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

FORM 10-K

(Amendment No. 1)

[x] ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 For the fiscal year ended October 31, 2019

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: 0-11254

ANIXA BIOSCIENCES, INC.

(Exact Name of Registrant as Specified in its Charter)

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

3150 Almaden Expressway, Suite 250
San Jose, CA 95118
(408) 708-9808

(Address, Including Zip Code, and Telephone Number, Including Area Code, of Registrant's Principal Executive Offices)

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

Title of Each Class:	**Name of Each Exchange on Which Registered:**
Common Stock, $.01 par value	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 [x]

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 [x]

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 [x] 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 [x] No [_]

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

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

Large accelerated filer [__]	Accelerated filer [__]
Non-accelerated filer [x]	Smaller reporting company [x]
Emerging growth company [__]	

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. [__]

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

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, 2019 (the last business day of the registrant's most recently completed second fiscal quarter), computed by reference to the closing sale price of the registrant's common stock on the NASDAQ on such date ($4.16): $72,311,537

On January 8, 2020**,**the registrant had outstanding 20,821,204 shares of common stock, par value $.01 per share, which is the registrant's only class of common stock.

DOCUMENTS INCORPORATED BY REFERENCE:
NONE

TABLE OF CONTENTS

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

Information included in this Annual Report on Form 10-K (this "Report") contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Forward-looking statements are not statements of historical facts, but rather reflect our current expectations concerning future events and results. We generally use the words "believes," "expects," "intends," "plans," "anticipates," "likely," "will" and similar expressions to identify forward-looking statements. Such forward-looking statements, including those concerning our expectations, involve risks, uncertainties and other factors, some of which are beyond our control, which may cause our actual results, performance or achievements, or industry results, to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. These risks, uncertainties and factors include, but are not limited to, those factors set forth in this Report under "Item 1A. – Risk Factors" below. Except as required by applicable law, including the securities laws of the United States, we undertake no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise. You are cautioned not to unduly rely on such forward-looking statements when evaluating the information presented in this Report.

CERTAIN TERMS USED IN THIS REPORT

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

PART I

Item 1. Business.

Overview

Anixa Biosciences, Inc. is a biotechnology company focused on using the body's immune system to diagnose, treat and prevent cancer. We were incorporated on November 5, 1982 under the laws of the State of Delaware. Effective October 1, 2018, the Company changed its name from ITUS Corporation to Anixa Biosciences, Inc. From inception through October 2012, our primary operations involved the development of patented technologies in the areas of thin-film displays and encryption. From October 2012 through June 2015, the primary operations of the Company involved the development, acquisition, licensing, and enforcement of patented technologies that were either owned or controlled by the Company.

In June 2015, we formed a subsidiary, Anixa Diagnostics Corporation ("Anixa Diagnostics"), to develop Cchek™ a platform for non-invasive blood tests for the early detection of cancer. We then began a collaboration with The Wistar Institute ("Wistar"), the nation's first independent biomedical research institute and a leading National Cancer Institute designated cancer research center, for the purpose of validating proprietary cancer detection methodologies and establishing protocols for identifying certain biomarker patterns in the blood which we identified and which are known to be associated with malignancies.

Through our collaboration with Wistar, we demonstrated the efficacy of our Cchek™ early cancer detection platform with 20 different types of cancer: breast, lung, colon, melanoma, ovarian, liver, thyroid, pancreatic, appendiceal, uterine, osteosarcoma, leiomyosarcoma, liposarcoma, vulvar, prostate, bladder, cervical, head and neck, gastric and testicular cancers. Breast, lung, colon and prostate cancers represent the four largest categories of cancer worldwide.

Based on a number of factors, including key scientific, clinical, and commercial considerations, for the past year the primary commercial focus for Cchek™ has been on developing a prostate cancer confirmatory test. In February 2019, we formed a strategic alliance with ResearchDx, a CLIA certified, CAP Accredited laboratory, to prepare the Cchek™ Prostate Cancer Confirmation ("Cchek™ PCC") test for launch as a laboratory developed test. In December 2019, upon completion of independent validation by ResearchDx, we announced the commercial launch of Cchek™ PCC. We are currently conducting a number of activities to support the marketing of Cchek™ PCC, including the development of marketing materials, education of key opinion leaders in urology and development of a reimbursement path for the test. We expect Cchek™ PCC to be broadly available throughout the U.S. by April 2020.

In November 2017, we formed a subsidiary, Certainty Therapeutics, Inc. ("Certainty"), to develop immuno-therapy drugs against cancer. Certainty entered into a license agreement with Wistar pursuant to which Certainty was granted an exclusive worldwide, royalty-bearing license to use certain intellectual property owned or controlled by Wistar relating to Wistar's chimeric endocrine receptor targeted therapy technology (such technology being akin to chimeric antigen receptor T-cell ("CAR-T") 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.

Following the formation of Certainty and the license agreement with Wistar, Certainty entered into a collaboration agreement with the H. Lee Moffitt Cancer Center and Research Institute, Inc. ("Moffitt") to advance 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 studies necessary to submit an Investigational New Drug ("IND") application with the U.S. Food and Drug Administration ("FDA").

In July 2019, we entered into a license agreement with The Cleveland Clinic Foundation ("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 Cleveland Clinic's breast cancer vaccine technology. This technology pertains to the use of vaccines for the treatment or prevention of triple negative breast cancer ("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.

We have been working with researchers at Cleveland Clinic to advance the breast cancer vaccine technology toward human clinical testing and are completing the activities necessary to submit an IND application with the FDA.

Over the next several quarters, we expect Cchek™, our CAR-T ovarian cancer treatment and our breast cancer vaccine to be the primary focus of the Company. As part of our legacy operations, the Company remains engaged in limited patent licensing activities in the area of encrypted audio/video conference calling. We do not expect these activities to be a significant part of the Company's ongoing operations nor do we expect these activities to require material financial resources or attention of senior management.

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. In addition to Anixa Diagnostics and Certainty, the Company may make investments in and form new companies to develop additional emerging technologies.

Cchek™

Our Cchek™ cancer detection platform measures a patient's immune response to a malignancy by detecting the presence, absence, and quantity of certain immune cells that can be found in the blood stream. These types of cells and the tumor micro-environment have been the focus of ground breaking published and reported research in immuno-oncology, enabling the development of revolutionary immunotherapies used for treating certain cancer types. We have developed proprietary techniques and protocols for measuring the subtle immunological changes that occur in the blood stream during tumor development. Specifically, we seek to identify a subset of myeloid cells that we believe are diagnostic. These cells, often referred to as Myeloid Derived Suppressor Cells ("MDSCs"), are identified by specific surface proteins enabling characterization. We generally refer to MDSCs and other cells of the immune system which we believe can be diagnostic in nature as biomarkers. Through our proprietary protocols, we have had early success and have demonstrated accuracy in detecting these biomarkers in the peripheral blood of biopsy verified cancer patients, and in distinguishing the blood of healthy patients from the blood of cancer patients. We utilize Artificial Intelligence ("AI"), specifically a Neural Network ("NN") to analyze our data and to determine the presence of a tumor. We believe that a NN is better able to identify subtle changes in immune response than other analytical approaches. The distinguishing feature of a NN is that it can be trained to answer the key biological questions of interest, in our case whether or not the patient is tumor-bearing, and as it is trained with more data, its ability to answer these questions may improve. Our goal is to establish Cchek™ as a non-invasive, inexpensive, cancer diagnostic blood test that can reduce or eliminate the need for traditionally expensive, invasive, painful, and often inaccurate cancer diagnostic procedures which are currently in use.

In each instance where we have demonstrated the efficacy of our cancer detection platform, fresh (utilized within 48 hours) blood samples from biopsy verified cancer patients have been tested using a variety of experimental methodologies and protocols, including the use of certain over the counter reagents and other supplies. Such un-blinded, non-uniform testing is common during the initial development stage of new technologies and diagnostic tests. Blood samples from patients with differing severities of cancers (with some cancers such as breast cancer stage I to stage IV) have been tested, including samples from both pre-treatment and post-treatment patients. In addition, we have also tested blood from healthy donors. A critical aspect of any cancer diagnostic is the ability to accurately distinguish patients with cancer from healthy patients. Based upon our encouraging results, we continue working to refine protocols and methodologies for identifying and classifying the immunologic biomarkers that are the foundation for our Cchek™ early cancer detection platform.

While studies comparing biopsy verified cancer patients to healthy donors are critical, it is also vital to evaluate the impact of benign conditions such as benign prostatic hyperplasia, non-malignant neoplasias, systemic inflammatory conditions, infections, and other potential conditions on the immune system. We have performed such testing comparing cancer patients to those with benign conditions in the development of Cchek™ PCC, as patients in need of a confirmatory test will not likely be healthy, but instead will have either prostate cancer or a benign condition.

As we develop our Cchek™ platform, there are multiple regulatory approval pathways available for each test. One manner of seeking regulatory approval is to have a lab certified to run our diagnotic tests pursuant to the Clinical Laboratory Improvement Act of 1967 and the Clinical Laboratory Improvement Amendments of 1988 (collectively, "CLIA"). Among other things, CLIA requires clinical laboratories that perform diagnostic testing to be certified by the state in which the lab is located, as well as the Center for Medicare and Medicaid Services. If we seek regulatory approval pursuant to CLIA, only those laboratories that are certified under CLIA to run our diagnostic test would be able to process test samples. CLIA certification may or may not require additional studies. We could seek to establish our own CLIA certified laboratory to run the diagnostic tests, or we could potentially contract with an existing CLIA certified lab and seek to have that laboratory certified to run our diagnostic test.

Another manner of obtaining regulatory approval would be to seek to have our diagnostic test approved by the FDA pursuant to what are commonly referred to as either the 510(K) process, or the Premarket Application ("PMA") process. The appropriate pathway for FDA approval would depend upon a variety of factors, including the intended use of the test, and the risks associated with such use. FDA approval can take several years and would entail additional clinical studies.

Our decision to seek CLIA certification or FDA approval of a diagnostic test or tests utilizing our Cchek™ technology will be dependent on a variety of factors, including the capital requirements of each approval process, the landscape for competitive diagnostic testing, and the time and resources required by each approval process. It is possible that we may seek to have one or more diagnostic tests approved via CLIA certification, and other diagnostic test or tests approved by the FDA, or that we may seek simultaneous FDA approval and CLIA certification of a particular diagnostic test or tests.

Based on a number of factors, we have launched our Cchek™ PCC test as a laboratory developed test under CLIA guidelines, and our CLIA certified commercialization partner, ResearchDx, will run the test. Under CLIA guidelines, the test must be run in ResearchDx's southern California facility, while the blood samples can come from patients anywhere in the U.S.

For other tests based on the Cchek™ platform, based upon and following the results of more extensive clinical studies, as well as potential discussions with the FDA, we will determine whether and when to begin the process of seeking regulatory approval.

While we believe our Cchek™ platform could eventually form the basis of a pan-cancer (all cancer) test, the decision to initially focus on a prostate cancer confirmation test incorporated a number of factors, including key scientific, clinical, and commercial considerations. The current method of diagnosing prostate cancer is highly inaccurate, with approximately 75% of all prostate biopsies in the U.S. being negative for high risk cancer. Our most recently reported studies with Cchek™ PCC have demonstrated sensitivity of 92%, meaning 92% of all men with prostate cancer may be correctly diagnosed with cancer, and specificity of 41%, meaning 41% of all men without cancer may be correctly diagnosed as not having cancer. With approximately 1-1.5 million prostate biopsies performed annually, Cchek™ PCC has the potential to eliminate hundreds of thousands of unnecessary prostate biopsies annually in the U.S. alone.

Historical Biomarker Studies

On December 7, 2016 we announced the preliminary results from our initial Cchek™ cancer patient efficacy study. Using our protocols and methods for measuring a patients' immunological response to a malignancy, we achieved sensitivity of 92% and specificity of 92% for 88 patient samples, including 54 samples from patients with multiple types and severities of cancer, and 34 healthy patients. During the initial phase of the study, which involved multiple experimental protocols and techniques for measuring immunological responses, we reviewed and analyzed data from a total of 315 patient samples, including 228 patients with varying stages of cancer, as well as blood samples from 87 healthy donors.

Patient samples representing 14 different types of cancer (breast cancer, lung cancer, colon cancer, melanoma, ovarian cancer, liver cancer, thyroid cancer, pancreatic cancer, appendiceal cancer, uterine cancer, osteosarcoma (cancer of the bone), leiomyosarcoma (cancer of the soft tissue), liposarcoma (cancer of the connective tissue), and vulvar cancer) were included in the study. The study included samples from patients with early and late stage, biopsy-verified, drug-naïve (before therapy) tumors, as well as biopsy-verified, refractory (unresponsive to attempted chemotherapy) tumors.

