

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

FORM 10-K

ANNUAL REPORT UNDER SECTION 13 OR 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934

FOR THE FISCAL YEAR ENDED OCTOBER 31, 2022

OR

TRANSITION REPORT UNDER SECTION 13 OR 15 (d)
OF THE SECURITIES EXCHANGE ACT OF 1934

FOR THE TRANSITION PERIOD FROM _____ TO _____

COMMISSION FILE NUMBER 001-36138

AYALA PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of
incorporation or organization)

9 Deer Park Drive, Suite K-1, Monmouth Junction, NJ

(Address of principal executive offices)

02-0563870

(IRS Employer
Identification No.)

08852

(Zip Code)

(609) 452-9813

(Registrant's telephone number)

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

Securities registered pursuant to Section 12(g) of the Act.

Common Stock, par value \$0.001 per share

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act.

Yes No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files).

Yes No

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

Large Accelerated Filer

Non-accelerated Filer

Emerging growth company

Accelerated Filer

Smaller Reporting Company

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

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

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements.

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes No

As of April 29, 2022, the aggregate market value of the voting common equity held by non-affiliates was approximately \$11,863,538 based on the closing bid price of the registrant's common stock on the -OTCQX ® Best Market (For purposes of determining this amount, only directors, executive officers, and 10% or greater shareholders and their respective affiliates have been deemed affiliates).

The registrant had 4,838,321 shares of common stock, par value \$0.001 per share, outstanding as of January 31, 2023.

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PART I

INTRODUCTORY NOTE REGARDING RECENT DEVELOPMENTS

On October 18, 2022, the Registrant entered into an Agreement and Plan of Merger (the “Merger Agreement”), by and among the Registrant, Old Ayala, Inc. (f/k/a Ayala Pharmaceuticals, Inc.), a Delaware corporation (“Old Ayala”), and Doe Merger Sub, Inc. (“Merger Sub”), a Delaware corporation and a wholly-owned subsidiary of Advaxis, Inc. (“New Ayala”). On January 19, 2023 (the “Closing Date”), pursuant to the Merger Agreement, Merger Sub merged with and into Old Ayala, with Old Ayala continuing as the surviving company and a wholly-owned subsidiary of the Registrant (the “Merger”).

The Merger Agreement and additional information on the details of the Merger may be found in the Current Report on Form 8-K filed with the Securities and Exchange Commission (“SEC”) by the Registrant on October 19, 2022.

At the effective time of the Merger (the “Effective Time”), (i) each share of the common stock, par value \$0.01 per share, of Old Ayala (the “Old Ayala Common Stock”) issued and outstanding immediately prior to the Merger was automatically converted into the right to receive 0.1874 shares (the “Exchange Ratio”) of the common stock, par value \$0.001 per share, of the Registrant (the “New Ayala Common Stock”), (ii) each outstanding option to purchase shares of the Old Ayala Common Stock (each, an “Old Ayala Option”) was substituted and converted automatically into an option (each, an “New Ayala Replacement Option”) to purchase the number of shares of New Ayala Common Stock equal to the product obtained by multiplying (a) the number of shares of Old Ayala Common Stock subject to such Old Ayala Option immediately prior to the effective time of the Merger, by (b) the Exchange Ratio, with any fractional shares rounded down to the nearest whole share, with each such New Ayala Replacement Option to have an exercise price per share of New Ayala Common Stock equal to (x) the per share exercise price for the shares of Old Ayala Common Stock subject to the corresponding Old Ayala Option immediately prior to the effective time of the Merger, divided by (y) the Exchange Ratio, rounded up to the nearest whole cent, and (iii) each restricted stock unit of Old Ayala (each, an “Old Ayala RSU”) outstanding immediately prior to the effective time of the Merger, whether or not vested or issuable, was substituted and converted automatically into a restricted stock unit award of New Ayala with respect to a number of shares of New Ayala Common Stock equal to the product obtained by multiplying (a) the total number of shares of Old Ayala Common Stock subject to such Old Ayala RSU immediately prior to the effective time of the Merger by (b) the Exchange Ratio, with any fractional shares rounded down to the nearest whole share.

The issuance of New Ayala Common Stock in connection with the Merger Agreement was registered under the Securities Act of 1933, as amended, pursuant to The Registrant’s registration statement on Form S-4 (Registration No. 333-268586) declared effective by the SEC on December 12, 2022 (the “Registration Statement”). The proxy statement/prospectus in the Registration Statement contains additional information about the Merger.

As a result of the consummation of the Merger, Old Ayala, the surviving entity in the Merger, became a wholly-owned subsidiary of the Registrant. For accounting purposes, the Merger was treated as a “reverse acquisition” and Old Ayala was considered the accounting acquirer. Accordingly, Old Ayala will be reflected as the predecessor and acquirer in the financial statements of the Registrant (the legal acquirer) for periods ending after December 31, 2022. The Registrant’s historical financial condition and results of operations shown for comparative purposes in future periodic filings will reflect Old Ayala’s historical results.

FORWARD LOOKING STATEMENTS

This annual report on Form 10-K (“Form 10-K”) includes statements that are, or may be deemed to be, “forward-looking statements.” In some cases, these forward-looking statements can be identified by the use of forward-looking terminology, including the terms “believes,” “estimates,” “anticipates,” “expects,” “plans,” “intends,” “may,” “could,” “might,” “will,” “should,” “approximately” or, in each case, their negative or other variations thereon or comparable terminology, although not all forward-looking statements contain these words. They appear in a number of places throughout this Form 10-K and include statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things, our ongoing and planned discovery and development of drug candidates, the strength and breadth of our intellectual property, our ongoing and planned preclinical studies and clinical trials, our available cash, liquidity, prospects, growth and strategies, the timing of and our ability to make regulatory filings and obtain and maintain regulatory approvals for our product candidates, the degree of clinical utility of our product candidates, particularly in specific patient populations, expectations regarding clinical trial data, our results of operations, financial condition, impacts of the ongoing conflict in the Ukraine, inflation and the Federal Reserve’s responses thereto, including increasing interest rates, the length of time that we will be able to continue to fund our operating expenses and capital expenditures, our expected financing needs and sources of financing, the industry in which we operate and the trends that may affect our industry or us.

By their nature, forward-looking statements involve risks and uncertainties because they relate to events, competitive dynamics, and healthcare, regulatory and scientific developments and depend on the economic circumstances that may or may not occur in the future or may occur on longer or shorter timelines than anticipated. Although we believe that we have a reasonable basis for each forward-looking statement contained in this Form 10-K, we caution you that forward-looking statements are not guarantees of future performance and that our actual results of operations, financial condition and liquidity, and the development of the industry in which we operate may differ materially from the forward-looking statements contained in this Form 10-K. In addition, even if our results of operations, financial condition and liquidity, and the development of the industry in which we operate are consistent with the forward-looking statements contained in this Form 10-K, they may not be predictive of results or developments in future periods.

Some of the factors that we believe could cause actual results to differ from those anticipated or predicted include:

- the success and timing of our clinical trials, including patient accrual;
- our available cash;
- our ability to obtain and maintain regulatory approval and/or reimbursement of our product candidates for marketing;
- our ability to obtain the appropriate labeling of our products under any regulatory approval;
- our plans to develop and commercialize our products;
- the successful development and implementation of future sales and marketing campaigns;
- the change of key scientific or management personnel;
- the size and growth of the potential markets for our product candidates and our ability to serve those markets;
- our ability to successfully compete in the potential markets for our product candidates, if commercialized;
- regulatory developments in the United States and foreign countries;
- our ability to continue as a going concern;
- the rate and degree of market acceptance of any of our product candidates;
- new products, product candidates or new uses for existing products or technologies introduced or announced by our competitors and the timing of these introductions or announcements;
- market conditions in the pharmaceutical and biotechnology sectors;
- the accuracy of our estimates regarding expenses, future revenues, capital requirements and needs for additional financing;
- our ability to obtain additional funding;
- any outcomes from our review of strategic transactions and options to maximize stockholder value;

- *the ability of our product candidates to successfully perform in clinical trials and to resolve any clinical holds that may occur;*
- *our ability to obtain and maintain approval of our product candidates for trial initiation;*
- *the performance of third-party manufacturers;*
- *our ability to identify license and collaboration partners and to maintain existing relationships;*
- *the performance of our clinical research organizations, clinical trial sponsors and clinical trial investigators, and collaboration partners for any clinical trials we conduct;*
- *our ability to successfully implement our strategy; and*
- *our ability to maintain the listing of our common stock on the OTCQX® Best Market (“OTCQX”).*

Any forward-looking statements that we make in this Form 10-K speak only as of the date of such statement, and we undertake no obligation to update such statements to reflect events or circumstances after the date of this Form 10-K. You should also read carefully the factors described in the “Risk Factors” section of this Form 10-K to better understand the risks and uncertainties inherent in our business and underlying any forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this Form 10-K will prove to be accurate.

This Form 10-K includes statistical and other industry and market data that we obtained from industry publications and research, surveys and studies conducted by third-parties. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. While we believe these industry publications and third-party research, surveys and studies are reliable, we have not independently verified such data.

We qualify all of our forward-looking statements by these cautionary statements. In addition, with respect to all of our forward-looking statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995.

In this Form 10-K, unless otherwise stated or the context otherwise indicates, references to “New Ayala,” “Advaxis,” the “Company,” “we,” “us,” “our” and similar references refer to Ayala Pharmaceuticals, Inc., a Delaware corporation, which prior to the change of its name effected on January 19, 2023 was known as Advaxis, Inc.

Item 1. Business.

Introductory Note

The following discussion relates to the business of New Ayala as it existed prior to the Merger. Following the Merger, New Ayala has combined such existing business and the business of Old Ayala. In accordance with Rule 12b-23 under the Securities Exchange Act of 1934, as amended (the “Exchange Act”), we are incorporating into this Item 1 the description of the business of Old Ayala set forth in pages 233-273 of the Definitive Proxy Statement of Old Ayala for the Special Meeting of Stockholders of Old Ayala held on January 13, 2023, which was filed with the Commission on December 12, 2022 and which pages are set forth on Exhibit 99.1 to this Annual Report on Form 10-K.

General

Prior to the Merger, New Ayala was a clinical-stage biotechnology company that was focused on the development and commercialization of proprietary *Listeria monocytogenes*, or *Lm*, Technology antigen delivery products based on a platform technology that utilizes live attenuated *Lm* bioengineered to secrete antigen/adjuvant fusion proteins. These *Lm*-based strains are believed to be a significant advancement in immunotherapy as they integrate multiple functions into a single immunotherapy and are designed to access and direct antigen presenting cells to stimulate anti-tumor T cell immunity, activate the immune system with the equivalent of multiple adjuvants, and simultaneously reduce tumor protection in the Tumor Microenvironment, or TME, to enable T cells to eliminate tumors. The Company believes that *Lm* Technology immunotherapies can complement and address significant unmet needs in the current oncology treatment landscape. Specifically, the Company's product candidates have the potential to optimize the clinical impact of checkpoint inhibitors while having a generally well-tolerated safety profile. The Company's passion for the clinical potential of *Lm* Technology is balanced by focus and fiscal discipline which is directed towards improving treatment options for cancer patients and increasing shareholder value.

Prior to the Merger, New Ayala was focused on multiple antigen delivery products which are in various stages of clinical development. All of the Company's products are anchored in the Company's *Lm* TechnologyTM, a unique platform designed for its ability to target various cancers in multiple ways. As an intracellular bacterium, *Lm* is an effective vector for the presentation of antigens through both the Major Histocompatibility Complex, or MHC, I and II pathways, due to its active phagocytosis by Antigen Presenting Cells, or APCs. Within the APCs, *Lm* produces virulence factors which allow survival in the host cytosol and potently stimulate the immune system.

Through a license from the University of Pennsylvania and through its own development efforts, New Ayala has exclusive access to a proprietary formulation of attenuated *Lm* that is called *Lm* Technology. *Lm* Technology is designed to optimize this natural system, and one of the keys to the enhanced immunogenicity of *Lm* Technology is the *tLLO*-fusion protein, which is made up of tumor associated antigen, or TAA, fused to a highly immunogenic bacterial protein that triggers potent cellular immunity. The *tLLO*-fusion protein is also designed to help reduce immune tolerance in the TME and to promote antigen spreading, thereby improving activity in the TME. Multiple copies of the *tLLO*-fusion protein within each construct may increase antigen presentation and TME impact.

As the field of immunotherapy continues to evolve, the flexibility of the *Lm* Technology platform allowed New Ayala to develop highly innovative products. To date, *Lm* Technology has demonstrated preclinical synergy with multiple checkpoint inhibitors, co-stimulatory agents and radiation therapy. The safety profile of all *Lm* Technology constructs seen to date across over 470 patients has been generally predictable and manageable, consisting mostly of mild to moderate flu-like symptoms that have been transient and associated with infusion.

The New Ayala Corporate Strategy and Strategic Considerations

Prior to the Merger, New Ayala's strategy was to advance the *Lm* Technology platform and leverage its unique capabilities to design and develop an array of cancer treatments. We are currently conducting clinical studies of *Lm* Technology immunotherapies in early prostate cancer. We identified and worked with collaborators and potential licensees for these programs and others for first-generation *Lm* immunotherapies like ADXS-HPV for HPV-associated cancer and ADXS-HER-2 for pediatric osteosarcoma.

New Ayala mainly concentrated on its disease-focused, hotspot/"off-the-shelf" neoantigen-directed therapies called ADXS-HOT. ADXS-HOT is a program that leverages the Company's proprietary *Lm* technology to target hotspot mutations that commonly occur in specific cancer types. ADXS-HOT drug candidates are designed to target acquired shared or "public" mutations in tumor driver genes along with other cancer-associated antigens that also commonly occur in specific cancer types.

Prior to the Merger, New Ayala expected to continue investing exclusively in the HOT construct ADXS-504 in early prostate cancer through an ongoing Investigator Sponsored Trial (IST) at Columbia University in NYC. The study with ADXS-503 immunotherapy in non-small cell lung cancer was stopped due to the difficulty in enrolling additional patients. The *Lm* Technology platform is protected by a range of patents, covering both product and process, some of which we believe can be maintained into 2039.

In October 2022, we announced that we had entered into the Merger Agreement with Old Ayala, pursuant to which Old Ayala is to merge with and into Merger Sub, a direct, wholly-owned subsidiary of Old Ayala, with New Ayala continuing as the surviving company and a wholly-owned subsidiary of the Merger. The Merger closed on January 19, 2023.

Lm Technology and the Immunotherapy Landscape

The challenge of cancer immunotherapy has been to find the best overall balance between efficacy and side effects when mobilizing the body's immune system to fight against cancer. The development of immune checkpoint inhibitors was a significant step forward, particularly with anti-PD-1 therapies, and brought with it impressive clinical activity in many different types of cancers, including melanoma, lung, head and neck and urothelial cancers. However, a literature review published in *Science* in 2018 noted that anti-PD-1 monotherapy response rates are only in the 15-25% range, and rise to $\geq 50\%$ only in selected groups of patients with desmoplastic melanoma, Merkel carcinoma or tumors with mismatch-repair deficiency. Development of secondary resistance with disease progression is yet another common limitation of these therapies. Therefore, for most cancer patients, there is room for improvement. Checkpoint inhibitors can expand existing cancer fighting cells that may already be present in low numbers and support their activity against cancer cells, but if the right cancer-fighting cells are not present, checkpoint inhibitors may not provide clinical benefit. Similarly, there are many mechanisms of immune tolerance that are distinct from the checkpoints which may also be blocking the immune system from fighting cancer. Based on both pre-clinical and early clinical data, New Ayala believes that checkpoint inhibitors, when combined with treatments such as *Lm* Technology, can have an amplified anti-tumor effect. *Lm* Technology incorporates several complementary elements that include innate immune stimulation, potent generation of cancer-targeted T cells, ability to boost immunity through multiple treatments, enhancing lymphocyte infiltration into tumors, reduction of non-checkpoint mediated immune tolerance within the tumor microenvironment, and promotion of antigen spreading which may amplify the effects of treatment. These results provide rationale for further testing of *Lm* Technology agents alone and in combination with checkpoint inhibitors.

Traditional cancer vaccines were another development within immunotherapy and have a history beginning over 30 years ago. Unfortunately, these vaccines have largely been unsuccessful for a variety of potential reasons. These include poor selection of targets, imbalanced antigen presentation by inclusion of certain immune enhancing agents (adjuvants), failure to consider the blocking actions of immune tolerance, and choice of vaccine vectors. In some cases, patients may develop neutralizing antibodies, preventing further treatments. In contrast to traditional cancer vaccines, *Lm* Technology takes advantage of a natural pathway in the immune system that evolved to protect us against *Listeria* infections, that also happens to generate the same type of immunity that is required when fighting cancer. The live but weakened (attenuated) bacteria stimulate a balanced concert of innate immune triggers and present the tumor antigen target precisely where it needs to be able to generate potent cancer fighting cells from within the immune system itself. The multitude of accompanying signals serves to broadly mobilize most of the immune system in support of fighting what seems to be a *Listeria* infection, and is then "re-directed" against cancer cell targets. Additionally, the unique intracellular lifecycle of *Listeria* avoids the creation of neutralizing antibodies, thereby allowing for repeat administration as a chronic therapy with a sustained enhancing of tumor antigen-specific T cell immunity.

Looking back on the last two decades, there have been promising technology advancements to harness and activate killer T cells against cancers and every day more is learned about the interplay between immunity and cancer that can lead to improved treatments. However, there are still significant unmet needs in the immunotherapy landscape that New Ayala, feels *Lm* Technology may be able to address and complement. Specifically, *Lm* Technology has the potential to optimize and expand checkpoint inhibitor activity in combination. It also avoids many of the limitations of previous cancer vaccine attempts by tapping into the pathway reserved for defense against *Listeria* infection while incorporating the best cancer targets science can identify, including neoantigens that result from mutations in the cancer. Moreover, these immunotherapies could be effectively used as adjuvant therapies for patients who have had clinical response to radical therapy, in order to prevent emergence of new metastases and disease progression. To date, *Lm* Technology products have a manageable safety profile, do not generate neutralizing antibodies lending themselves to retreatments, and most of the products are designed to be immediately available for treatment without the complication and expense of modifying a patient's own cells in a laboratory.

***Lm* Technology: An optimized *Listeria* -based antigen delivery system**

New Ayala's *Listeria* -based immunotherapies are designed for antigen delivery through a process of insertion of multiple copies of the proprietary *tLLO*-fusion protein into each extrachromosomal protein expression and secretion plasmid that makes and secretes the target protein right inside the patient's antigen presenting cells to initiate and/or boost their immune response. The *tLLO*-fusion protein approach was developed at the University of Pennsylvania as an improvement over insertion of a single copy of the target gene, as an ACT-A (or other *Lm* peptide) fusion, within the bacterial genome for four key reasons:

1. Multiple copies of the DNA in the plasmids per bacteria can result in larger amounts of *tLLO* -fusion protein being expressed simultaneously, versus a single copy. This is designed to improve antigen presentation and immunologic priming and increases the number of T cells generated for a particular treatment.

2. *tLLO* expressed on plasmids (with or without a tumor target protein attached) has been shown preclinically to reduce numbers and immune suppressive function of Tregs and myeloid-derived suppressor cells, or MDSCs, in the tumor microenvironment. Presented preclinical data demonstrates that Tregs are destroyed as soon as five days after the first *Lm* Technology treatment and that suppressive M2 tumor-associated macrophages, or TAMs, are replaced by M1 macrophages which support antigen presentation and adoptive immunity.
3. The extrachromosomal DNA plasmids themselves also contain CpG sequence patterns that trigger TLR-9, which confers additional innate immune stimulation beyond a *Listeria* without the plasmids.
4. The multiple copies of bacterial DNA plasmids (up to 80-100 per bacteria) confers additional stimulation of the STING receptor within APC's which has been associated with enhancing anti-cancer immunity in patients.

Clinical Pipeline

Prior to the Merger, New Ayala was focused on the development and commercialization of proprietary *Lm* Technology antigen delivery products. New Ayala is currently winding down or has wound down clinical studies of *Lm* Technology immunotherapies in four program areas:

- Non-small cell lung cancer (ADXS-503)
- Human Papilloma Virus ("HPV")-associated cancers
- Personalized neoantigen-directed therapies
- Human epidermal growth factor receptor-2 (HER-2) associated cancers

All these clinical program areas are anchored in the Company's *Lm* Technology™, a unique platform designed for its ability to safely and effectively target various cancers in multiple ways. The Phase 1/2 study with ADXS-PSA ± pembrolizumab in metastatic castration-resistant prostate cancer patients was closed on January 25, 2021. The MEDI Phase 2 combo study (AZ) with AXAL ± durvalumab in Cervical and Head and Neck Cancer and the AIM2CERV Phase 3 clinical trial with ADXS-HPV (AXAL) in cervical cancer were closed on August 22, 2019 and June 11, 2021, respectively. The study with personalized neoantigen-directed therapies (ADXS-NEO) was closed on May 22, 2020 and the NEO program-IND inactivation request was submitted to the FDA on May 10, 2021. On October 18, 2022, New Ayala announced that it would begin the orderly wind down of its ADXS-503 product in the 4Q 2022 to focus primarily on the Old Ayala product line and its other products.

While we are currently winding down clinical studies of *Lm* Technology immunotherapies in these program areas, our license agreements continue with OS Therapies, LLC, for ADXS-HER2, and with GBP for the exclusive license for the development and commercialization of ADXS-HPV or AXAL in Asia, Africa, and the former USSR territory, exclusive of India and certain other countries.

New Ayala Pipeline of Product Candidates

Disease-focused hotspot/off-the-shelf' neoantigen therapies (ADXS-HOT)

Prior to the Merger, New Ayala created a new group of immunotherapy constructs for major solid tumor cancers that combines our optimized *Lm* Technology vector with promising targets designed to generate potent anti-cancer immunity. The ADXS-HOT program is a series of novel cancer immunotherapies that will target somatic mutations, or hotspots; cancer testis antigens, or CTAs; and oncofetal antigens, or OFAs. These three types of targets form the basis of the ADXS-HOT program because they are designed to be more capable of generating potent, tumor-specific, and high-strength killer T cells, versus more traditional over-expressed native sequence tumor associated antigens. Most hotspot mutations and OFA/CTA proteins play critical roles in oncogenesis; targeting both at once could significantly impair cancer proliferation. The ADXS-HOT products will combine many of the potential high avidity targets that are expressed in all patients with the target disease into one "off-the-shelf," ready-to-administer treatment. The ADXS-HOT technology has a strong intellectual property, or IP, position, with potential protection into 2037, and an IP filing strategy provides for broad coverage opportunities across multiple disease platforms and combination therapies. New Ayala entered into an agreement with Columbia University Irving Medical Center in April 2021 to fund a phase 1 clinical study evaluating ADXS-504 in patients with biochemically recurrent prostate cancer. The study started early in 3Q 2021 and was the first clinical evaluation of ADXS-504, New Ayala's off-the-shelf neoantigen immunotherapy drug candidate for early prostate cancer.

Nearly 248,530 men in the United States will be diagnosed with prostate cancer in 2021. It has been estimated that ~135,000 new cases undergo radical prostatectomy (RP) or radiotherapy (RT). Of these cases, 20–40% of pts with RP and 30–50% with RT will experience rising prostate specific antigen (PSA) levels following local therapy (BCR) within 10 years, a condition known as biochemical recurrence (BCR). BCR is not typically associated with imminent death, and biochemical progression may occur over a prolonged period. Clinicians treating men with BCR thus face a difficult set of decisions in attempting to delay the onset of metastatic disease and death while avoiding over-treating patients whose disease may never affect their overall survival or quality of life.

The phase 1 open-label study is evaluating the safety and tolerability of ADXS-504 monotherapy, administered via infusion, in 9-18 patients with biochemically recurrent prostate cancer, i.e., those with elevation of prostate-specific antigen (PSA) in the blood after radical prostatectomy or radical radiotherapy (external beam or brachytherapy) and who are not currently receiving androgen ablation therapy. The study will also evaluate if the body's immune system can control the prostate cancer following treatment with ADXS-504 monotherapy.

HPV-Related Cancers

The Company conducted several studies evaluating axalimogene filolisbac, or AXAL, for HPV-related cancers. AXAL is an *Lm*-based antigen delivery product directed against HPV and designed to target cells expressing HPV.

In June 2019, the Company announced the closing of its AIM2CERV Phase 3 clinical trial with axalimogene filolisbac (AXAL) in high-risk locally advanced cervical cancer. Company estimates showed that the remaining cost to complete the AIM2CERV trial ranged from \$80 million to \$90 million, and initial efficacy data was not anticipated for at least three years. Therefore, results from the clinical trial were not the basis for the decision to close the study, nor was safety as the trial recently underwent its third Independent Data Monitoring Committee (IDMC) review with no safety issues noted. The Company has unblinded the AIM2CERV clinical data generated to date and currently has no plans to present it at any medical conference as the data set is incomplete and inconclusive. The Company's clinical study report of the AIM2CERV Phase 3 study was completed on January 3, 2022 and submitted to the FDA.

In 2014, New Ayala granted Global BioPharma, or GBP, an exclusive license for the development and commercialization of AXAL in Asia, Africa, and the former USSR territory, exclusive of India and certain other countries. GBP is responsible for all development and commercial costs and activities associated with the development in their territories.

Personalized Neoantigen-directed Therapies (ADXS-NEO)

ADXS-NEO is an individualized *Lm* Technology antigen delivery product developed using whole-exome sequencing of a patient's tumor to identify neoantigens. ADXS-NEO is designed to work by presenting a large payload of neoantigens directly into dendritic cells within the patient's immune system and stimulating a T cell response against cancerous cells. In October 2019, the Company announced that it has dosed its last patient in Part A, in monotherapy, and does not intend to continue into Part B, in combination with a checkpoint inhibitor. As a result, New Ayala has closed this study. The Company has completed the clinical study report from Part A of the ADXS-NEO study and the NEO program-IND inactivation request has been submitted to FDA.

