

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549**

FORM S- 8

REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

Anixa Biosciences, Inc.

(Exact name of registrant as specified in charter)

Delaware

(State or Other Jurisdiction of
Incorporation or Organization)

**3150 Almaden Expressway, Suite 250
San Jose, CA**

(Address of Principal Executive Offices)

11-2622630

(IRS Employer
Identification No.)

95118

(Zip Code)

**2018 Share Incentive Plan
Employee Stock Purchase Plan
2010 Share Incentive Plan**

(Full Title of the Plan)

**Dr. Amit Kumar
Chairman and Chief Executive Officer
Anixa Biosciences, Inc.**

**3150 Almaden Expressway, Suite 250
San Jose, California 95118**

(Name and Address of Agent For Service)

(408) 708-9808

Telephone Number, Including Area Code of Agent For Service.

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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. (Check one):

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 7(a)(2)(B) of the Securities Act.

Explanatory Note

This Registration Statement is being filed by the Registrant relating to 1,394,866 shares of our common stock which may be offered and sold pursuant to our 2018 Plan in connection with increases in the number of shares available for issuance under the 2018 Plan in 2023 pursuant to the evergreen provisions included therein.

This Registration Statement includes, pursuant to General Instruction E to Form S-8 and Rule 429 of the Securities Act, a re-offer prospectus in Part I (the “Reoffer Prospectus”). The Reoffer Prospectus may be utilized for reofferings and resales by certain executive officers and directors listed in the Reoffer Prospectus who may be deemed “affiliates” of the Company on a continuous or a delayed basis in the future of up to 11,548,227 shares of Common Stock. These shares constitute “control securities” or “restricted securities” which have been issued prior to or issuable after the filing of this Registration Statement. The Reoffer Prospectus does not contain all of the information included in the Registration Statement, certain items of which are contained in schedules and exhibits to the Registration Statement, as permitted by the rules and regulations of the SEC. Statements contained in this Reoffer Prospectus as to the contents of any agreement, instrument or other document referred to are not necessarily complete. With respect to each such agreement, instrument or other document filed as an exhibit to the Registration Statement, we refer you to the exhibit for a more complete description of the matter involved, and each such statement shall be deemed qualified in its entirety by this reference.

PART I

INFORMATION REQUIRED IN THE SECTION 10(a) PROSPECTUS

Anixa Biosciences, Inc., a Delaware corporation (the “Company”, “us”, “our” or “we”), has prepared this Registration Statement on Form S-8 (the “Registration Statement”) in accordance with the requirements of Form S-8 under the Securities Act of 1933, as amended (the “Securities Act”), to register 1,394,866 shares of our common stock, par value \$0.01 per share (the “Common Stock”), which may be offered and sold pursuant to the 2018 Share Incentive Plan (the “2018 Plan”) in connection with an increase in the number of shares available for issuance under such plan in 2023 pursuant to the evergreen provision included therein and to file a prospectus, prepared in accordance with the requirements of Part I of Form S-3 and, pursuant to General Instruction C of Form S-8, to be used for reoffers and resales of Common Stock acquired by persons to be named therein upon the exercise of options and restricted stock awards granted under the 2018 Plan, the 2010 Share Incentive Plan, as amended (the “2010 Plan”) and the purchase of shares pursuant to our Employee Stock Purchase Plan (the “ESPP”).

Pursuant to the Note to Part I on Form S-8, the documents containing the information specified in Part I of this Registration Statement will be sent or given to plan participants (including to all employees eligible to participate in the ESPP) as specified by Rule 428(b)(1) of the Securities Act. Such documents are not required to be filed, and are not filed, with the United States Securities and Exchange Commission either as part of this Registration Statement or as prospectuses or prospectus supplements pursuant to Rule 424 of the Securities Act. These documents and the documents incorporated by reference in this Registration Statement pursuant to Item 3 of Part II of this Form S-8, taken together, constitute a prospectus that meets the requirements of Section 10(a) of the Securities Act.

REOFFER PROSPECTUS

Anixa Biosciences, Inc.

Up to 11,548,227 shares of Common Stock under the 2018 Share Incentive Plan, Employee Stock Purchase Plan and the 2010 Share Incentive Plan, as amended

This prospectus relates to the resale of up to 11,548,227 shares (the “Shares”) of common stock, par value \$0.01 per share (the “Common Stock”), of Anixa Biosciences, Inc., a Delaware corporation (the “Company”, “us”, “our” or “we”), which may be offered and sold from time to time by certain stockholders of the Company (the “Selling Stockholders”) who have acquired or will acquire such Shares in connection with the exercise of stock options granted, and with stock or other awards made, and with the purchase of stock under, the Company’s 2018 Share Incentive Plan (the “2018 Plan”), the Company’s Employee Stock Purchase Plan (the “ESPP”) and the Company’s 2010 Share Incentive Plan, as amended (the “2010 Plan”). The 2018 Plan, ESPP and 2010 Plan are intended to provide incentives which will attract, retain, and motivate highly competent persons such as officers, employees, directors, and consultants to our Company by providing them opportunities to acquire shares of our Common Stock. Additionally, the 2018 Plan, ESPP and 2010 Plan are intended to assist in further aligning the interests of our officers, employees, directors and consultants to those of the Company’s other stockholders.

The persons who are issued such Shares may include our directors, officers, employees and consultants, certain of whom may be considered our “affiliates”. Such persons may, but are not required to, sell the Shares they acquire pursuant to this prospectus. If any additional awards are issued to or shares are purchased by affiliates under the 2018 Plan, ESPP or 2010 Plan, we will file with the Securities and Exchange Commission (the “Commission”) an update to this prospectus naming such person as a selling shareholder and indicating the number of shares such person is offering pursuant to the prospectus. See “Selling Stockholders” on page 31 of this prospectus. Our Common Stock is listed on The NASDAQ Capital Market under the symbol “ANIX.” On January 3, 2023, the closing price of the Common Stock on The NASDAQ Capital Market was \$4.19 per share.

We will not receive any of the proceeds from sales of the Shares by any of the Selling Stockholders. The Shares may be offered from time to time by any or all of the Selling Stockholders through ordinary brokerage transactions, in negotiated transactions or in other transactions, at such prices as such Selling Stockholder may determine, which may relate to market prices prevailing at the time of sale or be a negotiated price. See “Plan of Distribution.” Sales may be made through brokers or to dealers, who are expected to receive customary commissions or discounts. We are paying all expenses of registration incurred in connection with this offering but the Selling Stockholders will pay all brokerage commissions and other selling expenses.

The Selling Stockholders and participating brokers and dealers may be deemed to be “underwriters” within the meaning of the Securities Act, in which event any profit on the sale of shares of those Selling Stockholders and any commissions or discounts received by those brokers or dealers may be deemed to be underwriting compensation under the Securities Act.

SEE “RISK FACTORS” BEGINNING ON PAGE 13 OF THIS PROSPECTUS FOR A DISCUSSION OF CERTAIN RISKS AND OTHER FACTORS THAT YOU SHOULD CONSIDER BEFORE PURCHASING OUR COMMON STOCK.

Neither the Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is January 4, 2023.

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You should rely only on the information contained in or incorporated by reference into this prospectus or any prospectus supplement. We have not authorized any person to give any information or to make any representations other than those contained or incorporated by reference in this prospectus, and, if given or made, you must not rely upon such information or representations as having been authorized. This prospectus does not constitute an offer to sell or the solicitation of an offer to buy any securities other than our shares of common stock described in this prospectus or an offer to sell or the solicitation to buy such securities in any circumstances in which such offer or solicitation is unlawful. You should not assume that the information we have included in this prospectus is accurate as of any date other than the date of this prospectus or that any information we have incorporated by reference is accurate as of any date other than the date of the document incorporated by reference regardless of the time of delivery of this prospectus or of any securities registered hereunder

WHERE YOU CAN FIND MORE INFORMATION

The Company is subject to the information requirements of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and, in accordance therewith, files reports, proxy statements and other information with the Commission. We are required to file electronic versions of those materials with the Commission through the Commission's EDGAR system. The Commission maintains an Internet site at <http://www.sec.gov>, which contains reports, proxy and information statements and other information regarding registrants that file electronically with the Commission. You can read and copy the reports, proxy statements and other information filed by the Company with the Commission at such Internet site.

This prospectus constitutes part of a Registration Statement on Form S-8 filed on the date hereof (herein, together with all amendments and exhibits, referred to as the "Registration Statement") by the Company with the Commission under the Securities Act. This prospectus does not contain all of the information set forth in the Registration Statement, certain parts of which we have omitted, in accordance with the rules and regulations of the Commission. You should refer to the full Registration Statement for further information with respect to the Company and our Common Stock.