Sensitivity and specificity are scientific measurements commonly used to determine the accuracy of a diagnostic test, where sensitivity measures how good a test is at identifying people with a particular disease, and specificity measures how good a test is at identifying people without the disease. Although published results vary widely, established diagnostic tests such as Low Dose Computed Tomography (LDCT), which is used by other companies to screen for lung cancer, has sensitivity of approximately 93% and specificity of approximately 73%, the PSA test, which is used by other companies to screen for prostate cancer, has sensitivity of approximately 21% and specificity of approximately 91%, and mammography, used by other companies to screen for breast cancer and considered to be the "gold standard" for breast cancer screening, has reported sensitivity as low as approximately 68% and specificity as low as approximately 75%. As these results indicate, current diagnostic testing is hampered by low sensitivity, low specificity or both, meaning that the tests miss a substantial portion of the cancers they are supposed to detect, or miss-diagnose a large number of healthy patients as having cancer. There is currently no inexpensive, non-invasive, diagnostic test that excels in both sensitivity and specificity.

Initial samples in our study were tested utilizing immunostaining and fluorescent microscopic imaging. While results were promising, subjectivity in interpreting the imaging results together with labor intensive and time consuming sample processing hampered the commercial viability of this approach. Subsequently, patient samples were analyzed using flow cytometry, enabling more efficient processing and analysis. In addition, the Company implemented its proprietary NN software application for analysis, which currently relies on multiple quantitative parameters to analyze test results. This approach, which is highly data intensive and requires substantial computer processing power to develop, results in a test which can be performed using a desktop computer. An initial version of our NN, which was trained to distinguish between the immunological responses from cancer patients and healthy patients, was responsible for the sensitivity and specificity results reported above. We expect to continue to improve our protocols, continue to upgrade our NN software by increasing the number of patient samples used to train the software and expanding the range of markers, increase the data resolution, and enhance the architecture of the software, which may enable better results.

In a study released in January 2018, augmenting data from our preliminary study, we reported a sensitivity of 89% and a specificity of 95%. All cancer patients were biopsy-verified with all clinical stages (I to IV) included. The total number of patients in this study was 163, which included 81 cancer patients and 82 healthy donors. The majority of patient samples collected for this study were from breast cancer and prostate cancer patients, but several other types were also included, bringing the total number of cancer types where we have successfully used Cchek™ to 20.

In an additional study released in March 2018, we announced the results of a prostate cancer study with Serametrix Corporation ("Serametrix") in which data from a previous collaboration between Serametrix and Memorial Sloan Kettering Cancer Center ("MSK") was re-evaluated using our Cchek™ technology. Previously, Serametrix analyzed a number of metastatic prostate cancer and normal healthy blood samples using an MSK proprietary assay and algorithm for cancer detection. Following this, a blinded re-analysis of the data was performed by Anixa Diagnostics, using Cchek™. This study achieved 92% sensitivity and 92% specificity using 121 prostate cancer and 125 healthy donor samples.

In October 2018, at the 30th Anniversary AACR Special Conference – Convergence: Artificial Intelligence, we presented data demonstrating the ability of Cchek™ to distinguish, among patients scheduled for biopsy, those who had high risk prostate cancer and those who had benign conditions or low grade cancer, for whom surgery is not required and a biopsy is unnecessary. The Cchek™ data showed the ability to distinguish healthy males from high risk prostate cancer patients with a sensitivity of 89% and a specificity of 100%. This study further demonstrated the potential for Cchek™ to reduce the number of unnecessary prostate biopsies by up to 56%, while still retaining 89% sensitivity for detecting prostate cancers.

In November 2018, we released the results of our first study demonstrating the ability of Cchek™ to identify the presence of early stage breast cancer. Our Cchek™ technology demonstrated a sensitivity of 89% when detecting early stage breast cancer (Stage I or II) and a specificity of 95% when used to test blinded samples. Furthermore, Cchek™ was also able to detect the early stages of breast cancer (Stage 0) in subjects with biopsy-confirmed ductal carcinoma in situ (DCIS), a type of pre-cancerous/non-invasive breast lesion that often leads to invasive breast cancer, with 72% sensitivity.

Since that time, we have continued to process patient samples and refine our procedures and have presented data with consistent results at several conferences and meetings.

Related to our collaborative research agreement, the Company and/or Wistar currently have or have had collaborations with doctors from University of Pennsylvania Abramson Cancer Center, The Helen F. Graham Cancer Center and Research Institute at Christiana Hospital in Wilmington, Delaware, Virtua Healthcare System in southern New Jersey, New Jersey Urology, the largest urology practice in the country, MD Anderson Cancer Center at Cooper Hospital in southern New Jersey, Potomac Urology in northern Virginia, the University of Maryland School of Medicine, Urology San Antonio, Idaho Urologic Institute, Urology Centers of Alabama, Genesis Research, in the San Diego area, and several U.S. Department of Veterans Affairs VA Medical Centers. In most cases, patients from participating doctors at these healthcare institutions who are beginning or in some cases, continuing cancer treatment are asked to consent to have an additional tube of blood drawn for the purpose of participating in the Cchek™ patient efficacy trials. Because the number of cancer patients treated by these hospitals varies over time, and the decision whether to participate in the Cchek™ patient studies is ultimately at the discretion of the patient, it is difficult to predict the number of patient samples that we will receive in any given week, or during any given month. Due to this unpredictability in sample flow, the Company is currently in discussions with additional doctors and healthcare providers about providing blood samples for our patient efficacy trials, and the Company has capacity available to process an additional quantity of samples.

The Market

There are four primary markets for a cancer diagnostic test: screening, confirmatory testing, treatment monitoring, and recurrence testing.

Screening

Screening occurs when asymptomatic people are tested for indications of cancer. Examples of existing screening tests include the mammogram for breast cancer, PSA for prostate cancer, and colonoscopy for colon cancer. All screening tests have their strengths and weaknesses, and for many cancers there are currently no recommended screening tests available.

Confirmatory Testing

Confirmatory testing is used to confirm the results of a screening test. In certain instances, existing confirmatory testing can be invasive, painful, expensive, and have relatively high risks of complications. For example, a positive mammogram is often followed up with additional imaging, which can lead to a biopsy during which a needle is inserted into the breast to sample suspicious tissue or lesions. For lung cancer, existing confirmatory diagnostics include bronchoscopies, during which a flexible tube is inserted through the nose or mouth and into the lung, and needle biopsies, during which a long needle is inserted between the ribs and into the lung. One potential side effect of a lung biopsy is a pneumothorax (commonly referred to as a “collapsed lung”), which has been reported to occur in approximately fifteen percent (15%) of needle biopsies of the lung. A pneumothorax can lead to other complications and sometimes requires extended hospitalization. In addition to the potential side effects, biopsies of any sort can be extremely painful for the patient.

Treatment Monitoring

Treatment monitoring includes follow-on testing to monitor the effectiveness of a specific regimen of treatment. For example, diagnostic monitoring testing may be used to monitor the effectiveness of a particular type of chemotherapy, to determine how the cancer is responding and whether such treatment should be continued. Often, imaging techniques are not able to identify whether a treatment is working, so a biopsy is useful, however it is painful and impractical to perform multiple biopsies on a patient. Therefore, a "liquid biopsy" enabling therapy monitoring via a blood test can be useful.

Recurrence Testing

Recurrence testing is used for cancer survivors to test for cancer recurrence. According to the most recently published statistics from the American Cancer Society, there were more than 15.5 million Americans living with a history of cancer as of January 1, 2016. Most cancer survivors live in fear of recurrence, and limitations of existing diagnostics, including repeated exposure to radiation from imaging tests, and invasiveness and costs and pain from tests such as traditional biopsies, prevent cancer survivors from being tested as often as they would like.

The Company's long term vision is to have one or more tests based upon the Cchek™ platform to serve each of the markets identified above. We have made the initial market focus of Cchek™ confirmatory, or pre-biopsy, testing, and in particular, confirmatory testing of prostate cancer. We estimate that there is a U.S. market of roughly 12 million biopsies annually and a high rate of negative biopsy results. Accordingly, we believe that positioning Cchek™ as a pre-biopsy test will reduce the number of unnecessary biopsies, thus improving patient outcomes and reducing healthcare costs.

Competition

Background

Continuing scientific advances and discoveries, the ability to more quickly process and analyze large amounts of scientific data, and decreases in the cost of sophisticated equipment and technologies, have resulted in the potential for significant advances in cancer treatment, and in particular, cancer diagnostics. Cancer statistics gathered over the past several decades provide overwhelming evidence that the earlier that cancers are detected, the greater the survival rates. Up until now, doctors have primarily relied upon technologies such as imaging (x-rays, mammograms, CT scans, MRIs, PET scans, ultrasounds) and biopsies and other invasive procedures for cancer detection and cancer diagnoses. In many cases, these diagnostic procedures were performed after patients exhibited one or more symptoms of cancer, at which point the cancer may likely no longer be at an early stage. Existing diagnostic technologies such as imaging have gotten better, and invasive diagnostic procedures such as colonoscopies have become more accurate and less risky, and we expect these types of traditional diagnostic tools to continue to predominate the cancer diagnostic market for the foreseeable future.

We believe that with advancing medical knowledge, improvements in equipment and technologies, and reduction in costs of new technologies, new types of cancer diagnostics will be created and new types of cancer diagnostic testing that will outperform many of the traditional diagnostic tests, eliminate many of the negative consequences of existing diagnostic testing, and ultimately predominate the cancer diagnostic market.

We have identified a class and subclasses of biomarkers that we believe are measurable in the blood of patients with malignancies, and are perfecting a process and methodology for detecting those biomarkers. The goal is to create a platform, Cchek™, that can be used to launch a series of simple and affordable blood tests that can be used to detect and monitor many of the most deadly forms of cancer, including lung cancer, breast cancer, ovarian cancer, colon cancer, pancreatic cancer, prostate cancer and others. We will not initially simultaneously launch tests for each of the cancers identified above, but expect to develop and launch over time, specific and individual cancer tests for each of the four markets identified above (screening, confirmatory testing, treatment monitoring, recurrence).

Statistics from The American Cancer Society in 2019 indicate that one out of every three people that are born in the U.S. today, will develop some form of cancer during their lifetimes. With approximately 200 million adults in the United States alone, we believe that the market for new, non-invasive cancer diagnostic technologies and testing will be enormous, and that there will be sufficient demand to support many different technologies and tests.

Cancer Diagnostic Technologies

If successful, we believe Cchek™ will have several advantages over existing diagnostic technologies. For example, repeated exposure to radiation from x-ray technologies, such as mammograms, has become an increasing concern for the medical community, causing authorities to re-evaluate the recommended frequency of such x-ray based tests. Traditional biopsies are often impossible for some cancers depending on the location of the tumor, and are invasive, expensive, and painful enough to warrant only limited use for other cancers even when the tumor can be accessed. In addition, such biopsies are limited in their inability to detect the heterogeneity of many cancerous tumors, and the ongoing mutations that are often evident as the tumor progresses. False positives in existing testing such as the PSA test, result in otherwise healthy patients being misdiagnosed, and subject to unnecessary follow-on treatments and medical procedures. Patient inconvenience, risk of side effects from anesthesia, and risk of other complications result in low patient compliance with otherwise effective cancer screening tests such as the colonoscopy. These are just a few examples of the challenges with traditional diagnostic tests that we seek to eliminate with Cchek™. This will be the foundation for the competitive advantages that we expect to have over existing diagnostic testing. We expect Cchek™ will be utilized as a component of multiple diagnostic technologies and patient background information to diagnose and manage the patient's condition.

Many public and private companies have announced plans and ongoing research efforts to launch non-invasive cancer diagnostic tests and tools that can be used for non-invasive cancer testing. These companies include well established, and successful biotech companies, start-ups, and companies of all sizes. Almost every bodily fluid, including blood, plasma, urine, saliva, and excrement, are being studied for biomarkers or indicators of one or more types of cancer. The term that has been used to describe the category of this type of non-invasive cancer diagnostic testing is "liquid biopsy." In general, most of these companies are focused on identifying and analyzing one of three types of biomarkers: circulating tumor cells ("CTCs"), circulating tumor DNA ("ctDNA"), and exosomes. Each of these types of biomarkers has their advantages and disadvantages, and we expect that tests incorporating these and other biomarkers will make their way into the cancer diagnostic marketplace.

We believe that our Cchek™ diagnostic platform has the potential for at least three distinct advantages over the types of biomarker tests referred to above. First, it appears that the biomarkers that we are using may be present in multiple types of and varying severities of cancers. As a result, we anticipate that Cchek™ will become a platform from which multiple tests could be launched for multiple types of cancers. Second, it appears that the biomarkers utilized by Cchek™ may be present in both advanced, and early stages of cancers. Third, we expect Cchek™ to be significantly less expensive than the technologies commonly used for tests based on CTC's, ctDNA, and exosomes.

Commercialization of Cchek™ PCC

In order to prepare Cchek™ PCC for commercialization, ResearchDx, our CLIA certified CAP accredited laboratory partner, performed an independent CLIA validation study. For this study, ResearchDx processed blood samples from biopsy verified patients, then utilized our NN to distinguish between patients with high risk prostate cancer and those with benign conditions or low grade cancer, for whom a biopsy is unnecessary. This CLIA validation study resulted in a sensitivity of 96% and a specificity of 45%, meaning that nearly all patients with high risk prostate cancer were correctly identified and nearly half of all unnecessary biopsies could be avoided.

