed Patent Royalty Term for such Licensed Product in such country.

(b) In consideration of its license to the Licensed Know-how hereunder, Licensee shall pay to Licensor a quarterly royalty equal to *** of the Net Sales (the “**Earned Know-how Royalty**”) of a particular Licensed Product sold, transferred or otherwise disposed of in a particular country where no Valid Claim exists covering the sale of such Licensed Product in such country during the Licensed Know-how Royalty Term for such Licensed Product in such country. For avoidance of doubt, during the Licensed Know-how Royalty Term for a particular Licensed Product in a particular country, Earned Know-how Royalties shall be payable in respect of sales of such Licensed Product in such country if there are no Valid Claims covering the sale of such Licensed Product in such country.

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(c) The Earned Patent Royalty and the Earned Know-how Royalty shall not be cumulative, such that only one Earned Royalty (i.e., the Earned Patent Royalty or the Earned Know-how Royalty, as applicable) will be payable with respect to any Licensed Product sold during the Term. For avoidance of doubt, all sales, transfers or other dispositions of Licensed Products during the Term (other than any transfer or use of a Licensed Product for clinical trials or compassionate use) shall result in an Earned Royalty being due and payable hereunder. Accordingly, (i) if the sale, transfer or other disposition of a Licensed Product occurs during the Term and in a country in which a Valid Claim exists at the time of such sale, transfer or other disposition, then such sale, transfer or other disposition shall result in an Earned Patent Royalty payment obligation, and (ii) if the sale, transfer or other disposition of a Licensed Product occurs during the Term and in a country in which no Valid Claim exists at the time of such sale, transfer or other disposition (whether because patent protection was not sought or because all Valid Claims in such country have expired or otherwise), then such sale, transfer or other disposition shall result in an Earned Know-how Royalty payment obligation.

3.3 Annual Maintenance Fee. In consideration of its license to the Licensed Technology hereunder, for the first calendar year beginning after the Effective Date and each subsequent calendar year thereafter, but before the year of the First Commercial Sale, Licensee shall pay to Licensor an “**Annual Maintenance Fee**” in the amount of \$***. The first Annual Maintenance Fee shall be due and payable on or before January 15, 2025, and thereafter Licensee shall pay the Annual Maintenance Fee to Licensor within *** of the end of each calendar year for which an Annual Maintenance Fee is required. The Annual Maintenance Fee shall be fully creditable against any Milestone Payment received for such calendar year.

3.4 Sublicense Fees. In consideration of its license to the Licensed Technology hereunder, Licensee shall pay to Licensor sublicense fees (“**Sublicense Fees**”) for any Sublicense executed by the milestone and in an amount equal to a percent of Sublicensing Revenue, in each case identified in the table below. Consideration received by Licensee as Sublicensing Revenue in the form of equity or other securities shall be paid to Licensor in kind, and consideration received as Sublicensing Revenue in the form of goods shall be paid to Licensor in cash based upon the fair market value of such goods received.

Milestone

Sublicense Rate

For purposes of this Section 3.4, ***.

3.5 Minimum Annual Royalty.

(a) In consideration of its license to the Licensed Technology hereunder, Licensee shall pay to Licensor a minimum annual royalty (each, a "MAR") with respect to all Licensed Products, as set forth in the table below:

| <u>Year</u> | <u>MAR</u> |
|-------------|------------|
| *** | *** |
| *** | *** |
| *** | *** |
| *** | *** |

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(b) Each year's MAR payment shall be due and payable within *** following the end of the calendar year to which it applies (e.g., ***). If the total amount of Earned Royalties paid during any calendar year exceeds the MAR for such calendar year, then Licensee shall have no MAR payment obligation for such calendar year. In no event will the MAR be pro-rated for any partial calendar year. The MAR shall be fully creditable against any Milestone Payment received for such calendar year.

3.6 Product Development Milestone Payments. In consideration of its license to the Licensed Technology hereunder, Licensee shall pay to Licensor the following payments (each, a "Milestone Payment") within *** of the completion or occurrence of each Milestone Activity with respect to a Licensed Product:

| <u>Amount</u> | <u>Milestone Activity</u> |
|---------------|---------------------------|
| *** | *** |
| *** | *** |
| *** | *** |

For purposes of this Agreement, ***.

3.7 Payment Terms.

(a) Licensee shall pay all Earned Royalties and Sublicense Fees for each Quarterly Period within *** of the end of such Quarterly Period. Licensee shall make all payments under this Agreement in US dollars. If any payments required hereunder are not received by Licensor on the date the same has become due and payable, Licensee shall pay to Licensor interest on the overdue undisputed payment from the date such payment was due to the date of actual payment at a rate of ***, or if lower, the maximum amount permitted under applicable Law.

(b) Earned Royalties, MAR payments, Milestone Payments, Sublicense Fees and all other sums payable by Licensee under this Agreement shall be made free and clear of and without deduction or withholding for any Taxes except as required by applicable Law. If Licensee is required by applicable Law to deduct or withhold any Taxes from such payments, then: (i) the amount payable by Licensee shall be increased so that after all such required deductions or withholdings are made (including deductions or withholdings applicable to additional amounts payable under this Section), Licensor receives an amount equal to the amount it would have received had no such deduction or withholding been made; and (ii) Licensee shall make such deductions or withholdings and timely pay the full amount deducted or withheld to the relevant Governmental Authority in accordance with applicable Law. As soon as practicable after any payment of Taxes by Licensee to a Governmental Authority pursuant to this Section, Licensee shall deliver to Licensor the original or certified copy of a receipt issued by such Governmental Authority evidencing such payment, a copy of the relevant return reporting such payment or other evidence of such payment reasonably satisfactory to Licensor.

(c) For the purpose of converting the local currency in which any royalties or other payments arise into US dollars, the rate of exchange to be applied shall be the rate of exchange in effect on the last business day of the calendar quarter to which the payment relates as reported in the Wall Street Journal.

(d) If at any time any payment made by Licensee under this Agreement is rescinded or must otherwise be restored or returned upon the insolvency, bankruptcy or reorganization of Licensee or otherwise, Licensee's obligation to make such payment shall be reinstated as though such payment had not been made.

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3.8 Royalty Stacking. If Licensee determines that it is necessary that Licensee obtain a license from any third party ("Third Party License") in order to avoid infringing that third party's intellectual property rights in the manufacture, use, sale and/or importation of the Licensed Products, the royalty rate paid to Licensor shall be reduced by *** of the royalty rate paid for such additional patent or intellectual property rights (i.e. ***); provided, however, that in no event shall the royalty rate paid to Licensor be less than *** for Licensed Patent Products or *** for Licensed Know-how Products. Upon request, Licensee will promptly provide to Licensor reasonable documentation supporting the determination contemplated by this Section, provided that Licensee will not be required to disclose information subject to the attorney-client privilege.

This Section applies only to any prospective earned royalty payable to third parties for rights required to permit Licensee to make, use, offer to sell, sell and import the Licensed Product as provided in this Agreement, and no deduction of any Earned Royalty is allowed for payments to any third party of lump sum license fees, milestone payments, minimum annual royalties in excess of accrued royalties, any amounts paid for past infringement of any third-party's rights or any amount not paid for rights required to permit Licensee to make, use, offer to sell, sell and import the Licensed Product as provided in this Agreement.

Article 4

COMMERCIALIZATION AND DEVELOPMENT COVENANTS

4.1 Commercialization and Development Milestones.

(a) Licensee agrees to use commercially reasonable efforts to ***. In furtherance of, and without limiting, the foregoing, Licensee agrees to cause the occurrence of each of the following milestones (each, a "Milestone") by the corresponding milestone date (each, a "Milestone Date"):

| <u>Milestone</u> | <u>Milestone Date</u> |
|------------------|-----------------------|
| *** | *** |
| *** | *** |
| *** | *** |

When Licensee completes a Milestone by the applicable Milestone Date, it will provide Licensor with written notice of the achievement of the Milestone within *** of such completion, together with documentation evidencing such achievement. Any efforts of Licensee or its Affiliates and Sublicensees, or of Licensor or its Affiliates, will be deemed to be the efforts of Licensee for purposes of satisfying the obligations of this Section 4.1.

For purposes of this Section 4.1, ***.

(b) ***.

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(c) ***.

4.2 Updates.

(a) Not later than July 31 of each year prior to the First Commercial Sale, Licensee shall deliver a Development Report to Licensor.

(b) Not later than July 31 of each year prior to the First Commercial Sale, Licensee will provide to Licensor an update on the activities described in the Development Plan, in form and substance reasonably acceptable to Licensor in its reasonable discretion, describing in reasonable detail the material activities to be undertaken during the next *** and the estimated timing of such activities, including the estimated dates of the initiation and completion of such activities and a summary of Licensee’s material product development activities since the prior Annual Update (the “**Annual Update**”). Licensee’s obligation to provide Licensor with Annual Updates will continue for a Licensed Product until the First Commercial Sale of such Licensed Product. All such Development Reports and Annual Updates under this Section 4.2 shall be deemed Licensee’s Confidential Information.

(c) During the Term, Licensor shall promptly deliver to Licensee copies of such periodic reports that Licensor provides to the Department of Defense or other source of grant funding in connection with the development of Licensed Products (including progress reports and financial reports) and shall promptly provide Licensee with copies of all material correspondence with any such source of grant funding relating to the development of Licensed Products.

4.3 Regulatory Approval. Licensee and its Affiliates and Sublicensees will be solely responsible, at their sole cost and expense, for making all Regulatory Filings and securing all Regulatory Approvals, except to the extent performed by Licensor in accordance with Section 2.4.1. Licensee will provide notice to Licensor of the submission of all Regulatory Filings (including amendments to prior filings and correspondence related to any such filings) to Licensor within *** following the submission thereof. Licensee will provide copies of all Regulatory Approvals to Licensor within *** following the receipt thereof. Licensor will provide reasonable cooperation through providing Licensee, upon Licensee’s written request and in a timely fashion, with all documentation and information reasonably necessary to secure such Regulatory Approval, to the extent such documentation and information is in Licensor’s possession and not subject to any confidentiality or non-disclosure obligations.