Statements contained herein concerning the provisions of any contract, agreement or other document are not necessarily complete, and in each instance reference is made to the copy of such contract, agreement or other document filed as an exhibit to the Registration Statement or otherwise filed with the Commission. Each such statement is qualified in its entirety by such reference. Copies of the Registration Statement together with exhibits may be inspected at the offices of the Commission as indicated above without charge and copies thereof may be obtained therefrom upon payment of a prescribed fee.

No person is authorized to give any information or to make any representations, other than those contained in this prospectus, in connection with the offering described herein, and, if given or made, such information or representations must not be relied upon as having been authorized by the Company or any Selling Stockholder. This prospectus does not constitute an offer to sell, or a solicitation of an offer to buy, nor shall there be any sale of these securities by any person in any jurisdiction in which it is unlawful for such person to make such offer, solicitation or sale. Neither the delivery of this prospectus nor any sale made hereunder shall under any circumstances create an implication that the information contained herein is correct as of any time subsequent to the date hereto.

INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE

We are “incorporating by reference” in this prospectus certain documents we file with the Commission, which means that we can disclose important information to you by referring you to those documents. The information in the documents incorporated by reference is considered to be part of this prospectus. Statements contained in documents that we file with the Commission and that are incorporated by reference in this prospectus will automatically update and supersede information contained in this prospectus, including information in previously filed documents or reports that have been incorporated by reference in this prospectus, to the extent the new information differs from or is inconsistent with the old information. We have filed or may file the following documents with the Commission and they are incorporated herein by reference as of their respective dates of filing.

- (i) our Annual Report on Form 10-K for the fiscal year ended October 31, 2022;
- (ii) our Definitive Proxy Statements on [Schedule 14A](#) filed on January 28, 2022; and
- (iii) the description of our Common Stock contained in our Current Report on [Form 8-K](#) filed on March 31, 2014 and as it may further be amended from time to time.

All documents that we filed with the Commission pursuant to Sections 13(a), 13(c), 14, and 15(d) of the Exchange Act subsequent to the date of this prospectus that indicates that all securities offered under this prospectus have been sold, or that deregisters all securities then remaining unsold, will be deemed to be incorporated in this prospectus by reference and to be a part hereof from the date of filing of such documents.

Any statement contained in a document incorporated or deemed to be incorporated by reference in this prospectus shall be deemed modified, superseded or replaced for purposes of this prospectus to the extent that a statement contained in this prospectus, or in any subsequently filed document that also is deemed to be incorporated by reference in this prospectus, modifies, supersedes or replaces such statement. Any statement so modified, superseded or replaced shall not be deemed, except as so modified, superseded or replaced, to constitute a part of this prospectus. None of the information that we disclose under Items 2.02 or 7.01 of any Current Report on Form 8-K or any corresponding information, either furnished under Item 9.01 or included as an exhibit therein, that we may from time to time furnish to the Commission will be incorporated by reference into, or otherwise included in, this prospectus, except as otherwise expressly set forth in the relevant document. Subject to the foregoing, all information appearing in this prospectus is qualified in its entirety by the information appearing in the documents incorporated by reference.

You may request, orally or in writing, a copy of these documents, which will be provided to you at no cost (other than exhibits, unless such exhibits are specifically incorporated by reference), by contacting Dr. Amit Kumar, c/o Anixa Biosciences, Inc., at 3150 Almaden Expressway, Suite 250, San Jose, CA 95118. Our telephone number is (408) 708-9808. Information about us is also available at our website at <http://www.anixa.com>. However, the information in our website is not a part of this prospectus and is not incorporated by reference.

NOTE ON FORWARD LOOKING STATEMENTS

This prospectus and the documents incorporated by reference herein may contain forward looking statements that involve risks and uncertainties. All statements other than statements of historical fact contained in this prospectus and the documents incorporated by reference herein, including statements regarding future events, our future financial performance, business strategy, and plans and objectives of management for future operations, are forward-looking statements. We have attempted to identify forward-looking statements by terminology including “anticipates,” “believes,” “can,” “continue,” “could,” “estimates,” “expects,” “intends,” “may,” “plans,” “potential,” “predicts,” “should,” or “will” or the negative of these terms or other comparable terminology. Although we do not make forward looking statements unless we believe we have a reasonable basis for doing so, we cannot guarantee their accuracy. These statements are only predictions and involve known and unknown risks, uncertainties and other factors, including the risks outlined under “Risk Factors” or elsewhere in this prospectus and the documents incorporated by reference herein, which may cause our or our industry’s actual results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. Moreover, we operate in a highly regulated, very competitive, and rapidly changing environment. New risks emerge from time to time and it is not possible for us to predict all risk factors, nor can we address the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause our actual results to differ materially from those contained in any forward-looking statements.

We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our financial condition, results of operations, business strategy, short term and long term business operations, and financial needs. These forward-looking statements are subject to certain risks and uncertainties that could cause our actual results to differ materially from those reflected in the forward looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in this prospectus, and in particular, the risks discussed below and under the heading “Risk Factors” and those discussed in other documents we file with the Commission. The following discussion should be read in conjunction with the consolidated financial statements for the fiscal years ended October 31, 2022 and 2021 and notes incorporated by reference herein. We undertake no obligation to revise or publicly release the results of any revision to these forward-looking statements, except as required by law. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this prospectus may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statement.

You should not place undue reliance on any forward-looking statement, each of which applies only as of the date of this prospectus. Except as required by law, we undertake no obligation to update or revise publicly any of the forward-looking statements after the date of this prospectus to conform our statements to actual results or changed expectations.

Any forward-looking statement you read in this prospectus or any document incorporated by reference reflects our current views with respect to future events and is subject to these and other risks, uncertainties and assumptions relating to our operations, operating results, growth strategy and liquidity. You should not place undue reliance on these forward-looking statements because such statements speak only as to the date when made. We assume no obligation to publicly update or revise these forward-looking statements for any reason, or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future, except as otherwise required by applicable law. You are advised, however, to consult any further disclosures we make on related subjects in our reports on Forms 10-Q, 8-K and 10-K filed with the Commission. You should understand that it is not possible to predict or identify all risk factors. Consequently, you should not consider any such list to be a complete set of all potential risks or uncertainties.

THE COMPANY

Overview

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

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

Following the U.S. Food and Drug Administration’s (“FDA”) authorization to proceed with clinical trials in December 2020, in October 2021, we commenced dosing patients in a Phase 1 clinical trial of our breast cancer vaccine. This study, which is being funded by a U.S. Department of Defense grant, is a multiple-ascending dose Phase 1 trial to determine the maximum tolerated dose (“MTD”) of the vaccine in patients with early-stage, triple-negative breast cancer as well as monitor immune response. The study is being conducted at Cleveland Clinic and will consist of 18 to 24 patients who have completed treatment for early-stage, triple-negative breast cancer within the past three years and are currently tumor-free but at high risk for recurrence. During the course of the study, participants will receive three vaccinations, each two weeks apart, and will be closely monitored for side effects and immune response. Initial indications from preliminary analyses suggest that an immune response is being observed. In December 2022, we announced that we had reached the MTD. We are now expanding the MTD cohort and are vaccinating additional participants at that dose level. Upon completion of vaccination and follow-up tests of the expanded cohort, we will compile and analyze the data, and we anticipate presenting the complete immunological data from the trial at a scientific conference or similar setting in the second calendar quarter of 2023.

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

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

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

Certainty, in collaboration with the H. Lee Moffitt Cancer Center and Research Institute, Inc. (“Moffitt”), is advancing toward human clinical testing of the CAR-T technology licensed by Certainty from Wistar aimed initially at treating ovarian cancer. We received authorization from the FDA in August 2021, to commence enrollment and treatment of patients in a Phase 1 clinical trial. We began patient recruitment for the trial in March 2022, and in August 2022, we treated the first patient in the trial. The treatment appears to have been well-tolerated by the patient, and we continue to monitor her condition. The process of recruiting additional patients is ongoing. This study is a dose-escalation trial with two arms based on injection method—intraperitoneal or intravenous—to determine the maximum tolerated dose in patients with recurrent epithelial ovarian cancer and to assess persistence, expansion and efficacy of the modified T-cells. The study is being conducted at Moffitt and will consist of 24 to 48 patients who have received at least two prior lines of chemotherapy. The study is estimated to be completed in two to four years depending on multiple factors including when maximum tolerated dose is reached, the rate of patient recruitment, and how long we maintain the two different injection methods.