While Cchek™ PCC was commercially launched in December 2019, there are a number of activities we are currently conducting to support marketing of the test, including the development of marketing materials, education of key opinion leaders in urology and development of a reimbursement path for the test. We anticipate that once these activities are completed, we will have a team of key opinion leaders in urology using Cchek™ PCC in parallel with the standard methods of prostate cancer diagnosis. We believe that we will demonstrate to such key opinion leaders that Cchek™ PCC provides significantly greater diagnostic accuracy than standard methods, as well as improved patient care. We therefore believe that with favorable clinical experience amongst key opinion leaders in urology using Cchek™ PCC, we will be positioned to execute a strategic partnership with national or regional testing laboratories for the sales, marketing and operations of Cchek™ PCC.

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.

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 are in the process of optimizing the viral vector necessary for genetically engineering patient T-cells, thereupon we believe we will have the clinical grade vector manufactured and tested and we will then be prepared to file our IND application. We anticipate filing the IND by the end of 2020. 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 the the second calendar quarter of 2021.

The Market

According to American Cancer Society statistics, ovarian cancer accounts for just 2.5% 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 2019, 23,000 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 47%. However, ovarian cancer survival varies substantially by age, with the overall five-year survival rate for women 65 and older of only 30%.

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.

Breast Cancer vaccine

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.

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 technology licensed from Cleveland Clinic has identified a protein called 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.

While the data thus far has been positive, there are many uncertainties in drug development, and most drugs fail to reach commercialization. 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 therapeutic or prophylactic cancer vaccine.

We have been working with researchers at Cleveland Clinic to advance the breast cancer vaccine technology toward human clinical testing, and we are in the process of testing the clinical grade materials and upon completion we will then be prepared to file our IND application. We anticipate filing the IND in 2020. The IND application, after review and approval by the FDA, will enable us to begin testing our therapy in breast cancer patients. Assuming the FDA approves our IND application, we anticipate beginning the human clinical trial as soon as practicable thereafter.

The 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 2019, 269,000 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., 269,000 women are estimated to be diagnosed with breast cancer this year, there are approximately 75 million women over the age of 40—the time in life when women face an increased risk of developing breast cancer. Worldwide, the number is dramatically larger.

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 cancer vaccine technology and scientific expertise in the field of cell therapy provide us with competitive advantages, we face potential competition from various sources, including larger and better-funded pharmaceutical and biotechnology companies, as well as from academic institutions, governmental agencies and public and private research institutions.

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

Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated among a smaller number of our competitors. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical study sites and subject registration for clinical studies, as well as in acquiring technologies complementary to, or necessary for, our 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 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 opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market.

Employees

As of October 31, 2019, we had eight employees, seven full-time and one part time, working for our Company and subsidiaries.

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.

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, 2019, our accumulated deficit was approximately $181,817,000. As of October 31, 2019, we had approximately $5,842,000 in cash, cash equivalents and short-term investments, and working capital of approximately $4,612,000. In fiscal year 2019, we incurred losses of approximately $11,819,000 and we experienced negative cash flows from operations of approximately $4,773,000. 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 9, 2020, 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 complimentary 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.

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.

Our employees, scientific advisors, principal investigators, consultants and commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements, and insider trading.

We are exposed to the risk of fraud or other misconduct by our employees, scientific advisors, principal investigators, consultants and commercial partners. Misconduct by these parties could include intentional failures to comply with the regulations of the FDA or other regulatory bodies, comply with healthcare fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing, and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Such misconduct could also involve the improper use of information obtained in the course of clinical studies, which could result in regulatory sanctions and cause serious harm to our reputation. We currently have a code of conduct applicable to all of our employees, but it is not always possible to identify and deter employee misconduct, and our code of conduct and the other precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses, or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could result in the imposition of significant civil, criminal and administrative penalties, including, without limitation, damages, monetary fines, individual imprisonment, disgorgement of profits, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional reporting or oversight obligations if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with the law and curtailment or restructuring of our operations, which could have a significant impact on our business. Whether or not we are successful in defending against such actions or investigations, we could incur substantial costs, including legal fees and divert the attention of management in defending ourselves against any of these claims or investigations.

Risks Related to our Biotechnology Research & Development and Commercialization Activities

Our cancer diagnostic and cancer therapeutics businesses 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 cancer diagnostics and therapeutics 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. Therefore we are subject to all the risks and uncertainties inherent in a new business, in particular new businesses engaged in the early detection of certain cancers, CAR-T cancer therapeutics and cancer vaccines. CchekÔ, our CAR-T ovarian cancer therapeutic and our breast cancer vaccine 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:

- demonstrate the effectiveness and clinical utility of the Cchek™ platform;
- develop a reimbursement pathway for our Cchek™ PCC test;
- recruit key opinion leaders in urology to order Cchek™ PCC for their patients;
- successfully complete studies necessary to submit IND applications to the FDA for our CAR-T ovarian cancer therapeutic or breast cancer vaccine;
- obtain FDA approvals to commence human clinical trials of our CAR-T ovarian cancer therapeutic or breast cancer vaccine;
- 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.

Our current business model, as it relates to both our diagnostic and therapeutics businesses, 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.

We may have difficulty in raising capital for our cancer diagnostics and therapeutics businesses and may consume resources faster than expected.

We currently do not generate any revenue from CchekÔ, our CAR-T therapeutic or our breast cancer vaccine nor do we generate any other recurring revenues and as of October 31, 2019, the Company only had approximately $5,842,000 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 cancer vaccine and for Cchek™ for each type of cancer for which we desire to launch a diagnostic test. 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 diagnostic and therapeutics 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.

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 therapeutic clinical trials and broad commercialization of our diagnostic tests. 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.

Risks Related to Cchek™

While our CchekÔ diagnostic technology has shown favorable results from initial testing, we cannot guarantee that these results will be replicated in future testing nor can we guarantee the success of the technology at all.

We have initially used Cchek™ to test the blood of small groups of individuals consisting of cancer patients, patients with benign conditions and healthy patients and have in some studies reported sensitivity and specificity of over 90%. While these preliminary results far exceed existing diagnostic testing, and we have launched Cchek™ PCC based on these results, there is no guarantee that these results will be replicable when we test a larger group of patients, as we seek to commercialize CchekÔ PCC, or at all. If we are unable to consistently attain results that are necessary to realize economic benefit for CchekÔ PCC or for commercialization of additional Cchek™ tests, our diagnostic technology will not have any monetary value and we will be unable to generate any revenue from this technology.

Even if we are able to attain results necessary for the commercialization of any test based on the CchekÔ technology, our ability to commercialize the technology in the future will depend on our ability to provide evidence of clinical utility.

Our ability to successfully commercialize Cchek™ will depend on numerous factors, including whether health care providers believe that Cchek™ provides sufficient incremental clinical utility; whether the medical community accepts that Cchek™ has sufficient sensitivity (there are no or very few false positives), specificity (detects the cancer the test is supposed to detect) and predictive value to be meaningful in patient care and treatment decisions; whether the cost of the test is reasonably priced and commercially viable; and whether health insurers, government health programs and other third-party payers will cover and pay for Cchek™ and the amount that they will reimburse for such tests. These factors may present obstacles to commercial acceptance of Cchek™. To the extent these obstacles arise, we will need to devote substantial time and resources to overcome these obstacles, and we might not be successful. Failure to achieve market acceptance of Cchek™ would materially harm our business, financial condition and results of operations.

We are unable to give any assurance that we will be successful in providing sufficient evidence of clinical utility or any assurance that we will have adequate managerial, technical or financial resources to support the studies necessary to provide sufficient evidence of clinical utility of Cchek™ or to adequately differentiate our test from other diagnostic products in the manner, timeframe or cost parameters we anticipate, if at all. If we are unable to provide evidence of clinical utility and differentiate Cchek™, we will not be able to generate the revenues and market growth that we seek. Our failure to generate revenue from the sale of our products would materially adversely impact our business, financial condition, results of operations and prospects.

To run diagnostic tests on blood samples on our CchekÔ platform, we rely on certain over the counter reagents and other specialty raw materials which may not be available to us in a timely manner or at all.

When performing diagnostic tests on blood samples on our Cchek™ platform, we use certain over the counter reagents and other supplies. Generally, all of the reagents and other supplies that we use for our diagnostic tests are off the shelf, are available from multiple suppliers and are able to be obtained without significant lead time. However, there is no assurance that this will be true in the future. For example, if a supplier has quality control issues, the delivery of these materials may be slower than expected. Further, if we need to find a new supplier for any of these materials, there is a risk that the new materials will not perform precisely as the old materials performed. While we seek to mitigate these risks by keeping extra supplies of the necessary materials on hand, if we are unable to obtain the necessary materials to run our diagnostic tests, if the materials we are able to obtain do not perform precisely as expected, or if the materials are only available on terms that are unacceptable to us, it would have a material impact on our Cchek™ platform and operations.

Even though CchekÔ PCC has been commercially launched, we may not realize any revenues or any other economic benefit from the test.

While we have commercially launched CchekÔ PCC, the first test based on the CchekÔ technology platform, there can be no assurance that the test will find any commercial success. There are a number of factors that may limit our ability to generate an economic benefit from the CchekÔ PCC test, including the inability to:

- develop a reimbursement pathway for the test;
- maintain third party relationships with one or more CLIA certified labs to perform the test;
- negotiate and maintain a beneficial cost structure with third parties for performing the test;
- recruit key opinion leaders in urology to order the test for their patients;
- develop a strategic relationship with one or more national or regional CLIA certified laboratories to broadly market, sell and perform the test; and
- obtain patient test results consistent with results found during product development.

Any of the foregoing factors, or others, could significantly limit our ability to achieve economic success with our CchekÔ PCC test, and could result in the failure of the CchekÔ PCC test as well as the CchekÔ technology platform as a whole.

Diagnostic test development involves a lengthy and complex process, and we may be unable to commercialize additional tests based on the CchekÔ technology on a timely basis, or at all.

We have devoted considerable resources to research and development for Cchek™, however there can be no assurance that Cchek™ will be capable of reliably predicting the occurrence or recurrence of any cancers with the sensitivity and specificity necessary to be clinically and commercially useful, or, even if such technology is clinically and commercially useful, that it will result in commercially successful products. In addition, before we can fully develop Cchek™ and commercialize any additional products, we will need to:

- conduct substantial research and development;
- conduct validation studies;
- expend significant funds;
- enter into agreements and maintain relationships with third party vendors to provide third party blood samples;
- obtain regulatory approval (either CLIA, FDA or both); and
- depending on which regulatory pathway we select, establish or contract with the owner of a CLIA certified laboratory to process test samples.

Accordingly, our product development process involves a high degree of risk and may take several years, especially if we seek FDA approval for any of our diagnostic tests. If additional Cchek™ tests should fail at the research or development stage, not produce sufficient clinical validation data to support the effectiveness of the product or not gain regulatory approval or if we should run out of cash to devote towards the commercialization of the technology or fail to establish agreements with necessary third party vendors, we will not be able to commercialize any additional Cchek™ tests and we will not generate any revenue from the technology.

If we fail to obtain, or if there are delays in obtaining, required regulatory approvals, we will not be able to further commercialize our CchekÔ technology beyond CchekÔ PCC, and our ability to generate revenue and the viability of our Company will be materially impaired.

Commercialization of additional Cchek™ tests will require that we obtain either CLIA certification, FDA approval or both. If we are unable to timely obtain regulatory approval for additional Cchek™ tests, we will be unable to commercialize and generate revenue from the technology which would have a material adverse effect on our business, financial condition and results of operations.

Unless we obtain FDA approval for CchekÔ PCC or any other CchekÔ tests or we establish a CLIA certified laboratory, we will be dependent on laboratory contractors for performing the CchekÔ PCC test and any other CchekÔ tests we may develop in the future for commercial purposes.

To fulfill physician orders and perform the Cchek™ PCC test or any other Cchek™ tests we may develop in the future, we will require a CLIA certified laboratory to perform the test. We have currently contracted with ResearchDx to provide these services with respect to the Cchek™ PCC test. Unless and until Cchek™ PCC (or any other Cchek™ tests we may develop in the future) receives FDA approval, or we establish our own CLIA certified laboratory, we will continue to be dependent on contractors or collaborators such as ResearchDx for testing of patient blood samples.

We will be dependent on third parties for the patient samples that are essential to the development and validation of additional Cchek Ô tests.

To pursue our development and validation of Cchek™ tests beyond Cchek™ PCC, we will need access, over time, to patient blood samples and such patients will need to consent to the use of their blood. As a result, we have made arrangements with hospitals and medical practices to give us access to patient samples for the development and validation of Cchek™. In the event that we are unable to obtain patient samples, or access to patient samples becomes more limited due to changes in privacy laws governing the use and disclosure of medical information or due to changes in the laws restricting our ability to obtain patient samples and associated information, our ability to pursue the development of Cchek™ may be slowed or halted, which could have a material adverse effect on our business, financial condition and results of operations.