Article 5

ADDITIONAL COVENANTS: CLOSING CONDITIONS

5.1 Books and Records. Licensee will maintain documentation detailing Licensee’s efforts to develop Licensed Products for commercial sale in the Fields in the Territory, and thereafter will maintain accurate records detailing all commercial sales of Licensed Products. Such documentation may include invoices for studies advancing development of Licensed Products, laboratory notebooks, internal job cost records, filings made to the Internal Revenue Service to obtain tax credit, if available, for research and development of Licensed Products, records relating to obtaining Regulatory Approval, and sales records of Licensee or Sublicensees. Such books and records will be preserved for a period not less than *** after they are created during and after the Term.

5.2 Financial Audit. Upon reasonable notice and during regular business hours, Licensee will allow Licensor or its designee, at Licensor’s sole expense, to review (and audit) all books and records, including financial records, and inspect Licensee’s research and development facilities, in each case solely to verify the accuracy of Licensee’s Development Reports and Product Reports and Licensee’s compliance with its obligations, covenants and agreements under this Agreement; provided that Licensor will conduct such audit no more than *** upon reasonable notice, in a manner that does not interrupt Licensee’s operations, and not later than *** following the rendering of any such records pursuant to Section 5.1. Licensee shall also use commercially reasonable efforts to obtain a comparable right for Licensee to audit any Sublicensees, and, in the event Licensee obtains such right, shall perform a comparable audit of a Sublicensee and provide Licensor a summary of such audit upon Licensor’s written request. Should any of the foregoing examinations reveal an underpayment, then Licensee shall immediately pay to Licensor the underpaid amount, plus interest in the amount provided for in Section 3.6 (Payment Terms). Further, if such underpayment exceeds *** of the amount paid by Licensee to Licensor in the previous calendar year under this Agreement, then Licensee shall bear the reasonable out-of-pocket cost of such audit, including accountants’ and attorneys’ fees and expenses, and shall immediately reimburse Licensor for all such costs incurred by Licensor.

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5.3 Product Reports. Commencing in the Quarterly Period in which the First Commercial Sale occurs, within *** of the end of each Quarterly Period, Licensee shall deliver to Licensor a complete and accurate product report (each, a “**Product Report**”), giving such particulars of the business conducted by Licensee and Sublicensees during the preceding Quarterly Period under this Agreement as shall be pertinent to a royalty accounting hereunder. Without limiting the generality of the foregoing, the Product Reports shall be in substantially the form of Exhibit B attached hereto and include at least the following on a Licensed Product-by-Licensed Product basis: ***

Upon termination of this Agreement, Product Reports accompanied by any applicable Earned Royalties and Sublicense Fees shall continue to be due until a final Product Report is submitted, which shall be due within *** following the termination of this Agreement. All Product Reports shall be deemed Licensee’s Confidential Information.

5.4 Compliance Certificate. Together with each Product Report, Licensee shall deliver a duly executed compliance certificate from a Responsible Officer stating that (a) all such reports are true, accurate and correct in all material respects, (b) Licensee during such period has observed and performed all of the covenants and other agreements, and satisfied every condition contained in this Agreement to be observed, performed or satisfied by it, and that there has not occurred any Default except as specified in such certificate.

5.5 Affirmative and Negative Covenants. During the Term, Licensee shall:

(a) not take any action, or omit to take any action, if in the reasonable judgment of Licensor such act or omission has had, or could reasonably be expected to have, an adverse impact upon or to the brand, name, goodwill or image of Licensor;

(b) not use, practice, commercialize or otherwise exploit the Licensed Technology outside the Fields, excluding Licensed Know-how that becomes generally known to the public or otherwise becomes publicly available, other than through a breach of this Agreement by Licensee;

(c) comply with all Laws applicable to the conduct of Licensee's business and activities related to developing, manufacturing, marketing, offering for sale, selling, importing and exporting Licensed Products.

5.6 Notices. Licensee shall promptly give notice to Licensor of:

(a) the occurrence of the First Commercial Sale; and

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(b) the occurrence of any Default.

5.7 Development Plan. Licensee shall provide to Licensor a copy of a Development Plan within *** of execution of this Agreement, with an update prior to initiation of formal preclinical IND (as defined in Section 4.1) enabling toxicology studies, which shall be attached hereto as Exhibit A, which Development Plan shall be deemed to be Licensee's Confidential Information.

Article 6

PATENT PROSECUTION; INFRINGEMENT

6.1 Patent Prosecution. Licensor shall have exclusive responsibility for the preparation, filing, prosecution, issuance and maintenance of the Licensed Patents, using counsel reasonably acceptable to Licensee. Licensor shall keep Licensee informed of patent prosecution, shall keep Licensee reasonably informed and copied on all correspondence, shall provide Licensee with copies of all prosecution documentation (including office actions and draft patent applications) reasonably in advance of applicable deadlines such that Licensee has a reasonable opportunity to review and comment, will consider Licensee's comments and suggestions prior to taking material actions for the same, and will take all prosecution actions reasonably recommended by Licensee that would expand the scope of rights sought. The parties shall reasonably cooperate with each other to insure that each Licensed Patent reflects and will reflect, to the extent practicable and to the best of Licensee's knowledge, all items of commercial interest to Licensee. Licensor shall notify Licensee at least *** prior to any deadline if it intends to abandon, or otherwise elect to forego its rights in, any Licensed Patents and Licensee shall have the right (but not the obligation) to assume control of the preparation, filing, prosecution, issuance and maintenance of such Licensed Patents in the name of Licensor and at Licensee's expense.

6.2 Patent Reimbursements

6.2.1 Licensee shall reimburse Licensor for all Patenting Costs incurred by Licensor as of the Effective Date (the **'Patent Reimbursement Amount'**) in an amount equal to \$***. Payment by Licensee of the Patent Reimbursement Amount shall be due ***.

6.2.2 Licensee will be responsible for the payment of all Patenting Costs incurred or to be incurred by Licensor after the Effective Date.

6.2.3 With respect to any action necessary to protect a particular Licensed Patent in a particular country in the Territory, if Licensee instructs Licensor in writing not to take such action, the rights protected by such Licensed Patent shall be excluded from the license granted herein and Licensee shall be relieved from its obligation to pay for future Patenting Costs relating to such Licensed Patent in such country. Thereafter, Licensor shall have the right to (i) abandon some or all of such rights at Licensor's sole discretion, or (ii) incur those costs at its own expense; in either case, Licensor shall be free to license such rights to third parties without any further obligation to Licensee.

6.3 [Reserved]

6.4 Enforcement of Licensed Patents

6.4.1 Notice. If either party becomes aware of any infringement, anywhere in the Territory, of any issued patent within the Licensed Patents, such party will notify the other party of such infringement in writing as soon as reasonably practical thereafter (the **"Infringement Notice"**).

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6.4.2 Infringement of Licensed Patents by Third Parties

(a) In the case of any infringement within the Fields of any Licensed Patent by any third party during the Term, Licensee will have the first right, but not the obligation, at Licensee's expense, to cause such third party to cease infringement and to otherwise enforce such Licensed Patent, or to defend the Licensed Patent, or to defend the Licensed Patent in any declaratory judgment action brought by third parties that alleges the invalidity, unenforceability or non-infringement of the rights associated with the Licensed Patent in the Fields; provided, however, that Licensee will (i) use counsel reasonably acceptable to Licensor, (ii) keep Licensor reasonably informed regarding the progress of any litigation and settlement discussions with any alleged infringer, and (iii) copy Licensor on, or provide Licensor with copies of, all external documents and correspondence (i.e., documents and correspondence sent by Licensee to a third party or received by Licensee from a third party). Licensee will have control of the conduct of any such action that it brings, provided that Licensor will have the right to provide ongoing comments on documents prior to submission and advice regarding its position and interests in such action, which advice and comments will be considered in good faith by Licensee and incorporated or adopted by Licensee to the extent they are reasonable or support the validity, enforceability or scope of claims of a Licensed Patent, and (y) Licensee will not enter into any settlement, consent judgment or other voluntary disposition of any such action without the prior written consent of Licensor, which consent will not be unreasonably withheld, delayed or conditioned. For the purposes of this Section 6.4.2 (and without limiting generality of the foregoing) it will be reasonable to Licensor to withhold consent to a settlement if the settlement would admit the invalidity or unenforceability of or limit in any way any patent owned by Licensor. Licensor will, at the request and expense of Licensee, provide reasonable cooperation and assistance in any action described in this Section 6.4.2. Except for providing such reasonable assistance, Licensor will have no obligation regarding the legal actions described herein; provided, however, that Licensor will join such action at Licensee's request and expense if such joinder is, in the opinion of Licensee's counsel, required to enable Licensee to initiate or continue such action. Licensor, however, will have the right to participate in any such action through its own counsel and, except as provided in this Section 6.4.2(a), at its own expense.

(b) If Licensee does not, within a reasonable period after becoming aware of such infringement but no less than *** from the date of the Infringement Notice, (i) initiate legal proceedings against such threatened or actual infringement, or defend legal proceedings brought by a third party, as provided in Section 6.4.2(a), or (ii) cause such infringement to terminate, Licensor may thereafter take such action as it deems necessary to enforce its rights in the Licensed Patent, including the right, but not the obligation, to bring, at its own expense, an infringement action or file any other appropriate action or claim related to such infringement against any third party; provided, however, that Licensor shall have no obligation to bring any suit, action or other proceeding against any alleged infringer of any Licensed Patent. Licensee shall and hereby does irrevocably and unconditionally waive any objection to Licensor's joinder of Licensee to any proceeding described in Section 6.4.2(a) on any grounds whatsoever, including on the grounds of personal jurisdiction, venue or *forum non conveniens*. If Licensor brings or defends any such proceeding, Licensee shall reasonably cooperate in all respects with Licensor in the conduct thereof, and assist in all reasonable ways, including having its employees testify when requested and make available for discovery or trial exhibit relevant records, papers, information, samples, specimens, and the like at Licensee's own cost.