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

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

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

While use of preventative vaccines is widespread throughout much of the developed world, we believe that there is and will continue to be a need for effective treatments for COVID-19. We believe that there are a number of factors that have limited the effectiveness, both in the near and long term, of the vaccines currently in use, including, but not limited to, vaccine persistence, viral escape and perceptions of long-term safety resulting in vaccine resistance. Furthermore, there are currently new anti-viral treatments, such as Pfizer’s Paxlovid, which is a combination therapy consisting of the protease-inhibitor nirmatrelvir and the antiretroviral ritonavir, that have been authorized for use in the U.S. As the main component of Pfizer’s treatment is a protease-inhibitor targeting M^{Pro}, it is most similar to our compounds, and we therefore conducted a head-to-head analysis via a Fluorescence Resonance Energy Transfer (FRET) assay that tested the ability of the compounds to inhibit the function of M^{Pro}. The results of this head-to-head *in vitro* analysis suggested that our compounds may be five times more effective at inhibiting M^{Pro} than Pfizer’s nirmatrelvir.

Over the next several quarters, we expect the development of our breast and ovarian cancer vaccines, our COVID-19 therapeutic discovery program and Certainty’s CAR-T technology to be the primary focus of the Company. As part of our legacy operations, the Company remains engaged in limited patent licensing activities regarding its liquid biopsy platform and in the area of encrypted audio/video conference calling. We do not expect these activities to be a significant part of the Company’s ongoing operations nor do we expect these activities to require material financial resources or attention of senior management.

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

Breast and Ovarian Cancer vaccines

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

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

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

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

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

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

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

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

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

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

The Breast Cancer Market

According to American Cancer Society statistics, breast cancer accounts for over 30% of all female cancer cases, and 15% of cancer deaths in women. It is estimated that in 2022, 288,000 new cases of breast cancer will be diagnosed in the U.S. and 43,000 women will die from this disease. Despite continuous advances made in the field of cancer research every year, invasive female breast cancer incidence rates have been increasing by approximately 0.5% per year over the past 15 years.

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

While in the U.S., 288,000 women are estimated to be diagnosed with breast cancer this year, there are approximately 82 million women age 40 and over—the time in life when women face an increased risk of developing breast cancer. Worldwide, the number is dramatically larger.

The Ovarian Cancer Market

According to American Cancer Society statistics, ovarian cancer accounts for just 2% of all female cancer cases, but nearly 5% of cancer deaths in women due to the disease's low survival rate. It is estimated that in 2022, 20,000 new cases of ovarian cancer will be diagnosed and 13,000 American women will die from this disease. Despite continuous advances made in the field of cancer research every year, we believe there remains a significant unmet medical need, as the overall five-year relative survival rate for ovarian cancer patients is 49%. However, ovarian cancer survival varies substantially by age, with the overall five-year survival rate for women 65 and older of only 33%.

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

Competition

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

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

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

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

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

CAR-T therapeutics

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

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

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

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

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

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

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

In August 2022, we treated the first patient in the trial. The treatment appears to have been well-tolerated by the patient, and we continue to monitor her condition. The process of recruiting additional patients is ongoing. This study is a dose-escalation trial with two arms based on injection method—intraperitoneal or intravenous—to determine the maximum tolerated dose in patients with recurrent epithelial ovarian cancer and to assess persistence, expansion and efficacy of the modified T-cells. The study is being conducted at Moffitt and will consist of 24 to 48 patients who have received at least two prior lines of chemotherapy. The study is estimated to be completed in two to four years depending on multiple factors including when maximum tolerated dose is reached, the rate of patient recruitment, and how long we maintain the two different injection methods.

The Market

We believe that our CAR-T technology may be used as an effective treatment against multiple solid tumor types, however, we have initially focused on ovarian cancer. According to American Cancer Society statistics, ovarian cancer accounts for just 2% of all female cancer cases, but nearly 5% of cancer deaths in women due to the disease's low survival rate. It is estimated that in 2022, approximately 20,000 new cases of ovarian cancer will be diagnosed and 13,000 American women will die from this disease. Despite continuous advances made in the field of cancer research every year, there remains a significant unmet medical need, as the overall five-year relative survival rate for ovarian cancer patients is 49%. However, ovarian cancer survival varies substantially by age, with the overall five-year survival rate for women 65 and older of only 33%.

Competition

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

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

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

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

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

COVID-19 therapeutics

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

There are currently few broadly effective treatment options. Further, nearly all treatments currently in use or in clinical trials were originally developed for other indications, and were not designed specifically against SARS-CoV-2, and therefore may have limited effectiveness. We believe that newly designed drugs that are purposefully developed to specifically target SARS-CoV-2, enabled by recent studies of the molecular biology of the virus, will have the potential to be far more effective than repurposing existing drugs.

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

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

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

As SARS-CoV-2 has continued to mutate over the course of the pandemic, we have performed genomic variant analysis to determine whether our compounds may be effective against multiple variants. To date, the results of such analyses have shown that either no significant mutations have been found in or near the active site of the M^{Pro} enzyme or any known mutations do not change the function of the enzyme, and therefore we believe that our compounds should be effective against multiple variants, including the Omicron variant and its subvariants, though there is no assurance that this will be the case.

The Market

According to U.S. Centers for Disease Control and Prevention (“CDC”) data, as of the date of this Report, in the U.S., there have been over 100 million cases of COVID-19 and nearly 1.1 million deaths. According to World Health Organization (“WHO”) data, globally, there have been over 650 million cases and over 6.6 million people have died. While the infection and death rates have reduced significantly since the peak of the pandemic, according to the most recent CDC data, in the U.S. the current 7-day average of weekly new cases is approximately 65,000, the 7-day average daily hospitalizations is approximately 5,000 and the 7-day average daily deaths is over 400.

Currently, there are few broadly effective treatment options for COVID-19. Further, the most common treatments that are currently being employed, were originally developed for other indications, and were not designed specifically against SARS-CoV-2, and therefore may have limited effectiveness. In addition, the orally-available antiviral treatment developed by Pfizer has limitations as it requires a combination therapy with an antiretroviral drug commonly used to treat HIV and is known to have challenging side effects.

The market for orally delivered COVID-19 treatments that are effective against multiple variants of the virus, with limited side effects would be significant.

Competition

Competition in the COVID-19 treatment and prevention market is fierce, with hundreds of therapies and vaccines currently in development. There are currently a number of preventative vaccines that have received regulatory approvals globally. While these vaccines have been effective in reducing the spread of COVID-19, there remain challenges regarding persistence and viral escape as well as the resistance to vaccination by a significant portion of the population and also the difficulty in vaccinating and boosting the world population. Further, the current leading treatment is the orally-available combination protease-inhibitor-antiretroviral Paxlovid, developed by Pfizer. Any product candidates that we successfully develop and commercialize will have to compete with existing therapies and vaccines and new therapies and vaccines that may become available in the future. While we believe that our proprietary compounds for treating COVID-19 and scientific expertise in the field of synthetic chemistry provide us with competitive advantages, we face potential competition from various sources, including larger and better-funded pharmaceutical and biotechnology companies, as well as from academic institutions, governmental agencies and public and private research institutions.

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

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

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

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

Employees

As of October 31, 2022, we had five employees, four full-time and one part time, working for our Company and subsidiaries. In addition, we work with research teams at Moffitt, Cleveland Clinic, and MolGenie, as well as their subcontractors, to develop each of our projects.

Summary Risk Factors

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

Risks Relating to Our Financial Condition and Operations

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

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

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

Risks Related to our Intellectual Property

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

Risks Related to our Common Stock

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

Risks Related to the COVID-19 Pandemic

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

Other

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

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, 2022, our accumulated deficit was approximately \$218,385,000. As of October 31, 2022, we had approximately \$29,687,000 in cash, cash equivalents and short-term investments, and working capital of approximately \$28,163,000. In fiscal year 2022, we incurred losses of approximately \$13,771,000 and we experienced negative cash flows from operations of approximately \$6,492,000. We expect to continue incurring material research and development and general and administrative expenses in connection with our operations. As a result, we anticipate that we will incur losses in the future.

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

Based on currently available information as of January 4, 2023, we believe that our existing cash, cash equivalents and short-term investments will be sufficient to fund our activities for the next 12 months. However, our projections of future cash needs and cash flows may differ from actual results. If current cash on hand, cash equivalents and short-term investments are insufficient to continue to operate our business, or if we elect to invest in or acquire a company or companies that are synergistic with or complementary to our technologies, we may be required to obtain more working capital. We may seek to obtain working capital through sales of our equity securities, including through our current “at the market offering” program, or through bank credit facilities or public or private debt from various financial institutions where possible. We cannot be certain that additional funding will be available on acceptable terms, or at all. If we do identify sources for additional funding, the sale of additional equity securities or convertible debt could result in dilution to our stockholders. Additionally, the sale of equity securities or issuance of debt securities may be subject to certain security holder approvals or may result in the downward adjustment of the exercise or conversion price of our outstanding securities. We can give no assurance that we will generate sufficient cash flows in the future to satisfy our liquidity requirements or sustain future operations, or that other sources of funding, such as sales of equity or debt, would be available or would be approved by our security holders, if needed, on favorable terms or at all. If we fail to obtain additional working capital as and when needed, such failure could have a material adverse impact on our business, results of operations and financial condition. Furthermore, such lack of funds may inhibit our ability to respond to competitive pressures or unanticipated capital needs, or may force us to reduce operating expenses, which would significantly harm the business and development of operations.