Our business could be harmed from the loss or suspension of a license or imposition of a fine or penalties under, or future changes in, or changing interpretations of, the law or regulations of the Clinical Laboratory Improvement Act of 1967, the Clinical Laboratory Improvement Amendments of 1988, or the FDA or other federal, state or local agencies.

We will need to seek regulatory approval in order to market Cchek™. The clinical laboratory testing industry is subject to extensive federal and state regulation, and many of these statutes and regulations have not been interpreted by the courts. The Clinical Laboratory Improvement Act of 1967 and the Clinical Laboratory Improvement Amendments of 1988 are federal regulatory standards that apply to virtually all clinical laboratories (regardless of the location, size or type of laboratory), including those operated by physicians in their offices, by requiring that they be certified under federal law. CLIA does not pre-empt state law, which in some cases may be more stringent than federal law and require additional personnel qualifications, quality control, record maintenance and proficiency testing. The sanction for failure to comply with CLIA and state requirements may be suspension, revocation or limitation of a laboratory's CLIA certificate, which is necessary to conduct business, as well as significant fines and/or criminal penalties. Several states have similar laws and we may be subject to similar penalties. The FDA regulates diagnostic products and periodically inspects and reviews their manufacturing processes and product performance. We may choose to seek FDA approval for one or more Cchek™ tests, as opposed to seeking CLIA certification. We cannot assure that applicable statutes and regulations will not be interpreted or applied by a prosecutorial, regulatory or judicial authority in a manner that would adversely affect our business. Potential sanctions for violation of these statutes and regulations include significant fines and the suspension or loss of various licenses, certificates and authorizations, which could have a material adverse effect on our business. In addition, compliance with future legislation could impose additional requirements on us, which may be costly, including FDA regulation of laboratory developed tests.

Health insurers and other third-party payers may decide not to reimburse our Cchek™ diagnostic testing or may provide inadequate reimbursement, which could jeopardize our commercial prospects and require customers to pay for the tests out of pocket.

In the United States, the regulatory process that allows diagnostic tests to be marketed is independent of any coverage determinations made by third-party payers. For new diagnostic tests, private and government payers decide whether to cover the test, the reimbursement amount for a covered test and the specific conditions for reimbursement. Physicians may order diagnostic tests that are not reimbursed by third-party payers, but coverage determinations and reimbursement levels and conditions are critical to the commercial success of a diagnostic product. Each third-party payer makes its own decision about which tests it will cover and how much it will pay, although many payers will follow the lead of Medicare. As a result, the coverage determination process will be a time-consuming and costly process that requires us to provide scientific, clinical and economic support for the use of Cchek™ diagnostic testing to each payer separately, with no assurance that approval will be obtained. If third-party payers decide not to cover Cchek™ or if they offer inadequate payment amounts, our ability to generate revenue from Cchek™ could be limited since patients who want to take the diagnostic tests would have to pay for it out of pocket. Even if one or more third-party payers decide to reimburse for Cchek™ diagnostic testing, a third-party payer may stop or lower payment at any time, which could reduce revenue. We cannot predict whether third-party payers will cover Cchek™ diagnostic testing or offer adequate reimbursement. We also cannot predict the timing of such decisions. In addition, physicians or patients may decide not to order Cchek™ tests if third-party payments are inadequate, especially if ordering the test could result in financial liability for the patient.

Whether or not health insurers and other third-party payers decide to reimburse Cchek™, the technology may cost patients more than we anticipate.

We believe that our Cchek™ diagnostic testing will significantly reduce the cost to patients of screening and confirmatory testing for certain types of cancer. If, however, the cost to utilize Cchek™ is more expensive than we anticipate, many patients and third-party payers may elect not to utilize the technology which would significantly impact our ability to generate revenue on the technology.

We operate in a competitive market and expect to face intense competition, often from companies with greater resources and experience than us.

The clinical diagnostics industry is highly competitive and subject to rapid change. We are aware of many different types of diagnostic tests available to detect cancer that are currently in use or being developed and many more types of diagnostic tests may be developed in the future. If we are able to successfully commercialize Cchek™, all of these tests will compete with our products. If Cchek™ is more expensive than and/or does not have sufficient specificity, sensitivity or predictive value to compete with tests that are currently on the market, or if any other diagnostic tests that are under development, once successfully developed and commercialized, have greater specificity, sensitivity or predictive value and/or are cheaper than our technology, we may be unable to compete successfully with such products which would have a material adverse effect on our business, financial condition and results of operations.

Furthermore, as the industry continues to expand and evolve, an increasing number of competitors and potential competitors may enter the market. Many of these competitors and potential competitors have substantially greater financial, technological, managerial and research and development resources and experience than we do. Some of these competitors and potential competitors have more experience than we do in the development of diagnostic products, including validation procedures and regulatory matters. In addition, Cchek™ will compete with product offerings from large and well established companies that have greater marketing and sales experience and capabilities than we do. If we are unable to compete successfully, we may be unable to sustain and grow our revenue.

We are dependent upon a few key personnel and the loss of their services could adversely affect us.

Our future success of developing Cchek™ will depend on the efforts of the inventor of the technology, our President and Chief Executive Officer Dr. Amit Kumar. We do not have an employment agreement with Dr. Kumar which means that Dr. Kumar does not have a set term of employment and may renegotiate his employment arrangement with the Company at any time. Further, we do not maintain “key person” life insurance on Dr. Kumar. The loss of the services of Dr. Kumar could have a material adverse effect on our business and operating results.

Risks Related to our Therapeutics Business

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

We are in the pre-clinical stage of developing our CAR-T therapeutic and breast cancer vaccine technologies. 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 CAR-T therapeutic and breast cancer vaccine technologies depends heavily on our success in:

- progressing our pre-clinical programs into human clinical trials;
- completing requisite clinical trials through all phases of clinical development of our ovarian cancer therapy and other potential CAR-T product candidates and our breast cancer vaccine;
- seeking and obtaining marketing approvals for our ovarian cancer therapy and other potential CAR-T product candidates and out breast cancer vaccine that successfully complete clinical trials, if any;
- launching and commercializing our ovarian cancer therapy and other potential CAR-T product candidates and our breast cancer vaccine 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 CAR-T 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 product development, we are unable to predict the likelihood or timing for when we may receive regulatory approval of our ovarian cancer therapy and any other potential CAR-T product candidates and our breast cancer vaccine 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 both our CAR-T technology and our breast cancer vaccine have 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 each of our CAR-T ovarian cancer therapeutic and breast cancer vaccine 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 either of our ovarian cancer therapy or breast cancer vaccine in human patients. If we are unable to commence human clinical trials for either or both of our product candidates, or if commencement of such trials 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.

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 our ovarian cancer therapy or our breast cancer vaccine and we may not be able to commence clinical trials on the time frames we expect. As these product candidates have only been tested in animals, we face significant uncertainty regarding how effective and safe they will be in human patients and the results from preclinical studies may not be indicative of the results of clinical trials. Preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval for their products.

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

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

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

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

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

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

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

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

- the availability of financial resources to commence and complete our planned clinical trials;
- reaching agreement on acceptable terms with prospective clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different clinical trial sites;
- recruiting suitable patients to participate in a clinical trial;
- having patients complete a clinical trial or return for post-treatment follow-up;

- clinical trial sites deviating from clinical trial protocol, failing to follow GCPs, or dropping out of a clinical trial;
- adding new clinical trial sites; or
- manufacturing sufficient quantities of qualified materials under cGMPs and applying them on a subject by subject basis for use in clinical trials.

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

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

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

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

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

- the clinical indications for which our product candidates are approved;
- physicians, hospitals, cancer treatment centers and patients considering our product candidates as a safe and effective treatment;
- the potential and perceived advantages of our product candidates over alternative treatments;

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

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

Risks Related to Our Intellectual Property

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

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

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

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

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

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

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

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our product candidates, technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;

- the sublicensing of patent and other rights under the licensing agreement and our collaborative development relationships;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve both technological and legal complexity, and is therefore costly, time-consuming and inherently uncertain. In addition, the U.S. has recently enacted and is currently implementing wide-ranging patent reform legislation. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. For example, in the recent 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.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.

We have received confidential and proprietary information from third parties. In addition, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of these third parties or our employees' former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial cost and be a distraction to our management and employees.

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 Cchek™ platform, to pay for the development of our CAR-T cancer therapeutics, to pay for the development of our breast cancer vaccine and for acquisitions of companies. We have an at-the-market equity offering under which we may issue up to $50 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.

Delaware law and our charter documents contain provisions that could discourage or prevent a potential takeover of our company that might otherwise result in our stockholders receiving a premium over the market price of their shares.

Provisions of Delaware General Corporation Law ("DGCL") and our certificate of incorporation, as amended (the "Certificate of Incorporation"), and By-Laws could make the acquisition of our company by means of a tender offer, proxy contest or otherwise, and the removal of incumbent officers and directors, more difficult. These provisions include:

- Section 203 of the DGCL, which prohibits a merger with a 15%-or-greater stockholder, such as a party that has completed a successful tender offer, until three years after that party became a 15%-or-greater stockholder;
- the authorization in our Certificate of Incorporation of undesignated preferred stock, which could be issued without stockholder approval in a manner designed to prevent or discourage a takeover;
- provisions in our By-Laws establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted on by stockholders at stockholder meetings; and
- provisions in our By-Laws regarding stockholders' rights to call a special meeting of stockholders limit such rights to stockholders of record holding together at least 66 2/3% of shares of the Company entitled to vote at the meeting, which could make it more difficult for stockholders to wage a proxy contest for control of our Board of Directors or to vote to repeal any of the anti-takeover provisions contained in our Certificate of Incorporation and By-Laws.

Together, these provisions may make the removal of management more difficult and may discourage transactions that could otherwise involve payment of a premium over prevailing market prices for our common stock.

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 Cchek™ diagnostic technology, our CAR-T cancer therapeutics and our breast cancer vaccine. 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:

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

In addition, we believe that fluctuations in our stock price during applicable periods can also be impacted by changes in governmental regulations in the diagnostic testing and drug development industries and/or court rulings and/or other developments in our remaining patent licensing and enforcement actions. For example, if government regulators no longer allow for the use of diagnostic technology that has not been granted FDA approval (e.g. denying products that have only received CLIA certification), the time and cost to bring our technology to market will increase which will likely have an adverse impact on our stock price.

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 8,431,668 shares of our common stock with a weighted average exercise price of $3.30 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 2,800,000 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.

U.S. federal income tax reform could adversely affect us and holders of our common stock.

On December 22, 2017, President Trump signed into law H.R. 1, originally known as the "Tax Cuts and Jobs Act," which significantly reformed the Internal Revenue Code. The new legislation, among other things, changes the U.S. federal tax rates, imposes significant additional limitations on the deductibility of interest, allows the expensing of capital expenditures, and puts into effect the migration from a "worldwide" system of taxation to a territorial system. Additionally, the legislation imposes a reduction to the maximum deduction allowed for NOLs generated in tax years beginning after December 31, 2017, but allows such NOLs to be carried forward indefinitely. We continue to examine the impact this tax reform legislation may have on us. The impact of this tax reform, or of any future administrative guidance interpreting provisions thereof, on holders of our shares is uncertain and could be adverse. This annual report does not discuss any such tax legislation or the manner in which it might affect holders of our shares. We urge holders of our shares to consult with their legal and tax advisors with respect to any such legislation and the potential tax consequences of their ownership of our shares.

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.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock depends in part on the research and reports that securities or industry analysts publish about us or our business. In the event securities or industry analysts that cover us downgrade our stock or publish inaccurate or unfavorable research about our business, our stock price may decline. If one or more of these analysts ceases coverage of us or fails to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

We lease approximately 2,000 square feet of office space at 3150 Almaden Expressway, San Jose, California (our principal executive offices) from an unrelated party pursuant to a lease that expires September 30, 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 other than that which arise in the ordinary course of business. We believe that any liability that may ultimately result from the resolution of these matters will not, individually or in the aggregate, 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 8, 2020, the approximate number of record holders of our common stock was 337 and the closing price of our common stock was $3.00 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, 2019.

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, 2019 compared with Fiscal Year ended October 31, 2018

Revenue

In fiscal year 2019, we recorded revenue of $250,000 from one license agreement. In fiscal year 2018, we recorded revenue of approximately $1,113,000 from two license agreements. These license agreements each provided for a one-time, non-recurring, lump sum payment in exchange for non-exclusive retroactive and future licenses, and/or covenants not to sue. 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. Accordingly, the performance obligations from these licenses 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

Inventor royalties, contingent legal fees, litigation and licensing expenses related to patent assertion activities decreased by approximately $602,000 in fiscal year 2019, to approximately $166,000, from approximately $768,000 in fiscal year 2018. The decrease was primarily due to the decrease in related revenues. 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 increased by approximately $94,000 in fiscal year 2019, to approximately $419,000, from approximately $325,000 in fiscal year 2018. We capitalize patent and patent rights acquisition costs and amortize the cost over the estimated economic useful life. The increase in amortization of patents was due to a reduction in the estimated economic useful life of capitalized patents. During fiscal year 2019, 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 decreased by approximately $1,340,000 to approximately $5,473,000 in fiscal year 2019, from approximately $6,813,000 in fiscal year 2018. The decrease in research and development expenses was primarily due to a decrease of approximately $1,410,000 in employee stock option compensation expense, a decrease in employee stock award compensation expense of approximately $351,000 and a decrease in license fees of approximately $190,000, offset by an increase in Certainty's outside research and development expense, excluding license expense, primarily related to its collaboration agreement with Moffitt of approximately $344,000, an increase in Anixa Diagnostics' outside research and development expense, excluding license expense, primarily related to its agreement with our development partner, ResearchDx, of approximately $193,000 and an increase in depreciation expense of approximately $30,000. License fees in the fiscal year 2019 are related to our license agreement with Cleveland Clinic. License fees in fiscal year 2018 are related to our license agreement with Wistar.