Prostate Cancer (ADXS-PSA)

According to the American Cancer Society, prostate cancer is the second most common type of cancer found in American men and is the second leading cause of cancer death in men, behind only lung cancer. More than 160,000 men are estimated to be diagnosed with prostate cancer in 2018, with approximately 30,000 deaths each year. Unfortunately, in about 10-20% of cases, men with prostate cancer will go on to develop castration-resistant prostate cancer, or CRPC, which refers to prostate cancer that progresses despite androgen deprivation therapy. Metastatic CRPC, or mCRPC, occurs when the cancer spreads to other parts of the body and there is a rising prostate-specific antigen, PSA, level. This stage of prostate cancer has an average survival of 9-13 months, is associated with deterioration in quality of life, and has few therapeutic options available.

Recent data regarding checkpoint inhibitor monotherapy has shown some antitumor activity that provides disease control in a subset of patients with bone predominant mCRPC previously treated with next generation hormonal agents and docetaxel. Data from the KEYNOTE-199 trial in bone predominant-mCRPC patients treated with KEYTRUDA®, or pembrolizumab, was updated at the ASCO GU meeting in 2019. In this trial, the total stable disease/disease stabilization rate was 39% with no responses reported so far, and only one patient with $\geq 50\%$ decrease in the post-baseline PSA value. It is hypothesized that the limited activity in mCRPC may be due to 1) the inability of the checkpoint inhibitor to infiltrate the tumor microenvironment and 2) the presence of an immunosuppressive tumor micro-environment, or TME. The combination therapy with agents—like *Lm* constructs—that induce T cell infiltration within the tumor and decrease negative regulators in the TME may improve performance of checkpoints in prostate cancer.

Lm Technology constructs demonstrated the ability to induce anti-tumor T cell responses and T cell infiltration in the TME and to reduce the number and suppressive function of Tregs and MDSCs in the TME. For example, destruction of Tregs in the TME has been documented as soon as five days after dosing *Lm* constructs in models. This reduction of immune suppression in the tumors has been attributed to our proprietary *tLLO*-fusion peptides expressed by multiple copies of the plasmids in each bacteria. Because of all these effects, it is hypothesized that *Lm* constructs can turn “cold prostate tumors” into “hot tumors” that better respond to checkpoint inhibitors. Advaxis believes that the combination of ADXS-PSA, its immunotherapy designed to target the PSA antigen, with a checkpoint inhibitor may provide an alternative treatment option for patients with mCRPC.

New Ayala entered into a clinical trial collaboration and supply agreement with Merck to evaluate the safety and efficacy of ADXS-PSA as monotherapy and in combination with KEYTRUDA®, Merck's anti PD-1 antibody, in a Phase 1/2, open-label, multicenter, dose determination and expansion trial in patients with previously treated metastatic, castration-resistant prostate cancer (KEYNOTE-046). ADXS-PSA was tested alone or in combination with KEYTRUDA in an advanced and heavily pretreated patient population who had progressed on androgen deprivation therapy. A total of 13 and 37 patients were evaluated on monotherapy and combination therapy, respectively. For the ADXS-PSA monotherapy dose escalation and determination portion of the trial, cohorts were started at a dose of 1×10^9 cfu ($n=7$) and successfully escalated to higher dose levels of 5×10^9 cfu ($n=3$) and 1×10^{10} cfu ($n=3$) without achieving a maximum tolerated dose. TEAEs noted at these higher dose levels were generally consistent with those observed at the lower dose level (1×10^9 cfu) other than a higher occurrence rate of Grade 2/3 hypotension. The Recommended Phase II Dose of ADXS-PSA monotherapy was determined to be 1×10^9 cfu based on a review of the totality of the clinical data. This dose was used in combination with 200mg of pembrolizumab in a cohort of six patients to evaluate the safety of the combination before moving into an expanded cohort of patients. The safety of the combination was confirmed and enrollment in the expansion cohort phase was initiated. Enrollment in the study was completed in January 2017.

At the final data cutoff of September 16, 2019, median overall survival for 37 patients in the combination arm was 33.6 months (95% CI, range 15.4-33.6 months). This updated median overall survival is an increase from the previous data presented at the American Association for Cancer Research Annual Meeting in April 2019, where median overall survival was 21.1 months in the combination arm. The combination of ADXS-PSA with KEYTRUDA®, might be associated with prolonged OS in this population, particularly in patients with unmet medical needs like visceral metastasis (16.4 months, range 4.0 - not reached) and those with prior docetaxel (16 months, range 6.4-34.6). The majority of TEAEs consisted of transient and reversible Grade 1-2 chills/rigors, fever, hypotension, nausea and fatigue. The combination of ADXS-PSA and KEYTRUDA® has appeared to be well-tolerated to date, with no additive toxicity observed. The Company presented these new data at the ASCO Genitourinary Cancers Symposium in San Francisco, CA. on February 2020 and the final results were published in the peer-reviewed journal “The Oncologist” in 2022. New Ayala has also completed the clinical study report for the ADXS-PSA study.

Other Lm Technology Products

HER2 Expressing Solid Tumors

HER2 is overexpressed in a percentage of solid tumors including osteosarcoma. According to published literature, up to 60% of osteosarcomas are HER2 positive, and this overexpression is associated with poor outcomes for patients. ADXS-HER2 is an Lm Technology antigen delivery product candidate designed to target HER2 expressing solid tumors including human and canine osteosarcoma. ADXS-HER2 has received FDA and EMA ODD for osteosarcoma and has received Fast Track designation from the FDA for patients with newly-diagnosed, non-metastatic, surgically-resectable osteosarcoma.

A phase 1B dose escalation study of ADXS31-164 in subjects with HER-2 expressing tumors was completed, and the database lock was completed in November 2018. Overall, ADXS31-164 IV infusion at the dose of 1×10^9 CFU appeared to be safe and well tolerated in 12 subjects treated and evaluable. No objective responses were observed in this late stage heavily pre-treated patient cohort. The results of this study were primarily intended to describe the safety and tolerability of ADXS31-164. This study was not intended to contribute to the evaluation of the effectiveness of ADXS31-164 for the treatment of patients with a history of HER2 expressing tumors. New Ayala has completed the clinical study report and it has been transferred along with the ADXS31-164 program-IND to OS Therapies, as described below.

In September 2018, the Company announced that it had granted a license to OS Therapies, LLC, or OS Therapies, for the use of ADXS31-164, also known as ADXS-HER2, for evaluation in the treatment of osteosarcoma in humans. Under the terms of the license agreement, OS Therapies, in collaboration with the Children’s Oncology Group, will be responsible for the conduct and funding of a clinical study evaluating ADXS-HER2 in recurrent, completely resected osteosarcoma. In December 2020 and January 2021, we received an aggregate of \$1,415,000 from OS Therapies upon achievement of the \$1,550,000 funding milestone set forth in the license agreement. In April 2021, the Company achieved the second milestone set forth in the license agreement for evaluation in the treatment of osteosarcoma in humans and received the amount due from OS Therapies of \$1,375,000 in May 2021. For more information, see Note 12, “*Licensing Agreements*” of the “*Notes to the Consolidated Financial Statements*” included in Item 8.

Canine Osteosarcoma

On March 19, 2014, we entered into a definitive Exclusive License Agreement, or Aratana Agreement, with Aratana Therapeutics, Inc., or Aratana, where we granted Aratana an exclusive, worldwide, royalty-bearing license, with the right to sublicense, certain of our proprietary technology that enables Aratana to develop and commercialize animal health products that will be targeted for treatment of osteosarcoma and other cancer indications in animals. A product license request was filed by Aratana for ADXS-HER2 (also known as AT-014 by Aratana) for the treatment of canine osteosarcoma with the United States Department of Agriculture, or USDA. Aratana received communication in December 2017 that the USDA granted Aratana conditional licensure for AT-014 for the treatment of dogs diagnosed with osteosarcoma, one year of age or older. Initially, Aratana plans to make the therapeutic available for purchase at approximately two dozen veterinary oncology practice groups across the United States who participate in the study. Aratana received communication in December 2017 that the USDA granted Aratana conditional licensure for AT-014 for the treatment of dogs diagnosed with osteosarcoma, one year of age or older. Aratana is currently conducting an extended field study which is a requirement for full USDA licensure. Initially, Aratana plans to make the therapeutic available for purchase at approximately two dozen veterinary oncology practice groups across the United States who participate in the study.

Under the terms of the Aratana Agreement, Aratana paid an upfront payment to New Ayala in the amount of \$1,000,000 upon signing of the Aratana Agreement. Aratana will also pay New Ayala: (a) up to \$36.5 million based on the achievement of milestone relating to the advancement of products through the approval process with the USDA in the United States and the relevant regulatory authorities in the European Union, or E.U., in all four therapeutic areas and up to an additional \$15 million in cumulative sales milestones based on achievement of gross sales revenue targets for sales of any and all products for use in non-human animal health applications, or the Aratana Field, (regardless of therapeutic area), and (b) tiered royalties starting at 5% and going up to 10%, which will be paid based on net sales of any and all products (regardless of therapeutic area) in the Aratana Field in the United States. Royalties for sales of products outside of the United States will be paid at a rate equal to half of the royalty rate payable by Aratana on net sales of products in the United States (starting at 2.5% and going up to 5%). Royalties will be payable on a product-by-product and country-by-country basis from first commercial sale of a product in a country until the later of (a) the 10th anniversary of first commercial sale of such product by Aratana, its affiliates or sub licensees in such country or (b) the expiration of the last-to-expire valid claim of our patents or joint patents claiming or covering the composition of matter, formulation or method of use of such product in such country. Aratana will also pay us 50% of all sublicense royalties received by Aratana and its affiliates. In fiscal year 2019, the Company received approximately \$8,000 in royalty revenue from Aratana. Additionally, in July 2019, Aratana announced that their shareholders approved a merger agreement with Elanco Animal Health, or Elanco, whereby Elanco is now the majority shareholder of Aratana. On October 6, 2020, the Company received a notice from Aratana, dated September 17, 2020, indicating that Aratana was terminating the Exclusive License Agreement effective December 21, 2020. The Company did not incur any early termination penalties as a result of the termination. Aratana was required to make all payments to the Company that were otherwise payable under the Exclusive License Agreement through the effective date of termination.

Corporate Information

We were originally incorporated in the State of Colorado on June 5, 1987 under the name Great Expectations, Inc. We were a publicly-traded “shell” company without any business until November 12, 2004 when we acquired New Ayala, a Delaware corporation, through a Share Exchange and Reorganization Agreement, dated as of August 25, 2004, which we refer to as the Share Exchange, by and among New Ayala, the stockholders of New Ayala and us. As a result of the Share Exchange, New Ayala became our wholly-owned subsidiary and our sole operating company. On December 23, 2004, we amended and restated our articles of incorporation and changed our name to New Ayala. On June 6, 2006, our stockholders approved the reincorporation of our company from Colorado to Delaware by merging the Colorado entity into our wholly-owned Delaware subsidiary. Our date of inception, for financial statement purposes, is March 1, 2002 and the Company was listed on The Nasdaq Capital Market (“Nasdaq”) in 2014. In December 2021, the Company was delisted from Nasdaq and accepted onto the OTCQX. Shares of New Ayala’s common stock are currently quoted on the OTCQX under the symbol “ADXS.” We have filed an application for listing on Nasdaq, and intend to undertake the actions necessary to allow our common stock to be uplisted from the OTCQX to Nasdaq.

Our principal executive offices are located at 9 Deer Park Drive, Suite K-1, Monmouth Junction, New Jersey 08852, and our telephone number is (609) 452-9813. We maintain a corporate website at www.ayalapharma.com which contains descriptions of our technology, our product candidates and the development status of each drug. We make available free of charge through our internet website our annual reports on Form 10-K, quarterly reports on Form 10-Q and Current Reports on Form 8-K, and any amendments to these reports, as soon as reasonably practicable after we electronically file such material with, or furnish such material to, the SEC. We are not including the information on our website as a part of, nor incorporating it by reference into, this report. The SEC maintains a website that contains annual, quarterly, and current reports, proxy statements, and other information that issuers (including us) file electronically with the SEC. The SEC’s website address is <http://www.sec.gov>.

Intellectual Property

Protection of our intellectual property is important to our business. We have a robust patent portfolio that protects our product candidates and *Lm*-based immunotherapy technology. Currently, we own or have rights to several hundred patents and applications, which are owned, licensed from, or co-owned with University of Pennsylvania, or Penn, Merck, National Institute of Health, or NIH, and/or Augusta University. We aggressively prosecute and defend our patents and proprietary technology. Our patents and applications are directed to the compositions of matter, use, and methods thereof, of our *Lm*-LLO immunotherapies for our product candidates, including AXAL, ADXS-PSA, ADXS-HOT, ADXS-HER2. We have and may continue to abandon prosecuting certain patents that are not strategically aligned with the direction of the Company.

Our approach to the intellectual property portfolio is to create, maintain, protect, enforce and defend our proprietary rights for the products we develop from our immunotherapy technology platform. We endeavor to maintain a coherent and aggressive strategic approach to building our patent portfolio with an emphasis in the field of cancer vaccines. Issued patents which are directed to AXAL, ADXS-PSA, and ADXS-HER2 in the United States, will expire between 2021 and 2032. Issued patents directed to our product candidates AXAL, ADXS-PSA, and ADXS-HER2 outside of the United States, will expire in 2032. Issued patents directed to our *Lm*-based immunotherapy platform in the United States, will expire between 2021 and 2031. Issued patents directed to our *Lm*-based immunotherapy platform outside of the United States, will expire between 2021 and 2033.

We have pending patent applications directed to our product candidates AXAL, ADXS-PSA, ADXS-HER2, and ADXS-HOT that, if issued would expire in the United States and in countries outside of the United States between 2021 and 2037. We have pending patent applications directed to methods of using of our product candidates AXAL, ADXS-PSA, ADXS-HOT, ADXS-HER2 directed to the following indications and others: prostate cancer and her2/neu-expressing cancer, that, if issued would expire in the United States and in countries outside of the United States between 2021 and 2037, depending on the specific indications.

We will be able to protect our technology from unauthorized use by third parties only to the extent it is covered by valid and enforceable patents or is effectively maintained as trade secrets. Patents and other proprietary rights are an essential element of our business.

Our success will depend in part on our ability to obtain and maintain proprietary protection for our product candidates, technology, and know-how, to operate without infringing on the proprietary rights of others, and to prevent others from infringing our proprietary rights. Our policy is to seek to protect our proprietary position by, among other methods, filing U.S. and foreign patent applications related to our proprietary technology, inventions, and improvements that are important to the development of our business. We also rely on trade secrets, know-how, continuing technological innovation, and in-licensing opportunities to develop and maintain our proprietary position.

Any patent applications which we have filed or will file or to which we have or will have license rights may not issue, and patents that do issue may not contain commercially valuable claims. In addition, any patents issued to us or our licensors may not afford meaningful protection for our products or technology, or may be subsequently circumvented, invalidated, narrowed, or found unenforceable. Our processes and potential products may also conflict with patents which have been or may be granted to competitors, academic institutions or others. As the pharmaceutical industry expands and more patents are issued, the risk increases that our processes and potential products may give rise to interferences filed by others in the U.S. Patent and Trademark Office, or to claims of patent infringement by other companies, institutions or individuals. These entities or persons could bring legal actions against us claiming damages and seeking to enjoin clinical testing, manufacturing and marketing of the related product or process. In recent years, several companies have been extremely aggressive in challenging patents covering pharmaceutical products, and the challenges have often been successful. If any of these actions are successful, in addition to any potential liability for damages, we could be required to cease the infringing activity or obtain a license in order to continue to manufacture or market the relevant product or process. We may not prevail in any such action and any license required under any such patent may not be made available on acceptable terms, if at all. Our failure to successfully defend a patent challenge or to obtain a license to any technology that we may require to commercialize our technologies or potential products could have a materially adverse effect on our business. In addition, changes in either patent laws or in interpretations of patent laws in the United States and other countries may materially diminish the value of our intellectual property or narrow the scope of our patent protection.

We also rely upon unpatented proprietary technology, and in the future may determine in some cases that our interests would be better served by reliance on trade secrets or confidentiality agreements rather than patents or licenses. We may not be able to protect our rights to such unpatented proprietary technology and others may independently develop substantially equivalent technologies. If we are unable to obtain strong proprietary rights to our processes or products after obtaining regulatory clearance, competitors may be able to market competing processes and products.

Others may obtain patents having claims which cover aspects of our products or processes which are necessary for, or useful to, the development, use or manufacture of our services or products. Should any other group obtain patent protection with respect to our discoveries, our commercialization of potential therapeutic products and methods could be limited or prohibited.

The Drug Development Process

The product candidates in our pipeline are at various stages of clinical development. The path to regulatory approval includes multiple phases of clinical trials in which we collect data that will ultimately support an application to regulatory authorities to allow us to market a product for the treatment of a specific type of cancer. There are many difficulties and uncertainties inherent in research and development of new products, resulting in high costs and variable success rates. Bringing a drug from discovery to regulatory approval, and ultimately to market, takes many years and significant costs.

The process required by the FDA before product candidates may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests, animal studies, and formulation studies in compliance with the FDA's Good Laboratory Practice, or GLP, regulations;
- submission to the FDA of an IND which must become effective before human clinical trials may begin at United States clinical trial sites;
- approval by an IRB for each clinical site, or centrally, before each trial may be initiated;
- adequate and well-controlled human clinical trials to establish the product candidate's safety, purity, and potency for its intended use, performed in accordance with GCPs;
- development of manufacturing processes to ensure the product candidate's identity, strength, quality, purity, and potency;
- submission to the FDA of a BLA;
- satisfactory completion of an FDA advisory committee review, if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the products are produced to assess compliance with cGMPs and to assure that the facilities, methods, and controls are adequate to preserve the therapeutics' identity, strength, quality, purity, and potency as well as satisfactory completion of an FDA inspection of selected clinical sites and selected clinical investigators to determine GCP compliance; and

- FDA review and approval of the BLA to permit commercial marketing for particular indications for use.

Preclinical studies include laboratory evaluation of chemistry, pharmacology, toxicity, and product formulation, as well as animal studies to assess potential safety and efficacy. Such studies must generally be conducted in accordance with the FDA's GLPs. Prior to commencing the first clinical trial at a United States investigational site with a product candidate, an IND sponsor must submit the results of the preclinical tests and preclinical literature, together with manufacturing information, analytical data, any available clinical data or literature, and proposed clinical study protocols among other things, to the FDA as part of an IND. An IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA notifies the applicant of safety concerns or questions related to one or more proposed clinical trials and places the trial on a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Clinical holds also may be imposed by the FDA at any time before or during trials due to safety concerns or non-compliance. A separate submission to an existing IND must also be made for each successive clinical trial conducted during product development.

Clinical testing, known as clinical trials or clinical studies, is either conducted internally by pharmaceutical or biotechnology companies or managed on behalf of these companies by Clinical Research Organizations, or CROs. The process of conducting clinical studies is highly regulated by the FDA, as well as by other governmental and professional bodies. In a clinical trial, participants receive specific interventions according to the research plan or protocol created by the study sponsor and implemented by study investigators. Clinical trials must be conducted in accordance with federal regulations and GCP requirements, which include the requirements that all research subjects provide their informed consent in writing for their participation in any clinical trial, as well as review and approval of the study by an IRB. Additionally, some clinical trials are overseen by an independent data safety monitoring board, which reviews data and advises the study sponsor on study continuation. A protocol for each clinical trial, and any subsequent protocol amendments, must be submitted to the FDA as part of the IND.

Clinical trials may compare a new medical approach to a standard one that is already available or to a placebo that contains no active ingredients or to no intervention. Some clinical trials compare interventions that are already available to each other. When a new product or approach is being studied, it is not usually known whether it will be helpful, harmful, or no different than available alternatives. The investigators try to determine the safety and efficacy of the intervention by measuring certain clinical outcomes in the participants.

Phase 1. Phase 1 clinical trials begin when regulatory agencies allow initiation of clinical investigation of a new drug or product candidate. They typically involve testing an investigational new drug on a limited number of patients. Phase 1 studies determine a drug's basic safety, maximum tolerated dose, mechanism of action and how the drug is absorbed by, and eliminated from, the body. Typically, cancer therapies are initially tested on late-stage cancer patients.

Phase 2. Phase 2 clinical trials involve larger numbers of patients that have been diagnosed with the targeted disease or condition. Phase 2 clinical trials gather preliminary data on effectiveness (where the drug works in people who have a certain disease or condition) and to determine the common short-term side effects and risks associated with the drug. If Phase 2 clinical trials show that an investigational new drug has an acceptable range of safety risks and probable effectiveness, a company will continue to evaluate the investigational new drug in Phase 3 studies.

Phase 3. Phase 3 clinical trials are typically controlled multi-center trials that involve a larger number of patients to ensure the study results are statistically significant. The purpose is to confirm effectiveness and safety on a large scale and to provide an adequate basis for physician labeling. These trials are generally global in nature and are designed to generate clinical data necessary to submit an application for marketing approval to regulatory agencies. Typically, two Phase 3 trials are required for product approval. Under limited circumstances, however, approval may be based upon a single adequate and well-controlled clinical trial plus confirmatory evidence or a single large multicenter trial without confirmatory evidence.

The FDA may also consider additional kinds of data in support of a BLA, such as patient experience data and real-world evidence. For genetically targeted populations and variant protein targeted products intended to address an unmet medical need in one or more patient subgroups with a serious or life threatening rare disease or condition, the FDA may allow a sponsor to rely upon data and information previously developed by the sponsor or for which the sponsor has a right of reference, that was submitted previously to support an approved application for a product that incorporates or utilizes the same or similar genetically targeted technology or a product that is the same or utilizes the same variant protein targeted drug as the product that is the subject of the application.

Reports regarding clinical study progress must be submitted to the FDA and IRB on an annual basis. Additional reports are required if serious adverse events or other significant safety information is found. Certain reports may also be required to be submitted to the IBC. Investigational biologics must additionally be manufactured in accordance with cGMPs, imported in accordance with FDA requirements, and exported in accordance with the requirements of the receiving country as well as FDA.

Additionally, under the Pediatric Research Equity Act, or PREA, BLAs or BLA supplements for a new active ingredient, dosage form, dosage regimen, or route of administration, unless subject to the below requirement for molecularly targeted cancer products, must contain data to assess the safety and effectiveness of the product in all relevant pediatric subpopulations. The FDA may, however, grant deferrals or full or partial waivers of this requirement. PREA does not apply to orphan designated products approved solely for the orphan indication.

If a product is intended for the treatment of adult cancer and is directed at molecular targets that the FDA determines to be substantially relevant to the growth or progression of pediatric cancer, even if the product has orphan designation, the application sponsors must submit, reports from molecularly targeted pediatric cancer investigations designed to yield clinically meaningful pediatric study data, gathered using appropriate formulations for each applicable age group, to inform potential pediatric labeling. Like PREA, FDA may grant deferrals or waivers of some or all of this data requirement.

Certain gene therapy studies are also subject to the National Institutes of Health's Guidelines for Research Involving Recombinant DNA Molecules, or NIH Guidelines. The NIH Guidelines include the review of the study by a local institutional committee called an institutional biosafety committee, or IBC. The IBC assesses the compliance of the research with the NIH Guidelines, assesses the safety of the research and identifies any potential risk to public health or the environment.

In addition to the regulations discussed above, there are a number of additional standards that apply to clinical trials involving the use of gene therapy. The FDA has issued various guidance documents regarding gene therapies, which outline additional factors that the FDA will consider during product development. These include guidance regarding preclinical studies; chemistry, manufacturing, and controls; the measurement of product potency; how FDA will determine whether a gene therapy product is the same as another product for the purpose of the agency's orphan drug regulations; and long term patient and clinical study subject follow up and regulatory reporting.

To lessen the burden of subjects being required to travel to the clinic for an onsite visit during the *Lm* surveillance phase of the studies, the *Lm* surveillance period was reduced to 1 year instead of 3 years based on an agreement with the FDA in November 2020.

Biologic License Application (BLA). During clinical trials, companies usually also complete additional preclinical studies. Companies further develop additional information about the product candidate's physical characteristics and finalize the cGMP manufacturing process. The results of the clinical trials using biologics are submitted to the FDA as part of a BLA. Following the completion of Phase 3 studies, if the sponsor of a potential product in the United States believes it has sufficient information to support the safety and effectiveness of the investigational biologic, the sponsor submits a BLA to the FDA requesting marketing approval. The application is a comprehensive filing that includes the results of all preclinical and clinical studies, information about the product's composition, and the sponsor's plans for manufacturing, packaging, labeling and testing the investigational new product

Subject to certain exceptions, the BLA must be accompanied by a substantial user fee at the time of the first submission. FDA has 60 days from its receipt of a BLA to determine whether the application is sufficiently complete for filing and for a substantive review. If the FDA determines that the NDA is incomplete, the FDA may refuse to file the application, in which case the applicant must address the FDA identified deficiencies before refiling. After the BLA is accepted for filing, the FDA reviews the application to determine whether the product meets FDA's approval standards. The FDA aims to complete its review within ten months of the 60-day filing date. For products that present significant improvements in the safety or effectiveness of the treatment, diagnosis, or prevention of serious conditions FDA aims to complete its review within 6 months of the 60-day filing date. The FDA, however, does not always meet its review goal. The review goal date may also be extended if FDA requests or the sponsor provides additional information regarding the application. As part of the approval process, FDA will typically inspect one or more clinical sites, as well as the facility or the facilities at which the product is manufactured to ensure GCP and cGMP compliance.

FDA may also refer an application for review by an independent advisory committee. Specifically, for a product candidate for which no active ingredient (including any ester or salt of active ingredients) has previously been approved by the FDA, the FDA must either refer that product candidate to an advisory committee or provide in an action letter, a summary of the reasons why the FDA did not refer the product candidate to an advisory committee. While FDA is not bound by the recommendation of an advisory committee, it does carefully consider the committee's recommendations.