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

We currently do not generate any revenue from our therapeutics or vaccines nor do we generate any other recurring revenues and as of October 31, 2022, the Company had approximately \$29,687,000 in cash, cash equivalents and short-term investments. Therefore, we have a limited source of cash to meet our future capital requirements, which may include the expensive process of obtaining FDA approvals for our CAR-T ovarian cancer therapeutic, our breast and ovarian cancer vaccines and our COVID-19 therapy. We do not expect to generate significant revenues for the foreseeable future, which would leave us without resources to continue our operations and force us to resort to raising additional capital in the form of equity or debt financings, which may not be available to us. We may have difficulty raising needed capital in the near or longer term as a result of, among other factors, the very early stage of our therapeutics and vaccine businesses and our lack of revenues as well as the inherent business risks associated with an early stage, biotechnology company and present and future market conditions. Also, we may consume available resources more rapidly than currently anticipated, resulting in the need for additional funding sooner than anticipated. Our inability to raise funds could lead to decreases in the price of our common stock and the failure of our therapeutics and vaccine businesses which would have a material adverse effect on the Company.

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

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

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

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

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

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

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

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

Since the Company's primary focus for the foreseeable future will likely be our therapeutics and vaccine businesses, shareholders should understand that we are primarily an early stage biotechnology company with no history of revenue-generating operations, and our only assets consist of our proprietary and licensed technologies and the know-how of our officers and employees. Therefore we are subject to all the risks and uncertainties inherent in a new business, in particular new businesses engaged in CAR-T cancer therapeutics, cancer vaccines and anti-viral therapeutics, as well as whether our current business plan is sound. Our CAR-T ovarian cancer therapeutic, our breast and ovarian cancer vaccines and our COVID-19 treatment are in their early stages of development, and we still must establish and implement many important functions necessary to commercialize the technologies.

Accordingly, you should consider the Company's prospects in light of the costs, uncertainties, delays and difficulties frequently encountered by companies in their pre-revenue generating stages, particularly those in the biotechnology field. Shareholders should carefully consider the risks and uncertainties that a business with no operating history will face. In particular, shareholders should consider that there is a significant risk that we will not be able to:

- complete studies that successfully identify one or more clinical candidates to treat COVID-19;
- successfully complete animal studies necessary to submit an IND application to the FDA for our COVID-19 treatment;
- successfully enroll sufficient numbers of qualified patients to participate in our clinical trials;
- obtain sufficient quantity and quality of materials manufactured for use in our clinical trials;
- successfully meet the primary endpoints in our clinical trials;
- implement or execute our current business plan;
- raise sufficient funds in the capital markets or otherwise to fully effectuate our business plan;
- maintain our management team;
- determine that the processes and technologies that we have developed or will develop are commercially viable; and/or
- attract, enter into or maintain contracts with potential commercial partners such as licensors of technology and suppliers or licensees of our technologies.

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

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

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

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

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

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

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

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

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

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

We are in the discovery stage of developing our COVID-19 treatment and our ovarian cancer vaccine technology and in the clinical stage with our CAR-T therapeutic technology and with our breast cancer vaccine technology. Our ability to generate revenue depends in large part on our ability, alone or with partners, to successfully complete the development of, obtain the necessary regulatory approvals for, and commercialize, product candidates. We do not anticipate generating revenues from sales of such products for the foreseeable future. Our ability to generate future revenues from product sales of our technologies depends heavily on our success in:

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

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

Cancer vaccines are novel and present significant challenges.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

We depend and will continue to depend upon independent investigators and collaborators, such as universities, medical institutions, and strategic partners such as Moffitt for our CAR-T therapy, Cleveland Clinic for our breast and ovarian cancer vaccines and MolGenie, as well as other European partners, for our COVID-19 therapy to conduct our pre-clinical studies and clinical trials under agreements with us. Negotiations of budgets and contracts with study sites may result in delays to our development timelines and increased costs. We will rely heavily on these third parties over the course of our clinical trials, and we control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with applicable protocol, legal, regulatory and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. We and these third parties are required to comply with current good clinical practices, or cGCPs, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development. Regulatory authorities enforce these cGCPs through periodic inspections of clinical trial sponsors, principal investigators and clinical trial sites. If we or any of these third parties fail to comply with applicable cGCP regulations, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities could require us to perform additional clinical trials before approving our marketing applications. It is possible that, upon inspection, such regulatory authorities could determine that any of our clinical trials fail to comply with the cGCP regulations. In addition, our clinical trials must be conducted with biologic product produced under current good manufacturing practices, or cGMPs, and will require a large number of test patients. Our failure or any failure by these third parties to comply with these regulations or to recruit a sufficient number of patients may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

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

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

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

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

- the patient eligibility criteria defined in the clinical trial protocol;
- the size of the patient population required for analysis of the trial's primary endpoints;
- the proximity of patients to the study site;
- the design of the clinical trial;
- our ability to retain clinical trial investigators with the appropriate competencies and experience;
- our ability to obtain and maintain patient consents;
- the risk that patients enrolled in clinical trials will drop out of the clinical trials before completion;
- competing clinical trials and approved therapies available for patients; and
- the impact of the ongoing COVID-19 pandemic.

In particular, our CAR-T ovarian cancer clinical trial is enrolling 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 is enrolling patients who have undergone standard of care treatment for TNBC. Our second breast cancer vaccine clinical trial is enrolling 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 must be willing and able to undergo treatment at the Cleveland Clinic.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- the clinical indications for which our product candidates are approved;
- physicians, hospitals, cancer treatment centers and patients considering our product candidates as a safe and effective treatment;

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

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

Risks Related to Our Intellectual Property

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

Our ability to compete and to achieve sustained profitability will be impacted by our ability to protect our CAR-T cancer therapeutics technologies, our breast cancer vaccine technologies, our ovarian cancer vaccine technologies, our COVID-19 therapeutic technologies and other proprietary discoveries and technologies. We expect to rely on a combination of patent protection, copyrights, trademarks, trade secrets, know-how, and regulatory approvals to protect our technologies. Our intellectual property strategy is intended to help develop and maintain our competitive position. While we have been granted multiple patents related to our technologies, there is no assurance that we will be able to obtain further patent protection for our technologies or any other technologies, nor can we be certain that the steps we will have taken will prevent the misappropriation and unauthorized use of our technologies. If we are not able to obtain and maintain patent protection our competitive position may be harmed.

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

Our commercial success depends upon our ability to develop, manufacture, market and sell our CAR-T therapeutics, our breast cancer vaccine, our ovarian cancer vaccine, our COVID-19 treatment and other proprietary discoveries and technologies without infringing, misappropriating or otherwise violating the proprietary rights or intellectual property of third parties. We may become party to, or be threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our CAR-T therapeutics, our breast cancer vaccine, our ovarian cancer vaccine, our COVID-19 treatment and other proprietary discoveries and technologies. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future. If we are found to infringe a third-party's intellectual property rights, we could be required to obtain a license from such third-party to continue developing our CAR-T therapeutics, our breast cancer vaccine, our ovarian cancer vaccine, our COVID-19 treatment and other proprietary discoveries and technologies. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. We could be forced, including by court order, to cease developing the infringing technology or product. In addition, we could be found liable for monetary damages. Claims that we have misappropriated the confidential information or trade secrets of third parties can have a similar negative impact on our business, including our ability to license any product if we choose to have other parties commercialize them.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Our Common Stock

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

In the future, we may issue securities to raise cash for operations, to pay down then existing indebtedness, as consideration for the acquisition of assets, as consideration for receipt of goods or services, to pay for the development of our CAR-T cancer therapeutics, to pay for the development of our breast cancer vaccine, to pay for the development of our ovarian cancer vaccine, to pay for the development of our COVID-19 therapeutic and for acquisitions of companies. We have an at-the-market equity offering under which, as of January 4, 2022 we may issue up to approximately \$100 million of common stock, which is currently effective and under which we have not yet sold any shares, and which may remain available to us in the future. We also have and in the future may issue securities convertible into our common stock. Any of these events may dilute stockholders' ownership interests in our company and have an adverse impact on the price of our common stock.