General and Administrative Expenses

General and administrative expenses decreased by approximately $1,249,000 to approximately $5,663,000 in fiscal year 2019, from approximately $6,912,000 in fiscal year 2018. The decrease in general and administrative expenses was principally due to a decrease in employee stock option compensation expense of approximately $747,000, a decrease in employee stock award compensation expense of approximately $555,000, a decrease in consultant stock option expense of approximately $137,000, a decrease in outside services of approximately $63,000, a decrease in investor and public relations expense of approximately $59,000 and a decrease in rent expense of approximately $54,000, offset by patent expense reimbursement to Cleveland Clinic of approximately $164,000, an increase in corporate insurance expense of approximately $140,000 primarily due to an increase in our directors and officers insurance premium and an increase in employee compensation and related costs, other than equity-based compensation, of approximately $46,000.

Impairment in Carrying Amount of Patent Assets

The impairment in carrying amount of patent assets related to our legacy patent licensing activities of approximately $419,000 in the fiscal year ended 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 as of January 31, 2019 of approximately $168,000. The impairment in carrying amount of patent assets related to our legacy patent licensing activities of approximately $583,000 in the fiscal year 2018 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 as of October 31, 2018 of approximately $838,000. Our estimates of future cash flows were based on our most recent assessment of the market for potential licensees, as well as the status of ongoing negotiations with potential licensees.

Interest Income

Interest income increased to approximately $71,000 in fiscal year 2019 compared to approximately $46,000 in fiscal year 2018, due to an increase in funds available for short-term investments.

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 $75,000 to approximately $172,000 in fiscal year 2019, from approximately $247,000 in fiscal year 2018, as Certainty's net loss decreased. The decrease in Certainty's net loss was primarily due to decreases in employee stock option compensation expense and employee stock award compensation expense.

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 9, 2020, 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 2019, we raised approximately $5,527,000 through an at-the-market equity offering of 1,363,872 shares of common stock (as of October 31, 2019 an additional 112,238 shares were available for sale under our at-the-market equity program, which shares were sold in November 2019). Further, we have an additional at-the-market equity offering under which we may issue up to $50 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 may seek to obtain working capital during our fiscal year 2020 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. 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.

During the year ended October 31, 2019, cash used in operating activities was approximately $4,773,000. Cash used in investing activities was approximately $525,000, resulting from the purchases of certificates of deposit totaling $3,850,000 and the purchase of property and equipment of approximately $175,000, which was offset by the proceeds on maturities of certificates of deposit totaling $3,500,000. Cash provided by financing activities was approximately $5,734,000, resulting from the sale of 1,363,872 shares of common stock in an at-the-market equity offering of approximately $5,527,000, the proceeds from exercise of stock options of approximately $122,000, the proceeds from settlement of a shareholder derivative complaint of approximately $45,000 and the proceeds from the sale of common stock pursuant to employee stock purchase plan of approximately $39,000. As a result, our cash, cash equivalents, and short-term investments at October 31, 2019 increased approximately $786,000 to approximately $5,842,000 from approximately $5,056,000 at the end of fiscal year 2018.

Off-Balance Sheet Arrangements

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

Critical Accounting Policies

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

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

- Revenue Recognition; and
- Stock-Based Compensation

Revenue Recognition

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

On November 1, 2018 we adopted Accounting Standards Update 2014-09 ("ASU 2014-09"), Revenue from Contracts with Customers. 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. As such, the performance obligation is satisfied and revenue is recognized upon the execution of the agreement.

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 2018-027") 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."

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 2019.

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, 2019. 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, 2019.

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, 2019 has not been audited by our auditors, Haskell & White LLP.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting during the fourth quarter of fiscal year 2019 that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

Item 9B. Other Information.

At the Annual Meeting of Shareholders of the Company held on October 23, 2019, the Company's shareholders voted on, among other matters, an advisory vote regarding the frequency of future advisory votes on named executive officer compensation. The Company's shareholders voted for an advisory vote on named executive officer compensation to be held every year, consistent with the recommendation of the Company's Board of Directors. In response to the voting results and other factors, the Company's Board of Directors determined at a meeting held on December 12, 2019, that the Company will hold an advisory vote on named executive officer compensation every year. The Company will continue to hold advisory votes on named executive officer compensation every year until the Company's Board of Directors decides to hold the next shareholder advisory vote on the frequency of advisory votes, which shall be no later than the Company's Annual Meeting of Shareholders in 2025.

On January 6, 2020, the Board of Directors of the Company confirmed its intention to hold the Company's 2020 Annual Meeting of Shareholders (the "2020 Annual Meeting") on Wednesday, July 15, 2020. The time and location of the 2020 Annual Meeting, and the matters to be considered, will be as set forth in the Company's definitive proxy statement for the 2020 Annual Meeting to be filed in due course with the SEC.

Since the date of the 2020 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 2020 Annual Meeting in accordance with the rules and regulations of the SEC and the Company's By-laws (as amended on January 6, 2020). Accordingly, shareholders wishing to nominate a candidate for director or to propose other business at the 2020 Annual Meeting must ensure proper notice is received by the Company at its offices no later than May 11, 2020. The notice must include all of the information required by the Company's By-laws.

On January 6, 2020, the Board of Directors of the Company approved an amendment to the Company's By-laws to provide that if during the prior year the Company did not hold an annual meeting or if the date of the annual meeting was changed more than thirty (30) days from the anniversary of the prior year's meeting, notice of a proposal to be included at an annual meeting must be delivered to or mailed and received at the principal executive offices of the Company a reasonable time before the Company begins to print and send its proxy materials to be timely. No other changes were made to 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	55	2012
Lewis H. Titterton, Jr.	Lead Independent Director	75	2017
Dr. Arnold Baskies	Director	70	2018
David Cavalier	Director	50	2018
Emily Gottschalk	Director	59	2019
Dr. John Monahan	Director	73	2016
Michael J. Catelani	Chief Operating Officer and Chief Financial Officer	53	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:

Dr. Amit Kumar, 55, 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., 75, 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, 70, 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 at Virtua Health Systems in southern New Jersey, where he specializes in surgical oncology and general surgery. 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 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. 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 Board of the American Cancer Society. He presently serves as immediate past chair of the American Cancer Society Board of Directors, having served as a member of the Board of Directors since 2013. He currently chairs the Global Cancer Control Advisory Council for the society. 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, 50, 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, 59, 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.

Dr. John Monahan, 73, 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 Scientific Advisory Consultant for 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, and was a director of Tacere Therapeutics, Inc., a privately held biotechnology company, from 2006 to 2012. In addition to his work with public companies, Dr. Monahan is also currently a member of the Scientific Advisory Board of Agilis Biotherapeutics, Inc., a position that he has held since 2014, and is a board member of several other biotechnology companies. 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 B.V., 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, 53, 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 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.

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.

On November 5, 2018, a putative shareholder derivative complaint was filed in the Court of Chancery of the State of Delaware, captioned Howland v. Kumar et al., C.A. No. 2018-0804-KSJM (the "Derivative Action"), that alleged claims for breach of fiduciary duty and unjust enrichment. The Derivative Action named as defendants certain of the Company's current and former officers and directors (the "Individual Defendants"), and the Company was named solely as a nominal defendant. On August 21, 2019, the Company entered into a settlement pursuant to which the Company agreed to certain changes in its corporate governance policies and to reprice certain stock options that were repriced on September 6, 2017 to $0.67 to the option price immediately prior to that repricing. The Company also agreed to pay certain legal fees, with such fees to be paid from the Company's D&O insurance. As a result of this settlement, all of the claims asserted in the Derivative Action have been dismissed. The Individual Defendants have denied, and continue to deny, any and all allegations of wrongdoing or liability asserted in the Derivative Action. The Individual Defendants have further asserted, and continue to assert, that at all relevant times, they acted in good faith and in a manner that they reasonably believed to be in the best interests of the Company and its stockholders. The Individual Defendants entered into the settlement solely to eliminate the uncertainty, distraction, disruption, burden, risk, and expense of further litigation.

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 2019.

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.

- 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.

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, 2019 and 2018, 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 2019.

SUMMARY COMPENSATION TABLE

Name and Principal Position	Year	Salary ($)	Bonus ($)	Stock Awards ($) (1)	Option Awards ($) (1)	All Other Compensation ($) (2)	Total Compensation ($)
Dr. Amit Kumar Chairman of the Board, President and Chief Executive Officer	2019	$ 476,250	$ 150,000	$ -	$ -	$ 39,240	$ 665,490
	2018	$ 425,000	$ 233,333	$ 4,814,265	$ 6,085,336	$ 34,700	$ 11,592,634
Michael J. Catelani Chief Operating Officer and Chief Financial Officer	2019	$ 263,021	$ 50,000	$ -	$ -	$ -	$ 313,021
	2018	$ 248,583	$ 33,333	$ -	$ 1,625,000	$ -	$ 1,906,916

(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, 2019, 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. On January 1, 2018 and 2019, Dr. Kumar's annual salary was increased to $450,000 and $481,500, respectively.

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 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.

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, 2019:

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 (1)	9/19/2022
	106,667		$2.575 (1)	9/19/2022
	213,333		$2.575 (1)	9/19/2022
	40,000		$2.575 (1)	11/8/2023
	200,000		$2.92 (1)	2/18/2026
	300,000 (2)	300,000 (2)	$3.70	5/8/2028
Michael J. Catelani	50,000		$4.85 (1)	11/15/2026
	112,500 (3)	87,500 (3)	$0.96 (1)	7/6/2027
	250,000 (2)	250,000 (2)	$3.70	5/8/2028
Performance-based Option Awards				
Dr. Amit Kumar	500,000 (4)	1,000,000 (4)	$3.70	5/8/2028

(1) As a result of a settlement agreement related to the Derivative Action, the option was repriced to the option price immediately prior to the repricing effected on September 6, 2017.

(2) Options vest and become exercisable in 36 consecutive monthly installments, beginning May 31, 2018 and continuing through April 30, 2021.

(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.

Stock Option Grants

No stock options were granted to the Named Executive Officers during the year ended October 31, 2019.

Stock Option Exercises

During the year ended October 31, 2019, 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 $221,000, which was calculated by multiplying (a) 1,300,000 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, 2019 of $3.87 and (y) the options' exercise price of $3.70 per share.

Michael J. Catelani

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 $42,500, which was calculated by multiplying (a) 250,000 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, 2019 of $3.87 and (y) the options' exercise price of $3.70 per share.

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 $254,625, which was calculated by multiplying (a) 87,500 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 $3.87 and (y) the options' exercise price of $0.96 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:

  - o 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

  - o 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

There is no present arrangement for cash compensation of directors for services in that capacity. Consistent with the non-employee director compensation approved on March 28, 2013 for calendar year 2013, on November 8, 2013, the Board approved an amendment to the 2010 Share Incentive Plan to provide that on January 1st of each year commencing on January 1, 2014, 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"). In addition, each person who is a Director Participant and joins the Board after January 1 of any year, shall be granted on the date such person joins the Board, a nonqualified stock option to purchase 12,000 shares of common stock (or 16,000 in the case of the Chairman of the Board) pro-rated based upon the number of calendar quarters remaining in the calendar year in which such person joins the Board (rounded up for partial quarters) (the "New Director Grant"). Effective January 1, 2018 through the expiration of the 2010 Share Incentive Plan, each Director Participant has waived their right to receive the Annual Grant.

On October 23, 2019, each of our non-employee directors were granted a 10 year nonqualified stock option to purchase 45,000 shares of common stock exercisable at $3.87, 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 2019.

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 2019:

DIRECTORS' COMPENSATION

Name	Cash ($)	Option Awards ($) (1)(2)	All Other Compensation ($)	Total Compensation ($)
Lewis H. Titterton, Jr.	$ -	$144,495	$ -	$144,495
Dr. Arnold Baskies	$ -	$144,495	$ -	$144,495
David Cavalier	$ -	$144,495	$ -	$144,495
Emily Gottschalk (3)	$ -	$144,495	$ -	$144,495
Dr. John Monahan	$ -	$144,495	$ -	$144,495

(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, 2019, 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, 2019, Mr. Titterton, Dr. Baskies, Mr. Cavalier, Ms. Gosttschalk and Dr. Monahan held unexercised stock options to purchase 655,000, 128,000, 90,000, 45,000 and 158,000 shares respectively, of our common stock.