6.4.3 Infringement of Third Party Rights. In the event that any action, suit or proceedings brought against, or written notice of threat thereof is provided to Licensee alleging infringement of any patent or unauthorized use or misappropriation of technology arising out of or in connection with Licensee's exercise to Licensed Patents, Licensee

shall have the right to defend at its own expense such action, suit or proceeding. Licensee shall hold harmless and indemnify Licensor from and against any order to pay costs arising without fault of Licensor that may be made against Licensee or Licensor in such proceedings. Licensor agrees to cooperate with Licensee at Licensee's expense (excluding salaries, rent, utilities and other expenses typically treated as overhead) in connection with Licensee's response to or defense of such action, suit or proceeding, or notice of threat thereof.

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6.4.4 Recovery. If either party shall undertake the enforcement and/or defense of the Licensed Patents by litigation pursuant to Sections 6.4.2 and Section 6.4.3, any recovery or damages (whether by way of settlement or otherwise) received as a result of any such suit shall be applied first in satisfaction of any unreimbursed expenses and legal fees of either party, and then the remainder (related to the Licensed Patents) shall be divided between the Parties as follows: ****.

6.4.5 March-in Rights. If any suit, action or other proceeding alleging invalidity or non-infringement of any Licensed Patent is brought against Licensee, Licensor, at its option, shall have the right, within **** after commencement of such suit, action or other proceeding, to intervene and take over the sole defense of the suit, action or other proceeding at its own expense.

6.5 Licensed Patent Challenges.

(a) In the event that Licensee directly or indirectly disputes, challenges, or assists in the challenge of the validity, scope, construction, enforceability or Licensor's ownership of any issued patent comprising the Licensed Patents or any claims thereof, or opposes or assists in the opposition of the grant of any Letters Patent comprising the Licensed Patents, either in a court of law, before the U.S. Patent and Trademark Office, or other agency or tribunal ("**Licensed Patent Challenge**"), then (i) Licensor has the right to immediately terminate this Agreement upon written notice to Licensee and with no opportunity for Licensee to cure, and (ii) Licensee shall pay all of Licensor's costs, fees and expenses associated with its defense of such challenge or opposition.

(b) Licensee shall include provisions in all Sublicenses permitted under Section 2.2 providing that if the Sublicensee brings or participates in a Licensed Patent Challenge, the Sublicense will immediately terminate effective as of the first date of the Sublicensee's first filing or participation in the Licensed Patent Challenge. The failure to include such automatic termination provision in a Sublicense hereunder shall constitute a material breach of this Agreement. If a Sublicensee undertakes a Licensed Patent Challenge, Licensee, shall immediately terminate the applicable Sublicense upon becoming aware of such Licensed Patent Challenge. Any failure to immediately terminate the Sublicense as required by this Section 6.5(b) shall constitute a material breach of this Agreement.

(c) If Licensee directly or indirectly institutes or participates in a Licensed Patent Challenge and Licensor elects not to terminate this Agreement in accordance with Section 6.5(a), then ****.

6.6 Patent Extensions. Licensee and Licensor shall use reasonable efforts in its good faith determination to extend the Licensed Patents, which may include extensions provided under U.S. law at 35 U.S.C. §154(b), 155A, and 156, provided that Licensee shall have final decision-making authority with respect to any patent term extension with respect to Licensed Products. Licensee hereby agrees to provide Licensor with all necessary assistance in securing such extensions, including without limitation, providing all information regarding applications for Regulatory Approval, approvals granted, and the timing of same. To the extent applicable, Licensee acknowledges that extensions under 35 U.S.C. §156 must be applied for within **** of the date that a Licensed Product receives permission under the provision of law under which the applicable regulatory review period occurred for commercial marketing or use and that Licensee's failure to promptly provide the necessary information or assistance to Licensor during such **** period (with respect to a Licensed Patent for which Licensee has elected to pursue a patent term extension) will cause serious injury to Licensor, for which Licensee will be liable.

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Article 7
TERM AND TERMINATION

7.1 Contract Term. This Agreement shall commence on the Effective Date and, unless terminated earlier in accordance with this Article 7 or any other applicable provisions herein (including, without limitation, Section 6.5, Section 7.2, Section 7.3, Section 7.4 or Section 7.5) shall continue until the later to occur of (i) the five (5) year anniversary of the expiration of the last to expire Valid Claim of the Licensed Patents or (ii) the ten (10) year anniversary of the First Commercial Sale in each jurisdiction. The period set forth in this Section 7.1, or such shorter periods as may result from the earlier termination of this Agreement in accordance with this Article 7 or any other provision of this Agreement, shall collectively be referred to as the "**Term**".

7.2 Licensor Termination due to Licensee Insolvency.

(a) Licensor shall have the right to immediately terminate this Agreement upon written notice if Licensee:

- (i) becomes subject, voluntarily or involuntarily, to any proceeding under any Debtor Relief Law, which is not fully stayed within **** or is not dismissed or vacated within ****;
- (ii) is dissolved or liquidated;
- (iii) makes a general assignment for the benefit of creditors; or
- (iv) has a receiver, trustee, custodian or similar agent appointed by order of any court of competent jurisdiction to take charge of or sell any material portion of its property or business.

7.3 Licensor Termination due to Breach of Contract Claim

(a) Licensor shall have the right to immediately terminate this Agreement upon written notice if Licensee claims that Licensor breached this Agreement through the exercise by Licensor or an academic, government, or not-for-profit institution of any of the retained rights provided in Section 2.4 of this Agreement to:

- (i) perform research regarding the Licensed Technology;
- (ii) publish any results of the research described in Section 7.3(a)(i), provided such publication is made in compliance with Section 2.4.2; or
- (iii) disclose any results of the research described in Section 7.3(a)(i) to any Governmental Authorities, provide such disclosure is made in compliance with Section 2.4.2.

7.4 Licensor Termination for Cause.

(a) In addition to any rights of Licensor to terminate this Agreement as provided elsewhere in this Agreement, Licensor shall have the right, in its sole discretion, to terminate this Agreement upon written notice to Licensee for any of the following events:

(i) if Licensee fails to pay any undisputed amount under this Agreement when due and such failure remains unremedied for a period of *** after written notice to Licensee from Licensor;

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(ii) if any representation, warranty, certification or other statement of fact made by or on behalf of Licensee herein, or in any certificate, document, report, financial statement or other document furnished by or on behalf of Licensee under or in connection with this Agreement or any other agreement between Licensee and Licensor, proves to have been false or misleading in any material respect on or as of the date made and remains unremedied for a period of *** after written notice to Licensee from Licensor;

(iii) if Licensee fails to perform or observe any other material covenant, term, condition or agreement contained in this Agreement and, if such failure is curable, such failure continues unremedied for a period of *** after written notice to Licensee from Licensor; or

(iv) Licensee institutes a Licensed Patent Challenge as set forth in Section 6.5(a).

(b) Notwithstanding the foregoing, if Licensee disputes the grounds for such termination in accordance with Section 7.4(a), Licensee shall provide written notice of the dispute to Licensor, and Licensor’s right to terminate this Agreement for cause in accordance with Section 7.4(a) shall be tolled, pending final resolution of such dispute pursuant to Section 9.2.

(c) Notwithstanding the foregoing, non-payment of the Issue Fee pursuant to Section 3.1 or non-payment of the Patent Reimbursement Amount pursuant to Section 6.2.1, in each case within *** of the applicable payment date shall result in Licensor having the right to terminate this Agreement immediately upon written notice to Licensee.

7.5 Licensee Termination. Licensee may, at its option, terminate this Agreement upon any material breach by Licensor under this Agreement, which Licensor fails to remedy within *** after notice thereof by Licensee. In addition, Licensee may terminate this Agreement at any time, for any business reason based on Licensee’s reasonable business judgment, upon at least *** prior written notice to Licensor.

7.6 Disposition of Licensee Developments. In the event of termination of this Agreement pursuant to Section 7.2, Section 7.3, or Section 7.4, Licensee shall ***.

7.7 Accrued Obligations. Expiration or termination of the Agreement will not release either party from any obligation that matured prior to the effective date of such expiration or termination. Nothing herein shall be construed to release Licensee from any obligations (including, without limitation and by way of example only, obligations (a) in respect of Earned Royalties for sales of Licensed Products that occurred on or before the termination date and (b) to pay or reimburse Licensor for Patenting Costs that relate to any period before the termination date).

7.8 Effects of Termination.

7.8.1 Termination of License. Upon a termination of this Agreement in its entirety under Section 7.4 or Section 7.5, Licensee’s rights to the Licensed Technology granted hereunder and all use thereof will terminate and any and all rights in the Licensed Technology will revert back to Licensor. Upon Licensor’s request and at Licensor’s sole option, Licensee will destroy or return all copies, except for the copies to be retained by Licensee’s legal counsel, of any media or materials that are the property of and previously received from Licensor, including all documentation, notes, plans, drawings, copies, samples and computer code.

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7.8.2 Effect on Sublicenses. Any Sublicense granted by Licensee under this Agreement shall, subject to the prior written consent of Licensor (which consent shall not be unreasonably withheld, conditioned or delayed and which consent shall not be required if the applicable Sublicensee is a Sublicensee approved by Licensor in accordance with Section 2.2 and is not then in breach of this Agreement), survive termination of this Agreement, in which case such Sublicense shall be considered a direct license from Licensor to the applicable Sublicensee granting such Sublicensee a license to the Licensed Technology that was sublicensed to such Sublicensee in the sublicensed field, and such direct license will otherwise be on the terms and conditions of the Sublicense (to the extent applicable to the Licensed Technology); provided, however, that in the event of any inconsistencies between this Agreement and the Sublicense, this Agreement shall control; provided, further, that if this Agreement is terminated pursuant to Section 4.1 as a result of any Milestone not being achieved by the applicable Milestone Date (after giving effect to the *** cure period), then all Sublicenses shall automatically terminate effective immediately upon the termination of this Agreement.