After evaluating the application, FDA may issue an approval letter, authorizing product marketing, or a Complete Response Letter, or CRL, indicating that the application is not ready for approval. The CRL describes the application's deficiencies and conditions that must be met for product approval. If a CRL is issued, the applicant may resubmit the application, addressing the deficiencies, withdraw the application, or request a hearing. Even with submission of additional information, the FDA ultimately may decide that the application is not approvable.

If approval is granted, the FDA may limit the indications for use, including the indicated population, require contraindications, warnings or precautions be included in the product labeling, including black box warnings, or may not approve label statements necessary for successful commercialization. FDA may also require, or companies may conduct, additional clinical trials following approval, called Phase 4 studies, which can confirm or refute the effectiveness of a product candidate, and can provide important safety information. FDA may also require the implementation of a REMS which may include requirements for a medication guide or patient package insert, a communication plan on product risks, or other elements to assure safe use.

After approval, some types of changes to the approved product, such as adding new indications or label claims, which may themselves require further clinical testing, or changing the manufacturing process are subject to further FDA review and approval. FDA can also require the implementation REMS or the conduct of phase 4 studies after product approval.

Government Regulations

General

Government authorities in the United States and other countries extensively regulate, among other things, the preclinical and clinical testing, manufacturing, labeling, storage, record-keeping, advertising, promotion, import, export, marketing and distribution of biopharmaceutical and drug products. In the United States, the FDA subjects drugs to rigorous review under the Federal Food, Drug and Cosmetic Act, or FDCA, the Public Health Service Act, or PHSA, and implementing regulations.

Orphan Drug Designation

Under the ODA, the FDA may grant ODD, to a drug or biological product intended to treat a rare disease or condition, which means a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States, but for which there is no reasonable expectation that the cost of developing and making a drug or biological product available in the United States will be recovered from domestic sales of the product. Additionally, sponsors must present a plausible hypothesis for clinical superiority to obtain ODD if there is a product already approved by the FDA that that is considered by the FDA to be the same as the already approved product and is intended for the same indication. This hypothesis must be demonstrated to obtain orphan exclusivity.

The benefits of ODD can be substantial, including research and development tax credits, grants and exemption from user fees. The tax advantages, however, were limited in the 2017 Tax Cuts and Jobs Act. Moreover, if there is no other product that the FDA considers to be the same product that is approved for the orphan indication, the orphan designated product is eligible for 7 years of orphan market exclusivity once the product is approved. During that period, the FDA generally may not approve any other application for the same product for the same indication, although there are exceptions, most notably when the later product is shown to be clinically superior to the product with exclusivity. Other applicants, however, may receive approval of different products for the orphan indication or the same product for a different indication during the orphan exclusivity period. In order to qualify for these incentives, a company must apply for designation of its product as an “Orphan Drug” and obtain approval from the FDA. Orphan product designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

We currently have ODD with the FDA for AXAL for treatment of anal cancer (granted August 2013), HPV-associated head and neck cancer (granted November 2013); and treatment of Stage II-IV invasive cervical cancer (granted May 2014). We also have ODD with the FDA for ADXS-HER2 for the treatment of osteosarcoma (granted May 2014).

In Europe, the Committee for Orphan Medicinal Products, COMP, has issued a positive opinion on the application for ODD of AXAL for the treatment of anal cancer (December 2015) and on the application for ODD of ADXS-HER2 for osteosarcoma (November 2015).

Expedited Review and Approval Programs for Serious Conditions

Four core FDA programs are intended to facilitate and expedite development and review of new biologics to address unmet medical need in the treatment of serious or life-threatening conditions: Fast Track designation, breakthrough therapy designation, accelerated approval, and priority review. We intend to avail ourselves of any and all of these programs as applicable to our products.

FDA is required to facilitate the development, and expedite the review, of products that are intended for the treatment of a serious or life-threatening disease or condition, and which demonstrate the potential to address unmet medical needs for the condition. Under the Fast Track program, the sponsor of a new biologic product candidate may request that FDA designate the drug candidate for a specific indication as a Fast Track drug concurrent with, or after, the filing of the IND for the product candidate. FDA must determine if the product candidate qualifies for Fast Track designation within 60 days of receipt of the sponsor’s request. If Fast Track designation is obtained, sponsors may be eligible for more frequent development meetings and correspondence with the FDA. FDA may also initiate review of sections of a Fast Track product’s BLA before the application is complete. This rolling review is available if the applicant provides, and FDA approves, a schedule for the submission of the remaining information and the applicant pays applicable user fees. However, FDA’s time period goal for reviewing an application does not begin until the last section of the BLA is submitted.

Under FDA’s accelerated approval programs, FDA may approve a product for a serious or life-threatening illness that provides meaningful therapeutic benefit to patients over existing treatments based upon a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments.

In clinical trials, a surrogate endpoint is a measurement of laboratory or clinical signs of a disease or condition that substitutes for a direct measurement of how a patient feels, functions or survives. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. A product candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or confirm a clinical benefit during post-marketing studies, will allow FDA to withdraw the product from the market on an expedited basis. All promotional materials for product candidates approved under accelerated regulations are subject to prior review by FDA.

Under the provisions of the FDA Safety and Innovation Act, or FDASIA, enacted in 2012, a sponsor can request designation of a product candidate as a “breakthrough therapy.” A breakthrough therapy is defined as a product that is intended, alone or in combination with one or more other products, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Products designated as breakthrough therapies are eligible for intensive guidance on an efficient development program beginning as early as Phase 1 trials, a commitment from the FDA to involve senior managers and experienced review staff in a proactive collaborative and cross-disciplinary review, rolling review, and the facilitation of cross-disciplinary review.

Another expedited pathway is the Regenerative Medicine Advanced Therapy, or RMAT, designation. Qualifying products must be a cell therapy, therapeutic tissue engineering product, human cell and tissue product, or a combination of such products, and not a product solely regulated as a human cell and tissue product. The product must be intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition, and preliminary clinical evidence must indicate that the product has the potential to address an unmet need for such disease or condition. Advantages of the RMAT designation include all the benefits of the Fast Track and breakthrough therapy designation programs, including early interactions with the FDA. These early interactions may be used to discuss potential surrogate or intermediate endpoints to support accelerated approval.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

Disclosure of Clinical Trial Information

Sponsors of clinical trials of FDA regulated products, including biologics, are required to register and submit certain clinical trial information within specific timeframes to the National Institutes of Health, or NIH, for public dissemination on their clinicaltrials.gov website. Information related to the product, patient population, phase of investigation, Trial sites and investigators and other aspects of the clinical trial is then made public as part of the registration. Sponsors are also obligated to discuss the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed in certain circumstances for up to two years, depending on the circumstances, after the date of completion of the trial. Competitors may use this publicly available information to gain knowledge regarding the progress of development programs.

Coverage, Pricing and Reimbursement

Successful commercialization of new drug products depends in part on the extent to which reimbursement for those drug products will be available from government health administration authorities, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which drug products they will pay for and establish reimbursement levels. The availability and extent of reimbursement by governmental and private payors is essential for most patients to be able to afford a drug product. Sales of drug products depend substantially, both domestically and abroad, on the extent to which the costs of drugs products are paid for by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third-party payors.

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular drug products. In many countries, the prices of drug products are subject to varying price control mechanisms as part of national health systems. In general, the prices of drug products under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for drug products, but monitor and control company profits. Accordingly, in markets outside the United States, the reimbursement for drug products may be reduced compared with the United States. In the United States, the principal decisions about reimbursement for new drug products are typically made by CMS an agency within HHS. CMS decides whether and to what extent a new drug product will be covered and reimbursed under certain federal governmental healthcare programs, such as Medicare, and private payors tend to follow CMS to a substantial degree. However, no uniform policy of coverage and reimbursement for drug products exists among third-party payors and coverage and reimbursement levels for drug products can differ significantly from payor to payor. In the United States, the process for determining whether a third-party payor will provide coverage for a biological product typically is separate from the process for setting the price of such product or for establishing the reimbursement rate that the payor will pay for the product once coverage is approved. With respect to biologics, third-party payors may limit coverage to specific products on an approved list, also known as a formulary, which might not include all of the FDA-approved products for a particular indication, or place products at certain formulary levels that result in lower reimbursement levels and higher cost sharing obligation imposed on patients. A decision by a third-party payor not to cover our product candidates could reduce physician utilization of a product. Moreover, a third-party payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Adequate third-party reimbursement may not be available to enable a manufacturer to maintain price levels sufficient to realize an appropriate return on its investment in product development. Additionally, coverage and reimbursement for products can differ significantly from payor to payor. One third-party payor's decision to cover a particular medical product does not ensure that other payors will also provide coverage for the medical product, or will provide coverage at an adequate reimbursement rate. As a result, the coverage determination process usually requires manufacturers to provide scientific and clinical support for the use of their products to each payor separately and is a time-consuming process.

Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future. Third-party payors are increasingly challenging the prices charged for medical products and services, examining the medical necessity and reviewing the cost-effectiveness of pharmaceutical products, in addition to questioning safety and efficacy. If third-party payors do not consider a product to be cost-effective compared to other available therapies, they may not cover that product after FDA approval or, if they do, the level of payment may not be sufficient to allow a manufacturer to sell its product at a profit.

In addition, in many foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing and reimbursement vary widely from country to country. In the European Union, governments influence the price of products through their pricing and reimbursement rules and control of national healthcare systems that fund a large part of the cost of those products to consumers. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed to by the government. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost effectiveness of a particular product to currently available therapies. Other member states allow companies to fix their own prices for medicines, but monitor and control company profits. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. The downward pressure on healthcare costs in general, particularly prescription products, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross border imports from low-priced markets exert a commercial pressure on pricing within a country (particularly in the EEA where it is illegal to impede such imports from elsewhere within the EEA).

Other Healthcare Laws

Manufacturing, sales, promotion and other activities following product approval are also subject to regulation by numerous regulatory authorities in the United States in addition to the FDA, including CMS, the HHS Office of Inspector General and HHS Office for Civil Rights, other divisions of the HHS and the Department of Justice.

Healthcare providers, physicians, and third-party payors will play a primary role in the recommendation and prescription of any products for which we obtain marketing approval. Our current and future arrangements with third-party payors, healthcare providers and physicians may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute any drugs for which we obtain marketing approval. In the United States, these laws include, without limitation, state and federal anti-kickback, false claims, physician transparency, and patient data privacy and security laws and regulations, including but not limited to those described below.

The AKS prohibits, among other things, any person or entity from knowingly and willfully offering, paying, soliciting, receiving or providing any remuneration, directly or indirectly, overtly or covertly, to induce or in return for purchasing, leasing, ordering or arranging for or recommending the purchase, lease or order of any good, facility, item or service reimbursable, in whole or in part, under Medicare, Medicaid or other federal healthcare programs. The term “remuneration” has been broadly interpreted to include anything of value. The AKS has been interpreted to apply to arrangements between pharmaceutical and medical device manufacturers on the one hand and prescribers, purchasers, formulary managers and beneficiaries on the other hand. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the AKS. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all its facts and circumstances. Several courts have interpreted the statute’s intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the statute has been violated. In addition, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Moreover, a claim including items or services resulting from a violation of the AKS constitutes a false or fraudulent claim for purposes of the FCA.

Although we would not submit claims directly to payors, drug manufacturers can be held liable under the FCA, which imposes civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities (including manufacturers) for, among other things, knowingly presenting, or causing to be presented to federal programs (including Medicare and Medicaid) claims for items or services, including drugs, that are false or fraudulent, claims for items or services not provided as claimed, or claims for medically unnecessary items or services. The government may deem manufacturers to have “caused” the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off-label. Several biopharmaceutical, medical device and other healthcare companies have been prosecuted under the FCA and civil monetary penalty laws for, among other things, allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the companies’ marketing of products for unapproved (e.g., or off-label), and thus non-covered, uses. In addition, the civil monetary penalties statute imposes penalties against any person who is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent. Claims which include items or services resulting from a violation of the federal AKS are false or fraudulent claims for purposes of the FCA.

Our future marketing and activities relating to the reporting of wholesaler or estimated retail prices for our products, if approved, the reporting of prices used to calculate Medicaid rebate information and other information affecting federal, state and third-party reimbursement for our products, and the sale and marketing of our product candidates, are subject to scrutiny under these laws.

HIPAA, created additional federal criminal statutes that prohibit, among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud or to obtain, by means of false or fraudulent pretenses, representations or promises, any money or property owned by, or under the control or custody of, any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the AKS, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

In addition, there has been a recent trend of increased federal and state regulation of payments made to physicians and certain other healthcare providers. The Affordable Care Act, or the ACA, imposed, among other things, new annual reporting requirements through the Physician Payments Sunshine Act for covered manufacturers for certain payments and “transfers of value” provided to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Failure to submit timely, accurately and completely the required information for all payments, transfers of value and ownership or investment interests may result in civil monetary penalties. Covered manufacturers must submit reports by the 90th day of each subsequent calendar year and the reported information is publicly made available on a searchable website.

We may also be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA, as amended by HITECH and their respective implementing regulations, including the Final HIPAA Omnibus Rule published on January 25, 2013, impose specified requirements relating to the privacy, security and transmission of individually identifiable health information held by covered entities and their business associates. Among other things, HITECH made HIPAA's security standards directly applicable to "business associates," defined as independent contractors or agents of covered entities that create, receive, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity, although it is unclear that we would be considered a "business associate" in the normal course of our business. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same requirements, thus complicating compliance efforts.

Similar state and foreign fraud and abuse laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services. Such laws are generally broad and are enforced by various state agencies and private actions. Also, many states have similar fraud and abuse statutes or regulations that may be broader in scope and may apply regardless of payor, in addition to items and services reimbursed under Medicaid and other state programs. Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant federal government compliance guidance, and require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, marketing expenditures or drug pricing.

In order to distribute products commercially, we must comply with state laws that require the registration of manufacturers and wholesale distributors of drug and biological products in a state, including, in certain states, manufacturers and distributors who ship products into the state even if such manufacturers or distributors have no place of business within the state. Some states also impose requirements on manufacturers and distributors to establish the pedigree of product in the chain of distribution, including some states that require manufacturers and others to adopt new technology capable of tracking and tracing product as it moves through the distribution chain. Several states have enacted legislation requiring pharmaceutical and biotechnology companies to establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, clinical trials and other activities, and/or register their sales representatives, as well as to prohibit pharmacies and other healthcare entities from providing certain physician prescribing data to pharmaceutical and biotechnology companies for use in sales and marketing, and to prohibit certain other sales and marketing practices. All of our activities are potentially subject to federal and state consumer protection and unfair competition laws.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, contractual damages, reputational harm, diminished profits and future earnings, imprisonment, exclusion of drugs from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, any of which could adversely affect our ability to operate our business and our financial results. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. Ensuring business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time- and resource-consuming and can divert a company's attention from the business.

Current and Future Legislation

In the United States and foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidates for which we obtain marketing approval. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and additional downward pressure on the price that we, or any collaborators, may receive for any approved products.

The ACA, for example, contains provisions that subject biological products to potential competition by lower-cost biosimilars and may reduce the profitability of drug products through increased rebates for drugs reimbursed by Medicaid programs, extend Medicaid rebates to Medicaid managed care plans, provide for mandatory discounts for certain Medicare Part D beneficiaries and annual fees based on pharmaceutical companies' share of sales to federal healthcare programs. With the current Congress, there will likely be additional administrative or legislative changes, including modification, repeal or replacement of all, or certain provisions of the ACA, which may impact reimbursement for drugs and biologics. On January 20, 2017, former President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. On October 13, 2017, former President Trump signed an Executive Order terminating the cost-sharing subsidies that reimburse insurers under the ACA. Several state Attorneys General filed suit to stop the administration from terminating the subsidies, but their lawsuit was dismissed by a federal judge in California on July 18, 2018. In addition, CMS has recently finalized regulations that would give states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces. Further, each chamber of Congress has put forth multiple bills, and may do so again in the future, designed to repeal or repeal and replace portions of the ACA.

While Congress has not passed repeal legislation, the Tax Reform Act includes a provision that repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." Further, the Bipartisan Budget Act of 2018, or the BBA, among other things, amended the ACA, effective January 1, 2019, to increase from 50 percent to 70 percent the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." Congress may consider other legislation to repeal and replace elements of the ACA. On December 14, 2018, a U.S. District Court judge in the Northern District of Texas ruled that the individual mandate portion of the ACA is an essential and inseparable feature of the ACA, and therefore because the mandate was repealed as part of the Tax Cuts and Jobs Act, the remaining provisions of the ACA are invalid as well. The Trump administration and CMS have both stated that the ruling will have no immediate effect, and on December 30, 2018 the same judge issued an order staying the judgment pending appeal. A Fifth Circuit U.S. Court of Appeals hearing to determine whether certain states and the House of Representatives have standing to appeal the lower court decision was held on July 9, 2019, but it is unclear when a Court will render its decision on this hearing, and what effect it will have on the status of the ACA. Litigation and legislation over the ACA are likely to continue, with unpredictable and uncertain results.

Additionally, other federal health reform measures have been proposed and adopted in the United States since the ACA was enacted:

- The Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. These changes included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect in April 2013 and, due to subsequent legislative amendments to the statute, including the BBA, will remain in effect through 2027, unless additional Congressional action is taken.

- The American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.
- The Middle Class Tax Relief and Job Creation Act of 2012 required that CMS reduce the Medicare clinical laboratory fee schedule by 2% in 2013, which served as a base for 2014 and subsequent years. In addition, effective January 1, 2014, CMS also began bundling the Medicare payments for certain laboratory tests ordered while a patient received services in a hospital outpatient setting.

Further, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which have resulted in several recent Congressional inquiries and proposed and enacted bills designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. In addition, the U.S. government, state legislatures, and foreign governments have shown significant interest in implementing cost containment programs, including price-controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs to limit the growth of government paid healthcare costs. For example, the U.S. government has passed legislation requiring pharmaceutical manufacturers to provide rebates and discounts to certain entities and governmental payors to participate in federal healthcare programs. Further, Congress and the current administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs, and the current administration recently released a “Blueprint”, or plan, to reduce the cost of drugs. The Blueprint contains certain measures that HHS is already working to implement. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage Plans the option of using step therapy for Part B drugs beginning January 1, 2020. This final rule codified CMS’s policy change that was effective January 1, 2019. Congress has indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. Individual states in the United States have also been increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

Non-U.S. Regulation

Before our products can be marketed outside the United States, they are subject to regulatory approval of the respective authorities in the country in which the product should be marketed. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary widely from country to country. No action can be taken to market any product in a country until an appropriate application has been approved by the regulatory authorities in that country. The time spent in gaining approval varies from that required for FDA approval, and in certain countries, the sales price of a product must also be approved. The pricing review period often begins after market approval is granted. Even if a product is approved by a regulatory authority, satisfactory prices might not be approved for such product.

Collaborations, Partnerships and Agreements

Collaborations, partnerships and agreements are a key component of New Ayala's corporate strategy. As a clinical stage biotechnology company without sales revenue, partnerships are an essential part of the ongoing strategy. Additionally, the evolution of the field of immunotherapy has resulted in combination treatments becoming ubiquitous; ongoing clinical studies and agreements with many of the leading, large oncology pharmaceutical companies helps validate that *Lm* Technology may play a key role in the cancer treatment protocols of the future.

Our collaborators and partners include Merck, OS Therapies, Biocon, Global BioPharma, Knight, and others. For more information, see Note 12, "Licensing Agreements" of the "Notes to the Consolidated Financial Statements" included in Item 8.

We entered into an exclusive worldwide license agreement with Penn, on July 1, 2002 with respect to the innovative work of Yvonne Paterson, Ph.D., Associate Dean for Research at the School of Nursing at Penn, and former Professor of Microbiology at Penn, in the area of innate immunity, or the immune response attributed to immune cells, including dendritic cells, macrophages and natural killer cells, that respond to pathogens non-specifically (subject to certain U.S. government rights). This agreement was amended and restated as of February 13, 2007, and, thereafter, has been amended from time to time.

This license, unless sooner terminated in accordance with its terms, terminates upon the latter of (a) the expiration of the last to expire of the Penn patent rights; or (b) twenty years after the effective date of the license. Penn may terminate the license agreement early upon the occurrence of certain defaults by us, including, but not limited to, a material breach by us of the Penn license agreement that is not cured within 60 days after notice of the breach is provided to us.

The license provides us with the exclusive commercial rights to the patent portfolio developed by Penn as of the effective date of the license, in connection with Dr. Paterson and requires us to pay various milestone, legal, filing and licensing payments to commercialize the technology. In exchange for the license, Penn received shares of our Common Stock. In addition, Penn is entitled to receive a non-refundable initial license fee, royalty payments and milestone payments based on net sales and percentages of sublicense fees and certain commercial milestones. Under the amended licensing agreement, Penn is entitled to receive 2.5% of net sales in the territory. Should annual net sales exceed \$250 million, the royalty rate will increase to 2.75%, but only with respect to those annual net sales in excess of \$250 million. Additionally, Penn will receive tiered sales milestone payments upon the achievement of cumulative global sales ranging between \$250 million and \$2 billion, with the maximum aggregate amounts payable to Penn in the event that maximum sales milestones are achieved is \$40 million. Notwithstanding these royalty rates, upon first in-human commercial sale (U.S. & E.U.), we have agreed to pay Penn a total of \$775,000 over a four-year period as an advance minimum royalty, which shall serve as an advance royalty in conjunction with the above terms. In addition, under the license, we are obligated to pay an annual maintenance fee of \$100,000 commencing on December 31, 2010, and each December 31st thereafter for the remainder of the term of the agreement until the first commercial sale of a Penn licensed product. We are responsible for filing new patents and maintaining and defending the existing patents licensed to us and we are obligated to reimburse Penn for all attorney's fees, expenses, official fees and other charges incurred in the preparation, prosecution and maintenance of the patents licensed from Penn.

Upon first regulatory approval in humans (US or EU), Penn will be entitled to a milestone payment of \$600,000. Furthermore, upon the achievement of the first sale of a product in certain fields, Penn will be entitled to certain milestone payments, as follows: \$2.5 million will be due upon the first in-human commercial sale (US or EU) of the first product in the cancer field and \$1.0 million will be due upon the date of first in-human commercial sale (US or EU) of a product in each of the secondary strategic fields sold.

Manufacturing

cGMPs, are the standards identified to conform to requirements by governmental agencies that control authorization and licensure for manufacture and distribution of biologic products for either clinical investigations or commercial sale. GMPs identify the requirements for procurement, manufacturing, testing, storage, distribution and the supporting quality systems to ensure that a drug product is safe for its intended application. cGMPs are enforced in the United States by the FDA, under the authorities of the Federal Food, Drug and Cosmetic Act and its implementing regulations and use the phrase "current good manufacturing practices" to describe these standards.

Each of New Ayala's wholly owned product candidates is manufactured using a platform process, with uniform methods and testing procedures. This allows for an expedited pathway from construct discovery to clinical product delivery, while helping to keep cost of goods low.

New Ayala has entered into agreements with multiple third-party organizations, or CMOs, to handle the manufacturing, testing, and distribution of product candidates. These organizations have extensive experience within the biologics space and with the production of clinical and commercial GMP supplies.

Competition

The biotechnology and biopharmaceutical industries are characterized by rapid technological developments and a high degree of competition. As a result, our actual or proposed immunotherapies could become obsolete before we recoup any portion of our related research and development expenses. While we believe that our product candidates, technology, knowledge and experience provide us with competitive advantages, we face competition from established and emerging pharmaceutical and biotechnology companies, among others. The biotechnology and biopharmaceutical industries are highly competitive, and this competition comes from both biotechnology firms and from major pharmaceutical companies, including: BioNtech, Moderna, Gritstone, BMS, AstraZeneca, Merck, Neon Therapeutics, et al., each of which is pursuing cancer vaccines and/or immunotherapies.

Many of these companies have substantially greater financial, marketing, and human resources than we do (including, in some cases, substantially greater experience in clinical testing, manufacturing, and marketing of pharmaceutical products). We also experience competition in the development of our immunotherapies from universities and other research institutions and compete with others in acquiring technology from such universities and institutions. In addition, certain of our immunotherapies may be subject to competition from investigational new drugs and/or products developed using other technologies, some of which have completed numerous clinical trials.

Our competition will be determined in part by the potential indications for which drugs are developed and ultimately approved by regulatory authorities. Additionally, the timing of market introduction of some of our potential immunotherapies or of competitors' products may be an important competitive factor. Accordingly, the speed with which we can develop immunotherapies, complete preclinical testing, clinical trials and approval processes and supply commercial quantities to market are expected to be important competitive factors. We expect that competition among products approved for sale will be based on various factors, including product efficacy, safety, administration, reliability, acceptance, availability, price and patent position.

Experience and Expertise

Our management team has extensive experience in oncology development, including contract research, development, manufacturing and commercialization across a board range of science, technologies, and process operations. We have built internal capabilities supporting research, clinical, medical, manufacturing and compliance operations and have extended our expertise with collaborations.

Employees

As of October 31, 2022, we had 15 employees, 14 of which were full time employees. Of our full-time employees, 1 holds a Ph.D. degree. None of our employees are represented by a labor union, and we consider our relationship with our employees to be good.

Properties

New Ayala's principal office is located at 9 Deer Park Drive, Suite K-1, Monmouth Junction, New Jersey 08852. We will continue to rent necessary offices and laboratories to support our business. New Ayala believes that its facilities are sufficient to meet its current needs and that suitable additional space will be available as and when needed.

Legal Proceedings

The Company is from time to time involved in legal proceedings in the ordinary course of our business. The Company does not believe that any of these claims or proceedings against us is likely to have, individually or in the aggregate, a material adverse effect on the financial condition or results of operations. For more information regarding legal proceedings involving the Company, please see Note 8 – Commitments and Contingencies to our consolidated financial statements.

Item 1A. Risk Factors.

Summary of Risk Factors

Below is a summary of the principal factors that make an investment in New Ayala's Common Stock speculative or risky. This summary does not address all of the risks that New Ayala faces. Additional discussion of the risks summarized in this risk factor summary, and other risks that New Ayala faces, can be found below under the heading "Risk Factors" and should be carefully considered, together with other information in this Form 10-K and New Ayala's other filings with the SEC, before making an investment decision regarding New Ayala's Common Stock.