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

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

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

Our reported revenues and operating results have fluctuated in the past and may continue to fluctuate significantly from quarter to quarter in the future, specifically as we continue to devote our resources towards our CAR-T cancer therapeutics, our breast and ovarian cancer vaccines and our COVID-19 therapeutic. It is possible that in future periods, we will have no revenue or, in any event, revenues could fall below or expenses could rise above the expectations of securities analysts or investors, which could cause the market price of our common stock to decline. The following are among the factors that could cause our operating results to fluctuate significantly from period to period:

- patient enrollment rates for our clinical trials;
- delays with respect to our clinical trials;

- clinical trial results relating to our CAR-T cancer therapeutics;
- clinical trial results relating to our breast cancer vaccine;
- results of pre-clinical studies relating to our ovarian cancer vaccine;
- results of pre-clinical studies relating to our COVID-19 therapeutic;
- progress with regulatory authorities towards the certification/approval of our CAR-T cancer therapeutics, our breast cancer vaccine, our ovarian cancer vaccine or our COVID-19 therapeutic; and
- costs related to acquisitions, alliances and licenses.

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

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

- announcements of developments in the fields of CAR-T therapeutics, cancer vaccines or COVID-19 treatments;
- developments in relationships with third party vendors and laboratories;
- developments or disputes concerning our patents and other intellectual property;
- our or our competitors' technological innovations;
- variations in our quarterly operating results;
- our failure to meet or exceed securities analysts' expectations of our financial results;
- a change in financial estimates or securities analysts' recommendations;
- changes in management's or securities analysts' estimates of our financial performance;
- announcements by us or our competitors of significant contracts, acquisitions, strategic partnerships, joint ventures, capital commitments, new technologies, or patents; and
- the timing of or our failure to complete significant transactions.

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

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

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

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

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

As of the date of this Report, we have issued and outstanding options to purchase 11,621,500 shares of our common stock with a weighted average exercise price of \$3.58. Further, as of the date of this Report, our Board of Directors and Compensation Committee have the authority to issue awards totaling an additional 875,000 shares of our common stock which is replenished on a yearly basis in accordance with the provisions of our plan. Additionally, we have registered for resale all of the shares of common stock issuable under our incentive plans. Because the market for our common stock is thinly traded, the sales and/or the perception that those sales may occur, could adversely affect the market price of our common stock. Furthermore, the mere existence of a significant number of shares of common stock issuable upon vesting and, if applicable, exercise of these securities may be perceived by the market as having a potential dilutive effect, which could lead to a decrease in the price of our common stock.

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

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

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

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

Risks related to the COVID-19 pandemic

Our business activities may be adversely affected by the ongoing COVID-19 pandemic.

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

While the Company and its partners are not currently experiencing significant negative impact of COVID-19, there can be no assurance that the current situation will continue. Further, events such as natural disasters and public health emergencies divert our attention away from normal operations and limited resources. Our inability to timely resume normal operations following any pandemic disruption could adversely affect our business, financial condition or results of operations in a material manner.

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

SELLING STOCKHOLDERS

The following table sets forth (a) the name and position or positions with the Company of each Selling Stockholder; (b) the aggregate of (i) the number of shares of Common Stock held by each Selling Stockholder as of the date of this prospectus (including shares purchased pursuant to the ESPP) and (ii) the number of shares issuable upon exercise of options granted to each Selling Stockholder under the 2018 Plan and the 2010 Plan that are being registered pursuant to this Registration Statement for resale by each Selling Stockholder as of the date of this prospectus; (c) the number of shares of Common Stock that each Selling Stockholder may offer for sale from time to time pursuant to this prospectus, whether or not such Selling Stockholder has a present intention to do so; and (d) the number of shares of Common Stock to be beneficially owned by each Selling Stockholder following the sale of all shares that may be so offered pursuant to this prospectus, assuming no other change in ownership of Common Stock by such Selling Stockholder after the date of this prospectus. Unless otherwise indicated, beneficial ownership is direct and the person indicated has sole voting and investment power.

To our knowledge, none of our officers and directors have a present intention to offer shares of Common stock for sale, although they retain the right to do so.

Inclusion of an individual's name in the table below does not constitute an admission that such individual is an "affiliate" of the Company.

Selling Stockholder	Principal Position with the Company (1)	Shares Owned Prior to Resale		Number of Shares Offered for Resale	Shares Beneficially Owned After Resale (5)	
		(2)	(3)(4)(5)		Number	Percent
		Number	Percent			
Dr. Amit Kumar	Chief Executive Officer and Chairman of the Board	7,022,100	18.7%	6,708,100	314,000	*
Michael J. Catelani	President, Chief Financial Officer and Chief Operating Officer	2,120,290	6.4%	2,110,031	10,259	*
Lewis H. Titterton, Jr.	Director	1,728,070	5.4%	1,092,400	635,670	2.0%
Dr. Arnold Baskies	Director	413,000	1.3%	313,000	100,000	*
Emily Gottschalk	Director	275,665	*	230,000	45,665	*

* Less than 1%.

- (1) All positions described are with the Company, unless otherwise indicated.
- (2) The number of shares owned prior to resale by each Selling Stockholder includes (i) shares of Common Stock (inclusive of shares purchased pursuant to the ESPP) and (ii) shares issuable upon exercise of options granted to such Selling Stockholders under the 2018 Plan and the 2010 Plan that are being registered pursuant to this prospectus for resale. Some of these shares may have been sold prior to the date of this prospectus.
- (3) Includes 6,320,000 shares, 1,850,000 shares, 430,000 shares, 230,000 shares, 230,000 shares and 9,060,000 shares which Dr. Amit Kumar, Michael J. Catelani, Lewis H. Titterton, Jr., Dr. Arnold Baskies, Emily Gottschalk and all directors and executive officers as a group, respectively, have the right to acquire upon exercise of options granted pursuant to the 2018 Plan.
- (4) Includes 240,000 shares, 250,000 shares, 524,000 shares, 83,000 shares and 1,097,000 shares which Dr. Amit Kumar, Michael J. Catelani, Lewis H. Titterton, Jr., Dr. Arnold Baskies and all directors and executive officers as a group, respectively, have the right to acquire upon exercise of options granted pursuant to the 2010 Plan.
- (5) Percentage is computed with reference to 30,920,792 shares of our Common Stock outstanding as of January 4, 2023 and assumes for each Selling Stockholder the sale of all shares offered by that particular Selling Stockholder under this prospectus.

The Company may supplement this prospectus from time to time as required by the rules of the Commission to include certain information concerning the security ownership of the Selling Stockholders or any new Selling Stockholders, the number of securities offered for resale and the position, office or other material relationship which a Selling Stockholder has had within the past three years with the Company or any of its predecessors or affiliates.

USE OF PROCEEDS

We will not receive any proceeds from the resale of our Common Stock by the Selling Stockholders pursuant to this prospectus. However, we will receive the exercise price of any Common Stock issued to the Selling Stockholders upon cash exercise by them of their options. We would expect to use these proceeds, if any, for general working capital purposes. We have agreed to pay the expenses of registration of these shares.

PLAN OF DISTRIBUTION

In this section of the prospectus, the term “Selling Stockholder” means and includes:

- the persons identified in the table above as the Selling Stockholders;
- those persons whose identities are not known as of the date hereof but may in the future be eligible to receive options under the 2018 Plan or be eligible to purchase shares under the ESPP; and
- any of the donees, pledgees, distributees, transferees or other successors in interest of those persons referenced above who may: (a) receive any of the shares of our common stock offered hereby after the date of this prospectus and (b) offer or sell those shares hereunder.

The shares of our Common Stock offered by this prospectus may be sold from time to time directly by the Selling Stockholders. Alternatively, the Selling Stockholders may from time to time offer such shares through underwriters, brokers, dealers, agents or other intermediaries. The Selling Stockholders as of the date of this prospectus have advised us that there were no underwriting or distribution arrangements entered into with respect to the Common Stock offered hereby. The distribution of the Common Stock by the Selling Stockholders may be effected: in one or more transactions that may take place on The NASDAQ Capital Market (including one or more block transaction) through customary brokerage channels, either through brokers acting as agents for the Selling Stockholders, or through market makers, dealers or underwriters acting as principals who may resell these shares on The NASDAQ Capital Market; in privately-negotiated sales; by a combination of such methods; or by other means. These transactions may be effected at market prices prevailing at the time of sale, at prices related to such prevailing market prices or at other negotiated prices. Usual and customary or specifically negotiated brokerage fees or commissions may be paid by the Selling Stockholders in connection with sales of our Common Stock.

The Selling Stockholders may enter into hedging transactions with broker-dealers in connection with distributions of the shares or otherwise. In such transactions, broker-dealers may engage in short sales of the shares of our Common Stock in the course of hedging the positions they assume with the Selling Stockholders. The Selling Stockholders also may sell shares short and redeliver the shares to close out such short positions. The Selling Stockholders may enter into option or other transactions with broker-dealers which require the delivery to the broker-dealer of shares of our Common Stock. The broker-dealer may then resell or otherwise transfer such shares of Common Stock pursuant to this prospectus.

The Selling Stockholders also may lend or pledge shares of our Common Stock to a broker-dealer. The broker-dealer may sell the shares of Common Stock so lent, or upon a default the broker-dealer may sell the pledged shares of Common Stock pursuant to this prospectus. Any securities covered by this prospectus which qualify for sale pursuant to Rule 144 may be sold under Rule 144 rather than pursuant to this prospectus.