7.8.3 ****.

7.8.4 Survival. Upon expiration or termination of this Agreement, Section 2.5 (Regulatory Affairs), Article 3 (Financial Consideration), Section 5.1 (Books and Records), Section 5.2 (Financial Audits), Section 5.3 (Product Reports), Section 6.2 (Patent Reimbursements), this Article 7 (Term and Termination), Article 8 (Confidential Information), Article 9 (Governing Law; Dispute Resolution), Article 10 (Indemnification and Insurance), Section 11.3 (Disclaimers) and 11.4 (Exclusion of Consequential and Other Indirect Damages), Article 12 (Notices), Article 13 (Assignment), Article 14 (Use of Name) and Article 23 (Miscellaneous Provisions) will, along with all defined terms used herein (whether defined in Article 1 (Definitions) or elsewhere in this Agreement) and any right, obligation or required performance of the parties in this Agreement which, by its express terms or nature and context is intended to survive termination or expiration of this Agreement, survive and remain in full force and effect.

Article 8
CONFIDENTIALITY

8.1 Confidentiality Obligations. Each party (the “**Receiving Party**”) acknowledges that in connection with this Agreement it will gain access to Confidential Information of the other party (the “**Disclosing Party**”). As a condition to being provided with Confidential Information, the Receiving Party shall:

(a) not use the Disclosing Party’s Confidential Information other than as necessary to exercise its rights and perform its obligations under this Agreement; and

(b) maintain the Disclosing Party’s Confidential Information in strict confidence and, subject to Section 8.2, not disclose the Disclosing Party’s Confidential Information without the Disclosing Party’s prior written consent, provided, however, the Receiving Party may disclose the Confidential Information to its Representatives who:

(i) have a need to know the Confidential Information for purposes of the Receiving Party’s performance, or exercise of its rights concerning the Confidential Information, under this Agreement;

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(ii) have been apprised of this restriction; and

(iii) are themselves bound by written non-disclosure and non-use agreements at least as restrictive as those set forth in this Section 8.1, provided further that the

Receiving Party shall be responsible for ensuring its Representatives' compliance with, and shall be liable for any breach by its Representatives of, this Section 8.1.

The Receiving Party shall use reasonable care, at least as protective as the efforts it uses for its own confidential information, to safeguard the Disclosing Party's Confidential Information from use or disclosure other than as permitted hereby.

8.2 Exceptions. If the Receiving Party becomes legally compelled to disclose any Confidential Information, the Receiving Party shall:

(a) provide prompt written notice to the Disclosing Party so that the Disclosing Party may seek a protective order or other appropriate remedy or waive its rights pursuant to Article 12; and

(b) disclose only the portion of Confidential Information that it is legally required to furnish.

If a protective order or other remedy is not obtained, or the Disclosing Party waives compliance in accordance with Article 12 and Article 21, the Receiving Party shall, at the Disclosing Party's expense, use reasonable efforts to obtain assurance that confidential treatment will be afforded the Confidential Information.

8.3 Confidential Terms. Notwithstanding anything to the contrary herein, the parties may disclose the terms and existence of this Agreement to potential or actual investors, acquirers, Sublicensees, collaboration partners, consultants, advisors and others on a reasonable need to know basis subject to customary confidentiality restrictions, or as required by securities or other applicable Laws.

Article 9

GOVERNING LAW; DISPUTE RESOLUTION

9.1 Governing Law. This Agreement and all related documents, and all matters arising out of or relating to this Agreement, are governed by, and construed in accordance with, the laws of the State of Ohio, United States of America, without regard to the conflict of laws' provisions thereof to the extent such principles or rules would require or permit the application of the laws of any jurisdiction other than those of the State of Ohio.

9.2 Dispute Resolution.

9.2.1 Exclusive Dispute Resolution Mechanism. The parties shall resolve any dispute, controversy or claim arising out of or relating to this Agreement, or the breach, termination or invalidity hereof (each, a "**Dispute**"), under the provisions of this Section 9.2. The procedures set forth in this Section 9.2 shall be the exclusive mechanism for resolving any Dispute that may arise from time to time, subject to Section 23.7.

9.2.2 Good Faith Negotiations. If a party believes that a Dispute exists, then such party (the "**Declaring Party**") shall provide notice of such Dispute to the other party (the "**Notice**"), which Notice shall specify the nature and cause of the Dispute and the action that the Declaring Party deems necessary to resolve such Dispute. Following receipt of the Notice, the parties shall use good faith efforts to resolve the Dispute, including making personnel with appropriate decision-making authority available to the other party to discuss resolution of the Dispute. If a Dispute is not resolved within *** of the date of the non-Declaring Party's receipt of the Notice, then the Dispute shall be submitted to mandatory, final and binding arbitration before the American Arbitration Association, in accordance with the then-current rules of the American Arbitration Association, as modified herein.

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9.2.3 Arbitration. The parties shall use a panel of three arbitrators. The Declaring Party shall select one arbitrator, and the other party shall select a second arbitrator, and the two arbitrators so selected shall select a third arbitrator. The three arbitrators shall hear the Dispute. Such arbitrators shall be knowledgeable in intellectual property law and related matters. The arbitrators shall make each determination in a manner that is consistent with this Agreement, including the parties' intent as expressed herein. Without limiting the foregoing, the parties agree that the arbitrators are empowered to make determinations regarding the reasonableness of a party's acts or omissions. All decisions of the arbitrators shall be binding upon the parties. Each party shall be solely responsible for its own attorneys' fees and expenses, legal expenses and witness fees and expenses. Any other usual and customary expenses incurred by the arbitrators or the expense of such arbitration proceeding shall be equally divided between the parties, irrespective of the outcome of such proceeding. The arbitration will be conducted in Cleveland, Ohio. The arbitrators are to apply the laws of the State of Ohio, without regard to its conflict of laws' provisions. The parties agree that any award, order, or judgment pursuant to the arbitration is final and may be entered and enforced in any court of competent jurisdiction. The parties agree that all aspects of the dispute resolution process, including the arbitration, shall be conducted in confidence. The parties agree that all statements made in connection with informal dispute resolution efforts shall not be considered admissions or statements against interest by any party. The parties further agree that they will not attempt to introduce such statements at any later trial, arbitration or mediation between the parties.

9.3 Waiver of Jury Trial. Each party irrevocably and unconditionally waives any right it may have to a trial by jury for any legal action arising out of or relating to this Agreement or the transactions contemplated hereby.

Article 10

INDEMNIFICATION AND INSURANCE

10.1 Indemnification

10.1.1 Licensee Indemnification. Subject to Section 10.1.3, Licensee will indemnify, defend and hold harmless Licensor and its respective trustees, directors, officers, medical and professional staff, employees, students, and agents and their respective successors, heirs, and assigns (each a "**Licensor Indemnitee**"), against all Losses arising from any third party claim, suit, action or other proceeding (each, an "**Action**") which may be made or instituted against any Licensor Indemnitee related to, arising out of or resulting from (a) Licensee's material breach of any representation, warranty, covenant or obligation under this Agreement, (b) use by Licensee or its Sublicensee or any of the foregoing Persons' respective transferees of Licensed Technology, (c) any use, sale, transfer or other disposition by Licensee or its Sublicensee or any of the foregoing Persons' respective transferees of Licensed Products or any other products made by use of Licensed Technology, or (d) (i) Licensee's enforcement or defense of the Licensed Patents or (ii) prosecution actions in respect of the Licensed Patents, to the extent such prosecution actions were taken at the request of or under the direction or guidance of Licensee, except to the extent any such Action arises from any matter for which Licensor is obligated to provide indemnification pursuant to Section 10.1.2.

10.1.2 Licensor Indemnification. Subject to Section 10.1.3, to the extent allowed under applicable Laws, Licensor will indemnify, defend and hold harmless Licensee and its respective directors, officers, employees, consultants, and agents and their respective successors, heirs, and assigns (each a "**Licensee Indemnitee**"), against all Losses arising from any Action which may be made or instituted against any Licensee Indemnitee related to, arising out of or resulting from (a) Licensor's material breach of any representation, warranty, covenant or obligation under this Agreement, or (b) a Licensor Indemnitee's negligence, willful misconduct, or breach of any applicable Law, except to the extent any such Action arises from any matter for which Licensee is obligated to provide indemnification pursuant to Section 10.1.1.

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10.1.3 Indemnification Procedure. An Indemnitee (whether a Licensor Indemnitee or a Licensee Indemnitee) that intends to claim indemnification under this Section 10.1 will give notice to the indemnifying party of any Action which might be covered by this Section 10.1. The indemnifying party shall immediately take control of the defense and investigation of the Action, including selection of counsel reasonably acceptable to the Indemnitee, at the indemnifying party's sole cost and expense; provided, however,

that the indemnifying party will not, without the prior written consent of the Indemnitee, settle or consent to the entry of any judgment with respect to such Action (a) that does not release the Indemnitee from all liability with respect to such Action, or (b) that may adversely affect the Indemnitee or under which the Indemnitee would incur any obligation or liability, other than one as to which the indemnifying party has an indemnity obligation hereunder. The Indemnitee agrees to cooperate and provide reasonable assistance to such defense at the indemnifying party's expense. The Indemnitee at all times reserves the right to select and retain counsel of its own at its own expense to defend its interests, provided that the indemnifying party will remain in control of the defense. The Indemnitee's failure to perform any obligations under this Section 10.1.3 shall not relieve the indemnifying party of its obligation under Section 10.1 except to the extent that the indemnifying party can demonstrate that it has been materially prejudiced as a result of the failure.