- New Ayala has incurred significant losses since its inception and anticipate that it will continue to incur losses for the foreseeable future.
- New Ayala will require additional capital to fund its operations and if it fails to obtain necessary financing, it will not be able to complete the development and commercialization of its product candidates.
- The failure to successfully integrate the businesses and operations of Old Ayala and New Ayala in the expected time frame, and certain other factors relating to the Merger, may adversely affect the combined company's future results.
- Our auditor's report includes a going concern paragraph.
- New Ayala is significantly dependent on the success of its *Lm* Technology™ platform and its product candidates based on this platform.
- If New Ayala is unable to establish, manage or maintain strategic collaborations in the future, its revenue and drug development may be limited.
- New Ayala is subject to certain U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions and other trade laws and regulations ("Trade Laws"). New Ayala can face serious consequences for violations.
- New Ayala depends upon its senior management and key consultants and their loss or unavailability could put it at a competitive disadvantage.
- The biotechnology and immunotherapy industries are characterized by rapid technological developments and a high degree of competition. New Ayala may be unable to compete with more substantial enterprises.
- New Ayala can provide no assurance that its clinical product candidates will obtain regulatory approval or that the results of clinical studies will be favorable.

- Drug discovery and development is a complex, time-consuming and expensive process that is fraught with risk and a high rate of failure.
- New Ayala may face legal claims; legal disputes are expensive and New Ayala may not be able to afford the costs.
- New Ayala can provide no assurance of the successful and timely development of new products.
- Ongoing healthcare legislative and regulatory reform measures may have a material adverse effect on New Ayala's business and results of operations.
- New Ayala relies on patents to protect its technology. New Ayala may be unable to protect its intellectual property rights and it may be liable for infringing the intellectual property rights of others.
- The price of New Ayala's Common Stock and warrants may be volatile.

Risk Factors

You should carefully consider the risks described below as well as other information provided to you in this annual report, including information in the section of this document entitled "Forward-Looking Statements." The risks and uncertainties described below are not the only ones facing us. Additional risks and uncertainties not presently known to us or that we currently believe are immaterial may also impair our business operations. If any of the following risks actually occur, our business, financial condition or results of operations could be materially adversely affected, the value of our common stock could decline, and you may lose all or part of your investment.

Introductory Note

The following discussion sets forth the risk factors relating to the business of New Ayala as it existed prior to the Merger, as well as certain risk factors relating to the Merger and the combined business of the Company following the Merger. In addition, we are incorporating into this Item 1A the description of the risk factors relating to Old Ayala set forth in pages 64-131 of the Old Ayala Merger Proxy, which pages are set forth on Exhibit 99.2 to this Annual Report on Form 10-K.

Risks Related to New Ayala's Financial Position, Capital Needs and Strategic Considerations

New Ayala has incurred significant losses since its inception and anticipate that it will continue to incur losses for the foreseeable future.

New Ayala is a clinical-stage biotechnology company. Investment in biotechnology product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that a product candidate will fail to gain regulatory approval or become commercially viable. New Ayala has not generated any revenue from product sales to date, and it continues to incur significant development and other expenses related to its ongoing operations. As a result, New Ayala is not profitable and have incurred losses in each period since its inception.

New Ayala expects to continue to incur losses for the foreseeable future, and it expects these losses to increase as it continues its development of, and seek regulatory approvals for, New Ayala's product candidates, and begin to commercialize any approved products. New Ayala may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect its business. The size of New Ayala's future net losses will depend, in part, on the rate of future growth of its expenses and its ability to generate revenues. If any of New Ayala's product candidates fail in clinical studies or do not gain regulatory approval, or if approved, fails to achieve market acceptance, New Ayala may never become profitable. Even if New Ayala achieves profitability in the future, it may not be able to sustain profitability in subsequent periods. New Ayala's prior losses and expected future losses have had and will continue to have an adverse effect on its stockholders' (deficit) equity and working capital.

New Ayala will require additional capital to fund its operations and if it fails to obtain necessary financing, it will not be able to complete the development and commercialization of its product candidates.

The research and development of New Ayala's products have consumed substantial amounts of cash since inception. New Ayala expects to continue to invest in advancing the clinical development of its product candidates and to commercialize any product candidates for which it receives regulatory approval. As of October 31, 2022, New Ayala had cash and cash equivalents of approximately \$25.2 million. New Ayala will require additional capital for the further development of its product candidates. New Ayala is pursuing various ways to support its development efforts including debt and/or equity financing as well as targeting potential collaborators of its products.

New Ayala cannot be certain that additional funding will be available on acceptable terms, or at all. If New Ayala is unable to raise additional capital in sufficient amounts or on terms acceptable to it, New Ayala may have to significantly delay, scale back or discontinue the development or commercialization of one or more of its products or product candidates or one or more of its other research and development initiatives. New Ayala's forecast of the period of time through which its financial resources will be adequate to support its operations is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors, including the factors discussed elsewhere in this "Risk Factors" section. New Ayala has based this estimate on assumptions that may prove to be wrong, and it could utilize its available capital resources sooner than it currently expects. New Ayala's future funding requirements, both near and long-term, will depend on many factors, including, but not limited to:

- The progress, timing, costs and results of the clinical studies underway;
- future clinical development plans it establishes for New Ayala's product candidates;
- the number and characteristics of product candidates that New Ayala develops or may in-license;
- the outcome, timing and cost of meeting regulatory requirements established by the U.S. Food and Drug Administration, or the FDA, and comparable foreign regulatory authorities, including the potential for the FDA or comparable foreign regulatory authorities to require that New Ayala performs more studies than those that it currently expects;
- the cost of filing, prosecuting, defending and enforcing New Ayala's patent claims and other intellectual property rights;
- the cost of defending intellectual property disputes, including patent infringement actions brought by third parties against New Ayala or its product candidates;
- the effect of competing technological and market developments;
- the cost and timing of completion of commercial-scale outsourced manufacturing activities; and
- the cost of establishing sales, marketing and distribution capabilities for any product candidates for which New Ayala may receive regulatory approval in regions where it chooses to commercialize its products on its own.

The failure to successfully integrate the businesses and operations of Old Ayala and New Ayala in the expected time frame may adversely affect the combined company's future results.

New Ayala and Old Ayala operated independently and there can be no assurances that the businesses can be integrated successfully. It is possible that the integration process could result in the loss of key employees, independent contractors, principal investigators, Clinical Research Organizations ("CROs"), consultants, vendors, and any other third parties, the disruption of our ongoing businesses, inconsistencies in standards, controls, procedures and policies, unexpected integration issues, higher than expected integration costs and an overall integration process that takes longer than originally anticipated. Specifically, the following issues, among others, must be addressed in integrating the operations of Old Ayala and New Ayala in order to realize the anticipated benefits of the Merger so the combined company performs as expected:

- combining the companies' operations and corporate functions;
- combining the businesses of Old Ayala and New Ayala and meeting the capital requirements of the combined company, in a manner that permits the combined company to achieve any cost savings or other synergies anticipated to result from the Merger, the failure of which would result in the anticipated benefits of the Merger not being realized in the time frame currently anticipated or at all;
- integrating personnel from the two companies, especially in the COVID-19 environment which has required many people to work remotely in many locations;
- integrating and unifying Old Ayala's and New Ayala's pipeline of product candidates in development;
- identifying and eliminating redundant and underperforming functions and assets;
- harmonizing the companies' operating practices, employee development and compensation programs, internal controls and other policies, procedures and processes;
- maintaining existing agreements with employees, independent contractors, principal investigators, CROs, consultants, vendors, and any other third parties, avoiding delays in entering into new agreements with prospective employees, independent contractors, principal investigators, CROs, consultants, vendors, and any other third parties, and leveraging relationships with such third parties for the benefit of the combined company;
- addressing possible differences in business backgrounds, corporate cultures and management philosophies;
- consolidating the companies' administrative and information technology infrastructure;
- coordinating research, commercialization, and marketing efforts;
- coordinating geographically dispersed organizations; and
- effecting actions that may be required in connection with obtaining regulatory or other governmental approvals.

In addition, at times the attention our management may be focused on the integration of the businesses of the two companies and diverted from day-to-day business operations or other opportunities that may have been beneficial to us, which may disrupt our ongoing business.

New Ayala and Old Ayala incurred substantial direct and indirect costs as a result of the Merger and New Ayala will incur substantial direct and indirect costs in connection with combining the businesses of New Ayala and Old Ayala following the Merger.

New Ayala and Old Ayala will incur substantial expenses in connection with and as a result of consummating the Merger, and over a period of time following the consummation of the Merger, the combined company also expects to incur substantial expenses in connection with coordinating and, in certain cases, combining the businesses, operations, policies and procedures of New Ayala and Old Ayala. These expenses could adversely affect the financial condition, results of operations and cash flows of the combined company following the consummation of the Merger.

Sales of shares of New Ayala Common Stock after the completion of the Merger may cause the market price of New Ayala Common Stock to fall.

Old Ayala stockholders may decide not to hold the shares of New Ayala Common Stock they received in the Merger and other Old Ayala stockholders, such as funds with limitations on the amount of stock they are permitted to hold in individual issuers, may be required to sell shares of New Ayala Common Stock that they received in the Merger. Such sales, or market perception of such sales, of New Ayala Common Stock could result in higher than average trading volume and may cause the market price for New Ayala Common Stock to decline. Such sales may take place at anytime as there is no lock-up in place that would prevent institutional or larger stockholders from selling some or all of their New Ayala Common Stock now that the Merger has closed.

If third parties threaten to terminate, terminate or alter existing contracts or relationships with New Ayala or Old Ayala, New Ayala's and Old Ayala's respective businesses may be materially harmed.

Old Ayala had contracts with customers, suppliers, vendors, landlords, licensors and other business partners which may require Ayala to obtain consents from these other parties in connection with the Merger. If these consents cannot be obtained, the combined company may suffer a loss of potential future revenues and may lose rights that are material to the business of the combined company. In addition, third parties with whom Old Ayala or New Ayala had or have relationships may terminate or otherwise reduce the scope of their relationship with either. Any such disruptions could limit the Company's ability to achieve the anticipated benefits of the Merger.

Both Old Ayala and New Ayala have operated with a loss and negative cash flows for the entirety of their existence and it is expected the Company will have to raise significant capital in the future that could be dilutive to stockholders.

Both Old Ayala and New Ayala have operated with a loss and negative cash flows for the entirety of their existence. Old Ayala and New Ayala have incurred significant net operating losses in every year since inception and expect to continue to incur significant expenses and operating losses for the foreseeable future. New Ayala's net losses were approximately \$14.4 million for the year ended October 31, 2022. Ayala's net losses were approximately \$40.3 million for the year ended December 31, 2021 and \$28.4 million for the nine months ended September 30, 2022. Based on the combined company's anticipated cash balances and recurring losses, there is substantial doubt about the Company's ability to continue as a going concern as a standalone company.

The Company may not be able to raise capital to continue operations in the future which could result in bankruptcy or liquidation. As a result, adequate funding may not be available to the Company on acceptable terms, or at all.

Our auditor's report includes a going concern paragraph.

Our auditor's report on our financial statements for the year ended October 31, 2022 includes a going concern paragraph. The Company's products that are being developed have not generated significant revenue. As a result, the Company has suffered recurring losses and requires significant cash resources to execute its business plans. These losses are expected to continue for an extended period of time. The aforementioned factors raise substantial doubt about the Company's ability to continue as a going concern within one year from the date of filing. The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The financial statements do not include any adjustments relating to the recoverability and classification of asset amounts or the classification of liabilities that might be necessary should the Company be unable to continue as a going concern within one year after the date the financial statements are issued.

Historically, the major source of our cash has been from proceeds from various public and private offerings of our common stock. Management's plans to mitigate an expected shortfall of capital, to support future operations, include raising additional funds. The actual amount of cash that it will need to operate is subject to many factors.

The Company also recognizes it will need to raise additional capital in order to continue to execute its business plan in the future. There is no assurance that additional financing will be available when needed or that management will be able to obtain financing on terms acceptable to the Company or whether the Company will become profitable and generate positive operating cash flow. If the Company is unable to raise sufficient additional funds, it will have to scale back its operations.

Risks Related to New Ayala's Business, Industry and Strategy

New Ayala is currently operating in a period of economic uncertainty and capital markets disruption, which has been significantly impacted by geopolitical instability, an ongoing military conflict between Russia and Ukraine, and record inflation. New Ayala's business, financial condition and results of operations could be materially adversely affected by any negative impact on the global economy and capital markets resulting from the conflict in Ukraine, geopolitical tensions, or record inflation.

U.S. and global markets are experiencing volatility and disruption following the escalation of geopolitical tensions and the start of the military conflict between Russia and Ukraine. On February 24, 2022, a full-scale military invasion of Ukraine by Russian troops was reported. Although the length and impact of the ongoing military conflict is highly unpredictable, the conflict in Ukraine has led to market disruptions, including significant volatility in commodity prices, credit and capital markets, as well as supply chain interruptions, which has caused record inflation globally. New Ayala is continuing to monitor the situation in Ukraine and globally and assessing its potential impact on New Ayala's business.

Although, to date, New Ayala's business has not been materially impacted by the ongoing military conflict between Russia and Ukraine, geopolitical tensions, or record inflation, it is impossible to predict the extent to which its operations will be impacted in the short and long term, or the ways in which the conflict in Ukraine, geopolitical tensions, or record inflation may impact New Ayala's business. The extent and duration of the conflict in Ukraine, geopolitical tensions, record inflation and resulting market disruptions are impossible to predict, but could be substantial.

New Ayala is a clinical stage company.

New Ayala is a clinical stage biotechnology company with a history of losses and can provide no assurance as to future operating results. As a result of losses that will continue throughout New Ayala's clinical stage, it may exhaust its financial resources and be unable to complete the development of its products. New Ayala anticipates that it will continue to incur significant operational costs as New Ayala executes its clinical development strategy. New Ayala's deficit will continue to grow during its drug development period.

New Ayala has sustained losses from operations in each fiscal year since its inception, and it expects losses to continue for the foreseeable future due to its substantial investment in research and development. As of October 31, 2022, New Ayala had an accumulated deficit of approximately \$443 million and stockholders' equity of approximately \$23.6 million. New Ayala expects to spend substantial additional sums on the continued administration and research and development of proprietary products and technologies with no certainty that its immunotherapies will become commercially viable or profitable as a result of these expenditures. If New Ayala fails to raise a significant amount of capital, it may need to significantly curtail operations or cease operations in the near future. If any of New Ayala's product candidates fail in clinical trials or does not gain regulatory approval, New Ayala may never become profitable. Even if New Ayala achieves profitability in the future, it may not be able to sustain profitability in subsequent periods.

New Ayala is significantly dependent on the success of its Lm Technology platform and its product candidates based on this platform.

New Ayala is invested, and it expects to continue to invest, significant efforts and financial resources in the development of product candidates based on its Lm Technology. New Ayala's ability to generate meaningful revenue, which may not occur for the foreseeable future, if ever, will depend heavily on the successful development, regulatory approval and commercialization of one or more of these product candidates, and such regulatory approval and commercialization may never occur.

The successful development of immunotherapies is highly uncertain.

Successful development of immunotherapies is highly uncertain and is dependent on numerous factors, many of which are beyond New Ayala's control. Immunotherapies that appear promising in the early phases of development may fail to reach, or be delayed in reaching, the market for several reasons including:

- preclinical study results that may show the immunotherapy to be less effective than desired (e.g., the study failed to meet its primary objectives) or to have harmful or problematic side effects;
- clinical study results that may show the immunotherapy to be less effective than expected (e.g., the study failed to meet its primary endpoint) or to have unacceptable side effects;
- failure to receive the necessary regulatory approvals or a delay in receiving such approvals. Among other things, such delays may be caused by slow enrollment in clinical studies, length of time to achieve study endpoints, delays in receiving the necessary products or supplies for the conduct of clinical or pre-clinical trials, additional time requirements for data analysis, or Biologics License Application ("BLA") preparation, discussions with the FDA, an FDA request for additional preclinical or clinical data, FDA delays in inspecting manufacturing establishments, failure to receive FDA approval for manufacturing processes or facilities, or unexpected safety or manufacturing issues;

- manufacturing costs, formulation issues, pricing or reimbursement issues, or other factors that make the immunotherapy uneconomical; and
- the proprietary rights of others and their competing products and technologies that may prevent the immunotherapy from being commercialized.

Success in preclinical and early clinical studies does not ensure that large-scale clinical studies will be successful. Clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals. The length of time necessary to complete clinical studies and to submit an application for marketing approval for a final decision by a regulatory authority varies significantly from one immunotherapy to the next and may be difficult to predict.

Even if New Ayala's product candidates are approved, they may be subject to limitations on the indicated uses and populations for which they may be marketed. They may also be subject to other conditions of approval, may contain significant safety warnings, including boxed warnings, contraindications, and precautions, may not be approved with label statements necessary or desirable for successful commercialization, or may contain requirements for costly post-market testing and surveillance, or other requirements, including the submission of risk evaluation and mitigation strategies, or REMS, to monitor the safety or efficacy of the products. If New Ayala does not receive FDA approval for, and successfully commercialize its product candidates, it will not be able to generate revenue from these product candidates in the United States in the foreseeable future, or at all. Any significant delays in obtaining approval for and commercializing New Ayala's product candidates will have a material adverse impact on its business and financial condition.

New Ayala must rely upon third parties for manufacturing.

New Ayala currently has agreements with third party manufacturing facilities for production of many of its immunotherapies for research and development and testing purposes. New Ayala depends on third-party manufacturers to supply all of its clinical materials, but it does not have direct control over their personnel or operations. Third-party manufacturers must be able to meet New Ayala's deadlines as well as adhere to quality standards and specifications. New Ayala's reliance on third parties for the manufacturing of its drug substance, investigational new drugs and, in the future, any approved products, creates a dependency that could severely disrupt New Ayala's research and development, its clinical testing, and ultimately its sales and marketing efforts if the source of such supply proves to be unreliable or unavailable. For instance, manufacturers may experience unforeseen problems, such as material or personnel shortages, temporary or permanent facility closures, or scale up challenges. If any contracted manufacturing operation is unreliable or unavailable, New Ayala may not be able to manufacture clinical drug supplies of its immunotherapies, and its preclinical and clinical testing programs may not be able to move forward and its entire business plan could fail. If New Ayala is able to commercialize its products in the future, there is no assurance that any third-party manufacturers will be able to meet commercialized scale production requirements in a timely manner.

There is also no guarantee that New Ayala's third-party manufacturers will be able to manufacture its product candidates in accordance with current Good Manufacturing Practices, or cGMPs. Poor control of production processes can lead to the introduction of adventitious agents or other contaminants, or to inadvertent changes in the properties or stability of a product candidate that may not be detectable in final product testing. If these third-party manufacturers are not able to comply with cGMPs, New Ayala may not be able to conduct clinical trials, may need to conduct additional studies, and may not, eventually, receive and maintain FDA approval for those products. Deviations from manufacturing requirements may also require remedial measures that may be costly and/or time-consuming for a third party to implement and that may include the temporary or permanent suspension of a clinical trial or commercial sales or the temporary or permanent closure of a facility. Any such remedial measures imposed upon or by third parties with whom New Ayala contracts could materially harm its business. A failure to comply with the applicable regulatory requirements may also result in regulatory enforcement actions against New Ayala's manufacturers.

While New Ayala is ultimately responsible for the manufacturing of its product candidates, other than through its contractual arrangements, New Ayala has little control over its manufacturers' compliance with these regulations and standards. If New Ayala's manufacturers encounter manufacturing difficulties, including cGMP compliance, it may need to find alternative manufacturing facilities, which it may not be able to on favorable terms or at all, and which would significantly impact New Ayala's ability to develop, obtain and maintain regulatory approval for or market its product candidates, if approved. Any new manufacturers would need to either obtain or develop the necessary manufacturing know-how, and obtain the necessary equipment and materials, which may take substantial time and investment. New Ayala must also receive FDA approval for the use of any new manufacturers for commercial supply.

If New Ayala is unable to establish, manage or maintain strategic collaborations in the future, its revenue and drug development may be limited.

New Ayala's strategy includes eventual substantial reliance upon strategic collaborations for marketing and commercialization of its clinical product candidates, and it may rely even more on strategic collaborations for research, development, marketing and commercialization for some of New Ayala's immunotherapies. To date, New Ayala has been heavily reliant upon third party outsourcing for its clinical trials execution and production of drug supplies for use in clinical trials. Establishing strategic collaborations is difficult and time-consuming. New Ayala's discussions with potential collaborators may not lead to the establishment of collaborations on favorable terms, if at all. For example, potential collaborators may reject collaborations based upon their assessment of New Ayala's financial, clinical, regulatory or intellectual property position. New Ayala's current collaborations, as well as any future new collaborations, may never result in the successful development or commercialization of its immunotherapies or the generation of sales revenue. To the extent that New Ayala has entered or will enter into co-promotion or other collaborative arrangements, its product revenues are likely to be lower than if it directly marketed and sold any products that New Ayala may develop.

Management of New Ayala's relationships with its collaborators will require:

- significant time and effort from New Ayala's management team;
- financial funding to support said collaboration;
- coordination of New Ayala's research and development programs with the research and development priorities of its collaborators; and
- effective allocation of New Ayala's resources to multiple projects.

If New Ayala continues to enter into research and development collaborations at the early phases of drug development, its success will in part depend on the performance of its corporate collaborators. New Ayala will not directly control the amount or timing of resources devoted by its corporate collaborators to activities related to its immunotherapies and its collaborations may terminate at any time. New Ayala's corporate collaborators may not commit sufficient resources to its research and development programs or the commercialization, marketing or distribution of its immunotherapies. If any corporate collaborator fails to commit sufficient resources or terminate their collaborations with New Ayala, its preclinical or clinical development programs related to this collaboration could be delayed or terminated.

Further, New Ayala's collaborators may pursue existing or other development-stage products or alternative technologies in preference to those being developed in collaboration with New Ayala. Collaborators may also fail to comply with the applicable regulatory requirements, which may subject them or New Ayala to regulatory enforcement actions. Finally, if New Ayala fails to make required milestone or royalty payments to its collaborators or to observe other obligations in its agreements with them, New Ayala's collaborators may have the right to terminate those agreements.

Changes in product candidate manufacturing or formulation may result in additional costs or delay.

In an effort to optimize processes and results, it is common that various aspects of the development program, such as manufacturing methods, manufacturing sites, and formulation, are altered as product candidates are developed from preclinical studies to late-stage clinical trials toward approval and commercialization. Any of these changes could cause New Ayala's product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. Such changes may also require additional testing, regulatory disclosure, or prior approval from the FDA. For instance, the FDA may require that New Ayala conducts a comparability study that evaluates the potential differences in the product candidate resulting from the change. Delays in designing and completing such a study to the satisfaction of the FDA could delay or preclude New Ayala's development and commercialization plans, and the regulatory approval of its product candidates. It may also require the repetition of one or more clinical trials, increase clinical trial costs, delay approval of New Ayala's product candidates and jeopardize its ability to commence product sales and generate revenue. Any of the foregoing could limit New Ayala's future revenues and growth. Any changes would also require that New Ayala devotes time and resources to manufacturing development, including with third-party manufacturers, and would also likely require additional testing and regulatory actions on its part, which may delay the development of its product candidates.

New Ayala may incur significant costs complying with environmental laws and regulations.

New Ayala and its contracted third parties use hazardous materials, including chemicals and biological agents and compounds that could be dangerous to human health and safety or the environment. As appropriate, New Ayala stores these materials and wastes resulting from their use at New Ayala or its outsourced laboratory facility pending their ultimate use or disposal. New Ayala contract with a third party to properly dispose of these materials and wastes. New Ayala is subject to a variety of federal, state and local laws and regulations governing the use, generation, manufacture, storage, handling and disposal of these materials and wastes. Compliance with such laws and regulations may be costly.

Additional laws and regulations governing international operations could negatively impact or restrict New Ayala's operations.

If New Ayala further expands its operations outside of the United States, it must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which it plans to operate. The U.S. Foreign Corrupt Practices Act, or FCPA, prohibits any U.S. individual or business from paying, offering, authorizing payment or offering anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring New Ayala to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

Various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. If New Ayala expands its presence outside of the United States, it will require New Ayala to dedicate additional resources to comply with these laws, and these laws may preclude it from developing, manufacturing or selling certain products and product candidates outside of the United States, which could limit its growth potential and increase New Ayala's development costs.

The failure to comply with laws governing international business practices may result in substantial civil and criminal penalties and suspension or debarment from government contracting. The SEC also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions.

New Ayala is subject to certain U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions and other trade laws and regulations. New Ayala can face serious consequences for violations.

Among other matters, U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions and other trade laws and regulations, which are collectively referred to as Trade Laws, prohibit companies and their employees, agents, clinical research organizations, legal counsel, accountants, consultants, contractors and other partners from authorizing, promising, offering, providing, soliciting or receiving, directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Violations of Trade Laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, exclusion from public tenders, reputational harm and other consequences. New Ayala has direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. New Ayala plans to engage third parties for clinical trials and/or to obtain necessary permits, licenses, patent registrations and other regulatory approvals and it can be held liable for the corrupt or other illegal activities of its personnel, agents or partners, even if New Ayala does not explicitly authorize or have prior knowledge of such activities.

If New Ayala uses biological materials in a manner that causes injury, it may be liable for damages.

New Ayala's research and development activities involve the use of biological and hazardous materials. Although New Ayala believes its safety procedures for handling and disposing of these materials complies with federal, state and local laws and regulations, it cannot entirely eliminate the risk of accidental injury or contamination from the use, storage, handling or disposal of these materials. New Ayala does not carry specific biological waste or pollution liability or remediation insurance coverage, nor do its workers' compensation, general liability, and property and casualty insurance policies provide coverage for damages and fines/penalties arising from biological exposure or contamination. Accordingly, in the event of contamination or injury, New Ayala could be held liable for damages or penalized with fines in an amount exceeding its resources, and its clinical trials or regulatory approvals could be suspended or terminated.