(3) Ms. Gottshchalk became a director on October 23, 2019.

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 8, 2020 (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 (1) (2)(3)(4)(5)	Percent of Class (6)
Directors and Officers of the Company		
Dr. Amit Kumar 3150 Almaden Expressway, Suite 250 San Jose, CA 95118	3,464,000	15.3%
Lewis H. Titterton, Jr. 3150 Almaden Expressway, Suite 250 San Jose, CA 95118	1,381,544	6.5%
Michael J. Catelani 3150 Almaden Expressway, Suite 250 San Jose, CA 95118	492,851	2.3%
Dr. John Monahan 3150 Almaden Expressway, Suite 250 San Jose, CA 95118	178,900	*%
Dr. Arnold Baskies 3150 Almaden Expressway, Suite 250 San Jose, CA 95118	109,000	*%
David Cavalier 3150 Almaden Expressway, Suite 250 San Jose, CA 95118	62,000	*%
Emily Gottschalk 3150 Almaden Expressway, Suite 250 San Jose, CA 95118	15,000	*%
All Directors and Executive Officers as a Group (7 persons)	5,703,295	23.9%

* 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, 374,000 shares, 175,000 shares, 113,000 shares, 83,000 shares, 45,000 shares and 1,030,000 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 910,000 shares, 15,000 shares, 313,889 shares, 15,000 shares, 15,000 shares, 15,000 shares, 15,000 shares and 1,298,889 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.

(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 20,821,204 shares of common stock outstanding as of January 8, 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, 2019 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 2003 Share Incentive Plan, 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) (2)	3,697,068	$2.70	901,200
Equity compensation plans approved by security holders (3)	3,935,000	$3.74	1,543,000

(1) On April 23, 2003 the Board adopted the 2003 Share Incentive Plan. Officers, key employees and non-employee directors of, and consultants to, the Company or any of its subsidiaries and affiliates were eligible to participate in the 2003 Share Incentive Plan. The 2003 Share Incentive Plan provided for the grant of stock options, stock appreciation rights, stock awards, performance awards and stock units (the "2003 Benefits"). The maximum number of shares of common stock available for issuance under the 2003 Share Incentive Plan was 2,800,000. The 2003 Share Incentive Plan was administered by the Stock Option Committee through June 2004, from June 2004 through July 2010, by the Board of Directors, from July 2010 through August 2012, by the Stock Option Committee, from August 2012 through November 2012, by the Executive Committee of the Board of Directors, from November 2012 to July 2015, by the Board of Directors and since July 2015 by the Compensation Committee, which determined the option price, term and provisions of the 2003 Benefits. The 2003 Share Incentive Plan contains provisions for equitable adjustment of the 2003 Benefits in the event of a merger, consolidation, reorganization, recapitalization, stock dividend, stock split, reverse stock split, spinoff, combination of shares, exchange of shares, dividends in kind or other like change in capital structure or distribution (other than normal cash dividends) to stockholders of the Company. The 2003 Share Incentive Plan terminated with respect to additional grants on April 21, 2013.

(2) 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 terminates with respect to additional grants on July 14, 2020. The Board may amend, suspend or terminate the 2010 Share Incentive Plan at any time.

(3) 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.

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 2018 and 2017.

Type of Fee	2019	2018
Audit Fees (1)	$ 79,850	$ 82,035
Audit Related Fees (2)	6,500	17,750
Tax Fees (3)	33,000	22,000
All Other Fees (4)	8,150	15,950
Total	$ 127,500	$ 137,735

(1) Audit fees for fiscal years 2019 and 2018 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 2019 and 2018 represent fees billed for services rendered by Haskell & White LLP in connection with our Registration Statements filed during fiscal years 2019 and 2018.

(3) Tax Fees for fiscal years 2019 and 2018 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 2019 and 2018 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 our fiscal year 2019 audit was approved by our Board on August 8, 2019.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

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

See accompanying "Index to Consolidated Financial Statements."

(b) Exhibits

3.1	Certificate of Incorporation, as amended. (Incorporated by reference to Form 10-Q for the fiscal quarter ended July 31, 1992 and Form S-3, dated February 11, 2014.)
3.2	Amendment to the Certificate of Incorporation. (Incorporated by reference to Exhibit 3.2 to our Form 10-K for the fiscal year ended October 31, 2013.)
3.3	Certificate of Amendment to the Certificate of Incorporation. (Incorporated by reference to Exhibit 3.1 to our Form 8-K, dated September 4, 2014.)
3.4	Certificate of Designations, Preferences and Rights of Series A Convertible Preferred Stock. (Incorporated by reference to Exhibit 3.1 to our Form 8-K, dated September 10, 2014.)
3.5	Certificate of Amendment to the Certificate of Incorporation. (Incorporated by reference to Exhibit 3.1 to our Form 8-K, dated June 25, 2015.)
3.6	Certificate of Amendment to the Certificate of Incorporation. (Incorporated by reference to Exhibit 3.1 to our Form 10-Q for the fiscal quarter ended April 30, 2018.)
3.7	Certificate of Amendment to the Certificate of Incorporation. (Incorporated by reference to Exhibit 3.1 to our Form 8-K, dated October 1, 2018.)
3.8	Amended and Restated By-laws. (Incorporated by reference to Exhibit 3.8 to our Form 10-K, dated January 9, 2020)
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.).
10.1	2003 Share Incentive Plan. (Incorporated by reference to Exhibit 4 to our Form S-8 dated May 5, 2003.)
10.2	Amendment No. 1 to the 2003 Share Incentive Plan. (Incorporated by reference to Exhibit 4(e) to our Form S-8 dated November 9, 2004.)
10.3	Amendment No. 2 to the 2003 Share Incentive Plan. (Incorporated by reference to Exhibit 10.1 to our Quarterly Report on Form 10-Q for the fiscal quarter ended January 31, 2006.)
10.4	Amendment No. 3 to the 2003 Share Incentive Plan. (Incorporated by reference to Exhibit 10.2 to our Quarterly Report on Form 10-Q for the fiscal quarter ended January 31, 2006.)

10.5	Amendment No. 4 to the 2003 Share Incentive Plan. (Incorporated by reference to Exhibit 4(g) to our Form S-8 dated September 21, 2007.)
10.6	Amendment No. 5 to the 2003 Share Incentive Plan. (Incorporated by reference to Exhibit 4(g) to our Form S-8 dated January 21, 2009.)
10.7	Amendment No. 6 to the 2003 Share Incentive Plan. (Incorporated by reference to Exhibit 10.5 to our Form 8-K, dated July 20, 2010.)
10.8	2010 Share Incentive Plan. (Incorporated by reference to Exhibit 10.1 to our Form 8-K, dated July 20, 2010.)
10.9	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.)
10.10	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.)
10.11	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.)
10.12	2018 Share Incentive Plan. (Incorporated by reference to Exhibit 4.13 to our Form S-8 dated October 1, 2018.)
10.13	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.)
10.14	Letter Agreement, dated October 17, 2016, between the Company and Mike Catelani. (Incorporated by reference to Exhibit 10.21 to our Form 10-K, dated December 7, 2016.)
10.15	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.)
10.16	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.)
10.17	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.)
10.19	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.)
10.20	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.)
21	Subsidiaries of Anixa Biosciences, Inc. (Incorporated by reference to Exhibit 21 to our Form 10-K, dated January 9, 2020)

23.1	Consent of Haskell & White LLP. (Filed herewith.)
31.1	Certification of Chief Executive Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, dated January 10, 2020. (Filed herewith.)
31.2	Certification of Chief Financial Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, dated January 10, 2020. (Filed herewith.)
32.1	Statement of Chief Executive Officer, pursuant to Section 1350 of Title 18 of the United States Code, dated January 10, 2020. (Filed herewith.)
32.2	Statement of Chief Financial Officer, pursuant to Section 1350 of Title 18 of the United States Code, dated January 10, 2020. (Filed herewith.)

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 10, 2020 Chief Executive Officer

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

By: /s/ Amit Kumar
Dr. Amit Kumar
Chairman of the Board, President and
Chief Executive Officer
January 10, 2020 (Principal Executive Officer)

By: /s/ Michael J. Catelani
Michael J. Catelani
Chief Operating Officer and
Chief Financial Officer
(Principal Financial
January 10, 2020 and Accounting Officer)

By: /s/ Lewis H. Titterton, Jr.
Lewis H. Titterton, Jr.
January 10, 2020 Director

By: /s/ Arnold Baskies
Dr. Arnold Baskies
January 10, 2020 Director

By: /s/ David Cavalier
David Cavalier
January 10, 2020 Director

By: /s/ Emily Gottschalk
Emily Gottschalk
January 10, 2020 Director

By: /s/ John Monahan
Dr. John Monahan
January 10, 2020 Director

ANIXA BIOSCIENCES, INC. AND SUBSIDIARIES

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS
OCTOBER 31, 2019

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, 2019 and 2018, and the related consolidated statements of operations, equity, and cash flows for each of the two years in the period ended October 31, 2019, 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, 2019 and 2018, and the consolidated results of its operations and its cash flows for each of the two years in the period ended October 31, 2019, in conformity with accounting principles generally accepted in the United States.

Basis for Opinion

The 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 10, 2020

ANIXA BIOSCIENCES, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

	October 31, 2019	October 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	$ 3,491,625	$ 3,055,890
Short–term investments in certificates of deposit	2,350,000	2,000,000
Receivables	66,527	306,991
Prepaid expenses and other current assets	184,972	175,491
Total current assets	6,093,124	5,538,372
Patents, net of impairment of $1,001,729 and $582,979, respectively, and accumulated amortization of $2,034,381 and $1,615,632, respectively	-	837,500
Property and equipment, net of accumulated depreciation of $95,015 and $53,799, respectively	200,569	72,670
Total assets	$ 6,293,693	$ 6,448,542
LIABILITIES AND EQUITY		
Current liabilities:		
Accounts payable	$ 585,817	$ 582,012
Accrued expenses	895,498	683,099
Total current liabilities	1,481,315	1,265,111
Commitments and contingencies (Note 5)		
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; 48,000,000 shares authorized; 20,331,754 and 18,908,632 shares issued and outstanding, respectively	203,317	189,086
Additional paid-in capital	186,849,299	175,415,931
Accumulated deficit	(181,817,263)	(170,170,209)
Total shareholders' equity	5,235,353	5,434,808
Noncontrolling interest (Note 2)	(422,975)	(251,377)
Total equity	4,812,378	5,183,431
Total liabilities and equity	$ 6,293,693	$ 6,448,542

The accompanying notes are an integral part of these statements.

ANIXA BIOSCIENCES, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS

	For the years ended October 31,	
	2019	2018
Revenue	$ 250,000	$ 1,112,500
Operating costs and expenses:		
Inventor royalties, contingent legal fees, litigation and licensing expenses	166,250	768,410
Amortization of patents	418,750	325,296
Research and development expenses (including non-cash share based compensation expenses of $2,825,630 and $4,596,866, respectively)	5,473,427	6,813,043
General and administrative expenses (including non-cash share based compensation expenses of $2,888,115 and $4,298,748 respectively)	5,662,828	6,911,830
Impairment in carrying amount of patent assets (Note 2)	418,750	582,979
Total operating costs and expenses	12,140,005	15,401,558
Loss from operations	(11,890,005)	(14,289,058)
Interest income	71,353	45,974
Loss before income taxes	(11,818,652)	(14,243,084)
Provision for income taxes (Note 6)	-	-
Net loss	(11,818,652)	(14,243,084)
Less: Net loss attributable to noncontrolling interest	(171,598)	(247,059)
Net loss attributable to common stockholders	$ (11,647,054)	$ (13,996,025)
Net loss per share:		
Basic and diluted	$ (0.59)	$ (0.79)
Weighted average common shares outstanding:		
Basic and diluted	19,789,795	17,624,335

The accompanying notes are an integral part of these statements.

ANIXA BIOSCIENCES, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF EQUITY
FOR THE YEARS ENDED OCTOBER 31, 2019 and 2018

	Common Stock		Additional Paid-in	Accumulated	Total Shareholders	Non-controlling	Total
	Shares	Par Value	Capital	Deficit	Equity	Interest	Equity
BALANCE, October 31, 2017	16,602,759	$ 166,028	$163,931,079	$(156,174,184)	$ 7,922,923	$ -	$ 7,922,923
Stock option compensation to employees and directors	-	-	5,717,651	-	5,717,651	-	5,717,651
Stock options and warrants issued to consultants	-	-	318,139	-	318,139	-	318,139
Common stock issued upon exercise of stock options and warrants	76,636	766	57,372	-	58,138	-	58,138
Restricted stock award compensation to employee pursuant to stock incentive plan	1,500,000	15,000	2,844,824	-	2,859,824	-	2,859,824
Common stock issued to consultants	5,347	53	14,949	-	15,002	-	15,002
Common stock issued in at-the-market offering	723,890	7,239	2,462,943	-	2,470,182	-	2,470,182
Issuance of noncontrolling interest in Certainty Therapeutics, Inc.	-	-	68,974	-	68,974	(4,318)	64,656
Net Loss	-	-	-	(13,996,025)	(13,996,025)	(247,059)	(14,243,084)
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

CONTINUED

ANIXA BIOSCIENCES, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF EQUITY
FOR THE YEARS ENDED OCTOBER 31, 2019 and 2018

CONTINUED

	Common Stock		Additional Paid-in	Accumulated	Total Shareholders	Non-controlling	Total
	Shares	Par Value	Capital	Deficit	Equity	Interest	Equity
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

The accompanying notes are an integral part of this statement.