10.2 Insurance.

(a) Prior to using, selling, transferring or otherwise disposing of any Licensed Product (including for the purpose of obtaining regulatory approvals), Licensee shall, at its sole cost and expense, obtain, pay for and maintain commercial general liability and professional liability (Errors and Omissions) insurance in commercially reasonable and appropriate amounts that provides product liability coverage concerning the Licensed Products, including without limitation coverage for human trials, and contractual liability coverage for Licensee's defense and indemnification obligations under this Agreement. To the extent any insurance coverage required under this Section 10.2 is purchased on a "claims-made" basis, such insurance shall cover all prior acts of Licensee during the Term, and be continuously maintained until at least *** beyond the expiration or termination of the Term, or Licensee shall purchase "tail" coverage, effective upon termination of any such policy or upon termination or expiration of the Term, to provide coverage for at least *** from the occurrence of either such event. Promptly upon Licensor's request, Licensee will present evidence to Licensor that the coverage is being maintained. In addition, Licensee will provide Licensor with at least *** prior written notice of any material change in or cancellation of the insurance coverage.

(b) Licensee shall insert this Section 10.2 in any Sublicense, with the name of the Sublicensee substituted for the name of Licensee therein.

10.3 Lapse of Coverage. If Licensor elects to terminate this Agreement pursuant to (and subject to the cure period set forth in Section 7.4 for any breach of Section 10.2, then such termination shall occur and become effective pursuant to Section 7.4. Nothing herein shall be construed to release either party from any obligation that matured prior to the effective date of such termination. Notwithstanding the foregoing, in the *** period subsequent to the date of such a termination of this Agreement pursuant to Section 7.4, to the extent that such rights are still available for licensing, Licensee shall have the right to reinstate the effectiveness of this Agreement by obtaining the required insurance, whereupon this Agreement shall automatically become effective as of the date of reinstatement of said insurance and shall remain in full force and effect without any further action of the parties.

Redactions with respect to certain portions hereof denoted with "**"**

Article 11 REPRESENTATIONS AND WARRANTIES

11.1 Representations and Warranties of Licensee. Licensee represents and warrants to Licensor as follows:

(a) to the Licensee's knowledge, Licensee has not received any notice or threat of any claim, suit, action or proceeding, and has no knowledge or reason to know of any information, that could: (i) invalidate or render unenforceable any claim of any Licensed Patent; (ii) prove that the Licensed Products are not covered by any claim of any Licensed Patent; or (iii) cause any claim of any Licensed Patent to fail to issue or be materially limited or restricted as compared with its currently pending scope;

(b) to the Licensee's knowledge, the execution and performance of Licensee's obligations under this Agreement does not conflict with, cause a default under, or violate any existing contractual obligation that may be owed by Licensee to any third party;

(c) all Licensed Products will be manufactured in all material respects in accordance with applicable Laws, including, without limitation, all applicable Laws of the FDA and any other applicable Regulatory Authority;

(d) Licensee is a corporation duly organized, validly existing and in good standing under the laws of the state of its jurisdiction of organization;

(e) to the Licensee's knowledge, Licensee has all requisite corporate power and authority, and the legal right, to execute and deliver this Agreement and to perform its obligations hereunder;

(f) to the Licensee's knowledge, the execution and delivery of this Agreement by Licensee and the performance of its obligations hereunder have been duly authorized by all necessary corporate action in accordance with all applicable Laws. Licensee has duly executed and delivered this Agreement; and

(g) this Agreement is a valid, legal and binding obligation of Licensee, enforceable against Licensee in accordance with its terms.

11.2 Representations and Warranties of Licensor. Licensor represents and warrants to Licensee as follows:

(a) to Licensor's knowledge, it is the exclusive owner of all rights, title and interests in the Licensed Patents and has the right, power and authority to grant Licensee the licenses in Section 2.1 and it does not own any patents or patent applications other than the Licensed Patents the claims of which would dominate any practice of the Licensed Technology in the Fields.

(b) to Licensor's knowledge, the execution and performance of Licensor's obligations under this Agreement do not conflict with, cause a default under, or violate any existing contractual obligation that may be owed by Licensor to any third party.

Redactions with respect to certain portions hereof denoted with "**"**

(c) Licensor is a nonprofit corporation duly organized, validly existing and in good standing and has all requisite power and authority to execute and deliver, and perform its obligations under, this Agreement;

(d) to Licensor's knowledge, the execution and performance of Licensor's obligations under this Agreement do not conflict with, cause a default under, or violate any existing contractual obligation that may be owed by Licensor to any third party;

(e) this Agreement is a valid, legal and binding obligation of Licensor, enforceable against Licensor in accordance with its terms; and

(f) as of the Effective Date, to Licensor's knowledge, there is no infringement claim pending or threatened in writing against Licensor related to any of the Licensed Patents.

For purposes of this Section 11.2, "knowledge" means the actual knowledge of Vincent K. Tuohy and individuals employed by Licensor in the group known as "Cleveland Clinic Innovations" as of the Effective Date. For purposes of this Agreement, "Cleveland Clinic Innovations" means Tony Giordano and Greg Frykman.

11.3 Disclaimer of Representations and Warranties.

(a) Except as expressly provided herein, Licensee acknowledges and agrees that all rights licensed by Licensor hereunder are licensed "as is" and without any representation, indemnification or warranty with respect to possible infringement of third party rights. Except as expressly provided herein, nothing in this Agreement shall be construed as (i) a warranty or representation by Licensor as to the validity or scope of any Licensed Patents, (ii) a warranty or representation that anything made, used, imported, developed, promoted, offered for sale, sold, or otherwise disposed of under any license granted in this Agreement does not or will not infringe patents, trade secrets, copyrights or other intellectual or proprietary rights of third parties; (iii) a representation or warranty of operability or that development of a commercial products is possible; (iv) an obligation to bring or prosecute actions or suits against third parties for infringement; (v) conferring the right to use in advertising, publicity or otherwise any trademark, trade name, or names, or any contraction, abbreviation, simulation or adaptation thereof of Licensee or Licensor; (vi) conferring by implication, estoppel or otherwise any license or rights under any patents of Licensor other than the Licensed Patents; and (vii) any other representations or warranties, either express or implied, unless specified in this Agreement. Except as expressly provided herein, the furnishing of Confidential Information by either party shall not be interpreted to convey any grant of rights, titles, interests, options or licenses to the receiving party under any intellectual property rights owned or controlled by such party, other than the license under the Licensed Technology.

(b) EXCEPT AS EXPRESSLY PROVIDED HEREIN, EACH PARTY EXPRESSLY DISCLAIMS ALL REPRESENTATIONS AND WARRANTIES, WHETHER WRITTEN, ORAL, EXPRESS, IMPLIED STATUTORY OR OTHERWISE, CONCERNING THE VALIDITY, ENFORCEABILITY AND SCOPE OF THE LICENSED PATENTS, THE ACCURACY, COMPLETENESS, SAFETY, USEFULNESS FOR ANY PURPOSE OR, LIKELIHOOD OF SUCCESS (COMMERCIAL, REGULATORY OR OTHER) OF THE LICENSED PRODUCTS, LICENSED KNOW-HOW AND ANY OTHER TECHNICAL INFORMATION, TECHNIQUES, MATERIALS, METHODS, PRODUCTS, PROCESSES OR PRACTICES AT ANY TIME MADE AVAILABLE BY LICENSOR INCLUDING ALL IMPLIED WARRANTIES OF MERCHANTABILITY, QUALITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT AND WARRANTIES ARISING FROM A COURSE OF DEALING, COURSE OF PERFORMANCE, USAGE OR TRADE PRACTICE. WITHOUT LIMITATION TO THE FOREGOING, LICENSOR SHALL HAVE NO LIABILITY WHATSOEVER TO LICENSEE OR ANY OTHER PERSON FOR OR ON ACCOUNT OF ANY INJURY, LOSS, OR DAMAGE, OF ANY KIND OR NATURE, SUSTAINED BY, OR ANY DAMAGE ASSESSED OR ASSERTED AGAINST, OR ANY OTHER LIABILITY INCURRED BY OR IMPOSED ON LICENSEE OR ANY OTHER PERSON, ARISING OUT OF OR IN CONNECTION WITH OR RESULTING FROM: (X) THE MANUFACTURE, USE, OFFER FOR SALE, SALE, OR IMPORT OF A LICENSED PRODUCT, OR THE PRACTICE OF THE LICENSED PATENTS; (Y) THE USE OF OR ANY ERRORS OF OMISSIONS IN ANY KNOW-HOW, TECHNICAL INFORMATION, TECHNIQUES, OR PRACTICES DISCLOSED BY LICENSOR; OR (Z) ANY ADVERTISING OR OTHER PROMOTIONAL ACTIVITIES CONCERNING ANY OF THE FOREGOING.

Redactions with respect to certain portions hereof denoted with "**"**

11.4 Exclusion of Consequential and Other Indirect Damages EXCEPT FOR DAMAGES ARISING FROM A BREACH OF ARTICLE 8, FRAUD, WILLFUL MISCONDUCT, OR GROSS NEGLIGENCE, OR AS MAY BE PAYABLE PURSUANT TO A PARTY'S INDEMNIFICATION OBLIGATIONS UNDER ARTICLE 10, IN NO EVENT WILL EITHER PARTY, OR THE LICENSOR INDEMNITEES OR THE LICENSEE INDEMNITEES, BE LIABLE TO THE OTHER PARTY FOR ANY INJURY TO OR LOSS OF GOODWILL, REPUTATION, BUSINESS, PRODUCTION, REVENUES, PROFITS, ANTICIPATED PROFITS, CONTRACTS OR OPPORTUNITIES (REGARDLESS OF HOW THESE ARE CLASSIFIED AS DAMAGES), OR FOR ANY CONSEQUENTIAL, INCIDENTAL, INDIRECT, EXEMPLARY, SPECIAL, PUNITIVE OR ENHANCED DAMAGES WHETHER ARISING OUT OF BREACH OF CONTRACT, TORT (INCLUDING NEGLIGENCE), STRICT LIABILITY, PRODUCT LIABILITY OR OTHERWISE (INCLUDING THE ENTRY INTO, PERFORMANCE OR BREACH OF THIS AGREEMENT), REGARDLESS OF WHETHER SUCH LOSS OR DAMAGE WAS FORESEEABLE OR THE PARTY AGAINST WHOM SUCH LIABILITY IS CLAIMED HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH LOSS OR DAMAGE, AND NOTWITHSTANDING THE FAILURE OF ANY AGREED OR OTHER REMEDY OF ITS ESSENTIAL PURPOSE.