New Ayala needs to attract and retain highly skilled personnel; it may be unable to effectively manage growth with its limited resources.

As of October 31, 2022 New Ayala had 15 employees, 14 of which were full time employees. New Ayala's ability to attract and retain highly skilled personnel is critical to its operations and expansion. New Ayala faces competition for these types of personnel from other technology companies and more established organizations, many of which have significantly larger operations and greater financial, technical, human and other resources than it has. New Ayala may not be successful in attracting and retaining qualified personnel on a timely basis, on competitive terms, or at all. If New Ayala is not successful in attracting and retaining these personnel, or integrating them into its operations, business, prospects, financial condition and results of operations will be materially adversely affected. In such circumstances New Ayala may be unable to conduct certain research and development programs, unable to adequately manage its clinical trials and other products, unable to commercialize any products, and unable to adequately address its management needs.

New Ayala depends upon its senior management and key consultants and their loss or unavailability could put it at a competitive disadvantage.

New Ayala depends upon the efforts and abilities of its senior executives, as well as the services of several key consultants. The loss or unavailability of the services of any of these individuals for any significant period of time could have a material adverse effect on New Ayala's business, prospects, financial condition and results of operations. New Ayala has not obtained, does not own, nor is it the beneficiary of, key-person life insurance.

The biotechnology and immunotherapy industries are characterized by rapid technological developments and a high degree of competition. New Ayala may be unable to compete with more substantial enterprises.

The biotechnology and biopharmaceutical industries are characterized by rapid technological developments and a high degree of competition. As a result, New Ayala's actual or proposed immunotherapies could become obsolete before it recoups any portion of its related research and development and commercialization expenses. Competition in the biopharmaceutical industry is based significantly on scientific and technological factors. These factors include the availability of patent and other protection for technology and products, the ability to commercialize technological developments and the ability to obtain governmental approval for testing, manufacturing and marketing. New Ayala competes with specialized biopharmaceutical firms in the United States, Europe and elsewhere, as well as a growing number of large pharmaceutical companies that are applying biotechnology to their operations. Many biopharmaceutical companies have focused their development efforts in the human therapeutics area, including cancer. Many major pharmaceutical companies have developed or acquired internal biotechnology capabilities or made commercial arrangements with other biopharmaceutical companies. These companies, as well as academic institutions and governmental agencies and private research organizations, also compete with New Ayala in recruiting and retaining highly qualified scientific personnel and consultants. New Ayala's ability to compete successfully with other companies in the pharmaceutical field will also depend to a considerable degree on the continuing availability of capital to New Ayala.

New Ayala is aware of certain investigational new products under development or approved products by competitors that are used for the prevention, diagnosis, or treatment of certain diseases it has targeted for product development. Various companies are developing biopharmaceutical products that have the potential to directly compete with New Ayala's immunotherapies even though their approach may be different. The biotechnology and biopharmaceutical industries are highly competitive, and this competition comes from both biotechnology firms and major pharmaceutical companies, including companies like: Gritstone, Moderna, Bristol-Myers Squibb Company ("BMS"), Merck and Neon Therapeutics, among others, each of which is pursuing cancer vaccines and/or immunotherapies. Many of these companies have substantially greater financial, marketing, and human resources than New Ayala does (including, in some cases, substantially greater experience in clinical testing, manufacturing, and marketing of pharmaceutical products). New Ayala also experiences competition in the development of its immunotherapies from universities and other research institutions and compete with others in acquiring technology from such universities and institutions.

In addition, certain of New Ayala's immunotherapies may be subject to competition from investigational new drugs and/or products developed using other technologies, some of which have completed numerous clinical trials.

Risks Related to the Development and Regulatory Approval of New Ayala Product Candidates

New Ayala can provide no assurance that its clinical product candidates will obtain regulatory approval or that the results of clinical studies will be favorable.

New Ayala is currently evaluating the safety and efficacy of its product candidates in clinical trials. However, even though the initiation and conduct of the clinical trials is in accordance with the governing regulatory authorities in each country, as with any investigational new drug (under an Investigational New Drug Application, or IND, in the United States, or the equivalent in countries outside of the United States), New Ayala is at risk of a clinical hold at any time based on the evaluation of the data and information submitted to the governing regulatory authorities.

There can be delays in obtaining FDA and/or other necessary regulatory approvals in the United States and in countries outside the United States for any investigational new drug and failure to receive such approvals would have an adverse effect on the investigational new drug's potential commercial success and on New Ayala's business, prospects, financial condition and results of operations. The time required to obtain approval by the FDA and non-U.S. regulatory authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. For example, the FDA or non-U.S. regulatory authorities may disagree with the design or implementation of New Ayala's clinical trials or study endpoints; or it may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks. In addition, the FDA or non-U.S. regulatory authorities may disagree with New Ayala's interpretation of data from preclinical studies or clinical trials or the data collected from clinical trials of its product candidates may not be sufficient to support the submission of a BLA or New Drug Application ("NDA") or other submission or to obtain regulatory approval in the United States or elsewhere. The FDA or non-U.S. regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which New Ayala contracts for clinical and commercial supplies; and the approval policies or regulations of the FDA or non-U.S. regulatory authorities may significantly change in a manner rendering New Ayala's clinical data insufficient for approval.

In addition to the foregoing, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. New Ayala has not submitted for nor obtained regulatory approval for any product candidate in-humans (US & EU) and it is possible that none of its existing product candidates or any product candidates New Ayala may seek to develop in the future will ever obtain regulatory approval.

Drug discovery and development is a complex, time-consuming and expensive process that is fraught with risk and a high rate of failure.

Product candidates are subject to extensive pre-clinical testing and clinical trials to demonstrate their safety and efficacy in humans. Conducting pre-clinical testing and clinical trials is a lengthy, time-consuming and expensive process that takes many years. New Ayala cannot be sure that pre-clinical testing or clinical trials of any of its product candidates will demonstrate the safety, efficacy and benefit-to-risk profile necessary to obtain marketing approvals. In addition, product candidates that experience success in pre-clinical testing and early-stage clinical trials will not necessarily experience the same success in larger or late-stage clinical trials, which are required for marketing approval.

Even if New Ayala is successful in advancing a product candidate into the clinical development stage, before obtaining regulatory and marketing approvals, it must demonstrate through extensive human clinical trials that the product candidate is safe and effective for its intended use. Human clinical trials must be carried out under protocols that are acceptable to regulatory authorities and to the independent committees responsible for the ethical review of clinical studies. There may be delays in preparing protocols or receiving approval for them that may delay the start or completion of the clinical trials. In addition, clinical practices vary globally, and there is a lack of harmonization among the guidance provided by various regulatory bodies of different regions and countries with respect to the data that is required to receive marketing approval, which makes designing global trials increasingly complex. There are a number of additional factors that may cause New Ayala's clinical trials to be delayed, prematurely terminated or deemed inadequate to support regulatory approval, such as:

- safety issues up to and including patient death (whether arising with respect to trials by third parties for compounds in a similar class as our product or product candidate), inadequate efficacy, or an unacceptable risk-benefit profile observed at any point during or after completion of the trials;
- slower than expected rates of patient enrollment, which could be due to any number of factors, including failure of New Ayala's third-party vendors, including its CROs, to effectively perform their obligations to New Ayala, a lack of patients who meet the enrollment criteria or competition from clinical trials in similar product classes or patient populations, or onerous treatment administration requirements;
- subjects may drop out of New Ayala's clinical trials, be lost to follow-up at a higher rate than it anticipates, or not comply with the required clinical trial procedures;
- New Ayala may experience delays in reaching, or fail to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites and its CROs;
- the cost of clinical trials may be greater than New Ayala anticipates or it may have insufficient funds for a clinical trial or to pay the substantial FDA user fees;

- the FDA or comparable foreign regulatory authorities may disagree with New Ayala's study design, including endpoints, its intended indications, or its interpretation of data;
- the risk of failure of New Ayala's clinical investigational sites and related facilities, including its suppliers and CROs, to maintain compliance with the FDA's cGMP and Good Clinical Practices, or GCP, regulations or similar regulations in countries outside of the U.S., including the risk that these sites fail to pass inspections by the appropriate governmental authority, which could invalidate the data collected at that site or place the entire clinical trial at risk;
- any inability to reach agreement or lengthy discussions with the FDA, equivalent regulatory authorities, or ethical review committees on trial design that New Ayala is able to execute or it may be required to modify its trial design such that studies are impracticable;
- regulators may require New Ayala to perform additional or unanticipated clinical trials to obtain approval or it may be subject to additional post-marketing testing, surveillance, or REMS requirements to maintain regulatory approval;
- FDA refusal to accept the data from foreign clinical trial sites to the extent New Ayala uses such sites;
- changes in laws, regulations, regulatory policy or clinical practices, especially if they occur during ongoing clinical trials or shortly after completion of such trials; and
- clinical trial record keeping or data quality and accuracy issues.

Any deficiency in the design, implementation or oversight of New Ayala's development programs could cause it to incur significant additional costs, conduct additional trials, experience significant delays, prevent it from obtaining marketing approval for any product candidate or abandon development of certain product candidates, any of which could harm its business and cause its stock price to decline.

New Ayala may face legal claims; legal disputes are expensive and it may not be able to afford the costs.

New Ayala may face legal claims involving stockholders, consumers, clinical trial subjects, competitors, regulators and other parties. New Ayala is engaged in legal proceedings. Litigation and other legal proceedings are inherently uncertain, and adverse rulings could occur, including monetary damages, or an injunction stopping New Ayala from engaging in business practices, or requiring other remedies, including, but not limited to, compulsory licensing of patents.

The costs of litigation or any proceeding, including, but not limited to, those relating to New Ayala's intellectual property or contractual rights, could be substantial, even if resolved in its favor. Some of New Ayala's competitors or financial funding sources have far greater resources than it does and may be better able to afford the costs of complex litigation. Also, a lawsuit, even if frivolous, will require considerable time commitments on the part of management, New Ayala's attorneys and consultants. Defending these types of proceedings or legal actions involve considerable expense and could negatively affect New Ayala's financial results. Legal claims may also adversely impact New Ayala in other ways, such as the withdrawal or slower enrollment in or from its clinical trials, regulatory enforcement actions, and negative media attention, any of which could materially and negatively harm New Ayala and its operations.

New Ayala can provide no assurance of the successful and timely development of new products.

New Ayala immunotherapies are at various stages of development. Further development and extensive testing will be required to determine their technical feasibility and commercial viability. New Ayala will need to complete significant additional clinical trials demonstrating that its product candidates are safe and effective to the satisfaction of the FDA and other non-U.S. regulatory authorities. The drug approval process is time-consuming, involves substantial expenditures of resources, and depends upon a number of factors, including the severity of the illness in question, the availability of alternative treatments, and the risks and benefits demonstrated in the clinical trials. New Ayala's success will depend on its ability to achieve scientific and technological advances and to translate such advances into licensable, FDA-approvable, commercially competitive products on a timely basis. Failure can occur at any stage of the process. If such programs are not successful, New Ayala may invest substantial amounts of time and money without developing revenue-producing products. As New Ayala enters a more extensive clinical program for its product candidates, the data generated in these studies may not be as compelling as the earlier results.

The proposed development schedules for New Ayala immunotherapies may be affected by a variety of factors, including technological difficulties, clinical trial failures, regulatory hurdles, clinical holds, competitive products, intellectual property challenges and/or changes in governmental regulation, many of which will not be within its control. Any delay in the development, introduction or marketing of New Ayala products could result either in such products being marketed at a time when their cost and performance characteristics would not be competitive in the marketplace or in the shortening of their commercial lives. In light of the long-term nature of New Ayala's projects, the unproven technology involved, and the other factors described elsewhere in this section, there can be no assurance that New Ayala will be able to successfully complete the development or marketing of any new products which could materially harm its business, results of operations and prospects.

New Ayala research and development expenses are subject to uncertainty.

Factors affecting New Ayala research and development expenses include, but are not limited to:

- competition from companies that have substantially greater assets and financial resources than New Ayala has;
- need for market acceptance of New Ayala's immunotherapies if it receives regulatory approval;
- ability to anticipate and adapt to a competitive market and rapid technological developments;
- ability to raise sufficient capital to fund New Ayala research and development activities;
- amount and timing of operating costs and capital expenditures relating to expansion of New Ayala business, operations and infrastructure;
- need to rely on multiple levels of outside funding due to the length of drug development cycles and governmental approved protocols associated with the pharmaceutical industry; and
- dependence upon key personnel including key independent consultants and advisors.

There can be no guarantee that New Ayala research and development expenses will be consistent from period to period. New Ayala may be required to accelerate or delay incurring certain expenses depending on the results of its studies and the availability of adequate funding.

New Ayala may be required to suspend or discontinue clinical trials for a number of reasons, which could preclude approval of any of its product candidates.

New Ayala clinical trials may be suspended at any time for a number of reasons. A clinical trial may be suspended or terminated by New Ayala, an Institutional Review Board (“IRB”), the FDA or other regulatory authorities due to a failure to conduct the clinical trial in accordance with regulatory requirements or its clinical protocols, presentation or identification of unforeseen safety signals or issues, failure to demonstrate a benefit from using the investigational drug, changes in governmental regulations or administrative actions, lack of adequate funding to continue the clinical trial, or for other business-related reasons. For example, in June 2019, New Ayala announced that it was closing its AIM2CERV Phase 3 clinical trial with AXAL in cervical cancer due to the delays New Ayala incurred as a result of the recent FDA partial clinical hold on the trial, as well as the estimated cost and time to completion of the trial. Furthermore, New Ayala has completed the clinical study report from Part A of the ADXS-NEO study and plans to close its ADXS-NEO program IND as next step. In addition, clinical trials for New Ayala’s product candidates could be suspended due to adverse side effects. Drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. New Ayala may also voluntarily suspend or terminate its clinical trials if at any time it believes that they present an unacceptable risk to patients or do not demonstrate clinical benefit. If New Ayala elects or is forced to suspend or terminate any clinical trial of any product candidates that it develops, the commercial prospects of such product candidates will be harmed and its ability to generate product revenues from any of these product candidates will be delayed or eliminated. Any of these occurrences may significantly harm New Ayala’s business, financial condition, results of operations and prospects.

Preliminary or interim results of a clinical trial are not necessarily predictive of future or final results.

Interim or preliminary data from clinical trials that New Ayala may conduct may not be indicative of the final results of the trial and are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Interim or preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the interim or preliminary data. As a result, interim or preliminary data should be viewed with caution until the final data are available. Even if New Ayala’s clinical trials are completed as planned, it cannot be certain that their results will support its proposed indications.

New Ayala is subject to numerous risks inherent in conducting clinical trials.

New Ayala outsources the management of its clinical trials to third parties. Agreements with CROs, clinical investigators and medical institutions for clinical testing and data management services, place substantial responsibilities on these parties that, if unmet, could result in delays in, or termination of, New Ayala’s clinical trials. For example, if any of New Ayala’s clinical trial sites or CROs fail to comply with FDA-approved good clinical practices, New Ayala may be unable to use the data gathered at those sites. If these clinical investigators, medical institutions or other third parties do not carry out their contractual duties or regulatory obligations or fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to their failure to adhere to New Ayala’s clinical protocols or for other reasons, its clinical trials may be extended, delayed or terminated, and New Ayala may be unable to obtain regulatory approval for, or successfully commercialize, its agents. New Ayala is not certain that it will successfully recruit enough patients to complete its clinical trials nor that it will reach its primary endpoints. Delays in recruitment, lack of clinical benefit or unacceptable side effects would delay or prevent the initiation of future development of New Ayala’s agents.

While New Ayala has agreements governing the activities of such third parties and are responsible for its third-party service provider’s activities and regulatory compliance, it has limited influence and control over their actual performance and activities and cannot control whether or not they devote sufficient time and resources to New Ayala’s ongoing clinical, non-clinical, and preclinical programs and cannot control whether they maintain regulatory compliance. New Ayala’s third-party service providers may also have relationships with other entities, some of which may be its competitors, for whom they may also be conducting trials or other therapeutic development activities that could harm New Ayala’s competitive position.

Agreements with third parties conducting or otherwise assisting with New Ayala's clinical or preclinical studies might terminate for a variety of reasons, including a failure to perform by the third parties. If any of New Ayala's relationships with these third parties terminate, it may not be able to enter into arrangements with alternative providers or to do so on commercially reasonable terms. Switching or adding additional third parties involve additional cost and requires management time and focus. In addition, there is a natural transition period when a new third party commences work. As a result, if New Ayala needs to enter into alternative arrangements, it could delay its product development activities and adversely affect its business. Though New Ayala carefully manages its relationships with third parties, there can be no assurance that it will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on New Ayala's business, financial condition and prospects, and results of operations.

New Ayala or its regulators may suspend or terminate its clinical trials for a number of reasons. New Ayala may voluntarily suspend or terminate its clinical trials if at any time it believes they present an unacceptable risk to the patients enrolled in its clinical trials or do not demonstrate clinical benefit. In addition, regulatory agencies may order the temporary or permanent discontinuation of New Ayala's clinical trials, or place its products on temporary or permanent hold, at any time if they believe that the clinical trials are not being conducted in accordance with applicable regulatory requirements or that they present an unacceptable safety risk to the patients enrolled in New Ayala's clinical trials.

New Ayala's clinical trial operations are subject to regulatory inspections at any time. If regulatory inspectors conclude that New Ayala or its clinical trial sites are not in compliance with applicable regulatory requirements for conducting clinical trials, it may receive reports of observations or warning letters detailing deficiencies, and it will be required to implement corrective actions. If regulatory agencies deem New Ayala's responses to be inadequate or are dissatisfied with the corrective actions it or its clinical trial sites have implemented, New Ayala's clinical trials may be temporarily or permanently discontinued, may be fined, New Ayala or its investigators may be precluded from conducting any ongoing or any future clinical trials, the government may refuse to approve its marketing applications or allow it to manufacture or market its products, and New Ayala may be criminally prosecuted.

The lengthy approval process as well as the unpredictability of future clinical trial results may result in New Ayala failing to obtain regulatory approval for its product candidates, which would materially harm its business, results of operations and prospects.

New Ayala employees, independent contractors, consultants, commercial partners, principal investigators, or CROs may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have a material adverse effect on its business.

New Ayala is exposed to the risk of employee and third-party fraud or other misconduct. Misconduct by employees, independent contractors, consultants, commercial partners, manufacturers, investigators, or CROs could include intentional, reckless, negligent, or unintentional failures to comply with FDA regulations, comply with applicable fraud and abuse laws, provide accurate information to the FDA, properly calculate pricing information required by federal programs, comply with federal procurement rules or contract terms, report financial information or data accurately or disclose unauthorized activities to New Ayala. This misconduct could also involve the improper use or misrepresentation of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to New Ayala's reputation. It is not always possible to identify and deter this type of misconduct, and the precautions New Ayala takes to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting it from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. Moreover, it is possible for a whistleblower to pursue a federal False Claims Act, or FCA, case against New Ayala even if the government considers the claim unmeritorious and declines to intervene, which could require New Ayala to incur costs defending against such a claim. Further, due to the risk that a judgment in an FCA case could result in exclusion from federal health programs or debarment from government contracts, whistleblower cases often result in large settlements. If any such actions are instituted against New Ayala, and it is not successful in defending itself or asserting its rights, those actions could have a significant impact on its business, financial condition, and results of operations, including the imposition of significant fines or other sanctions.

New Ayala must comply with significant government regulations.

The research and development, manufacturing and marketing of human therapeutic and diagnostic products are subject to regulation, primarily by the FDA in the United States and by comparable authorities in other countries. These national agencies and other federal, state, local and foreign entities regulate, among other things, research and development activities (including testing in animals and in humans) and the testing, manufacturing, handling, labeling, storage, record keeping, approval, distribution, advertising and promotion of the products that New Ayala is developing. If New Ayala obtains approval for any of its product candidates, its operations will be directly or indirectly through its customers, subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute and the FCA, and privacy laws. New Ayala, its product candidates, and its products, if it receives marketing approval are and will continue to be subject to extensive governmental regulation and regulatory authorities do and will continue to closely monitor New Ayala and its contractor's compliance through, among other methods, inspections. Noncompliance with applicable laws and requirements can result in various adverse consequences and regulatory enforcement actions, including delay in approving or refusal to approve product licenses or other applications, suspension or termination of clinical investigations, revocation of approvals previously granted, fines, criminal prosecution, civil and criminal penalties, restitution or disgorgement of profits, recall or seizure of products, exclusion from having its products reimbursed by federal health care programs, the curtailment or restructuring of New Ayala's operations, corporate integrity agreements or consent decrees, refusal to permit product import or export, modifications to labeling or promotional materials, issuance of corrective information, regulatory authority public statements, warning, untitled, or cyber letters, requirements for post-market studies or REMS, injunctions against shipping products and total or partial suspension of production and/or refusal to allow a company to enter into governmental supply contracts. Any of these events could prevent New Ayala from achieving or maintaining product approval and market acceptance of the particular product candidate, if approved, or could substantially increase the costs and expenses of developing and commercializing such product, which in turn could delay or prevent New Ayala from generating significant revenues from its sale. Any of these events could further have other material and adverse effects on New Ayala's operations and business and could adversely impact its stock price and could significantly harm New Ayala's business, financial condition, results of operations, and prospects.

The process of obtaining requisite FDA approval has historically been costly and time-consuming. Current FDA requirements for a new human biological product to be marketed in the United States include: (1) the successful conclusion of preclinical laboratory and animal tests, if appropriate, to gain preliminary information on the product's safety; (2) filing with the FDA of an IND to conduct human clinical trials for drugs or biologics; (3) the successful completion of adequate and well-controlled human clinical trials to establish the safety and efficacy of the investigational new drug for its recommended use; and (4) filing by a company and acceptance and approval by the FDA of a BLA for marketing approval of a biologic, to allow commercial distribution of a biologic product. The FDA also requires that any drug or formulation to be tested in humans be manufactured in accordance with its cGMP regulations. This has been extended to include any drug that will be tested for safety in animals in support of human testing. The cGMPs set certain minimum requirements for procedures, record-keeping and the physical characteristics of the laboratories used in the production of these drugs. A delay in one or more of the procedural steps outlined above could be harmful to New Ayala in terms of getting its immunotherapies through clinical testing and to market.

New Ayala may not obtain or maintain the benefits associated with Orphan Drug Designation, including market exclusivity.

Although New Ayala has been granted a designation from the FDA under the Orphan Drug Act, or ODA, intended to treat a rare disease or condition (Orphan Drug Designation, or "ODD") for AXAL for use in the treatment of anal cancer, HPV-associated head and neck cancer, Stage II-IV invasive cervical cancer and for ADXS-HER2 for the treatment of osteosarcoma in the United States, as well as the European Medicines Agency, or EMA, ODD for AXAL for the treatment of anal cancer and for ADXS-HER2 for the treatment of osteosarcoma in the EU, New Ayala may not receive the benefits associated with ODD. This may result from a failure to maintain orphan drug status or result from a competing product reaching the market that has an orphan designation for the same disease indication. Moreover, while ODD does provide New Ayala with certain advantages, it neither shortens the development time or regulatory review time of a product candidate nor gives the product candidate any advantage in the regulatory review or approval process.

Under U.S. rules for orphan drugs, if such a competing product reaches the market before New Ayala does, if such product is considered by FDA to be the same as New Ayala's, and if such product is intended for the same orphan indication, the competing product could potentially obtain a scope of market exclusivity that limits or precludes its product from being sold in the United States for seven years unless New Ayala can demonstrate that its product is clinically superior. Even if New Ayala obtains exclusivity, the FDA could subsequently approve the same drug for the same condition if the FDA concludes that the later drug is clinically superior to New Ayala in that it is shown to be safer, more effective or makes a major contribution to patient care. A competitor also may receive approval of different products for the same indication for which New Ayala's orphan product has exclusivity or obtain approval for the same product but for a different indication for which the orphan product has exclusivity. Moreover, New Ayala may not be able to maintain its ODD or exclusivity and its product candidates would not be eligible for exclusivity if the approved indication is broader than the ODD.

In addition, if and when New Ayala requests ODD in Europe, the European exclusivity period is ten years but can be reduced to six years if the drug no longer meets the criteria for ODD or if the drug is sufficiently profitable so that market exclusivity is no longer justified. Orphan drug exclusivity may be lost if the FDA or EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition.

New Ayala may incur substantial liabilities from any product liability claims if its insurance coverage for those claims is inadequate.

New Ayala faces an inherent risk of product liability exposure related to the testing of its immunotherapies in human clinical trials and will face an even greater risk if the approved products are sold commercially. An individual may bring a liability claim against New Ayala if one of the immunotherapies causes, or merely appears to have caused, an injury. If New Ayala cannot successfully defend itself against the product liability claim, it will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for New Ayala's immunotherapies;
- damage to New Ayala's reputation;
- withdrawal of clinical trial participants;
- costs of related litigation;
- substantial monetary awards to patients or other claimants;
- loss of revenues;
- the inability to commercialize immunotherapies; and
- increased difficulty in raising required additional funds in the private and public capital markets.

New Ayala has product liability and clinical trial liability insurance coverage for each clinical trial. New Ayala does not have product liability insurance for sold commercial products because it does not have products on the market. New Ayala plans to expand such coverage to include the sale of commercial products if marketing approval is obtained for any of its immunotherapies. However, insurance coverage is increasingly expensive and New Ayala may not be able to maintain insurance coverage at a reasonable cost. Further, New Ayala may not be able to obtain insurance coverage that will be adequate to satisfy any liability that may arise.

New Ayala may not receive Fast Track designation, Breakthrough Therapy Designation or any other designation that it may apply for from the FDA and, if granted, such designations may not actually lead to a faster development or regulatory review or approval process.