The Selling Stockholders have advised us that they have not entered into any agreements, understandings or arrangements with any underwriters or broker-dealers regarding the sale of their securities. There is no underwriter or coordinating broker acting in connection with the proposed sale of shares of Common Stock the Selling Stockholders.

Although the shares of Common Stock covered by this prospectus are not currently being underwritten, the Selling Stockholders or their underwriters, brokers, dealers or other agents or other intermediaries, if any, that may participate with the selling security holders in any offering or distribution of Common Stock may be deemed “underwriters” within the meaning of the Securities Act and any profits realized or commissions received by them may be deemed underwriting compensation thereunder.

Under applicable rules and regulations under the Exchange Act, any person engaged in a distribution of shares of the Common Stock offered hereby may not simultaneously engage in market making activities with respect to the Common Stock for a period of up to five days preceding such distribution. The Selling Stockholders will be subject to the applicable provisions of the Exchange Act and the rules and regulations promulgated thereunder, including without limitation Regulation M, which provisions may limit the timing of purchases and sales by the Selling Stockholders.

In order to comply with certain state securities or blue sky laws and regulations, if applicable, the Common Stock offered hereby will be sold in such jurisdictions only through registered or licensed brokers or dealers. In certain states, the Common Stock may not be sold unless they are registered or qualified for sale in such state, or unless an exemption from registration or qualification is available and is obtained.

We will bear all costs, expenses and fees in connection with the registration of the Common Stock offered hereby. However, the Selling Stockholders will bear any brokerage or underwriting commissions and similar selling expenses, if any, attributable to the sale of the shares of Common Stock offered pursuant to this prospectus. We have agreed to indemnify the Selling Stockholders against certain liabilities, including liabilities under the Securities Act, or to contribute to payments to which any of those security holders may be required to make in respect thereof.

There can be no assurance that the Selling Stockholders will sell any or all of the securities offered by them hereby.

LEGAL MATTERS

The validity of the securities being offered herein has been passed upon for us by Ellenoff Grossman & Schole LLP, New York, New York.

EXPERTS

The consolidated financial statements of Anixa Biosciences, Inc. and subsidiaries as of October 31, 2022 and 2021, and for each of the years in the two-year period ended October 31, 2022, have been included in the registration statement in reliance upon the report of Haskell & White LLP, independent registered public accounting firm, and upon the authority of said firm as experts in accounting and auditing.

DISCLOSURE OF COMMISSION POSITION ON INDEMNIFICATION FOR SECURITIES LAWS VIOLATIONS

Section 145 of the DGCL *inter alia*, empowers a Delaware corporation to indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding (other than an action by or in the right of the corporation) by reason of the fact that such person is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation or other enterprise, against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by him in connection with such action, suit or proceeding if he acted in good faith and in a manner he reasonably believed to be in or not opposed to the best interests of the corporation, and, with respect to any criminal action or proceeding, had no reasonable cause to believe his conduct was unlawful. Similar indemnity is authorized for such persons against expenses (including attorneys' fees) actually and reasonably incurred in connection with the defense or settlement of any such threatened, pending or completed action or suit if such person acted in good faith and in a manner he reasonably believed to be in or not opposed to the best interests of the corporation, and provided further that (unless a court of competent jurisdiction otherwise provides) such person shall not have been adjudged liable to the corporation. Any such indemnification may be made only as authorized in each specific case upon a determination by the stockholders or disinterested directors or by independent legal counsel in a written opinion that indemnification is proper because the indemnitee has met the applicable standard of conduct.

Section 145 further authorizes a corporation to purchase and maintain insurance on behalf of any person who is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation or enterprise, against any liability asserted against him and incurred by him in any such capacity, or arising out of his status as such, whether or not the corporation would otherwise have the power to indemnify him under Section 145. We maintain policies insuring our officers and directors against certain liabilities for actions taken in such capacities, including liabilities under the Securities Act.

Section 102(b)(7) of the DGCL permits a corporation to include in its certificate of incorporation a provision eliminating or limiting the personal liability of a director to the corporation or its shareholders for monetary damages for breach of fiduciary duty as a director, provided that such provision shall not eliminate or limit the liability of a director (i) for any breach of the director's duty of loyalty to the corporation or its stockholders, (ii) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (iii) under Section 174 of the DGCL (relating to unlawful payment of dividends and unlawful stock purchase or redemption) or (iv) for any transaction from which the director derived an improper personal benefit.

Article 10 of the bylaws of the Company contains provisions which are designed to provide mandatory indemnification of directors and officers of the Company to the full extent permitted by law, as now in effect or later amended. The bylaws further provide that, if and to the extent required by the DGCL, an advance payment of expenses to a director or officer of the Company that is entitled to indemnification will only be made upon delivery to the Company of an undertaking, by or on behalf of the director or officer, to repay all amounts so advanced if it is ultimately determined that such director is not entitled to indemnification.

You should rely only on the information contained in this document. We have not authorized anyone to provide you with information that is different. This document may only be used where it is legal to sell these securities. The information in this document may only be accurate on the date of this document.

Additional risks and uncertainties not presently known or that are currently deemed immaterial may also impair our business operations. The risks and uncertainties described in this document and other risks and uncertainties which we may face in the future will have a greater impact on those who purchase our common stock. These purchasers will purchase our common stock at the market price or at a privately negotiated price and will run the risk of losing their entire investment.

ANIXA BIOSCIENCES, INC.

11,548,227 Shares of
Common Stock

PROSPECTUS

January 4, 2023

PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 3. Incorporation of Documents by Reference

We are “incorporating by reference” in this prospectus certain documents we file with the Commission, which means that we can disclose important information to you by referring you to those documents. The information in the documents incorporated by reference is considered to be part of this prospectus. Statements contained in documents that we file with the Commission and that are incorporated by reference in this prospectus will automatically update and supersede information contained in this prospectus, including information in previously filed documents or reports that have been incorporated by reference in this prospectus, to the extent the new information differs from or is inconsistent with the old information. We have filed or may file the following documents with the Commission and they are incorporated herein by reference as of their respective dates of filing.

- (i) our Annual Report on [Form 10-K](#) for the fiscal year ended October 31, 2022;
- (ii) our Definitive Proxy Statements on [Schedule 14A](#) filed on January 28, 2022; and
- (iii) the description of our Common Stock contained in our Current Report on [Form 8-K](#) filed on March 31, 2014 and as it may further be amended from time to time.

All documents that we filed with the Commission pursuant to Sections 13(a), 13(c), 14, and 15(d) of the Exchange Act subsequent to the date of this prospectus that indicates that all securities offered under this prospectus have been sold, or that deregisters all securities then remaining unsold, will be deemed to be incorporated in this prospectus by reference and to be a part hereof from the date of filing of such documents.

Any statement contained in a document incorporated or deemed to be incorporated by reference in this prospectus shall be deemed modified, superseded or replaced for purposes of this prospectus to the extent that a statement contained in this prospectus, or in any subsequently filed document that also is deemed to be incorporated by reference in this prospectus, modifies, supersedes or replaces such statement. Any statement so modified, superseded or replaced shall not be deemed, except as so modified, superseded or replaced, to constitute a part of this prospectus. None of the information that we disclose under Items 2.02 or 7.01 of any Current Report on Form 8-K or any corresponding information, either furnished under Item 9.01 or included as an exhibit therein, that we may from time to time furnish to the Commission will be incorporated by reference into, or otherwise included in, this prospectus, except as otherwise expressly set forth in the relevant document. Subject to the foregoing, all information appearing in this prospectus is qualified in its entirety by the information appearing in the documents incorporated by reference.

You may request, orally or in writing, a copy of these documents, which will be provided to you at no cost (other than exhibits, unless such exhibits are specifically incorporated by reference), by contacting Dr. Amit Kumar, c/o Anixa Biosciences, Inc., at 3150 Almaden Expressway, Suite 250, San Jose, CA 95118. Our telephone number is (408) 708-9808. Information about us is also available at our website at <http://www.anixa.com>. However, the information in our website is not a part of this prospectus and is not incorporated by reference.

Item 4. Description of Securities

Not applicable.

Item 5. Interests of Named Experts and Counsel

Not applicable.