Article 12
NOTICES

Any payment, notice or other communication to be given pursuant to the provisions of this Agreement shall be in writing by means of a letter or electronic mail directed:

If to Licensor:

General correspondence to:

The Cleveland Clinic Foundation
9500 Euclid Avenue, Mailstop GC10
Cleveland, OH 44195
Attn: CCF Innovations – Executive Director
Email: gjordat@ccf.org
With a copy to: ccilicense@ccf.org

Payments to:

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With copies to:

Law Department
The Cleveland Clinic Foundation
3050 Science Park Drive, AC321
Beachwood, OH 44122
Attn: Chief Legal Counsel, CC Innovations
Email: legalcontracts@ccf.org
With a copy to: cicarej@ccf.org

If to Licensee:

General correspondence to:

Anixa Biosciences, Inc.
3150 Almaden Expressway, Suite 250
San Jose, CA 95118
Attn: Amit Kumar, CEO
Email: ak@anixa.com

Notices sent in accordance with this Section 12 shall be deemed effectively given: (a) when received, if sent by a nationally or internationally recognized courier (receipt requested); or (b) on the date sent by e-mail (with confirmation of transmission), if sent during normal business hours of the recipient, and on the next business day if sent after normal business hours of the recipient.

Article 13
ASSIGNMENT

This Agreement will be binding upon and will inure to the benefit of each party and each party's respective transferees, successors and assigns. Notwithstanding the foregoing, Licensee may not transfer, delegate or assign this Agreement or any rights or obligations hereunder (for clarity, excluding the grant of Sublicenses approved by Licensor in accordance with Section 2.2) without the prior written consent of Licensor (not to be unreasonably withheld, conditioned or delayed). For purposes of this ~~Article 13~~, transfer or assignment that will require such prior written consent will include any express assignment, Change in Control of Licensee, or other transfer or assignment by operation of law; provided that such consent will not be required in the case of transfer or assignment in connection with a Change in Control in which the successor entity is a Sublicensee approved by Licensor in accordance with Section 2.2. Upon written request, Licensee may obtain Licensor's prior written consent to the transfer or assignment of this Agreement to a particular entity in connection with a Change in Control in advance of the negotiation of such Change in Control. Any such request shall identify the potential successor entity(ies), but shall not be required to contain any terms or conditions of the potential Change in Control. Licensor shall respond to any such request within *** of receipt. Any failure by Licensor to respond to any such request within such period shall be deemed to constitute Licensor's prior written consent to the transfer or assignment of this Agreement to the entity(ies) identified in such request. In addition, any such consent given (or deemed to have been given) by Licensor shall remain in effect with respect to each potential successor entity for *** after the effective date of such consent and shall apply to the applicable entity(ies) identified in such request and any Affiliates thereof.

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Article 14
USE OF NAME

Licensee shall not use the name, logo, likeness, trademarks, or image of Licensor for advertising, marketing, endorsement or any other purposes without the specific prior written consent of an authorized representative of Licensor as to each such use. Licensee shall not make any public announcements, make any public statements, issue any press releases or otherwise communicate with any news media in respect of this Agreement or the transactions contemplated hereby without the specific prior written consent of an authorized representative of Licensor. Licensee shall not be required to attain consent under this Article 14 for use that, based on the written legal opinion of Licensee's legal counsel, is required pursuant to applicable law or regulation, including Licensee's obligations under disclosure rules of the Securities and Exchange Commission (SEC). Licensor's specific prior written consent to one use shall apply only to other uses of substantially similar form and content (e.g. various iterations of investor presentations) but not to any other uses. Notwithstanding anything to the contrary contained herein, Licensor shall have the right to withdraw any consent previously provided (e.g., if Licensor has previously consented to Licensee's use of Licensor's name and logo on Licensee's website or in investor presentations). For clarity, this Article 14 shall not restrict Licensee (or its Affiliates or Sublicensees) from publicly disclosing information regarding the status of the development, or manufacture or commercialization of any Licensed Product, provided that any such disclosure does not use the name, logo, likeness, trademark or image of Licensor.

Article 15
EXPORT CONTROLS; REGULATORY CLEARANCE

15.1 Export Controls. Neither Licensee nor any of its Sublicensees shall, directly or indirectly, export (including any "deemed export"), nor re-export (including any "deemed re-export") the Licensed Products (including any associated products, items, articles, computer software, media, services, technical data, and other information) in violation of any applicable U.S. Laws. Licensee and each Sublicensee shall include a provision identical in substance to this Section 15.1 in its agreements with its Sublicensees, third party wholesalers, distributors, customers and end-users requiring that these Persons comply with all applicable U.S. Laws, including all applicable U.S. export Laws. For the purposes of this Section 15.1, the terms "deemed export" and "deemed re-export" have the meanings set forth in Section 734.2(b)(2)(ii) and Section 734.2(b)(4), respectively, of the Export Administration Regulations (EAR) (*15 CFR §§ 734.2(b)(2)(ii) and 734.2(b)(4)*).

15.2 Regulatory Clearances. Licensee shall, at Licensee's expense, comply with all regulations and safety standards concerning Licensed Products developed and commercialized by or under the authority of Licensee and obtain all necessary governmental approvals for the development, production, distribution, sale and use of Licensed Products developed and commercialized by or under the authority of Licensee, including any safety or clinical studies. Licensee shall have responsibility for and provide suitable warning labels, packaging and instructions as to the use for such Licensed Products.

Article 16
MARKING

Licensee shall and shall require any Sublicensee to comply with any applicable patent marking provisions of 35 USC § 287(a) by marking all Licensed Products with the word "patent" or the abbreviation "pat." and either the numbers of the relevant Licensed Patents or a web address that is freely accessible to the public and that associates the Licensed Products with the relevant Licensed Patents. Licensee shall include in all Sublicenses a patent marking requirement substantially identical to this Article 16. Licensee shall and shall require any Sublicensee to also comply with the patent marking laws of the relevant countries in the Territory.

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Article 17
SEVERABILITY

If any term or provision of this Agreement is invalid, illegal or unenforceable in any jurisdiction, such invalidity, illegality or unenforceability shall not affect any other term or provision of this Agreement or invalidate or render unenforceable such term or provision in any other jurisdiction. Upon a determination that any term or other provision is invalid, illegal or unenforceable, the parties hereto shall negotiate in good faith to modify this Agreement so as to effect the original intent of the parties as closely as possible in a mutually acceptable manner in order that the transactions contemplated hereby be consummated as originally contemplated to the greatest extent possible.

Article 18
ANTI-KICKBACK AND STARK LAW

Licensee agrees to comply with all applicable Laws. Without limiting the foregoing, by entering into this Agreement, the Licensee will comply with all applicable laws, rules and regulations including (i) the federal anti-kickback statute (42 U.S.C. §1320a-7b) and the related safe harbor regulations; and (ii) the Limitation on Certain Physician Referrals, also referred to as the "Stark Law" (42 U.S.C. 1395nn). Accordingly, no part of any consideration paid hereunder is a prohibited payment for the recommendation of or arranging for the referral of business or the ordering of items or services; nor are the payments intended to induce illegal referrals of business. In the event that any part of this Agreement is determined to violate federal, state, or local laws, rules or regulations, the Parties agree to negotiate in good faith revisions to the provision or provisions that are in violation.

Article 19
CONFLICT OF INTEREST

Licensor maintains and adheres to a Conflict of Interest Policy. In that connection Licensee represents that no Licensor employees, officers, trustees or directors are consultants, employees, officers or directors or, to the best of Licensee's knowledge, owners of Licensee or any of its Affiliates or serve on any boards or committees of or in any advisory capacity with Licensee or any of its Affiliates, except as disclosed in Exhibit D attached hereto. Any payments made to such parties listed on Exhibit D are at fair market value for services rendered

Article 20
HEADERS

The descriptive headings of this Agreement are for convenience only and will be of no force or effect in construing or interpreting any of the provisions of this Agreement.

Article 21
BENEFIT AND WAIVER

The failure of either party to comply with any obligation, covenant, agreement or condition under this Agreement may be waived by the party entitled to the benefit thereof only by a written instrument signed by the party on granting such waiver, but such waiver or failure to insist upon strict compliance with such obligation, covenant, agreement or condition will not operate as a waiver of, or estoppel with respect to, any subsequent or other failure. The failure of any party to enforce at any time any of the provisions of this Agreement will in no way be construed to be a waiver of any such provision, nor in any way to affect the validity of the Agreement or any part thereof or the right of any party thereafter to enforce each and every such provision. No waiver of any breach of such provisions will be held to be waiver of any other or subsequent breach.

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Article 22
ENTIRE AGREEMENT

This Agreement (together with any exhibits, schedules or appendices attached hereto) constitutes the entire agreement between the Parties hereto with respect to the subject matter hereof and supersedes all previous or contemporaneous negotiations, commitments, and writings with respect to such subject matter. Neither party shall be obligated by any undertaking nor representation regarding the subject matter hereof other than those expressly stated herein or as may be subsequently agreed to by the parties hereto in writing.

Article 23
MISCELLANEOUS PROVISIONS

23.1 Amendment. No amendment, modification or supplement of any provision of this Agreement will be valid or effective unless made in writing and signed by a duly authorized officer of each party.