The FDA has granted a designation to facilitate development and expedite the review of therapies with the potential to treat a serious condition where there is an unmet medical need (the "Fast Track" designation) for AXAL for adjuvant therapy for high-risk locally advanced cervical cancer patients, and has granted Fast Track designation for ADXS-HER2 for patients with newly-diagnosed, non-metastatic, surgically-resectable osteosarcoma. New Ayala may seek Breakthrough Therapy Designation for its product candidates or Fast Track designation for certain of its other product candidates. There is no guarantee, however, that New Ayala will be able to obtain or maintain such designations.

The FDA has broad discretion whether or not to grant any special designation, so even if New Ayala believes one of its product candidates is eligible for this designation, it cannot assure you that the FDA would decide to grant it. Additionally, even if New Ayala receives a special designation, it may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may also withdraw the designation if it believes that the designation is no longer supported by data from New Ayala's clinical development program.

The results of clinical trials conducted at clinical trial sites outside the United States might not be accepted by the FDA, and data developed outside of a foreign jurisdiction similarly might not be accepted by such foreign regulatory authority.

Some of the clinical trials for New Ayala product candidates that are being or will be conducted through its partnerships and collaborations may be conducted outside the United States, and it intends in the future to conduct additional clinical trials outside the United States. Although the FDA, EMA or comparable foreign regulatory authorities may accept data from clinical trials conducted outside the relevant jurisdiction, acceptance of these data is subject to certain conditions. For example, the FDA requires that the clinical trial must be well designed and conducted and performed by qualified investigators in accordance with ethical principles such as IRB or ethics committee approval and informed consent, the trial population must adequately represent the U.S. population, and the data must be applicable to the U.S. population and U.S. medical practice in ways that the FDA deems clinically meaningful. In addition, while these clinical trials are subject to the applicable local laws, acceptance of the data by the FDA will be dependent upon its determination that the trials were conducted consistent with all applicable U.S. laws and regulations. There can be no assurance that the FDA will accept data from trials conducted outside of the United States as adequate support of a marketing application. Similarly, New Ayala must also ensure that any data submitted to foreign regulatory authorities adheres to their standards and requirements for clinical trials and there can be no assurance a comparable foreign regulatory authority would accept data from trials conducted outside of its jurisdiction.

New Ayala's relationships with healthcare providers and physicians and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose it to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians and third-party payors in the United States and elsewhere play a primary role in the recommendation and prescription of pharmaceutical products. Arrangements with third-party payors and customers can expose pharmaceutical manufacturers to broadly applicable fraud and abuse and other healthcare laws and regulations, including, without limitation, the federal Anti-Kickback Statute (the "AKS") and the FCA which may constrain the business or financial arrangements and relationships through which such companies sell, market and distribute pharmaceutical products. In particular, the research of New Ayala's product candidates, as well as the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission(s), certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials. The applicable federal, state and foreign healthcare laws and regulations that may affect New Ayala's ability to operate include, but are not limited to:

- the AKS, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. A person or entity can be found guilty of violating the statute without actual knowledge of the statute or specific intent to violate it. In addition, a claim including items or services resulting from a violation of the AKS constitutes a false or fraudulent claim for purposes of the FCA. The AKS has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers, and formulary managers on the other. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution;

- the federal civil and criminal false claims laws and civil monetary penalty laws, including the FCA, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, false or fraudulent claims for payment to, or approval by Medicare, Medicaid or other federal healthcare programs, knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim or an obligation to pay or transmit money to the federal government, or knowingly concealing or knowingly and improperly avoiding or decreasing or concealing an obligation to pay money to the federal government. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to “cause” the submission of false or fraudulent claims. The government may deem manufacturers to have “caused” the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off-label. The FCA also permits a private individual acting as a “whistleblower” to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created additional federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the AKS, a person or entity can be found guilty of violating HIPAA without actual knowledge of the statute or specific intent to violate it;
- HIPAA, as amended by HITECH, and their respective implementing regulations, which impose, among other things, requirements on certain healthcare providers, health plans and healthcare clearinghouses, known as covered entities, as well as their respective business associates, independent contractors that perform services for covered entities that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys’ fees and costs associated with pursuing federal civil actions;

- the federal Physician Payments Sunshine Act, created under the Patient Protection and Affordable Care Act, as amended, or ACA, and its implementing regulations, which require some manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program (with certain exceptions) to report annually to the Centers for Medicare & Medicaid Services, or CMS, of the U.S. Department of Health and Human Services, or HHS, information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, and may be broader in scope than their federal equivalents; state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, marketing expenditures or drug pricing; state and local laws that require the registration of pharmaceutical sales representatives; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

The distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products. Pharmaceutical companies may also be subject to federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies continue to closely scrutinize interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Ensuring business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time and resource-consuming and can divert a company’s attention from the business.

It is possible that governmental and enforcement authorities will conclude that New Ayala's business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against New Ayala, and it is not successful in defending itself or asserting its rights, those actions could have a significant impact on its business, including the imposition of civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in federal and state funded healthcare programs, contractual damages and the curtailment or restricting of New Ayala's operations, as well as additional reporting obligations and oversight if it becomes subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws. Further, if any of the physicians or other healthcare providers or entities with whom New Ayala expects to do business is found to be not in compliance with applicable laws, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. Any action for violation of these laws, even if successfully defended, could cause a biopharmaceutical manufacturer to incur significant legal expenses and divert management's attention from the operation of the business. Prohibitions or restrictions on sales or withdrawal of future marketed products could materially affect business in an adverse way.

Obtaining and maintaining regulatory approval of New Ayala's product candidates in one jurisdiction does not mean that it will be successful in obtaining regulatory approval of its product candidates in other jurisdictions.

Obtaining and maintaining regulatory approval of New Ayala's product candidates in one jurisdiction does not guarantee that it will be able to obtain or maintain regulatory approval in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval of a product candidate, the EMA or comparable foreign regulatory authorities must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials, as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that New Ayala intends to charge for its products are also subject to approval.

New Ayala may also submit marketing applications in other countries. Regulatory authorities in jurisdictions outside of the United States have requirements for approval of product candidates with which it must comply prior to marketing in those jurisdictions. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for New Ayala and could delay or prevent the introduction of its products in certain countries. If New Ayala fails to comply with the regulatory requirements in international markets and/or receive applicable marketing approvals, its target market will be reduced and its ability to realize the full market potential of its product candidates will be harmed.

Even if New Ayala receives regulatory approval of any product candidates, it will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and it may be subject to penalties if it fails to comply with regulatory requirements or experience unanticipated problems with its product candidates.

If any of New Ayala's product candidates are approved, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, distribution, sampling, record-keeping, conduct of post-marketing studies and submission of safety, efficacy and other post-market information, including both federal and state requirements in the United States and requirements of comparable foreign regulatory authorities. In addition, New Ayala will be subject to continued compliance with cGMP and GCP requirements for any clinical trials that it conducts post-approval.

Manufacturers and manufacturers' facilities are required to comply with extensive FDA, EMA and comparable foreign regulatory authority requirements, including ensuring that quality control and manufacturing procedures conform to cGMP regulations. As such, New Ayala and its contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any BLA, other marketing application and previous responses to inspection observations. Accordingly, New Ayala and others with whom it works must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control.

Any regulatory approvals that New Ayala receives for its product candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials and surveillance to monitor the safety and efficacy of the product candidate. Certain endpoint data New Ayala hopes to include in any approved product labeling also may not make it into such labeling, including exploratory or secondary endpoint data such as patient-reported outcome measures. The FDA may also require a REMS program as a condition of approval of New Ayala's product candidates, which could entail requirements for long-term patient follow-up, a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA, EMA or a comparable foreign regulatory authority approves New Ayala's product candidates, it will have to comply with requirements including submissions of safety and other post-marketing information and reports and registration.

The FDA may impose consent decrees or withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with New Ayala's product candidates, including adverse events of unanticipated severity or frequency, or with its third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information, imposition of post-market studies or clinical trials to assess new safety risks or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of New Ayala's products, withdrawal of the product from the market or voluntary or mandatory product recalls;
- fines, warning letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by New Ayala or suspension or revocation of license approvals;
- product seizure or detention or refusal to permit the import or export of New Ayala's product candidates; and
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Products may be promoted only for the approved indications and in accordance with the provisions of the approved label. The policies of the FDA, EMA and comparable foreign regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of New Ayala's product candidates. New Ayala cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If New Ayala is slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if New Ayala is not able to maintain regulatory compliance, it may lose any marketing approval that it may have obtained and it may not achieve or sustain profitability.

Coverage and reimbursement may be limited or unavailable in certain market segments for New Ayala's product candidates, if approved, which could make it difficult for New Ayala to sell any product candidates profitably.

The success of New Ayala's product candidates, if approved, depends on the availability of coverage and adequate reimbursement from third-party payors. New Ayala cannot be sure that coverage and reimbursement will be available for, or accurately estimate the potential revenue from, its product candidates or assure that coverage and reimbursement will be available for any product that it may develop.

Patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Coverage and adequate reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance.

Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, decide which drugs and treatments they will cover and the amount of reimbursement. Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. As a result, obtaining coverage and reimbursement approval of a product from a government or other third-party payor is a time-consuming and costly process that could require New Ayala to provide to each payor supporting scientific, clinical and cost-effectiveness data for the use of its products on a payor-by-payor basis, with no assurance that coverage and adequate reimbursement will be obtained. Even if New Ayala obtains coverage for a given product, the resulting reimbursement payment rates might not be adequate for it to achieve or sustain profitability or may require co-payments that patients find unacceptably high. Additionally, third-party payors may not cover, or provide adequate reimbursement for, long-term follow-up evaluations required following the use of product candidates, once approved. Patients are unlikely to use New Ayala's product candidates, once approved, unless coverage is provided and reimbursement is adequate

Ongoing healthcare legislative and regulatory reform measures may have a material adverse effect on New Ayala's business and results of operations.

Changes in regulations, statutes or the interpretation of existing regulations could impact New Ayala's business in the future by requiring, for example: (i) changes to its manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the recall or discontinuation of its products; or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of New Ayala's business.

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, the ACA was passed, which substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacted the U.S. biopharmaceutical industry. The ACA, among other things, addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extended the rebate program to individuals enrolled in Medicaid managed care organizations, established annual fees and taxes on manufacturers of certain branded prescription drugs and created a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D.

Some of the provisions of the ACA have yet to be fully implemented, while certain provisions have been subject to judicial and Congressional challenges to repeal or replace certain aspects of the ACA. For example, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed repeal legislation, the Tax Reform Act includes a provision that repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the “individual mandate.” As a result of the individual mandate repeal, subsequent litigation challenged the validity of the ACA. On December 14, 2018, a U.S. District Court judge in the Northern District of Texas ruled that the individual mandate portion of the ACA is an essential and inseparable feature of the ACA, and therefore because the mandate was repealed as part of the Tax Cuts and Jobs Act, or TCJA, the remaining provisions of the ACA are invalid as well. The Trump administration and CMS have both stated that the ruling will have no immediate effect, and on December 30, 2018 the same judge issued an order staying the judgment pending appeal. A Fifth Circuit U.S. Court of Appeals hearing to determine whether certain states and the House of Representatives have standing to appeal the lower court decision was held on July 9, 2019, but it is unclear when the court will render its decision on this hearing, and what effect it will have on the status of the ACA. Litigation and legislation over the ACA are likely to continue, with unpredictable and uncertain results. New Ayala will continue to evaluate the effect that the ACA and its possible repeal and replacement has on its business.

Since January 2017, President Trump has signed two Executive Orders designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Further, the Trump administration has concluded that cost-sharing reduction, or CSR, payments to insurance companies required under the ACA have not received necessary appropriations from Congress and announced that it will discontinue these payments immediately until those appropriations are made. The loss of the CSR payments is expected to increase premiums on certain policies issued by qualified health plans under the ACA. Bipartisan bills to appropriate funds for CSR payments were proposed in 2017 and 2018, but the proposals have not been enacted into law. Multiple state Attorneys General filed suit to stop the administration from terminating the subsidies, but their case was dismissed by a federal judge in California on July 18, 2018. Furthermore, on June 14, 2018, the U.S. Court of Appeals for the Federal Circuit ruled that the federal government was not required to pay more than \$12 billion in ACA risk corridor payments to third-party payors who argued were owed to them. The effects of this gap in reimbursement on third-party payors, the viability of the ACA marketplace and providers, and the potential effect on New Ayala’s business, are not yet known.

Inadequate funding for the FDA and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of New Ayala’s business may rely, which could negatively impact its business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect New Ayala’s business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process New Ayala’s regulatory submissions, which could have a material adverse effect on its business. Further, upon completion of this offering and in New Ayala’s operations as a public company, future government shutdowns could impact its ability to access the public markets and obtain necessary capital in order to properly capitalize and continue its operations.

Approval of New Ayala’s product candidates does not ensure successful commercialization and reimbursement.

New Ayala is not currently marketing its product candidates, nor can it until they are approved; however, New Ayala is seeking partnering and commercial opportunities for its products. New Ayala cannot assure you that it will be able to commercialize any of its product candidates itself or find a commercialization partner or that it will be able to agree to acceptable terms with any partner to launch and commercialize its products.

The commercial success of New Ayala's product candidates is subject to risks in both the United States and European countries. In addition, in European countries, pricing and payment of prescription pharmaceuticals is subject to more extensive governmental control than in the United States. Pricing negotiations with European governmental authorities can take six to 12 months or longer after the receipt of regulatory approval and product launch. If reimbursement is unavailable in any country in which reimbursement is sought, limited in scope or amount, or if pricing is set at or reduced to unsatisfactory levels, New Ayala's ability or any potential partner's ability to successfully commercialize in such a country would be impacted negatively. Furthermore, if these measures prevent New Ayala or any potential partner from selling on a profitable basis in a particular country, they could prevent the commercial launch or continued sale in that country and could adversely impact the commercialization market opportunity in other countries.

Moreover, as a condition of approval, the regulatory authorities may require that New Ayala conduct post-approval studies. Those studies may reveal new safety or efficacy findings regarding New Ayala's drug that could adversely impact the continued commercialization or future market opportunity in other countries.

In addition, New Ayala predominantly relies on a network of suppliers and vendors to manufacture its products. Should a regulatory authority make any significant findings on an inspection of New Ayala's own operations or the operations of those companies, the ability for it to continue producing its products could be adversely impacted and further production could cease. Regulatory GMP requirements are extensive and can present a risk of injury or recall, among other risks, if not manufactured or labeled properly under GMPs.

New Ayala's potential revenues from the commercialization of its product candidates are subject to these and other factors, and therefore it may never reach or maintain profitability.

Even if New Ayala is successful in obtaining market approval, commercial success of any of its product candidates will also depend in large part on the availability of coverage and adequate reimbursement from third-party payers, including government payers such as the Medicare and Medicaid programs and managed care organizations, which may be affected by existing and future health care reform measures designed to reduce the cost of health care. Third-party payers could require New Ayala to conduct additional studies, including post-marketing studies related to the cost effectiveness of a product, to qualify for reimbursement, which could be costly and divert its resources. If government and other health care payers were not to provide adequate coverage and reimbursement levels for one any of New Ayala's products once approved, market acceptance and commercial success would be reduced.

In addition, if one of New Ayala's products is approved for marketing, it will be subject to significant regulatory obligations regarding product promotion, the submission of safety and other post-marketing information and reports and registration, and will need to continue to comply (or ensure that New Ayala's third-party providers comply) with cGMPs, and GCPs for any clinical trials that it conducts post-approval. In addition, there is always the risk that New Ayala or a regulatory authority might identify previously unknown problems with a product post-approval, such as adverse events of unanticipated severity or frequency. Compliance with these requirements is costly, and any failure to comply or other issues with New Ayala product candidates' post-market approval could have a material adverse effect on its business, financial condition and results of operations.

Risks Related to New Ayala's Intellectual Property

New Ayala relies on patents to protect its technology. New Ayala may be unable to protect its intellectual property rights and it may be liable for infringing the intellectual property rights of others.

New Ayala's ability to compete effectively will depend on its ability to maintain the proprietary nature of its technologies, including the *Lm*-LLO based immunotherapy platform technology, and the proprietary technology of others with whom New Ayala has entered into collaboration and licensing agreements.

Currently, New Ayala owns or have rights to several hundred patents and applications, which are owned, licensed from, or co-owned with Penn and Merck. New Ayala has obtained the rights to all future patent applications in this field originating in the laboratories of Dr. Yvonne Paterson and Dr. Fred Frankel, at the University of Pennsylvania.

New Ayala owns or hold licenses to a number of issued patents and U.S. pending patent applications, as well as foreign patents and foreign counterparts. New Ayala's success depends in part on its ability to obtain patent protection both in the United States and in other countries for its product candidates, as well as the methods for treating patients in the product indications using these product candidates. Such patent protection is costly to obtain and maintain, and New Ayala cannot guarantee that sufficient funds will be available. New Ayala's ability to protect its product candidates from unauthorized or infringing use by third parties depends in substantial part on its ability to obtain and maintain valid and enforceable patents. Due to evolving legal standards relating to the patentability, validity and enforceability of patents covering pharmaceutical inventions and the scope of claims made under these patents, New Ayala's ability to obtain, maintain and enforce patents is uncertain and involves complex legal and factual questions. Even if New Ayala's product candidates, as well as methods for treating patients for prescribed indications using these product candidates are covered by valid and enforceable patents and have claims with sufficient scope, disclosure and support in the specification, the patents will provide protection only for a limited amount of time. Accordingly, rights under any issued patents may not provide New Ayala with sufficient protection for its product candidates or provide sufficient protection to afford it a commercial advantage against competitive products or processes.

In addition, New Ayala cannot guarantee that any patents will issue from any pending or future patent applications owned by or licensed to New Ayala. Even if patents have issued or will issue, New Ayala cannot guarantee that the claims of these patents are or will be valid or enforceable or will provide it with any significant protection against competitive products or otherwise be commercially valuable to New Ayala. The laws of some foreign jurisdictions do not protect intellectual property rights to the same extent as in the United States and many companies have encountered significant difficulties in protecting and defending such rights in foreign jurisdictions. Furthermore, different countries have different procedures for obtaining patents, and patents issued in different countries offer different degrees of protection against use of the patented invention by others. If New Ayala encounters such difficulties in protecting or are otherwise precluded from effectively protecting its intellectual property rights in foreign jurisdictions, its business prospects could be substantially harmed.

The patent positions of biotechnology and pharmaceutical companies, including New Ayala's patent position, involve complex legal and factual questions, and, therefore, validity and enforceability cannot be predicted with certainty. Patents may be challenged, deemed unenforceable, invalidated, or circumvented as a result of laws, rules and guidelines that are changed due to legislative, judicial or administrative actions, or review, which render New Ayala's patents unenforceable or invalid. New Ayala's patents can be challenged by its competitors who can argue that its patents are invalid, unenforceable, lack utility, sufficient written description or enablement, or that the claims of the issued patents should be limited or narrowly construed. Patents also will not protect New Ayala's product candidates if competitors devise ways of making or using these product candidates without infringing its patents.

New Ayala will be able to protect its proprietary rights from unauthorized use by third parties only to the extent that its technologies, methods of treatment, product candidates, and any future products are covered by valid and enforceable patents or are effectively maintained as trade secrets and New Ayala has the funds to enforce its rights, if necessary.

The expiration of New Ayala's owned or licensed patents before completing the research and development of its product candidates and receiving all required approvals in order to sell and distribute the products on a commercial scale can adversely affect New Ayala's business and results of operations.

Litigation regarding patents, patent applications and other proprietary rights may be expensive and time consuming. If New Ayala is involved in such litigation, it could cause delays in bringing product candidates to market and harm its ability to operate.

New Ayala's success will depend in part on its ability to operate without infringing the proprietary rights of third parties. The pharmaceutical industry is characterized by extensive litigation regarding patents and other intellectual property rights. Other parties may obtain patents in the future and allege that the products or use of New Ayala's technologies infringe these patent claims or that it is employing their proprietary technology without authorization.

In addition, third parties may challenge or infringe upon New Ayala's existing or future patents. Proceedings involving New Ayala's patents or patent applications or those of others could result in adverse decisions regarding:

- the patentability of New Ayala's inventions relating to its product candidates; and/or
- the enforceability, validity or scope of protection offered by New Ayala's patents relating to its product candidates.

Even if New Ayala is successful in these proceedings, it may incur substantial costs and divert management time and attention in pursuing these proceedings, which could have a material adverse effect on New Ayala. If New Ayala is unable to avoid infringing the patent rights of others, it may be required to seek a license, defend an infringement action or challenge the validity of the patents in court. Patent litigation is costly and time consuming. New Ayala may not have sufficient resources to bring these actions to a successful conclusion. In addition, if New Ayala does not obtain a license, develop or obtain non-infringing technology, fail to defend an infringement action successfully or have infringed patents declared valid, New Ayala may:

- incur substantial monetary damages;
- encounter significant delays in bringing New Ayala product candidates to market; and/or
- be precluded from participating in the manufacture, use or sale of New Ayala product candidates or methods of treatment requiring licenses.

New Ayala may be unable to adequately prevent disclosure of trade secrets and other proprietary information.

New Ayala also relies on trade secrets to protect its proprietary technologies, especially where it does not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. New Ayala relies in part on confidentiality agreements with its employees, consultants, outside scientific collaborators, sponsored researchers, and other advisors to protect its trade secrets and other proprietary information. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, others may independently discover New Ayala's trade secrets and proprietary information. Costly and time-consuming litigation could be necessary to enforce and determine the scope of New Ayala's proprietary rights, and failure to obtain or maintain trade secret protection could adversely affect its competitive business position.

Some of New Ayala's products are dependent upon its license agreement with Penn; if New Ayala breaches the license agreement and/or fail to make payments due and owing to Penn under its license agreement, its business may be materially and adversely affected.

Pursuant to the terms of New Ayala's license agreement with Penn, which has been amended from time to time, it has acquired exclusive worldwide licenses for patents and patent applications related to its proprietary *Listeria* vaccine technology. The license provides New Ayala with the exclusive commercial rights to the patent portfolio developed at Penn as of the effective date of the license, in connection with Dr. Paterson and requires New Ayala to pay various milestone, legal, filing and licensing payments to commercialize the technology. As of October 31, 2022, New Ayala did not have outstanding payables to Penn. New Ayala can provide no assurance that it will be able to make all future payments due and owing thereunder, that such licenses will not be terminated or expire during critical periods, that it will be able to obtain licenses from Penn for other rights that may be important to New Ayala, or, if obtained, that such licenses will be obtained on commercially reasonable terms. The loss of any current or future licenses from Penn or the exclusivity rights provided therein could materially harm New Ayala's business, financial condition and operating results.

If New Ayala is unable to obtain licenses needed for the development of its product candidates, or if it breaches any of the agreements under which New Ayala licenses rights to patents or other intellectual property from third parties, it could lose license rights that are important to its business.

If New Ayala is unable to maintain and/or obtain licenses needed for the development of its product candidates in the future, it may have to develop alternatives to avoid infringing on the patents of others, potentially causing increased costs and delays in drug development and introduction or precluding the development, manufacture, or sale of planned products. Some of New Ayala's licenses provide for limited periods of exclusivity that require minimum license fees and payments and/or may be extended only with the consent of the licensor. New Ayala can provide no assurance that it will be able to meet these minimum license fees in the future or that these third parties will grant extensions on any or all such licenses. This same restriction may be contained in licenses obtained in the future.

Additionally, New Ayala can provide no assurance that the patents underlying any licenses will be valid and enforceable. To the extent any products developed by New Ayala are based on licensed technology, royalty payments on the licenses will reduce its gross profit from such product sales and may render the sales of such products uneconomical. In addition, the loss of any current or future licenses or the exclusivity rights provided therein could materially harm New Ayala's business, financial condition and its operations.

Risks Related to Ownership of New Ayala's Securities

Because New Ayala is quoted on the OTCQX instead of an exchange or national quotation system, its investors find it more difficult to trade in its stock or might experience volatility in the market price of New Ayala's Common Stock.

New Ayala's Common Stock is quoted on the OTCQX. The OTCQX is often highly illiquid, in part because it does not have a national quotation system by which potential investors can follow the market price of shares except through information received and generated by a limited number of broker-dealers that make markets in particular stocks. There is a greater chance of volatility for securities that are quoted on the OTCQX as compared to a national exchange or quotation system. This volatility may be caused by a variety of factors, including the lack of readily available price quotations, the absence of consistent administrative supervision of bid and ask quotations, lower trading volume, and market conditions. Investors in New Ayala's Common Stock may experience high fluctuations in the market price and volume of the trading market for its securities. These fluctuations, when they occur, have a negative effect on the market price for New Ayala's securities. Accordingly, New Ayala stockholders may not be able to realize a fair price from their shares when they determine to sell them or may have to hold them for a substantial period of time until the market for its Common Stock improves.

New Ayala's stock is quoted on the OTCQX, if it fails to remain current on its reporting requirements, New Ayala could be removed from the OTCQX which would limit the ability of broker-dealers to sell its securities in the secondary market.

Companies trading on the OTCQX, must be reporting issuers under Section 12 of the Exchange Act, and must be current in their reports under Section 13, in order to maintain price quotation privileges on the OTCQX. As a result, the market liquidity for New Ayala's securities could be severely adversely affected by limiting the ability of broker-dealers to sell its securities and the ability of stockholders to sell their securities in the secondary market. In addition, it may be unable to get requoted on the OTCQX, which may have an adverse material effect on New Ayala.

On January 10, 2023, New Ayala, was notified by the OTC Markets Group Inc., that its market capitalization has stayed below \$5 million for the past 30 consecutive calendar days and no longer meets the Standards for Continued Qualification for the OTCQX U.S. tier as per the OTCQX Rules for U.S. Companies section 3.2.b.2. If the Company's market capitalization has not stayed at or above \$5 million for ten consecutive trading days by July 10, 2023, then its common stock will be moved from OTCQX to the OTCQB market.

New Ayala could issue additional "blank check" preferred stock without stockholder approval with the effect of diluting then current stockholder interests and impairing their voting rights, and provisions in its charter documents and under Delaware law could discourage a takeover that stockholders may consider favorable.