Item 6. Indemnification of Officers and Directors

Section 145 of the DGCL inter alia, empowers a Delaware corporation to indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding (other than an action by or in the right of the corporation) by reason of the fact that such person is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation or other enterprise, against expenses (including attorneys’ fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by him in connection with such action, suit or proceeding if he acted in good faith and in a manner he reasonably believed to be in or not opposed to the best interests of the corporation, and, with respect to any criminal action or proceeding, had no reasonable cause to believe his conduct was unlawful. Similar indemnity is authorized for such persons against expenses (including attorneys’ fees) actually and reasonably incurred in connection with the defense or settlement of any such threatened, pending or completed action or suit if such person acted in good faith and in a manner he reasonably believed to be in or not opposed to the best interests of the corporation, and provided further that (unless a court of competent jurisdiction otherwise provides) such person shall not have been adjudged liable to the corporation. Any such indemnification may be made only as authorized in each specific case upon a determination by the stockholders or disinterested directors or by independent legal counsel in a written opinion that indemnification is proper because the indemnitee has met the applicable standard of conduct.

Section 145 further authorizes a corporation to purchase and maintain insurance on behalf of any person who is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation or enterprise, against any liability asserted against him and incurred by him in any such capacity, or arising out of his status as such, whether or not the corporation would otherwise have the power to indemnify him under Section 145. We maintain policies insuring our officers and directors against certain liabilities for actions taken in such capacities, including liabilities under the Securities Act.

Section 102(b)(7) of the DGCL permits a corporation to include in its certificate of incorporation a provision eliminating or limiting the personal liability of a director to the corporation or its shareholders for monetary damages for breach of fiduciary duty as a director, provided that such provision shall not eliminate or limit the liability of a director (i) for any breach of the director's duty of loyalty to the corporation or its stockholders, (ii) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (iii) under Section 174 of the DGCL (relating to unlawful payment of dividends and unlawful stock purchase or redemption) or (iv) for any transaction from which the director derived an improper personal benefit.

Article 10 of the bylaws of the Company contains provisions which are designed to provide mandatory indemnification of directors and officers of the Company to the full extent permitted by law, as now in effect or later amended. The bylaws further provide that, if and to the extent required by the DGCL, an advance payment of expenses to a director or officer of the Company that is entitled to indemnification will only be made upon delivery to the Company of an undertaking, by or on behalf of the director or officer, to repay all amounts so advanced if it is ultimately determined that such director is not entitled to indemnification.

Item 7. Exemption from Registration Claimed

Not applicable.

Item 8. Exhibits

The following exhibits are filed with this Registration Statement.

Number	Description
4.1	2010 Share Incentive Plan. (Incorporated by reference to Exhibit 10.1 to our Form 8-K, dated July 20, 2010.)
4.2	Amendment No. 1 to the 2010 Share Incentive Plan. (Incorporated by reference to Exhibit 10.1 to our Form 8-K, dated July 7, 2011.)
4.3	Amendment No. 2 to the 2010 Share Incentive Plan. (Incorporated by reference to Exhibit 10.1 to our Form 8-K, dated September 5, 2012.)
4.4	Amendment No. 3 to the 2010 Share Incentive Plan (Incorporated by reference to Exhibit 10.1 to our Form 10-Q for the fiscal quarter ended January 31, 2014.)
4.5	Form of Time Based Stock Option Award Agreement (Incorporated by reference to Exhibit 4.13 to our Form S-8 dated October 12, 2012.)
4.6	Form of Time Based Stock Option Award Agreement (Incorporated by reference to Exhibit 4.14 to our Form S-8 dated October 12, 2012.)
4.7	Form of Performance Based Stock Option Award Agreement (Portions of Section 12 of this exhibit have been redacted and filed separately with the Commission in accordance with a request for confidential treatment, dated October 12, 2012, pursuant to Rule 406 under the Securities Act of 1933, as amended.) (Incorporated by reference to Exhibit 4.15 to our Form S-8 dated October 12, 2012.)
4.8	Form of Stock Option Agreement under the 2010 Share Incentive Plan (time based vesting for employee participants). (Incorporated by reference to Exhibit 4.16 to our Form S-8 dated October 12, 2012.)
4.9	Form of Stock Option Agreement under the 2010 Share Incentive Plan (for employee participants). (Incorporated by reference to Exhibit 10.2 to our Form 8-K dated July 20, 2010.)
4.10	Form of Stock Option Agreement under the 2010 Share Incentive Plan (for director participants). (Incorporated by reference to Exhibit 10.3 to our Form 8-K dated July 20, 2010.)
4.11	Form of Stock Award Agreement under the 2010 Share Incentive Plan. (Incorporated by reference to Exhibit 10.4 to our Form 8-K dated July 20, 2010.)
4.12	Form of Time Based Stock Option Award Agreement (Incorporated by reference to Exhibit 4.21 to our Form S-8 dated March 3, 2015.)
4.13	2018 Share Incentive Plan (Incorporated by reference to Exhibit 4.13 of our Registration Statement on Form S-8 filed on October 1, 2018.)
4.14	Form of Stock Option Agreement (Incorporated by reference to Exhibit 4.14 of our Registration Statement on Form S-8 filed on October 1, 2018.)
4.15	Form of Restricted Stock Award (Incorporated by reference to Exhibit 4.15 of our Registration Statement on Form S-8 filed on October 1, 2018.)
4.16	Employee Stock Purchase Plan (Incorporated by reference to Exhibit 4.16 of our Registration Statement on Form S-8 filed on October 1, 2018.)
5.1	Opinion of Ellenoff Grossman & Schole LLP (Filed herewith)
5.2	Opinion of Ellenoff Grossman & Schole LLP (Incorporated by reference to Exhibit 5.1 of our Registration Statement on Form S-8 filed on January 7, 2021.)
5.3	Opinion of Ellenoff Grossman & Schole LLP (Incorporated by reference to Exhibit 5.1 of our Registration Statement on Form S-8 filed on October 1, 2018.)
5.4	Opinion of Ellenoff Grossman & Schole LLP (Incorporated by reference to Exhibit 5.1 of our Registration Statement on Form S-8 filed on February 14, 2018.)

- 5.5 [Opinion of Ellenoff Grossman & Schole LLP \(Incorporated by reference to Exhibit 5.1 of our Registration Statement on Form S-8 filed on March 3, 2015.\)](#)
- 5.6 [Opinion of Duane Morris LLP \(Incorporated by reference to Exhibit 5.1 of our Registration Statement on Form S-8 filed on October 12, 2012.\)](#)
- 5.7 [Opinion of Duane Morris LLP \(Incorporated by reference to Exhibit 5.1 of our Registration Statement on Form S-8 filed on July 7, 2011.\)](#)
- 5.8 [Opinion of Duane Morris LLP \(Incorporated by reference to Exhibit 5.1 of our Registration Statement on Form S-8 filed on July 20, 2010.\)](#)
- 23.1 [Consent of Haskell & White LLP \(Filed herewith.\)](#)
- 23.2 [Consent of Ellenoff Grossman & Schole LLP \(included in Exhibit 5.1\)](#)
- 24 [Powers of Attorney \(included on signature page\)](#)
- 107 [Calculation of Filing Fee Table \(Filed herewith.\)](#)

Item 9. Undertakings.

(a) The undersigned registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement

(i) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement.

(2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(4) That prior to any public reoffering of the securities registered hereunder through use of a prospectus which is a part of this registration statement, by any person or party who is deemed to be an underwriter within the meaning of Rule 145(c), such reoffering prospectus will contain the information called for by the applicable registration form with respect to reofferings by persons who may be deemed underwriters, in addition to the information called for by the other items of the applicable form.

(5) That every prospectus (i) that is filed pursuant to paragraph (4) immediately preceding, or (ii) that purports to meet the requirements of Section 10(a)(3) of the Securities Act of 1933 and is used in connection with an offering of securities subject to Rule 415, will be filed as a part of an amendment to the registration statement and will not be used until such amendment is effective, and that, for purposes of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(6) That, for purposes of determining any liability under the Securities Act of 1933, each filing of the registrant's annual report pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(7) To respond to requests for information that is incorporated by reference into the joint proxy statement/prospectus pursuant to Item 4, 10(b), 11 or 13 of this form, within one business day of receipt of such request, and to send the incorporated documents by first class mail or other equally prompt means. This includes information contained in documents filed subsequent to the effective date of the registration statement through the date of responding to the request.

(8) To supply by means of a post-effective amendment all information concerning a transaction, and the company being acquired involved therein, that was not the subject of and included in the registration statement when it became effective.

(b) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

(c) The undersigned registrant hereby undertakes that, for purposes of determining any liability under the Securities Act of 1933, each filing of the registrant's annual report pursuant to section 13(a) or section 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan's annual report pursuant to section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-8 and has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, on January 4, 2023.

ANIXA BIOSCIENCES, INC.

By: /s/ Dr. Amit Kumar
Dr. Amit Kumar
Chairman and Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Dr. Amit Kumar his true and lawful attorney-in-fact, with full power of substitution and resubstitution for him and in his name, place and stead, in any and all capacities to sign any and all amendments including post-effective amendments to this registration statement, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Commission, hereby ratifying and confirming all that said attorney-in-fact or his substitute, each acting alone, may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Act of 1933, as amended, this Registration Statement has been signed by the following persons in the capacities and on the dates indicated.