ANIXA BIOSCIENCES, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

	For the years ended October 31,	
	2019	2018
Cash flows from operating activities:		
Reconciliation of net loss to net cash used in operating activities:		
Net loss	$ (11,818,652)	$ (14,243,084)
Stock option compensation to employees and directors	3,560,883	5,717,651
Stock options and warrants issued to consultants	198,421	318,139
Restricted stock award compensation to employee pursuant to stock incentive plan	1,954,441	2,859,824
Common stock issued to consultants	-	15,002
Amortization of patents	418,750	325,296
Depreciation of property and equipment	47,558	18,435
Impairment in carrying amount of patent assets	418,750	582,979
Issuance of noncontrolling interest in Certainty Therapeutics, Inc. expensed as a license fee	-	64,656
Change in operating assets and liabilities:		
Receivables	271,700	(258,991)
Prepaid expenses and other current assets	(9,481)	(48,925)
Accounts payable	3,805	101,688
Accrued expenses	212,399	273,930
Net cash used in operating activities	(4,741,426)	(4,273,400)
Cash flows from investing activities:		
Disbursements to acquire short-term investments in certificates of deposit	(3,850,000)	(4,250,000)
Proceeds from maturities of short-term investments in certificates of deposit	3,500,000	5,750,000
Purchase of property and equipment	(175,457)	(38,404)
Net cash (used in) provided by investing activities	(525,457)	1,461,596
Cash flows from financing activities:		
Proceeds from sale of common stock in at-the-market offering	5,527,428	2,470,182
Proceeds from sale of common stock pursuant to employee stock purchase plan	39,086	-
Proceeds from settlement of shareholder derivative complaint	14,034	-
Proceeds from exercise of stock options and warrants	122,070	58,138
Net cash provided by financing activities	5,702,618	2,528,320
Net increase (decrease) in cash and cash equivalents	435,735	(283,484)
Cash and cash equivalents at beginning of year	3,055,890	3,339,374
Cash and cash equivalents at end of year	$ 3,491,625	$ 3,055,890
Supplemental cash flow information:		
Cash proceeds from interest income	$ 55,729	$ 12,684
Supplemental disclosure of non-cash investing activity:		
Disposal of fully depreciated property and equipment	$ (6,343)	$ -
Supplemental disclosure of non-cash financing activity:		
Note receivable issued for settlement of shareholder derivative complaint	$ 31,236	$ -

The accompanying notes are an integral part of these statements.

ANIXA BIOSCIENCES, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. BUSINESS AND FUNDING

Description of Business

As used herein, "we," "us," "our," the "Company" or "Anixa" means Anixa Biosciences, Inc. and its consolidated subsidiaries. Our primary operations involve research and development of cancer therapeutics and diagnostics. Our cancer therapeutics programs consist of development of a vaccine against triple negative breast cancer ("TNBC") and development of chimeric endocrine receptor T-cell ("CER-T") technology, a novel form of CAR-T technology, initially focused on treating ovarian cancer. Our cancer diagnostics program consists of development of the artificial intelligence (AI) driven Cchek™ liquid biopsy platform for early cancer detection.

We hold an exclusive worldwide, royalty-bearing license to use certain intellectual property owned or controlled by The Cleveland Clinic Foundation ("Cleveland Clinic") related 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, the most lethal form of the disease. 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 at Cleveland Clinic to advance this vaccine toward human clinical testing, and are completing the activities necessary to submit an Investigational New Drug ("IND") application with the U.S. Food and Drug Administration ("FDA").

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 CER-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 CER-T technology for treating ovarian cancer. Certainty is working with researchers at Moffitt to complete studies necessary to submit an IND application with the FDA.

Our subsidiary, Anixa Diagnostics Corporation ("Anixa Diagnostics"), is developing Cchek™, an AI driven platform of non-invasive blood tests for the early detection of cancer which is based on the body's immune response to the presence of a malignancy. We have demonstrated the efficacy of Cchek™ with 20 different types of cancer: breast, lung, colon, melanoma, ovarian, liver, thyroid, pancreatic, appendiceal, uterine, osteosarcoma, leiomyosarcoma, liposarcoma, vulvar, prostate, bladder, cervical, head and neck, gastric and testicular cancers. Breast, lung, colon and prostate cancers represent the four largest categories of cancer worldwide.

ANIXA BIOSCIENCES, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Based on a number of factors, including key scientific, clinical, and commercial considerations, for the past year the primary commercial focus for Cchek™ has been on developing a prostate cancer confirmatory test. In February 2019 we formed a strategic alliance with ResearchDx, a CLIA certified, CAP Accredited laboratory, to prepare the Cchek™ Prostate Cancer Confirmation ("Cchek™ PCC") test for launch as a laboratory developed test. In December 2019, upon completion of independent validation by ResearchDx, we announced the commercial launch of Cchek™ PCC. We are currently conducting a number of activities to support the marketing of Cchek™ PCC, including the development of marketing materials, education of key opinion leaders in urology and development of a reimbursement path for the test. We expect Cchek™ PCC to be broadly available throughout the U.S. by April 2020.

Over the next several quarters, we expect the development of our breast cancer vaccine, Certainty's CER-T technology and Anixa Diagnostic's Cchek™ to be the primary focus of the Company. As part of our legacy operations, the Company remains engaged in limited patent licensing activities in the area of encrypted audio/video conference calling. We do not expect these activities to be a significant part of the Company's ongoing operations nor do we expect these activities to require material financial resources or attention of senior management.

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 cancer therapeutics and diagnostics programs. In addition, while we pursue our cancer therapeutics and diagnostics programs, we may also make investments in and form new companies to develop additional emerging technologies.

Funding

Based on currently available information as of January 9, 2020, 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 2019, we raised approximately $5,527,000 through an at-the-market equity offering of 1,363,872 shares of common stock (as of October 31, 2019 an additional 112,238 shares were available for sale under our 2018 at-the-market equity program, which shares were sold in November 2019). Further, we have an additional at-the-market equity offering under which we may issue up to $50 million of common stock, which has been effective since June 2019 and under which we commenced selling shares in November 2019, and which may remain available to us in the future. We may seek to obtain working capital during our fiscal year 2020 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.

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, 2019:

Balance October 31, 2017	$ -
Issuance of noncontrolling interest in Certainty	(4,318)
Net loss attributable to noncontrolling interest	(247,059)
Balance October 31, 2018	(251,377)
Net loss attributable to noncontrolling interest	(171,598)
Balance October 31, 2019	$ (422,975)

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. The adoption of ASU 2014-09 had no impact on revenue recognized.

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 and development of our breast cancer vaccine, 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 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.

ANIXA BIOSCIENCES, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

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

The following table presents the hierarchy for our financial assets measured at fair value on a recurring basis as of October 31, 2018:

	Level 1	Level 2	Level 3	Total
Money market funds –				
Cash and cash equivalents	$ 2,031,331	$ -	$ -	$ 2,031,331
Certificates of deposit –				
Cash and cash equivalents	750,000	-	-	750,000
Short term investments	-	2,000,000	-	2,000,000
Total financial assets	$ 2,781,331	$ 2,000,000	$ -	$ 4,781,331

Our non-financial assets that are measured on a non-recurring basis include our patents and 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 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

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, 2019 and 2018, we had certificates of deposit with maturities greater than 90 days and less than 12 months when acquired of $2,350,000 and $2,000,000, respectively, that were classified as short-term investments and reported at fair value.

ANIXA BIOSCIENCES, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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, 2019 and 2018. We recorded patent amortization expense of approximately $419,000 and $325,000, respectively, during the years ended October 31, 2019 and 2018.

In evaluating the carrying amount of capitalized patents at October 31, 2018, we determined that a write-down of the carrying amount of approximately $583,000, to a carrying value of approximately $838,000, should be recorded as of October 31, 2018. 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-downs were based on estimated undiscounted future cash flows of the capitalized patents compared to the carrying value.

Our estimates of future cash flows were 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, 2019, we cannot reasonably determine an estimate of any such future cash flows. The carrying value of capitalized patents has been amortized to $-0- as of October 31, 2019.

Property and equipment

We capitalize computers and test equipment used in our cancer diagnostics and therapeutics programs and charge depreciation on a straight-line basis over 60 months. Equipment purchases during the years ended October 31, 2019 and 2018 were approximately $175,000 and $38,000, respectively. We recorded depreciation expense of approximately $48,000 and 18,000, respectively, during the years ended October 31, 2019 and 2018.

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 and performance-based awards, or 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 $3,185,000 and $1,959,000, during the years ended October 31, 2019 and 2018, respectively.

ANIXA BIOSCIENCES, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Included in stock-based compensation cost for service-based options granted to employees and directors during the years ended October 31, 2019 and 2018 was approximately $3,166,000 and $785,000, respectively, related to the amortization of compensation cost for stock options granted in prior periods but not yet vested. As of October 31, 2019, there was unrecognized compensation cost related to non-vested service-based stock options granted to employees and directors of approximately $5,122,000, which will be recognized over a weighted-average period of 1.6 years.

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 approximately $376,000 and $3,759,000 during the years ended October 31, 2019 and 2018, respectively. Included in stock-based compensation cost related to market condition stock options granted to employees during the years ended October 31, 2019 and 2018 was approximately $376,000 and $-0-, respectively, related to the amortization of compensation cost for stock options granted in prior periods but not yet vested. As of October 31, 2019, 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 US 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, 2019 and 2018 of approximately $113,000 and $261,000, respectively. Included in stock-based consulting expense for the years ended October 31, 2019 and 2018 was approximately $99,000 and $47,000, respectively, related to compensation cost for stock options granted in prior periods but not yet vested. As of October 31, 2019, there was unrecognized consulting expense related to non-vested stock options granted to consultants, related to service-based options of approximately $274,000, which will be recognized over a weighted-average period of 2.1 years.

ANIXA BIOSCIENCES, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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 the year ended October 31, 2019 consisted of awards with 5-year and 10-year terms that vest over 12 to 36 months. The stock options we granted during the year ended October 31, 2018 consisted of awards with 10-year terms that vest over 12 to 36 months

The following weighted average assumptions were used in estimating the fair value of stock options granted during the years ended October 31, 2019 and 2018:

	For the Year Ended October 31,	
	2019	2018
Weighted average fair value at grant date	$3.87	$3.31
Valuation assumptions:		
Expected life (years)	5.47	5.74
Expected volatility	116.72%	124.94%
Risk-free interest rate	1.61%	2.80%
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.

ANIXA BIOSCIENCES, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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, 2019 and 2018 we recorded compensation expense related to the restricted stock award of approximately $1,954,000 and $2,860,000. We did not issue any restricted stock awards during fiscal year 2019. As of October 31, 2019, there was no unrecognized compensation cost related to the restricted stock awards.

During the year ended October 31, 2018, we issued 5,347 shares of common stock vested at date of grant to consultants for services rendered. We accounted for the stock awards in accordance with ASC 505-50 and recognized expense based on the grant date market price of the underlying common stock. We recorded consulting expense for the year ended October 31, 2018 of approximately $15,000 for the shares of common stock issued to consultants. We did not issue any stock awards to consultants during fiscal year 2019.

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, 2019 and 2018 we recorded consulting expense, based on the fair value, of approximately $85,000 and $57,000, 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, 2019 and 2018, were options to purchase 7,632,068 and 7,405,868 shares, respectively, and warrants to purchase 525,000 shares and 829,400 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.

ANIXA BIOSCIENCES, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Subsequent Events

We evaluated all events and transactions that occurred after the balance sheet date through the date of this filing. During this period, the Company did not have any material subsequent events that impacted its financial statements other than the discharge of a disputed trade payable. The Company discharged the approximately $337,000 disputed liability upon the expiration of the vendor's statutory right to pursue collection of the disputed liability.

Effect of Recently Issued Pronouncements

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update 2014-09 (“ASU 2014-09”), Revenue from Contracts with Customers. This amendment updates addressing revenue from contracts with customers, which clarifies existing accounting literature relating to how and when a company recognizes revenue. Under the standard, a company will recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods and services. This standard update was effective for interim and annual reporting periods beginning after December 15, 2016, and was to be applied retrospectively or the cumulative effect as of the date of adoption, with early application not permitted. In July 2015, a one-year deferral of the effective date of the new guidance was approved. The Company adopted ASU 2014-09 on November 1, 2018. The adoption of ASU 2014-09 did not have a material impact on our consolidated financial statements, other than required additional disclosure of accounting policies See disclosure above of our revenue recognition policy.