New Ayala's certificate of incorporation, as amended, provides that it may authorize and issue up to 5,000,000 shares of "blank check" preferred stock with designations, rights, and preferences as may be determined from time to time by New Ayala's Board. New Ayala's Board is empowered, without stockholder approval, to issue one or more series of preferred stock with dividend, liquidation, conversion, voting, or other rights, which could dilute the interest of or impair the voting power of its holders of Common Stock. The issuance of a series of preferred stock could be used as a method of discouraging, delaying, or preventing a change in control. For example, it would be possible for New Ayala's Board to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to change control of New Ayala.

Sales of additional equity securities may adversely affect the market price of New Ayala's Common Stock and your rights may be reduced.

New Ayala expects to continue to incur drug development and selling, general and administrative costs, and to satisfy its funding requirements, it will need to sell additional equity securities, which may be subject to registration rights and warrants with anti-dilutive protective provisions. The sale or the proposed sale of substantial amounts of New Ayala's Common Stock or other equity securities in the public markets may adversely affect the market price of its Common Stock and stock price may decline substantially. New Ayala shareholders may experience substantial dilution and a reduction in the price that they are able to obtain upon sale of their shares. Also, new equity securities issued may have greater rights, preferences or privileges than New Ayala's existing Common Stock.

The price of New Ayala's Common Stock and warrants may be volatile.

The trading price of New Ayala's Common Stock and warrants may fluctuate substantially. The price of New Ayala's Common Stock and warrants that will prevail in the market may be higher or lower than the price you have paid, depending on many factors, some of which are beyond New Ayala's control and may not be related to its operating performance. These fluctuations could cause you to lose part or all of your investment in New Ayala's Common Stock and warrants. Those factors that could cause fluctuations include, but are not limited to, the following:

- price and volume fluctuations in the overall stock market from time to time;
- fluctuations in stock market prices and trading volumes of similar companies;
- actual or anticipated changes in New Ayala's net loss or fluctuations in its operating results or in the expectations of securities analysts;
- the issuance of new equity securities pursuant to a future offering, including issuances of preferred stock;
- general economic conditions and trends;
- positive and negative events relating to healthcare and the overall pharmaceutical and biotech sector;
- major catastrophic events;
- sales of large blocks of New Ayala stock;
- significant dilution caused by the anti-dilutive clauses in New Ayala's financial agreements;
- departures of key personnel;
- changes in the regulatory status of New Ayala's immunotherapies, including results of its clinical trials;
- events affecting Penn or any current or future collaborators;
- announcements of new products or technologies, commercial relationships or other events by New Ayala or its competitors;
- regulatory developments in the United States and other countries;
- failure of New Ayala's Common Stock or warrants to be listed or quoted on the OTCQX® Best Market or on a national market system;

- changes in accounting principles; and
- discussion of New Ayala or its stock price by the financial and scientific press and in online investor communities.

In the past, following periods of volatility in the market price of a company's securities, securities class action litigation has often been brought against that company. Due to the potential volatility of New Ayala's stock price, it may therefore be the target of securities litigation in the future. Securities litigation could result in substantial costs and divert management's attention and resources from its business.

The market prices for New Ayala's Common Stock may be adversely impacted by future events.

New Ayala's Common Stock began trading on the over-the-counter-markets on July 28, 2005 and is currently quoted on the OTCQX under the symbol ADXS. Market prices for New Ayala's Common Stock and warrants will be influenced by a number of factors, including:

- the issuance of new equity securities pursuant to a future offering, including issuances of preferred stock;
- changes in interest rates;
- significant dilution caused by the anti-dilutive clauses in New Ayala's financial agreements;
- competitive developments, including announcements by competitors of new products or services or significant contracts, acquisitions, strategic partnerships, joint ventures or capital commitments;
- variations in quarterly operating results;
- change in financial estimates by securities analysts;
- the depth and liquidity of the market for New Ayala's Common Stock and warrants;
- investor perceptions of New Ayala and the pharmaceutical and biotech industries generally; and
- general economic and other national conditions.

So long as New Ayala's Common Stock continues to be quoted on the OTCQX, it could be subject to the so-called "penny stock" rules that impose restrictive sales practice requirements.

As New Ayala's Common Stock has been de-listed from the Nasdaq Capital Market and is now quoted on the OTCQX, which is not a "national securities exchange" as defined by the Exchange Act, and thus its Common Stock will become subject to the so-called "penny stock" rules if the shares have a market value of less than \$5.00 per share. The SEC has adopted regulations that define a penny stock to include any stock that has a market price of less than \$5.00 per share, subject to certain exceptions, including an exception for stock traded on a national securities exchange. The SEC regulations impose restrictive sales practice requirements on broker-dealers who sell penny stocks to persons other than established customers and accredited investors. An accredited investor generally is a person whose individual annual income exceeded \$200,000, or whose joint annual income with a spouse exceeded \$300,000 during the past two years and who expects their annual income to exceed the applicable level during the current year, or a person with net worth in excess of \$1.0 million, not including the value of the investor's principal residence and excluding mortgage debt secured by the investor's principal residence up to the estimated fair market value of the home, except that any mortgage debt incurred by the investor within 60 days prior to the date of the transaction shall not be excluded from the determination of the investor's net worth unless the mortgage debt was incurred to acquire the residence. For transactions covered by this rule, the broker-dealer must make a special suitability determination for the purchaser and must have received the purchaser's written consent to the transaction prior to sale. This means that so long as New Ayala's Common Stock is not listed on a national securities exchange, the ability of stockholders to sell their Common Stock in the secondary market could be adversely affected.

If a transaction involving a penny stock is not exempt from the SEC's rule, a broker-dealer must deliver a disclosure schedule relating to the penny stock market to each investor prior to a transaction. The broker-dealer also must disclose the commissions payable to both the broker-dealer and its registered representative, current quotations for the penny stock, and, if the broker-dealer is the sole market-maker, the broker-dealer must disclose this fact and the broker-dealer's presumed control over the market. Finally, monthly statements must be sent disclosing recent price information for the penny stock held in the customer's account and information on the limited market in penny stocks.

New Ayala may be at an increased risk of securities litigation, which is expensive and could divert management attention.

The market price of New Ayala's Common Stock may be volatile, and in the past companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. New Ayala may be the target of this type of litigation in the future. Securities litigation against New Ayala could result in substantial costs and divert its management's attention from other business concerns, which could seriously harm its business.

New Ayala does not intend to pay cash dividends.

New Ayala has not declared or paid any cash dividends on its Common Stock, and it does not anticipate declaring or paying cash dividends for the foreseeable future. Any future determination as to the payment of cash dividends on New Ayala's Common Stock will be at its Board of Directors' discretion and will depend on its financial condition, operating results, capital requirements and other factors that its Board of Directors considers to be relevant.

New Ayala's certificate of incorporation, bylaws and Delaware law have anti-takeover provisions that could discourage, delay or prevent a change in control, which may cause New Ayala's stock price to decline.

New Ayala's certificate of incorporation, Bylaws and Delaware law contain provisions which could make it more difficult for a third party to acquire New Ayala, even if closing such a transaction would be beneficial to its shareholders. New Ayala is authorized to issue up to 5,000,000 shares of preferred stock. This preferred stock may be issued in one or more series, the terms of which may be determined at the time of issuance by New Ayala's Board of Directors without further action by shareholders. The terms of any series of preferred stock may include voting rights (including the right to vote as a series on particular matters), preferences as to dividend, liquidation, conversion and redemption rights and sinking fund provisions. The issuance of any preferred stock could materially adversely affect the rights of the holders of New Ayala's Common Stock, and therefore, reduce the value of its Common Stock. In particular, specific rights granted to future holders of preferred stock could be used to restrict New Ayala's ability to merge with, or sell its assets to, a third party and thereby preserve control by the present management.

Provisions of New Ayala's certificate of incorporation, Bylaws and Delaware law also could have the effect of discouraging potential Acquisition Proposals or making a tender offer or delaying or preventing a change in control, including changes a shareholder might consider favorable. Such provisions may also prevent or frustrate attempts by New Ayala shareholders to replace or remove its management. In particular, the certificate of incorporation, Bylaws and Delaware law, as applicable, among other things; provide the Board of Directors with the ability to alter the By-laws without shareholder approval and provide that vacancies on the Board of Directors may be filled by a majority of directors in office, and less than a quorum.

These provisions are expected to discourage certain types of coercive takeover practices and inadequate takeover bids and to encourage persons seeking to acquire control of New Ayala to first negotiate with its board. These provisions may delay or prevent someone from acquiring or merging with New Ayala, which may cause the market price of its Common Stock to decline.

Item 1B: Unresolved Staff Comments.

None.

Item 2. Properties.

Our corporate offices are located at 9 Deer Park Drive, Suite K-1, Monmouth Junction, NJ 08852 which is occupied pursuant to a lease that expires on March 31, 2023.

Item 3. Legal Proceedings.

Atachbarian

On November 15, 2021, a purported stockholder of the Company commenced an action against the Company and certain of its directors in the U.S. District Court for the District of New Jersey, entitled *Atachbarian v. Advaxis, Inc., et al.*, No. 3:21-cv-20006. The plaintiff alleges that the defendants breached their fiduciary duties and violated Section 14(a) and Rule 20(a) of the Securities Exchange Act of 1934 and Rule 14a-9 promulgated thereunder by allegedly failing to disclose certain matters in its Registration Statement on Form S-4 (Commission File No. 333-259065 (the “Registration Statement”) filed in connection with a proposed merger with Biosight Ltd. (the “Previously Proposed Merger”). On December 15, 2021, pursuant to an understanding reached with the plaintiff, the Company made certain other additional disclosures that mooted the demands asserted in the complaint. On December 17, 2021, the plaintiff filed a notice of voluntary dismissal with prejudice. On February 7, 2022, the Company and the plaintiff reached a settlement agreement, which is recorded in general and administrative expenses in the consolidated statement of operations.

Purported Stockholder Claims Related to Biosight Transaction

Between September 16, 2021, and November 4, 2021, the Company received demand letters on behalf of six purported stockholders of the Company, alleging that the Company failed to disclose certain matters in the Registration Statement, and demanding that the Company disclose such information in a supplemental disclosure filed with the SEC. On October 14, 2021, the Company filed an amendment to the Registration Statement and on November 8, 2021, the Company made certain other additional disclosures that mooted the demands asserted in the above-referenced letters. The six plaintiffs have made settlement demands. On May 20, 2022, the Company and one of the plaintiffs have reached a settlement agreement, which is recorded in general and administrative expenses in the consolidated statement of operations. At this time, the Company is unable to predict the likelihood of an unfavorable outcome.

In addition, the Company received certain additional demands from stockholders asserting that the proxy materials filed by the Company in connection with the Previously Proposed Merger contained alleged material misstatements and/or omissions. Certain stockholders also demanded books and records of the Company pursuant to Delaware law. In response to these demands, the Company agreed to make, and did make, certain supplemental disclosures to the proxy materials. The stockholders have made settlement demands. On July 18, 2022, the Company and the plaintiffs consummated settlement agreements, which is recorded in general and administrative expenses in the consolidated statement of operations.

Purported Stockholder Claims Related to Series D Convertible Preferred Stock Offering

On February 17, 2022, the Company received a letter on behalf of purported stockholders of the Company, demanding certain books and records pursuant to Delaware law regarding the proposed issuance of super voting preferred stock. The Company agreed to provide certain books and records to the stockholders and agreed to make, and did make, a supplemental disclosure to the proxy materials. The stockholders have made settlement demands. On July 18, 2022, the Company and the plaintiffs consummated settlement agreements, which is recorded in general and administrative expenses in the consolidated statement of operations.

Purported Stockholder Claims Related to Merger with Old Ayala

On December 15, 2022, a purported stockholder of Old Ayala filed a complaint in the U.S. District Court for the Southern District of New York against Old Ayala and the members of its Board, captioned *Stephen Bushansky v. Ayala Pharmaceuticals, Inc.*, Case No.1:22-cv-10621 (S.D.N.Y.) (the “Complaint”).

The Complaint asserts claims against all defendants under Section 14(a) of the Securities Exchange Act of 1934, as amended (the “Exchange Act”) and Rule 14a-9 promulgated thereunder for omitting or misrepresenting material information from Old Ayala’s Proxy Statement and against the individual defendants under Section 20(a) of the Exchange Act for alleged “control person” liability with respect to such alleged omissions and misrepresentations. The allegations in the Complaint include that the Proxy Statement omitted material information regarding Old Ayala’s financial projections and the financial analyses of Old Ayala’s financial advisor for the Merger. The Complaint seeks, among other relief, (1) to enjoin defendants from consummating the Merger; (2) to enjoin a vote on the Merger; (3) to rescind the Merger Agreement or recover damages, if the Merger is completed; (4) a declaration that defendants violated Sections 14(a) or 20(a) and Rule 14a-9 of the Exchange Act; and (5) attorneys’ fees and costs.

In addition, approximately nine purported stockholders of Old Ayala sent letters to those noted in the above-referenced Complaint alleging similar deficiencies in Old Ayala’s Proxy Statement (collectively, the “Demand Letters”).

At this time, the Company is unable to predict the likelihood of an unfavorable outcome with respect to the Complaint and the Demand Letters.

Item 4. Mine Safety Disclosures.

None.

PART II

Item 5. Market for Our Common stock and Related Shareholder Matters.

Our common stock is quoted on the OTCQX under the symbol “ADXS”.

As of October 31, 2022 there were approximately 80 holders of our common stock. The actual number of holders of our common stock is greater than this number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers or held by other nominees.

We have not declared or paid any cash dividends on our common stock, and we do not anticipate declaring or paying cash dividends for the foreseeable future.

Recent Sales of Unregistered Securities

None.

ITEM 6. Selected Financial Data.

[Reserved].

ITEM 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations.

This Management’s Discussion and Analysis of Financial Conditions and Results of Operations and other portions of this report contain forward-looking information that involves risks and uncertainties. Our actual results could differ materially from those anticipated by the forward-looking information. Factors that may cause such differences include, but are not limited to, availability and cost of financial resources, product demand, market acceptance and other factors discussed in this report under the heading “Risk Factors”. This Management’s Discussion and Analysis of Financial Conditions and Results of Operations should be read in conjunction with our financial statements and the related notes included elsewhere in this report.

Overview

Ayala Pharmaceuticals, Inc. (“New Ayala” or the “Company”) is a clinical-stage biotechnology company focused on the development and commercialization of proprietary *Lm* Technology antigen delivery products based on a platform technology that utilizes live attenuated *Listeria monocytogenes*, or *Lm*, bioengineered to secrete antigen/adjuvant fusion proteins. These *Lm*-based strains are believed to be a significant advancement in immunotherapy as they integrate multiple functions into a single immunotherapy by accessing and directing antigen presenting cells to stimulate anti-tumor T cell immunity, stimulate and activate the innate immune system with the equivalent of multiple adjuvants, and simultaneously reduce tumor protection in the Tumor Microenvironment, or TME, to enable the T cells to attack tumor cells.

The Company believes that *Lm* Technology immunotherapies can complement and address significant unmet needs in the current oncology treatment landscape. Specifically, our product candidates (i.e., ADXS-PSA and ADXS-504) have the potential to optimize, enhance checkpoint performance of other oncology treatments, while having a generally well-tolerated safety profile.

New Ayala is currently winding down or has wound down clinical studies of *Lm* Technology immunotherapies in three program areas:

- Human Papilloma Virus (“HPV”)-associated cancers
- Personalized neoantigen-directed therapies
- Human epidermal growth factor receptor-2 (HER-2) associated cancers

All these clinical program areas are anchored in the Company's *Lm* Technology™, a unique platform designed for its ability to safely and effectively target various cancers in multiple ways. While we are currently winding down clinical studies of *Lm* Technology immunotherapies in these three program areas, our license agreements continue with OS Therapies, LLC for ADXS-HER2 and with Global BioPharma, or GBP, for the exclusive license for the development and commercialization of ADXS-HPV, or AXAL, in Asia, Africa, and the former USSR territory, exclusive of India and certain other countries.

Recent Developments

Merger with Ayala Pharmaceuticals, Inc.

On October 18, 2022, the Company entered into a Merger Agreement (the "Merger Agreement"), subject to shareholder approval, with Ayala Pharmaceuticals, Inc. ("Old Ayala") and Doe Merger Sub, Inc. ("Merger Sub"), a direct, wholly-owned subsidiary of New Ayala. Under the terms of the agreement, the Merger Sub merged with and into Old Ayala, with Old Ayala continuing as the surviving company and a wholly-owned subsidiary of New Ayala (the "Merger"). Immediately after the Merger, New Ayala stockholders as of immediately prior to the Merger owned approximately 37.5% of the outstanding shares of the combined company and former Old Ayala shareholders owned approximately 62.5% of the outstanding shares of the combined company. The Merger was accounted for a reverse acquisition pursuant to ASC 805-40.

At the effective time of the Merger (the "Effective Time"), each share of share capital of Old Ayala issued and outstanding immediately prior to the Effective Time was converted into the right to receive a number of shares of New Ayala common stock, par value \$0.001 per share, equal to the exchange ratio, 0.1874 shares of New Ayala common stock per Old Ayala share.

Results of Operations for the Fiscal Year Ended October 31, 2022 Compared to the Fiscal Year Ended October 31, 2021

Revenue

Revenue was \$250,000 for the year ended October 31, 2022 compared to \$3,240,000 for the year ended October 31, 2021. In the prior period, we recognized royalty payments from OST.

Research and Development Expenses

We invest in research and development to advance our *Lm* technology through our preclinical and clinical development programs. Research and development expenses for the years ended October 31, 2022 and 2021 were categorized as follows (in thousands):

	Fiscal Years Ended October 31,		Increase (Decrease)	
	2022	2021	\$	%
Hotspot/Off-the-Shelf therapies	\$ 4,323	\$ 4,261	\$ 62	1%
Prostate cancer	94	30	64	213%
HPV-associated cancers	263	2,069	(1,806)	(87)%
Personalized neoantigen-directed therapies	11	495	(484)	(98)%
Other expenses	2,925	3,707	(782)	(21)%
Total research & development expense	\$ 7,616	\$ 10,562	\$ (2,946)	(28)%
Stock-based compensation expense included in research and development expense	\$ 47	\$ 164	\$ (117)	(71)%

Hotspot/Off-the-Shelf Therapies (ADXS-HOT)

Research and development costs associated with our hotspot mutation-based therapy for the fiscal year ended October 31, 2022 increased approximately 1% to \$4,323,000 compared to the same period in 2021. The increase is attributable to patient recruitment costs and manufacturing costs pertaining to the HOT-503 study incurred in the current period and partially offset by a slowdown in patient enrollment. On October 18, 2022, we announced that we are conducting an orderly wind down of our HOT-503 study.

Prostate Cancer (ADXS-PSA)

Research and development costs associated with our prostate cancer therapy for the year ended October 31, 2022 increased approximately \$64,000, or 213%, compared to the same period in 2021. The increase is not significant. The Phase 1/2 study of our ADXS-PSA compound in combination with KEYTRUDA® (pembrolizumab), Merck's humanized monoclonal antibody, has been completed and we do not anticipate that we will continue to incur significant costs associated with the wind down of the study.

HPV-Associated Cancers (AXAL)

The majority of the HPV-associated research and development costs include clinical trial and other related costs associated with our AXAL programs in cervical and head and neck cancers. HPV-associated costs for the year ended October 31, 2022 decreased approximately \$1,806,000, or 87%, compared to the same period in 2021. The decrease is attributable to wind down costs associated with the closure of our Phase 3 AIM2CERV study in high-risk locally advanced cervical cancer. We do not anticipate that we will continue to incur significant costs associated with the wind down of our Phase 3 AIM2CERV study.

Personalized Neoantigen-Directed Therapies (ADXS-NEO)

Research and development costs associated with personalized neoantigen-directed therapies for the year ended October 31, 2022 decreased approximately \$484,000, or 98%, compared to the same period in 2021. The study has been completed and we do not anticipate that we will continue to incur significant costs associated with the wind down of the study.

Other Expenses

Other expenses include salary and benefit costs, stock-based compensation expense, professional fees, laboratory costs and other internal and external costs associated with our research & development activities. Other expenses for the year ended October 31, 2022 decreased approximately \$782,000, or 21%, compared to the same period in 2021. The decrease is attributable to (1) prior period losses on disposal of property and equipment in connection with the termination of our office lease at our former location, (2) decrease in personnel costs due to decreases in headcount, stock compensation and bonus accruals, and (3) decrease in depreciation expense. The decreases were partially offset by increases in (1) clinical trial expenses due to credit memos issued by vendors in the prior year and (2) consulting expenses.

General and Administrative Expenses

General and administrative expenses primarily include salary and benefit costs and stock-based compensation expense for employees included in our finance, legal and administrative organizations, outside legal and professional services, and facilities costs. General and administrative expenses for the years ended October 31, 2022 and 2021 were as follows (in thousands):

	Years Ended October 31,		Increase (Decrease)	
	2022	2021	\$	%
General and administrative expense	\$ 8,891	\$ 11,464	\$ (2,573)	(22)%
Stock-based compensation expense included in general and administrative expense	\$ 50	\$ 402	\$ (352)	(88)%

General and administrative expenses for the year ended October 31, 2022 decreased approximately \$2,573,000, or 22%, compared to the same period in 2021. This decrease primarily relates to (1) legal and consulting fees related to the Previously Proposed Merger in the prior period, (2) prior period losses on disposal of property and equipment in connection with the termination of our office lease at our former location, (3) prior period sublicense fees paid to the University of Pennsylvania for the OST milestones reached, (4) decrease in personnel costs due to decreases in stock compensation and bonus accruals, (5) decreases in rent, utilities and depreciation due to the termination of our office lease at our former location and (6) decreases in Director and Officer insurance. These decreases were partially offset by (1) an increase in proxy solicitation fees related to the Previously Proposed Merger and the reverse stock split and (2) an increase in amounts paid in settlement of shareholder demand letters in the current period.

Intangible Asset Impairment

During the year ended October 31, 2022, the Company recorded an impairment charge under ASC 350 for its patents owned and in-licensed intellectual property of approximately \$3,053,000.

Changes in Fair Values

For the year ended October 31, 2022, we recorded non-cash income from changes in the fair value of derivative liabilities of approximately \$4,853,000. The decrease in the derivative liabilities was attributable to a decrease in our share price from \$38.77 at October 31, 2021 to \$1.86 at October 31, 2022.

For the year ended October 31, 2021, we recorded non-cash income from changes in the fair value of the warrant liability of approximately \$970,000. The decrease in the fair value of liability warrants resulted primarily from the issuance of warrants in the April 2021 Private Placement. The warrants issued in the April 2021 Private Placement decreased in fair value from date of issuance to October 31, 2021 due to a decrease in our share price from \$45.36 at April 14, 2021 to \$38.77 at October 31, 2021.

Liquidity and Capital Resources

Going Concern and Management's Plans

Similar to other development stage biotechnology companies, our products that are being developed have not generated significant revenue. As a result, we have historically suffered recurring losses and we have required significant cash resources to execute our business plans. These losses are expected to continue for the foreseeable future. Additionally, due to the Merger, we will need additional cash resources to properly integrate and implement the operations of Old Ayala. The aforementioned factors raise substantial doubt about our ability to continue as a going concern. The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The financial statements do not include any adjustments relating to the recoverability and classification of asset amounts or the classification of liabilities that might be necessary should we be unable to continue as a going concern within twelve months after the date the financial statements are issued.

Historically, the Company's major sources of cash have comprised proceeds from various public and private offerings of its securities (including common stock), debt financings, clinical collaborations, option and warrant exercises, income earned on investments and grants, and interest income. From October 2013 through October 31, 2022, the Company raised approximately \$339.4 million in gross proceeds from various public and private offerings of our common stock. The Company has sustained losses from operations in each fiscal year since our inception, and we expect losses to continue for the indefinite future. As of October 31, 2022 and October 31, 2021, the Company had an accumulated deficit of approximately \$443 million and \$428.6 million, respectively, and stockholders' equity of approximately \$23.6 million and \$38.9 million, respectively.

The COVID-19 pandemic has created significant volatility and disruption of financial markets. An extended period of economic disruption could negatively affect the Company's business, financial condition, and access to sources of liquidity. As of October 31, 2022, the Company had approximately \$25.2 million in cash and cash equivalents. The actual amount of cash that the Company will need to continue operating is subject to many factors.

The Company recognizes that it will need to raise additional capital in order to continue to execute its business plan in the future. There is no assurance that additional financing will be available when needed or that the Company will be able to obtain financing on terms acceptable to it or whether the Company will become profitable and generate positive operating cash flow. If the Company is unable to raise sufficient additional funds, it will have to further scale back its operations. The Company based this estimate on assumptions that may prove to be incorrect, and we could use available capital resources sooner than currently expected.

Cash Flows

Operating Activities

Net cash used in operating activities was approximately \$15,284,000 for the fiscal year ended October 31, 2022 compared to \$15,439,000, for the fiscal year ended October 31, 2021. Net cash used in operating activities includes reduced spending associated with our clinical trial programs and general and administrative activities. The variance is insignificant.

Investing Activities

Net cash used in investing activities was approximately \$166,000 for the fiscal year ended October 31, 2022 compared to \$11,000 for the fiscal year ended October 31, 2021. The decrease is the result of proceeds on a prior period disposal of property and equipment partially offset by reductions in purchases for intangible assets.

Financing Activities

Net cash used in financing activities was approximately \$956,000 for the fiscal year ended October 31, 2022 as compared to net cash provided by financing activities of \$31,886,000 for the fiscal year ended October 31, 2021. On January 31, 2022, the Company closed on an offering with certain institutional investors for the private placement of 1,000,000 shares of Series D Preferred Stock. The shares sold had an aggregate stated value of \$5,000,000. Each share of the Series D Preferred Stock was sold for a purchase price of \$4.75, representing an original issue discount of 5% of the stated value. Total net proceeds from the offering, after deducting the financial advisor's fees and other estimated offering expenses, were approximately \$4.3 million. The Series D preferred stock also had a liquidation preference over the shares of common stock, and could be redeemed by the investors, in accordance with certain terms, for a redemption price equal to 105% of the stated value, or in certain circumstances, 110% of the stated value. On April 6, 2022, the holders of all 1,000,000 outstanding shares of the Series D Preferred Stock exercised their right to cause the Company to redeem all of such shares at a price per share equal to 105% of the stated value per share of \$5.00, and such shares were redeemed accordingly.