By: /s/ Dr. Amit Kumar January 4, 2023
Dr. Amit Kumar
Chief Executive Officer and Chairman of the Board
(Principal Executive Officer)

By: /s/ Michael J. Catelani January 4, 2023
Michael J. Catelani
President, Chief Financial Officer and Chief Operating Officer
(Principal Financial and Accounting Officer)

By: /s/ Lewis H. Titterton Jr. January 4, 2023
Lewis H. Titterton Jr.
Director

By: /s/ Dr. Arnold Baskies January 4, 2023
Dr. Arnold Baskies
Director

By: /s/ Emily Gottschalk January 4, 2023
Emily Gottschalk
Director

ELLENOFF GROSSMAN & SCHOLE LLP
1345 Avenue of the Americas, 11th Floor
New York, New York 10105
Telephone: (212) 370-1000 Facsimile: (212) 370-7889
www.egslp.com

January 4, 2023

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

Re: Registration Statement on Form S-8

Ladies and Gentlemen:

We have acted as counsel to Anixa Biosciences, Inc. (the “Company”) in connection with the preparation of the Company’s Registration Statement on Form S-8 (the “Registration Statement”) being filed with the Securities and Exchange Commission under the Securities Act of 1933, as amended (the “Securities Act”). The Registration Statement has been filed to (i) register 1,394,866 shares (the “Plan Shares”) of common stock, par value \$0.01 per share (the “Common Stock”), issuable pursuant to the Company’s 2018 Share Incentive Plan (the “2018 Plan”), (ii) serve as a post-effective amendment, pursuant to Rule 429 under the Securities Act, to the Company’s Registration Statement on Form S-8 (File No. 333-261999) filed on January 4, 2022, to the Company’s Registration Statement on Form S-8 (File No. 333-251942) filed on January 7, 2021, the Company’s Registration Statement on Form S-8 (File No. 333-227653) filed on October 1, 2018, the Company’s Registration Statement on Form S-8 (File No. 333-223040) filed on February 14, 2018, the Company’s Registration Statement on Form S-8 (File No. 333-202473) filed on March 3, 2015, the Company’s Registration Statement on Form S-8 (File No. 333-184410) filed on October 12, 2012, the Company’s Registration Statement on Form S-8 (File No. 333-175392) filed on July 7, 2011, and the Company’s Registration Statement on Form S-8 (File No. 333-168223) filed on July 20, 2010, and (iii) register for resale up to 11,548,227 shares of Common Stock (collectively, the “Resale Shares”), issued or issuable pursuant to the exercise of options granted pursuant to the 2018 Plan, the Company’s 2010 Share Incentive Plan, as amended (the “2010 Plan”) and the purchase of shares pursuant to the Employee Stock Purchase Plan (the “ESPP”), such Resale Shares or related awards being held by the executive officers and directors of the Company.

In arriving at the opinion expressed below, we have examined and relied on the following documents:

- (1) the Certificate of Incorporation and the Amended and Restated Bylaws of the Company, each as amended as of the date hereof;
- (2) the 2018 Plan, the ESPP, and the 2010 Plan; and
- (3) records of meetings and consents of the Board of Directors of the Company provided to us by the Company.

In addition, we have examined and relied on the originals or copies certified or otherwise identified to our satisfaction of all such corporate records of the Company and such other instruments and other certificates of public officials, officers and representatives of the Company and such other persons, and we have made such investigations of law, as we have deemed appropriate as a basis for the opinion expressed below. In such examination, we have assumed, without independent verification, the genuineness of all signatures (whether original or photostatic), the accuracy and completeness of each document submitted to us, the authenticity of all documents submitted to us as originals, the conformity to original documents of all documents submitted to us as facsimile, electronic, certified, conformed or photostatic copies thereof. We have further assumed the legal capacity of natural persons, that persons identified to us as officers of the Company are actually serving in such capacity, that the representations of officers and employees of the Company are correct as to questions of fact and that each party to the documents we have examined or relied on (other than the Company) has the power, corporate or other, to enter into and perform all obligations thereunder and also have assumed the due authorization by all requisite action, corporate or other, of the execution and delivery by such parties of such documents, and the validity and binding effect thereon on such parties. We have also assumed that the Company will not in the future issue or otherwise make available so many shares of its Common Stock that there are insufficient authorized and unissued shares of Common Stock for issuance of the shares issuable upon exercise of the options being registered in the Registration Statement. We have not independently verified any of these assumptions.

The opinions expressed in this opinion letter are limited to the General Corporation Law of the State of Delaware. We are not opining on, and we assume no responsibility for, the applicability or effect on any of the matters covered herein of: (a) any other laws; (b) the laws of any other jurisdiction; or (c) the laws of any country, municipality or other political subdivision or local government agency or authority. The opinions set forth below are rendered as of the date of this opinion letter. We assume no obligation to update or supplement such opinions to reflect any change of law or fact that may occur.

Based upon and subject to the foregoing, it is our opinion that the Plan Shares have been duly authorized and, upon issuance and payment therefor in accordance with the terms of the 2018 Plan, and the awards, agreements or certificates issued thereunder, will be validly issued, fully paid and nonassessable.

We hereby consent to the filing of this opinion as an exhibit to the Registration Statement. In giving such consent, we do not thereby admit that we are experts with respect to any part of the Registration Statement within the meaning of the term "expert" as used in Section 11 of the Securities Act or the rules and regulations promulgated thereunder by the Securities and Exchange Commission, nor do we admit that we are within the category of persons whose consent is required under Section 7 of the Securities Act or the rules and regulations of the Securities and Exchange Commission promulgated thereunder.

Very truly yours,

/s/ Ellenoff Grossman & Schole LLP
ELLENOFF GROSSMAN & SCHOLE LLP

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in this Registration Statement on Form S-8 of Anixa Biosciences, Inc. (the "Company") of our report dated January 4, 2023 relating to our audits of the Company's consolidated financial statements as of October 31, 2022 and 2021, and for each of the years in the two year period ended October 31, 2022, included in the Company's Annual Report on Form 10-K for the fiscal year ended October 31, 2022. We also consent to the reference to us under the heading "Experts" in this Registration Statement.

/s/ Haskell & White LLP
HASKELL & WHITE LLP

Irvine, California
January 4, 2023

Calculation of Filing Fee Tables

Form S-8
(Form Type)Anixa Biosciences, Inc.
(Exact Name of Registrant as Specified in its Charter)

Table 1: Newly Registered Securities

Security Type	Security Class Title	Fee Calculation Rule	Amount Registered ⁽¹⁾	Proposed Maximum Offering Price Per Share	Maximum Aggregate Offering Price	Fee Rate	Amount of Registration Fee
Equity	Common Stock	Other	1,394,866 ⁽²⁾	\$ 4.20 ⁽³⁾	\$ 5,858,437.20	0.00011020	\$ 645.60
Equity	Common Stock	Other	15,759,267 ⁽⁴⁾	-	-	-	-
Total Offering Amounts					N/A		\$
Total Fee Offsets							\$ -
Net Fee Due							\$ 645.60

- (1) Pursuant to Rule 416 under the Securities Act of 1933, as amended (the “Securities Act”), this Registration Statement on Form S-8 shall also cover any additional shares of the Registrant’s common stock that become issuable in respect of the securities identified in the above table by reason of any stock dividend, stock split, recapitalization or other similar transaction effected without the Registrant’s receipt of consideration which results in an increase in the number of the outstanding shares of the Registrant’s common stock. In addition, this Registration Statement covers the resale by certain selling stockholders named in the prospectus included in and filed with this Registration Statement of certain of the shares of Registrant’s common stock subject to this Registration Statement, for which no additional registration fee is required pursuant to Rule 457(h)(3).
- (2) Shares of common stock represents the number of additional shares available for issuance pursuant to the Anixa Biosciences, Inc. 2018 Share Incentive Plan (the “2018 Plan”) pursuant to the evergreen provision of such plan for the fiscal year 2023.
- (3) Estimated solely for the purpose of calculating the registration fee pursuant to Rules 457(c) and 457(h) of the Securities Act, based on \$4.20, the average of the high and low sales price of a share of Common Stock as reported on Nasdaq on January 3, 2023.
- (4) Shares of common stock issuable pursuant to the 2018 Plan, the Company’s Employee Stock Purchase Plan (the “ESPP”), and the Company’s 2010 Share Incentive Plan, as amended (the “2010 Plan”) have been previously registered on registration statements on Form S-8 (File Nos. 333-261999, 333-251942, 333-223040, 333-202473, 333-184410, 333-175392, 333-168223 and 333-227653) (collectively, the “Prior Registration Statements”). As described in more detail in the Explanatory Note, pursuant to Rule 429 under the Securities Act this Registration Statement is deemed to be a post-effective amendment to the Prior Registration Statements.