In February 2016, the FASB issued Accounting Standards Update 2016-02 (“ASU 2016-02”) which requires lessees to recognize most leases on the balance sheet. This is expected to increase both reported assets and liabilities. The new lease standard does not substantially change lessor accounting. For public companies, the standard will be effective for the first interim reporting period within annual periods beginning after December 15, 2018, although early adoption is permitted. Lessees and lessors will be 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, using a modified retrospective transition method. The requirements of this standard include a significant increase in required disclosures. The disclosure requirements of ASU 2016-02 will be effective for the Company on November 1, 2019. The adoption of this guidance will not have a material impact on our consolidated financial statements, other than additional disclosures.

Concentration of Credit Risks

Financial instruments that potentially subject us to concentrations of credit risk are cash equivalents, short-term investments and accounts receivable. Cash equivalents are primarily highly rated money market funds. Short-term investments are certificates of deposit within federally insured limits. Where applicable, management reviews our accounts receivable and other receivables for potential doubtful accounts and maintains an allowance for estimated uncollectible amounts. Our policy is to write-off uncollectable amounts at the time it is determined that collection will not occur.

One licensee accounted for 100% of revenues from patent licensing activities during fiscal year 2019. Two licensees accounted for 67% and 33%, respectively, of revenues from patent licensing during fiscal year 2018.

ANIXA BIOSCIENCES, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

3. ACCRUED EXPENSES

Accrued liabilities consist of the following as of:

	October 31,	
	2019	2018
Payroll and related expenses	72,850	62,965
Accrued royalty and contingent legal fees	449,691	366,670
Accrued collaborative research and license expense	371,710	187,500
Accrued other	1,247	65,964
	$ 895,498	$ 683,099

4. SHAREHOLDERS' EQUITY

Stock Option Plans

As of October 31, 2019, we have 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, 2019 and 2018, stock options to purchase 47,600 and 76,178 shares of common stock, respectively, were exercised with aggregate proceeds of approximately $122,000 and $58,000, respectively. Under certain circumstances, stock options may be exercised on a cashless basis. During the year ended October 31, 2018, 9,459 shares of common stock were withheld in connection with cashless exercises of stock options. During the year ended October 31, 2019 no shares of common stock were withheld in connection with cashless exercises of stock options.

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, 2019 is as follows:

ANIXA BIOSCIENCES, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

	Shares	Weighted Average Exercise Price Per Share	Aggregate Intrinsic Value
Options Outstanding at October 31, 2017	30,600	$ 3.16	
Exercised	(10,600)	$ 0.67	
Forfeited	(8,000)	$ 7.04	
Options Outstanding at October 31, 2018	12,000	$ 2.77	
Exercised	(11,600)	$ 2.94	
Options Outstanding and Exercisable at October 31, 2019	400	$ 17.00	$ -0-

The following table summarizes information about stock options outstanding and exercisable under the 2003 Share Plan as of October 31, 2019:

Range of Exercise Prices	Number Outstanding	Weighted Average Remaining Contractual Life (in years)	Weighted Average Exercise Price
$ 17.00	400	0.03	$ 17.00

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. As of October 31, 2019, the 2010 Share Plan had 901,200 shares available for future grants. Information regarding the 2010 Share Plan for the two years ended October 31, 2019 is as follows:

	Shares	Weighted Average Exercise Price Per Share	Aggregate Intrinsic Value
Options Outstanding at October 31, 2017	1,637,246	$ 1.50	
Granted	610,000	$ 3.68	
Exercised	(65,578)	$ 1.33	
Forfeited	(49,800)	$ 2.15	
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	$ 2,422,486
Options Exercisable at October 31, 2019	1,700,194	$ 2.85	$ 2,008,344

The following table summarizes information about stock options outstanding under the 2010 Share Plan as of October 31, 2019:

	Options Outstanding			Options Exercisable		
Range of Exercise Prices	Number Outstanding	Weighted Average Remaining Contractual Life (in years)	Weighted Average Exercise Price	Number Exercisable	Weighted Average Remaining Contractual Life (in years)	Weighted Average Exercise Price
$0.67 - $2.30	574,000	6.56	$1.54	458,026	6.27	$1.70
$2.58 - $3.13	890,134	3.63	$2.79	890,134	4.26	$2.79
$3.46 - $5.75	534,534	8.19	$4.16	352,034	7.99	$4.52

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, 2018, the 2018 Share Plan had 1,543,000 shares available for future grants. Information regarding the 2018 Share Plan for the two years ended October 31, 2019 is as follows:

	Shares	Weighted Average Exercise Price Per Share	Aggregate Intrinsic Value
Options Outstanding at October 31, 2017	-		
Granted	3,482,000	$ 3.65	
Options Outstanding at October 31, 2018	3,482,000	$ 3.73	
Granted	465,000	$ 3.87	
Exercised	(4,000)	$ 3.84	
Forfeited	(8,000)	$ 3.84	
Options Outstanding at October 31, 2019	3,935,000	$ 3.74	$ 536,300
Options Exercisable at October 31, 2019	1,485,280	$ 3.73	$ 225,908

The following table summarizes information about stock options outstanding under the 2018 Share Plan as of October 31, 2019:

	Options Outstanding			Options Exercisable		
Range of Exercise Prices	Number Outstanding	Weighted Average Remaining Contractual Life (in years)	Weighted Average Exercise Price	Number Exercisable	Weighted Average Remaining Contractual Life (in years)	Weighted Average Exercise Price
$3.70	3,100,000	8.53	$3.70	1,300,000	8.53	$3.70
$ 3.84 - $4.61	835,000	9.09	$3.91	185,280	8.47	$3.93

Outside of Plans

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.

Information regarding stock options that were not granted under the 2003 Share Plan, the 2010 Share Plan or the 2018 Share Plan for the two years ended October 31, 2019 is as follows:

	Shares	Weighted Average Exercise Price Per Share	Aggregate Intrinsic Value
Options Outstanding at October 31, 2017	1,780,000	$ 1.58	
Options Outstanding at October 31, 2018	1,780,000	$ 1.58	
Forfeited	(82,000)	$ 5.32	
Options Outstanding and exercisable at October 31, 2019	1,698,000	$ 2.58	$ 2,198,910

The following table summarizes information about stock options outstanding and exercisable that were not granted under the 2003 Share Plan, the 2010 Share Plan or the 2018 Share Plan as of October 31, 2019:

Range of Exercise Prices	Number Outstanding and Exercisable	Weighted Average Remaining Contractual Life (in years)	Weighted Average Exercise Price
$2.58	1,698,000	2.74	$ 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 stock options that were not granted under the 2003 Share Plan, the 2010 Share Plan or the 2018 Share Plan 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.

ANIXA BIOSCIENCES, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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 year ended October 31, 2019, employees purchased 11,650 shares with aggregate proceeds of approximately $39,000.

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. 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.

In July 2018 we issued a warrant exercisable at $3.65 per share vested upon grant to purchase 25,000 shares of common stock to a consultant for investor relations services. We recorded consulting expense of approximately $57,000 during the year ended October 31, 2018, based on the fair value of the warrant. This warrant was exercised in October 2018.

As of October 31, 2019, we also had warrants outstanding to purchase 500,000 shares of common stock at $5.03 per share expiring on November 30, 2021.

5. COMMITMENTS AND CONTINGENCIES

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 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. Under a 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. As of October 31, 2019, our non-cancelable operating lease commitments for the San Jose lease for the years ending October 31, 2020 and 2021, was approximately $63,000 and $59,000, respectively. Rent expense for the years ended October 31, 2019 and 2018, was approximately $60,000 and $114,000, respectively.

Litigation Matters

Other than lawsuits we bring to enforce our patent rights we are not a party to any material pending legal proceedings other than that which arise in the ordinary course of business. We believe that any liability that may ultimately result from the resolution of these matters will not, individually or in the aggregate, have a material adverse effect on our financial position or results of operations.

ANIXA BIOSCIENCES, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Collaborative Research and License Commitments

As of October 31, 2019, our commitments under the collaborative agreement with Moffitt and the license agreement with Cleveland Clinic for the year ending October 31, 2020 were approximately $401,000.

6. INCOME TAXES

Income tax provision (benefit) consists of the following:

	Year Ended October 31,	
	2019	2018
Federal:		
Current	$ -	$ -
Deferred	(948,000)	(1,784,000)
State:		
Current	-	-
Deferred	(995,000)	(1,206,000)
Adjustment to valuation allowance related to net deferred tax assets	1,943,000	2,990,000
	$ -	$ -

The tax effects of temporary differences that give rise to significant portions of the deferred tax asset, net, at October 31, 2019 and 2018, are as follows:

	2019	2018
Long-term deferred tax assets:		
Federal and state NOL and tax credit carryforwards	$ 19,593,000	$ 19,282,000
Deferred compensation	7,619,000	6,176,000
Intangibles	943,000	754,000
Other	205,000	205,000
Subtotal	28,360,000	26,417,000
Less: valuation allowance	(28,360,000)	(26,417,000)
Deferred tax asset, net	$ -	$ -

As of October 31, 2019, we had tax net operating loss and tax credit carryforwards of approximately $81,242,000 and $1,519,000, respectively, available within statutory limits (expiring at various dates between 2020 and 2039), 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, 2019, management has not determined the extent of any such limitations, if any.

We had New York and California tax net operating loss carryforwards of approximately $63,485,000 and $20,441,000, respectively, as of October 31, 2019, available within statutory limits (expiring at various dates between 2020 and 2039), to offset future corporate taxable income and taxes payable, if any, under certain computations of such taxes.

ANIXA BIOSCIENCES, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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 certain permanent differences 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,			
	2019		2018	
Income tax benefit at U.S. Federal statutory income tax rate	$ (2,482,000)	(21.00%)	$ (3,276,000)	(23.00%)
State income taxes	(1,045,000)	(8.84%)	(1,259,000)	(8.84%)
Permanent differences	30,000	0.25%	14,000	0.10%
Expiring net operating losses, credits and other	1,554,000	13.15%	1,246,000	9.12%
Rate changes	-	-	285,000	2.00%
Change in valuation allowance	1,943,000	16.44%	2,990,000	20.62%
Income tax provision	$ -	0.00%	$ -	0.00%

During the two fiscal years ended October 31, 2019, we incurred no Federal and no State income taxes. We have no unrecognized tax benefits as of October 31, 2019 and 2018 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 authorities and other jurisdictions to the extent which the net operating losses have yet to be utilized.

7. 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 three reportable segments, each with different operating and potential revenue generating characteristics: (i) cancer diagnostics, (ii) cancer therapeutics and (iii) our legacy patent licensing activities. The following represents selected financial information for our segments for the years ended October 31, 2019 and 2018:

ANIXA BIOSCIENCES, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

	Year Ended October 31,	
	2019	2018
Net loss:		
Cancer diagnostics	$ (5,196,471)	$ (5,920,457)
Cancer therapeutics	(5,752,318)	(7,073,322)
Patent licensing	(869,863)	(1,249,305)
Total	$ (11,818,652)	$ (14,243,084)
Total operating costs and expenses	$ 12,140,005	$ 15,401,558
Less non-cash share-based compensation	(5,713,746)	(8,895,614)
Operating costs and expenses excluding non-cash share-based compensation	$ 6,426,259	$ 6,505,944
Operating costs and expenses excluding non-cash share based compensation expense:		
Cancer diagnostics	$ 2,689,761	$ 2,431,810
Cancer therapeutics	2,670,482	2,120,614
Patent licensing	1,066,016	1,953,520
Total	$ 6,426,259	$ 6,505,944

	October 31,	
	2019	2018
Total assets:		
Cancer diagnostics	$ 2,921,784	$ 2,545,803
Cancer therapeutics	2,872,341	2,157,359
Patent licensing	499,568	1,745,380
Total	$ 6,293,693	$ 6,448,542

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 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. The Company's consolidated revenue of $1,112,500 and impairment in carrying amount of patent assets of $582,979 for the year ended October 31, 2018 were solely related to our patent licensing segment. All our revenue is generated domestically (United States) based on the country in which the licensee is located.

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Post-Effective Amendment No. 2 to the Registration Statement on Form S-1 on Form S-3 (No. 333-193869), 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) and the Registration Statement on Form S-8 (No. 333-277653) of Anixa Biosciences, Inc. (the "Company") of our report dated January 9, 2020 relating to our audits of the Company's consolidated financial statements as of October 31, 2019 and 2018, 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, 2019.

/s/ Haskell & White LLP

Irvine, California
January 10, 2020

Exhibit 31.1

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

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

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

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

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

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

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

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

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

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

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

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

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

Date: January 10, 2020

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

Exhibit 31.2

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

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

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

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

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

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

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

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

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

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

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

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

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

Date: January 10, 2020

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

Exhibit 32.1

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

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

1. The Company's Form 10-K Annual Report for the fiscal year ended October 31, 2019 (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 10, 2020

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

Exhibit 32.2

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

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

1. The Company's Form 10-K Annual Report for the fiscal year ended October 31, 2019 (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 10, 2020

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