23.2 Further Assurances. Each party shall, upon the request of the other party, promptly execute such documents and take such further actions as may be necessary to give full effect to the terms of this Agreement.

23.3 Debarment. Licensee hereby represents and warrants that it has not been debarred, suspended, excluded or otherwise determined to be ineligible to participate in federal healthcare programs or federal procurement and non-procurement programs (collectively, "**Debarred**") and Licensee agrees not to engage or assign any employee, agent or contractor ("**Agent**") to perform services under this Agreement who has been Debarred. Licensee acknowledges that Licensor shall have the right to terminate this Agreement in accordance with Section 7.4 in the event that Licensee or an Agent is Debarred and not promptly removed. Accordingly, Licensee shall provide Licensor with immediate notice if during the Term of this Agreement Licensee (a) receives notice of action or threat of action with respect to its Debarment or (b) becomes Debarred.

23.4 Independent Contractors. Both parties are independent contractors under this Agreement. Nothing contained in this Agreement will be deemed to create an employment, agency, joint venture or partnership relationship between the Parties hereto or any of their agents or employees, or any other legal arrangement that would impose liability upon one Party for the act or failure to act of the other Party. Neither Party will have any express or implied power to enter into any contracts or commitments or to incur any liabilities in the name of, or on behalf of, the other Party, or to bind the other Party in any respect whatsoever.

23.5 Tax Exempt Status. The parties recognize that Licensor is a non-profit, tax-exempt organization and agree that this Agreement will take into account and be consistent with Licensor's tax-exempt status. If any part or all of this Agreement is determined to jeopardize the overall tax-exempt status of Licensor and/or any of its exempt Affiliates, the parties will negotiate in good faith an amendment of this Agreement pursuant to Article 17 so as to address such tax consideration while effecting the original intent of the parties as closely as possible in a mutually acceptable manner.

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Redactions with respect to certain portions hereof denoted with "**"**

23.6 Waiver of Automatic Stay. In the event Licensee is the subject of any voluntary or involuntary proceeding under the Bankruptcy Code, Licensee hereby unconditionally and irrevocably agrees that Licensor is immediately entitled, without notice, demand or any other action, to relief from the automatic stay so as to allow Licensor to enforce its rights and remedies under this Agreement, or at law and in equity under applicable state law. Licensee hereby consents to the immediate lifting, without notice, demand or any other action, of any such automatic stay and agrees that it shall not, in any manner, contest or otherwise delay any motion filed by Licensor for relief from the automatic stay. Licensor's enforcement of this stay waiver is subject to the approval of the bankruptcy court in which the case is then pending.

23.7 Equitable Relief. Each party acknowledges that a breach by the other party of this Agreement may cause the non-breaching party irreparable harm, for which an award of damages would not be adequate compensation and, in the event of such a breach or threatened breach, the non-breaching party shall be entitled to seek equitable relief, including in the form of a restraining order, orders for preliminary or permanent injunction, specific performance and any other relief that may be available from any court, and the parties hereby waive any requirement for the securing or posting of any bond or the showing of actual monetary damages in connection with such relief. These remedies shall not be deemed to be exclusive but shall be in addition to all other remedies available under this Agreement at law or in equity, subject to any express exclusions or limitations in this Agreement to the contrary.

23.8 Counterparts. This Agreement may be executed in any number of counterparts, each of which need not contain the signature of more than one party but all such counterparts taken together will constitute one and the same agreement. A signed copy of this Agreement delivered by e-mail to which a PDF copy is attached shall be deemed to have the same legal effect as delivery of an original signed copy of this Agreement.

[SIGNATURE PAGE FOLLOWS]

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

The Cleveland Clinic Foundation

By /s/ Steven C. Glass
 Name Steven C. Glass
 Title Chief Financial Officer

Anixa Biosciences, Inc.

By /s/ Amit Kumar
 Name Dr. Amit Kumar
 Title Chief Executive Officer

Redactions with respect to certain portions hereof denoted with "****"

Appendix A

LICENSED TECHNOLOGY

Licensed Patents:

Licensed Know-how:

Appendix A -1

Redactions with respect to certain portions hereof denoted with "****"

**Exhibit A
DEVELOPMENT PLAN**

To be provided pursuant to Section 5.7.

A -1

Redactions with respect to certain portions hereof denoted with "****"

**Exhibit B
FORM OF ROYALTY REPORT**

Licensee/Sublicensee: _____
 Period Reported: _____

Agreement Effective Date: _____

| Product name or Catalog number | Description | Activity Type (External Sales / Internal Sales) | Country | Sold to: | Number of units sold | Total Quarterly Gross Sales | Less Allowable Deductions | Net Sales | Royalty Rate | Other Income (including Sublicensing Revenue) | Total Due |
|--------------------------------|-------------|---|---------------------------|------------------|----------------------|-----------------------------|---------------------------|-----------|--------------|---|-----------|
| | | | (US, Canada, Japan, etc.) | (Note CCF Sales) | | | | | | | |
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| | | | | | | | | | | | |
| Total: | Total: | | | | | | | | | | \$ - |

Total Royalties Due \$ -

Prior Quarterly Payments: \$ -

Minimum Annual \$ - \$ -

Redactions with respect to certain portions hereof denoted with “****”

Exhibit C
FORM OF DEVELOPMENT REPORT

Date development plan initiated and time period covered by this report.

Development Report.

- Activities completed since last report including the object and parameters of the development, when initiated, when completed, a summary of the data collected, and the results.
- Activities currently under investigation, *i.e.*, ongoing activities including object and parameters of such activities when initiated, and projected date of completion.

Future Development Activities.

- Activities to be undertaken before next report including the type and object of any studies conducted and their projected starting and completion dates.
- Estimated total development time remaining before a product will be commercialized.

Changes to initial Development Plan.

- Reasons for change.
- Variables that may cause additional changes.

Items to be provided if applicable:

- Information relating to Licensed Product that has become publicly available, *e.g.*, published Sections, competing products, patents, etc.
- Development work being performed by third parties other than Licensee to include name of third party, reasons for use of third party, planned future uses of third parties including reasons why and type of work.
- Update of competitive information trends in industry, government compliance (if applicable) and market plan.
- *** estimate of Net Sales

Redactions with respect to certain portions hereof denoted with “****”

Exhibit D
CONFLICT OF INTEREST

None.

Anixa Biosciences, Inc.**Code Of Business Conduct And Ethics****As Approved by the Board of Directors January 17, 2018**

This Code of Business Conduct and Ethics covers a wide range of business practices and procedures. It does not cover every issue that may arise, but it sets out basic principles to guide the Company's principal executive officer, principal financial officer, principal accounting officer or controller and persons performing similar functions for the Company or any of the Company's subsidiaries (collectively, "Covered Persons"). All of the Covered Persons must conduct themselves accordingly and seek to avoid even the appearance of improper behavior.

1. Compliance with Laws, Rules, and Regulations

Obedying the law, both in letter and in spirit, is the foundation on which this Company's ethical standards are built. All Covered Persons must respect and obey the laws and regulations of the cities, states, and countries in which we operate. Although not all Covered Persons are expected to know the details of these laws and regulations, it is important to know enough to determine when to seek advice from other persons.

2. Conflicts of Interest

A "conflict of interest" exists when the private interest of a Covered Person interferes in any way with the interests of the Company. A conflict situation can arise when a Covered Person takes actions or has interests that may make it difficult to perform his or her duties for the Company objectively and effectively. Conflicts of interest also arise when a Covered Person, or a member of his or her family, receives improper personal benefits as a result of his or her position with the Company. Loans and guarantees by the Company may also create conflicts of interest, and certain loans to and guarantees of obligations of Covered Persons are prohibited by federal securities laws.

Conflicts of interest arise when a Covered Person works simultaneously for a competitor, customer, or supplier. No Covered Person may work for a competitor as a consultant or board member except as specifically approved in accordance with Section 12 of this Code. The best policy is to avoid any direct or indirect business connection with our customers, suppliers, or competitors, except on behalf of the Company. Any Covered Person who becomes aware of a conflict or potential conflict should bring it to the attention of the Board of Directors.

3. Insider Trading

Covered Persons who have access to or become aware of confidential information are not permitted to use or share that information for stock trading purposes or for any other purpose except the conduct of our business. All non-public information about the Company, as well as non-public information about our customers and suppliers, should be considered confidential information. To use non-public information for personal financial benefit or to "tip" others who might make an investment decision on the basis of this information is not only unethical but also illegal.

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4. Corporate Opportunities

Covered Persons are prohibited from taking for themselves personally, or diverting to other persons, opportunities that are discovered through the use of corporate property, information, or position without the consent of the Board of Directors. No Covered Person may use corporate property, information, or position for personal gain, and no Covered Person may compete with the Company directly or indirectly during his or her tenure with the Company. Covered Persons owe a duty to the Company to advance its legitimate interests when the opportunity to do so arises.

5. Confidentiality

All Covered Persons must maintain the confidentiality of confidential information entrusted to them by the Company, its customers or suppliers, or others, except when disclosure is authorized by the Board of Directors or the Company's Chief Executive Officer or required by laws or regulations. Confidential information includes all non-public information that might be of use to competitors, or harmful to the Company, its customers or suppliers, or others, if disclosed. It also includes information that customers or suppliers have entrusted to us. The obligation to preserve confidential information continues even after your employment or other association with the Company ends.

6. Competition and Fair Dealing

We seek to outperform our competition fairly and honestly. Stealing proprietary information, possessing trade secret information that was obtained without the owner's consent, or inducing such disclosures by past or present directors, officers, or employees of other companies is prohibited. Each Covered Person should endeavor to respect the rights of and deal fairly with the Company's customers, suppliers, competitors, and employees. No Covered Person should take unfair advantage of anyone through manipulation, concealment, abuse of privileged information, misrepresentation of material facts, or any other intentional unfair-dealing practice.

The purpose of business entertainment and gifts in a commercial setting is to create good will and sound working relationships, not to gain unfair advantage with customers. No gift or entertainment should ever be offered, given, provided, or accepted by any Covered Person, or any of their family members, unless it: (1) is not a cash gift, (2) is consistent with customary business practices, (3) is not excessive in value, (4) cannot be construed as a bribe or payoff, and (5) does not violate any laws or regulations. See also Section 10 of this Code concerning gifts and other payments to government representatives.

7. Discrimination and Harassment

The diversity of the Company's employees, consultants, and contractors is a tremendous asset. We are firmly committed to providing equal opportunity in all aspects of employment and contractual relations and will not tolerate any unlawful discrimination or workplace harassment of any kind or violent, coercive, or threatening behavior. Examples include derogatory comments based on racial or ethnic characteristics and unwelcome sexual advances.

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8. Record-Keeping

The Company requires honest and accurate recording and reporting of information to make responsible business decisions. For example, only the true and actual number of hours worked should be reported.

Business expense accounts must be documented and recorded accurately and should not be used for personal expenses, except where specifically permitted under the

Company's policies. Any personal expenses paid by use of the Company's expense account must be reimbursed promptly.

All of the Company's books, records, accounts, and financial statements must be maintained in reasonable detail, must appropriately reflect the Company's transactions, and must conform both to applicable legal requirements and to the Company's system of internal controls. Unrecorded or "off the books" funds or assets may not be maintained unless permitted by applicable law or regulation.

Business records and communications often become public, and we should avoid exaggeration, derogatory remarks, guesswork, or inappropriate characterizations of people and companies that can be misunderstood. This applies equally to e-mail, internal memos, and formal reports.

9. Protection and Proper Use of Company Assets

All Covered Persons should endeavor to protect the Company's assets and ensure their efficient use. Theft, carelessness, and waste have a direct effect on the Company's profitability. Company equipment should not be used for non-Company business, though incidental personal use may be permitted.

The obligation of Covered Persons to protect the Company's assets includes the obligation to protect the Company's proprietary information. Proprietary information includes intellectual property such as trade secrets, patents, trademarks, and copyrights, as well as business, marketing and service plans, engineering and manufacturing ideas, designs, databases, records, salary information, and any unpublished financial data and reports. Unauthorized use or distribution of this information violates Company policy. It could also be illegal and result in civil or criminal penalties.

10. Payments to Government Personnel

The U.S. Foreign Corrupt Practices Act prohibits giving anything of value, directly or indirectly, to officials of foreign governments or foreign political candidates to obtain or retain business. No illegal payments may be made to government officials of any country.

In addition, the U.S. government has a number of laws and regulations regarding business gratuities which may be accepted by U.S. government personnel. The promise, offer, or delivery to an official or employee of the U.S. government of a gift, favor, or other gratuity in violation of these rules would not only violate Company policy but could also be a criminal offense. State and local governments, as well as foreign governments, may have similar rules.

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11. Disclosures to the Board of Directors

Covered Persons are responsible for full, fair, accurate, timely, and understandable disclosure in the periodic reports required to be filed by the Company with the SEC. Accordingly, it is the responsibility of each Covered Person promptly to bring to the attention of the Board of Directors any material information of which he or she may become aware that affects the disclosures made by the Company in its public filings or otherwise assist the Board of Directors in fulfilling its responsibilities.

Each Covered Person shall promptly bring to the attention of the Board of Directors any information he or she may have concerning (1) significant deficiencies in the design or operation of internal controls which could adversely affect the Company's ability to record, process, summarize, and report financial data or (2) any fraud, whether or not material, that involves management or other employees who have a significant role in the Company's financial reporting, disclosures, or internal controls.

Each Covered Person shall promptly bring to the attention of the Board of Directors any information he or she may have concerning any violation of this Code, including any actual or apparent conflicts of interest between personal and professional relationships, involving any management or other employees who have a significant role in the Company's financial reporting, disclosures, or internal controls.

Each Covered Person shall promptly bring to the attention of the Board of Directors any information he or she may have concerning evidence of a material violation of the securities or other laws, rules, or regulations applicable to the Company and the operation of its business, by the Company or any agent thereof, or of violation of this Code.

12. Waivers of the Code of Business Conduct and Ethics

Any waiver of this Code for directors or executive officers may be made only by the Board of Directors and will be promptly disclosed as required by law or stock market regulation. Waivers for other personnel may be made by the Board of Directors or officers to which the Board may delegate such authority from time to time.

13. Investigation and Corrective Action

Upon receipt of a complaint under this Code, the Company will promptly investigate the complaint and will involve agencies and resources outside the Company if and when such outside involvement appears advisable or necessary. The Company will exercise discretion regarding the confidentiality of the report and investigation to the extent consistent with the need for a thorough investigation and response and taking into consideration the Company's disclosure obligations and requirements.

The Board of Directors shall conduct, or designate appropriate persons within or outside of the Company to conduct, any investigation concerning alleged violations of this Code by any Covered Person. Covered Persons are expected to cooperate in internal investigations of alleged misconduct.

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At the conclusion of any such investigation involving any Covered Person, the person leading the investigation will report to the Board of Directors the results of the investigation and any remedial measures such investigator recommends.

The Company will take all actions deemed appropriate by the Board of Directors as a result of any such investigation. If it is determined that a Covered Person has violated this Code, such action may include disciplinary action, up to and including termination of employment. Such actions shall be reasonably designed to deter wrongdoing and to promote accountability for adherence to this Code, and may include written notices to the individual involved of the determination that there has been a violation, censure, demotion or re-assignment of the individual involved, suspension with or without pay or benefits, or termination of the individual's employment. In determining what action is appropriate in a particular case, the Board of Directors shall take into account all relevant information, including the nature and severity of the violation, whether the violation was a single occurrence or repeated occurrences, whether the violation appears to have been intentional or inadvertent, whether the individual in question had been advised prior to the violation as to the proper course of action, and whether or not the individual in question had committed other violations in the past.

Any and all complaints and related information received under this Code will be retained for seven years from the date of the complaint, or such other period of time as may be required by law.

14. Whistleblower Protections

Federal and state laws prohibit retaliatory action by public companies against their employees who take certain lawful actions when they suspect wrongdoing on the part of their employer. In furtherance of the Company's obligations under federal law, as well as to preserve the integrity of this Code, neither the Company nor any Covered

Person may discharge, demote, suspend, threaten, harass, or in any other manner punish, discriminate, or otherwise retaliate against an employee because of any lawful act done by the employee to:

- a. provide information, cause information to be provided to, or otherwise assist in an investigation by a federal regulatory or law enforcement agency, any member of Congress or committee of Congress, or any person with supervisory authority over the employee or such other person working for the Company who has the authority to investigate, discover, or terminate misconduct, where such information or investigation relates to any conduct that the employee reasonably believes constitutes a violation of federal mail fraud, wire fraud, bank fraud, or securities fraud laws, any SEC rule or regulation, or any other federal law relating to fraud against shareholders;
- b. file, cause to be filed, testify, participate in, or otherwise assist in a proceeding relating to alleged violations of any of the federal fraud or securities laws described in (a) above; or
- c. report, or cause to be reported, any complaint under this Code.

The Company is committed to maintaining an environment in which people feel free to report all suspected incidents of inaccurate financial reporting or fraud. No retaliatory action will be taken against any person who in good faith reports any conduct which he or she reasonably believes may violate this Code. In addition, no retaliatory action will be taken against any individual who in good faith assists or participates in an investigation, proceeding, or hearing relating to a complaint about the Company's auditing or financial disclosures, or who files, causes to be filed, testifies, or otherwise assists in such a proceeding. However, a person who files a report or provides evidence which he or she knows to be false or without a reasonable belief in the truth and accuracy of such information will not be protected by the above policy statement and may be subject to disciplinary action, including termination of employment or other association with the Company.

SUBSIDIARIES OF ANIXA BIOSCIENCES, INC.

| <u>Name of Company and Name Doing Business</u> | <u>Jurisdiction of Organization</u> |
|--|-------------------------------------|
| Anixa Diagnostics Corporation | State of Delaware |
| Certainty Therapeutics, Inc. | State of Delaware |
| CopyTele International Ltd. | British Virgin Islands |
| CopyTele Marketing Inc. | British Virgin Islands |
| ITUS Patent Acquisition Corporation | State of Delaware |
| J-Channel Industries Corporation | State of Delaware |
| Loyalty Conversion Systems Corporation | State of Delaware |
| Secure Web Conference Corporation | State of Delaware |
| Encrypted Cellular Communications Corporation | State of Delaware |
| Auction Acceleration Corp. | State of Delaware |
| Cyber Instruments Technologies Corporation | State of Delaware |
| Meetrix IP, LLC | State of Texas |

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), Amendment No. 1 to the Registration Statement on Form S-3 (No. 333-206782), Registration Statements on Form S-3 (Nos. 333-220963, 333-217060 and 333-232067), the Registration Statement on Form S-8 (No. 333-277653) and Prospectus Supplement No. 1 to the Registration Statement on form S-8 (No. 333-227653) of Anixa Biosciences, Inc. (the "Company") of our report dated January 7, 2020 relating to our audits of the Company's consolidated financial statements as of October 31, 2020 and 2019, 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, 2020.

/s/ Haskell & White LLP

HASKELL & WHITE LLP

Irvine, California
January 7, 2021

**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 7, 2021

/s/ Amit Kumar

Dr. Amit Kumar

Chairman of the Board, President and Chief Executive Officer

**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 7, 2021

/s/ Michael J. Catelani

Michael J. Catelani
Chief Operating Officer and Chief Financial Officer

**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, 2020 (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 7, 2021

/s/ Amit Kumar

Dr. Amit Kumar
Chairman of the Board, President and Chief Executive Officer

**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, 2020 (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 7, 2021

/s/ Michael J. Catelani

Michael J. Catelani
Chief Operating Officer and Chief Financial Officer