In November 2020, the Company closed on a public offering of 383,333 shares of its common stock at a public offering price of \$24.00 per share. After deducting the underwriting discounts and commissions and other offering expenses, the net proceeds from the offering were approximately \$8.5 million. In addition, the Company also undertook a concurrent private placement of warrants to purchase up to 191,674 shares of common stock. The warrants have an exercise price per share of \$28.00, are exercisable immediately and will expire five years from the date of issuance.

On April 12, 2021, the Company completed an offering of (i) 219,718 shares of common stock, (ii) 95,899 pre-funded warrants to purchase 95,899 shares of common stock and (iii) registered common share purchase warrants to purchase 140,552 shares of common stock with two healthcare focused, institutional investors. The Company also issued to the investors, in a concurrent private placement, unregistered common share purchase warrants to purchase 175,065 shares of the Company's common stock. We received gross proceeds of approximately \$20 million, before deducting the fees and expenses payable by us in connection with the offering.

During the year ended October 31, 2021, warrant holders from the Company's November 2020 and April 2021 offerings exercised 230,343 warrants in exchange for 230,343 shares of the Company's common stock. Pursuant to these warrant exercises, the Company received aggregate proceeds of approximately \$3.8 million.

Off-Balance Sheet Arrangements

As of October 31, 2022, we had no off-balance sheet arrangements.

Critical Accounting Estimates

The preparation of financial statements and related disclosures in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the financial statements, and income and expenses during the periods reported. Actual results could materially differ from those estimates. We have identified the following critical accounting estimates:

Warrant Liabilities

We account for our warrants as either equity-classified or liability-classified instruments based on an assessment of the warrant's specific terms and applicable authoritative guidance in ASC 480, Distinguishing Liabilities from Equity ("ASC 480") and ASC 815, Derivatives and Hedging ("ASC 815"). The assessment considers whether the warrants are freestanding financial instruments pursuant to ASC 480, meet the definition of a liability pursuant to ASC 480, and whether the warrants meet all of the requirements for liability classification under ASC 815, including whether the warrants are indexed to the Company's own ordinary shares, among other conditions for equity classification. This assessment, which requires the use of professional judgment, is conducted at the time of warrant issuance and as of each subsequent quarterly period end date while the warrants are outstanding.

Some of our warrants meet the criteria as liability classified derivative instruments and are recorded at fair value on the grant date and re-valued at each reporting date, with changes in the fair value reported in the statements of operations. Warrant liabilities are classified on the balance sheet as current or non-current based on whether or not net-cash settlement or conversion of the instrument could be required within 12 months of the balance sheet date. Volatility in our common stock may result in significant changes in the value of the warrant liabilities and resulting gains and losses on our consolidated statement of operations.

Intangible Assets

Intangible assets primarily consist of legal and filing costs associated with obtaining patents and licenses and are amortized on a straight-line basis over their remaining useful lives which are estimated to be twenty years from the effective dates of the University of Pennsylvania (Penn) License Agreements, beginning in July 1, 2002. These legal and filing costs are invoiced to the Company through Penn and its patent attorneys.

Critical Accounting Policies

Revenue Recognition

Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, the Company assesses the goods or services promised within each contract, determines those that are performance obligations and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

The Company enters into licensing agreements that are within the scope of ASC 606, under which it may exclusively license rights to research, develop, manufacture and commercialize its product candidates to third parties. The terms of these arrangements typically include payment to the Company of one or more of the following: non-refundable, upfront license fees; reimbursement of certain costs; customer option exercise fees; development, regulatory and commercial milestone payments; and royalties on net sales of licensed products.

In determining the appropriate amount of revenue to be recognized as it fulfills its obligations under its agreements, the Company performs the following steps: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) the Company satisfies each performance obligation. As part of the accounting for these arrangements, the Company must use significant judgment to determine: (a) the number of performance obligations based on the determination under step (ii) above; (b) the transaction price under step (iii) above; and (c) the stand-alone selling price for each performance obligation identified in the contract for the allocation of transaction price in step (iv) above. The Company uses judgment to determine whether milestones or other variable consideration, except for royalties, should be included in the transaction price as described further below. The transaction price is allocated to each performance obligation on a relative stand-alone selling price basis, for which the Company recognizes revenue as or when the performance obligations under the contract are satisfied.

Amounts received prior to revenue recognition are recorded as deferred revenue. Amounts expected to be recognized as revenue within the 12 months following the balance sheet date are classified as current portion of deferred revenue in the accompanying consolidated balance sheets. Amounts not expected to be recognized as revenue within the 12 months following the balance sheet date are classified as deferred revenue, net of current portion.

Exclusive Licenses. If the license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenue from non-refundable, upfront fees allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. In assessing whether a performance obligation is distinct from the other performance obligations, the Company considers factors such as the research, development, manufacturing and commercialization capabilities of the collaboration partner and the availability of the associated expertise in the general marketplace. In addition, the Company considers whether the collaboration partner can benefit from a performance obligation for its intended purpose without the receipt of the remaining performance obligation, whether the value of the performance obligation is dependent on the unsatisfied performance obligation, whether there are other vendors that could provide the remaining performance obligation, and whether it is separately identifiable from the remaining performance obligation. For licenses that are combined with other performance obligation, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition. The measure of progress, and thereby periods over which revenue should be recognized, are subject to estimates by management and may change over the course of the research and development and licensing agreement. Such a change could have a material impact on the amount of revenue the Company records in future periods.

Milestone Payments. At the inception of each arrangement that includes research or development milestone payments, the Company evaluates whether the milestones are considered probable of being achieved and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. An output method is generally used to measure progress toward complete satisfaction of a milestone. Milestone payments that are not within the control of the Company or the licensee, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. The Company evaluates factors such as the scientific, clinical, regulatory, commercial, and other risks that must be overcome to achieve the particular milestone in making this assessment. There is considerable judgment involved in determining whether it is probable that a significant revenue reversal would not occur. At the end of each subsequent reporting period, the Company re-evaluates the probability of achievement of all milestones subject to constraint and, if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenue and earnings in the period of adjustment.

Stock Based Compensation

The Company has an equity plan which allows for the granting of stock options to its employees, directors and consultants for a fixed number of shares with an exercise price equal to the fair value of the shares at date of grant. The Company measures the cost of services received in exchange for an award of equity instruments based on the fair value of the award. The fair value of the award is measured on the grant date and is then recognized over the requisite service period, usually the vesting period, in both research and development expenses and general and administrative expenses on the consolidated statement of operations, depending on the nature of the services provided by the employees or consultants.

The process of estimating the fair value of stock-based compensation awards and recognizing stock-based compensation cost over their requisite service period involves significant assumptions and judgments. The Company estimates the fair value of stock option awards on the date of grant using the Black Scholes Model (“BSM”) for the remaining awards, which requires that the Company makes certain assumptions regarding: (i) the expected volatility in the market price of its common stock; (ii) dividend yield; (iii) risk-free interest rates; and (iv) the period of time employees are expected to hold the award prior to exercise (referred to as the expected holding period). As a result, if the Company revises its assumptions and estimates, stock-based compensation expense could change materially for future grants.

The Company accounts for stock-based compensation using fair value recognition and records forfeitures as they occur. As such, the Company recognizes stock-based compensation cost only for those stock-based awards that vest over their requisite service period, based on the vesting provisions of the individual grants.

Warrant Liabilities

We account for our warrants as either equity-classified or liability-classified instruments based on an assessment of the warrant’s specific terms and applicable authoritative guidance in ASC 480, Distinguishing Liabilities from Equity (“ASC 480”) and ASC 815, Derivatives and Hedging (“ASC 815”). The assessment considers whether the warrants are freestanding financial instruments pursuant to ASC 480, meet the definition of a liability pursuant to ASC 480, and whether the warrants meet all of the requirements for liability classification under ASC 815, including whether the warrants are indexed to the Company’s own ordinary shares, among other conditions for equity classification. This assessment, which requires the use of professional judgment, is conducted at the time of warrant issuance and as of each subsequent quarterly period end date while the warrants are outstanding.

Some of our warrants meet the criteria as liability classified derivative instruments and are recorded at fair value on the grant date and re-valued at each reporting date, with changes in the fair value reported in the statements of operations. Warrant liabilities are classified on the balance sheet as current or non-current based on whether or not net-cash settlement or conversion of the instrument could be required within 12 months of the balance sheet date. Volatility in our common stock may result in significant changes in the value of the warrant liabilities and resulting gains and losses on our consolidated statement of operations.

Intangible Assets

Intangible assets primarily consist of legal and filing costs associated with obtaining patents and licenses and are amortized on a straight-line basis over their remaining useful lives which are estimated to be twenty years from the effective dates of the University of Pennsylvania (Penn) License Agreements, beginning in July 1, 2002. These legal and filing costs are invoiced to the Company through Penn and its patent attorneys.

Management reviews its long-lived assets for impairment whenever events and circumstances indicate that the carrying value of an asset might not be recoverable. Net assets are recorded on the balance sheet for patents related to ADXS-HER2 and the Lm technology licensed from the University of Pennsylvania. There are various scenarios under which an impairment charge may be recorded, which include if a competitor were to gain FDA approval for a similar treatment before the Company, if future clinical trials fail to meet the targeted endpoints, or if a drug application is rejected or fails to be issued. Lastly, if the Company is unable to raise enough capital to continue funding its studies and developing its intellectual property, the Company would likely record an impairment to these assets.

Leases

At the inception of an arrangement, the Company determines whether an arrangement is or contains a lease based on the facts and circumstances present in the arrangement. An arrangement is or contains a lease if the arrangement conveys the right to control the use of an identified asset for a period of time in exchange for consideration. Most leases with a term greater than one year are recognized on the consolidated balance sheet as operating lease right-of-use assets and current and long-term operating lease liabilities, as applicable. The Company has elected not to recognize on the consolidated balance sheet leases with terms of 12 months or less. The Company typically only includes the initial lease term in its assessment of a lease arrangement. Options to extend a lease are not included in the Company's assessment unless there is reasonable certainty that the Company will renew.

Operating lease liabilities and their corresponding right-of-use assets are recorded based on the present value of lease payments over the expected remaining lease term. Certain adjustments to the right-of-use asset may be required for items such as prepaid or accrued rent. The interest rate implicit in the Company's leases is typically not readily determinable. As a result, the Company utilizes its incremental borrowing rate, which reflects the fixed rate at which the Company could borrow on a collateralized basis the amount of the lease payments in the same currency, for a similar term, in a similar economic environment. In transition to ASC 842, the Company utilized the remaining lease term of its leases in determining the appropriate incremental borrowing rates.

New Accounting Standards

See Note 2 to our financial statements that discusses new accounting standards.

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

At October 31, 2022, we had approximately \$25.2 million in cash and cash equivalents, which consisted primarily of bank deposits and money market funds. Our investment policy and strategy are focused on preservation of capital and supporting our liquidity requirements. We use a combination of internal and external management to execute our investment strategy and achieve our investment objectives. We typically invest in highly-rated securities (such as money market funds), and our investment policy generally limits the amount of credit exposure to any one issuer. The policy requires investments generally to be investment grade, with the primary objective of minimizing the potential risk of principal loss. Such interest-earning instruments carry a degree of interest rate risk; however, historical fluctuations of interest income have not been significant.

We have not been exposed nor do we anticipate being exposed to material risks due to changes in interest rates. A hypothetical 10% change in interest rates during any of the periods presented would not have had a material impact on our financial statements.

Item 8. Financial Statements and Supplementary Data.

The information required by this Item 8 is incorporated by reference to our financial statements and the related notes and the report of our independent registered public accounting firm beginning at page F-1 of this report.

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

None.

Item 9A: Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and our Interim Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures reflects the fact that there are resource constraints and that management is required to apply its judgment in evaluating the benefits of possible controls and procedures relative to their costs.

As required by Rule 13a-15(b) under the Exchange Act, our management, under the supervision and with the participation of our Chief Executive Officer and our Interim Chief Financial Officer, conducted an evaluation of the effectiveness of our disclosure controls and procedures as of October 31, 2022. Based on such evaluation, our Chief Executive Officer and our Interim Chief Financial Officer concluded that, as of October 31, 2022, our disclosure controls and procedures were effective.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rule 13a-15(f) under the Exchange Act. With the participation of our Chief Executive Officer and our Interim Chief Financial Officer, our management conducted an evaluation of the effectiveness of our internal control over financial reporting as of October 31, 2022. In conducting such evaluation, management used the criteria set forth in the report entitled "*Internal Control — Integrated Framework*" published by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) to evaluate the effectiveness of our internal control over financial reporting. Based on this evaluation, management has concluded that our internal control over financial reporting was effective as of October 31, 2022, based on those criteria.

This report does not include an attestation report of our independent registered public accounting firm regarding our internal control over financial reporting, in accordance with applicable SEC rules that permit us to provide only management's report in this report.

Changes in Internal Control Over Financial Reporting

There was no change in our internal control over financial reporting during the fiscal year ended October 31, 2022, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements prepared for external purposes in accordance with generally accepted accounting principles. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Item 9B. Other Information

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions That Prevent Inspections.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Legal Proceedings Involving Directors

None.

Board Leadership Structure

On May 27, 2015, David Sidransky was appointed Chairman of the Board of Directors (the “Board”) and continues to serve as Chairman. Dr. Sidransky’s experience in life science companies, as well as his scientific knowledge, his history with our Company and his own history of innovation and strategic thinking, qualify him to serve as our Chairman. Additionally, on April 23, 2018, Kenneth Berlin was appointed President and Chief Executive Officer and named a member of the Board of Directors. Mr. Berlin’s knowledge of industry standards and his experience in industry operations, and his leadership experience complements Dr. Sidransky’s scientific knowledge.

While we do not have a formal policy regarding the separation of our principal executive officer and chairman of our Board, we believe the current structure is in the best interest of the Company at this time. Further, this structure demonstrates to our employees and stockholders that we are under strong leadership, with multiple skills and sets the tone for managing our operations. This leadership structure promotes strategic development and execution, timely decision-making and effective management of our resources. We believe that we are well-served by this structure.

New Ayala’s directors are elected annually by the stockholders and serve for one-year terms until his/her successor is elected and qualified or until such director’s earlier death, resignation or removal. The executive officers and key personnel are appointed by and serve at the discretion of the Board of Directors. The executive officers and directors of New Ayala and their respective ages as of October 31, 2022 were as follows:

<u>Name</u>	<u>Age</u>	<u>Position</u>
Dr. David Sidransky (2) (3) (4)	62	Chairman of our Board of Directors
Dr. James P. Patton (1) (3) (4)	65	Vice Chairman of our Board of Directors
Roni A. Appel (1) (3)	56	Director
Kenneth A. Berlin	58	President and Chief Executive Officer, Director
Richard J. Berman (1) (2)	80	Director
Dr. Samir N. Khleif (2) (4)	59	Director
Andres Gutierrez	62	Chief Medical Officer and Executive Vice President
Igor Gitelman	47	Interim Chief Financial Officer, VP of Finance

(1) Member of the Audit Committee

(2) Member of the Compensation Committee

(3) Member of the Nominating and Corporate Governance Committee

(4) Member of the Research & Development Committee

In connection with the Merger, Dr. Patton and Mr. Berman stepped down from the Board and were replaced by Dr. Vered Bisker-Leib, Murray A. Goldberg, and Dr. Robert Spiegel.

Dr. David Sidransky

Dr. Sidransky currently serves as the Chairman of our Board of Directors and has served as a member of our Board of Directors since July 2013. He is a renowned oncologist and research scientist named and profiled by TIME magazine in 2001 as one of the top physicians and scientists in America, recognized for his work with early detection of cancer. Since 1994, Dr. Sidransky has been the Director of the Head and Neck Cancer Research Division and Professor of Oncology, Otolaryngology, Genetics, and Pathology at Johns Hopkins University School of Medicine. He has served as Chairman or Lead of the Board of Directors of Champions Oncology since October 2007 and was a director and Vice-Chairman of ImClone Systems until its merger with Eli Lilly Inc. He is the Chairman of Tamir Biotechnology and Ayala and serves on the Board of Directors of Galmed and Orgenesis. He has served on scientific advisory boards of MedImmune, Roche, Amgen, and Veridex, LLC (a Johnson & Johnson diagnostic company), among others. Dr. Sidransky served as Director (2005-2008) of the American Association for Cancer Research (AACR). He earned his B.S. from Brandeis University and his Medical Doctorate from Baylor College of Medicine. Dr. Sidransky’s experience in life science companies, as well as his scientific knowledge, qualify him to service as our director and non-executive chairman.

Roni A. Appel

Mr. Appel has served as a member of our Board of Directors since November 2004. He was our President and Chief Executive Officer from January 1, 2006 until December 2006 and Secretary and Chief Financial Officer from November 2004 to September 2006. From December 15, 2006 to December 2007, Mr. Appel served as a consultant to us. Mr. Appel currently is a self-employed consultant and the Co-Founder and President of Spirify Pharma Inc. Previously, he served as Chief Executive Officer of Anima Biotech Inc., from 2008 through January 31, 2013. From 1999 to 2004, he was a partner and managing director of LV Equity Partners (f/k/a LibertyView Equity Partners). From 1998 until 1999, he was a director of business development at Americana Financial Services, Inc. From 1994 to 1996, he worked as an attorney. Mr. Appel holds an M.B.A from Columbia University (1998) and an LL.B. from Haifa University (1994). Mr. Appel's longstanding service with us and his entrepreneurial investment career in early stage biotech businesses qualify him to serve as our director.

Kenneth Berlin

Mr. Berlin has served as our President and Chief Executive Officer and a member of our Board of Directors since April 2018. Mr. Berlin served as our Interim Chief Financial Officer from September 2020 to May 2022. Prior to joining New Ayala, Mr. Berlin served as President and Chief Executive Officer of Rosetta Genomics from November 2009 until April 2018. Prior to Rosetta Genomics, Mr. Berlin was Worldwide General Manager at cellular and molecular cancer diagnostics developer Veridex, LLC, a Johnson & Johnson company. At Veridex he grew the organization to over 100 employees, launched three cancer diagnostic products, led the acquisition of its cellular diagnostics partner, and delivered significant growth in sales as Veridex transitioned from an R&D entity to a commercial provider of oncology diagnostic products and services. Mr. Berlin joined Johnson & Johnson in 1994 and served as corporate counsel for six years. From 2001 until 2004 he served as Vice President, Licensing and New Business Development in the pharmaceuticals group, and from 2004 until 2007 served as Worldwide Vice President, Franchise Development, Ortho-Clinical Diagnostics. Mr. Berlin holds an A.B. degree from Princeton University and a J.D. from the University of California Los Angeles School of Law. Mr. Berlin's experience in life science companies, as well as his business experience in general, qualify him to service as our director.

Dr. Samir Khleif

Dr. Khleif has served as a member of our Board of Directors since October 2014. He currently serves as the Director of the State of Georgia Cancer Center, Georgia Regents University Cancer Center and the Cancer Service Line. Dr. Khleif was formerly Chief of the Cancer Vaccine Section at the NCI, and also served as a Special Assistant to the Commissioner of the FDA leading the Critical Path Initiative for oncology. Dr. Khleif is a Georgia Research Alliance Distinguished Cancer Scientist and Clinician and holds a professorship in Medicine, Biochemistry and Molecular Biology, and Graduate Studies at Georgia Regents University. Dr. Khleif's research program at Georgia Regents University Cancer Center focuses on understanding the mechanisms of cancer-induced immune suppression, and utilizing this knowledge for the development of novel immune therapeutics and vaccines against cancer. His research group designed and performed some of the first cancer vaccine clinical trials targeting specific genetic changes in cancer cells. He led many national efforts and committees on the development of biomarkers and integration of biomarkers in clinical trials, including the AACR-NCI-FDA Cancer Biomarker Collaborative and the ASCO Alternative Clinical Trial Design. Dr. Khleif is the author of many book chapters and scientific articles on tumor immunology and biomarkers process development, and he is the editor for two textbooks on cancer therapeutics, tumor immunology, and cancer vaccines. Dr. Khleif was inducted into the American Society for Clinical Investigation, received the National Cancer Institute's Director Golden Star Award, the National Institutes of Health Award for Merit, the Commendation Medal of the US Public Health Service, and he was recently appointed to the Institute of Medicine National Cancer Policy Forum. Dr. Khleif's distinguished career as well as his extensive expertise in vaccines and immunotherapies qualify him to serve as our director.

Vered Bisker-Leib, Ph.D., M.B.A.

Dr. Bisker-Leib has served as a member of the Old Ayala Board of Directors since January 2023. Dr. Bisker-Leib is the President and Chief Operating Officer of Compass Therapeutics, Inc. where she has been a member of the executive leadership team since November 2017. Prior to Compass, Dr. Bisker-Leib advised Atlas Ventures portfolio companies as an entrepreneur-in-residence from November 2016 to November 2017. Previously, as the Chief Business Officer of Cydan Development, Inc. from October 2014 to October 2016, Dr. Bisker-Leib founded biotech companies focused on therapies addressing rare diseases, including Imara Inc. Dr. Bisker-Leib was a member of BMS' strategic transactions group where she assumed roles of increasing responsibility across five therapeutic areas, most recently as an Executive Director and Global Head of business development for the cardiovascular and metabolic franchises. Dr. Bisker-Leib received a Ph.D. in Chemical Engineering and an M.B.A. from the University of Massachusetts, Amherst. Dr. Bisker-Leib has a B.Sc. in Chemical Engineering from the Israel Institute of Technology, Haifa. We believe that Dr. Bisker-Leib's extensive experience in the life-science industry qualifies her to serve on our board of directors.

Murray A. Goldberg, M.B.A.

Mr. Goldberg has served as a member of the Old Ayala Board of Directors since January 2023. Mr. Goldberg held various management positions at Regeneron Pharmaceuticals, Inc., a biopharmaceutical company, from March 1995 to March 2015, including as Senior Vice President of Administration and Assistant Secretary from October 2013 to March 2015, as Chief Financial Officer and Senior Vice President, Finance and Administration and Assistant Secretary from March 1995 to October 2013 and as Treasurer from March 1995 to October 2012. Mr. Goldberg previously served on the boards of directors of Aerie Pharmaceuticals Inc., a biopharmaceutical company, from August 2013 to June 2020, where he also served as the chairman of its audit committee, and Teva Pharmaceuticals Industries Ltd. from July 2017 to June 2020. Mr. Goldberg received a B.S. in Engineering from New York University, a Master's degree in International Economics from the London School of Economics and an M.B.A. from the University of Chicago. We believe that Mr. Goldberg is qualified to serve on our board of directors because of his broad financial, operational and transactional experience in the industry.

Robert Spiegel, M.D., F.A.C.P.

Dr. Spiegel has served as a member of the Old Ayala Board of Directors since January 2023. Since 2012, Dr. Spiegel has served as an Associate Professor at the Weill Cornell Medical School. In addition, Dr. Spiegel has served as a Senior Advisor to Warburg Pincus, a private equity firm, and an Advisor to the Israel Biotech Fund, a venture investment fund since 2010 and 2016, respectively. Prior to these positions, Dr. Spiegel served as Chief Medical Officer of PTC Therapeutics, Inc., a biopharmaceutical company, from March 2011 to April 2016. Prior to his time at PTC Therapeutics, Dr. Spiegel held various management positions at Schering-Plough Corporation, a global healthcare company, including as Chief Medical Officer and Senior Vice President of the Schering-Plough Research Institute, the pharmaceutical research arm of the Schering-Plough Corporation from 1998 to 2009. Dr. Spiegel is currently a member of the board of directors of Geron Corporation and Cyclacel Pharmaceuticals, Inc., biopharmaceutical company, since 2010 and 2018, respectively. Dr. Spiegel has previously served as a member of the board of directors for Sucampo Pharmaceuticals, Inc., a biopharmaceutical company, Edge Therapeutics, Inc., a biotechnology company, Avior Computing Corporation, a privately-held governance risk and compliance process technology company, Talon Therapeutics, Inc., a biopharmaceutical company, Capstone Therapeutics Corp., a biotechnology company, the Cancer Institute of New Jersey and Cancer Care New Jersey. Dr. Spiegel received a B.A. in 1971 from Yale University and an M.D. from the University of Pennsylvania in 1975. Following his residency in internal medicine, Dr. Spiegel completed a fellowship in medical oncology at the National Cancer Institute. We believe that Dr. Spiegel's extensive medical and scientific knowledge as well as his experience in the life science industry qualifies him to serve on our board of directors.

Igor Gitelman

Mr. Gitelman has served as our Interim Chief Financial Officer since May of 2022, VP of Finance since November 2020 and Chief Accounting Officer since February 2021. Before joining the Company, Mr. Gitelman served as CFO Executive Financial Consultant for Accu Reference Medical Labs, a clinical diagnostic laboratory. Before that, from February 2017 through November 2018, Mr. Gitelman served as a chief accounting officer of Cancer Genetics, Inc., a drug discovery, preclinical oncology, and immuno-oncology services company. Prior to that, Mr. Gitelman served as an Assistant to Vice President (AVP) of Finance and Tax at clinical diagnostic laboratory, BioReference Laboratories, Inc., from October 2005 to October 2016. During this time at BioReference Laboratories, Inc., Mr. Gitelman held various positions of increasing responsibility managing the company's internal audit function, SEC financial reporting, tax, and corporate finance functions.

Andres Gutierrez, M.D., Ph.D.

Dr. Gutierrez has served as our Executive Vice President and Chief Medical Officer since April 2018. Prior to joining New Ayala, Dr. Gutierrez served as Chief Medical Officer for Oncolytics Biotech, Inc. from November 2016 to April 2018. Prior to Oncolytics, Dr. Gutierrez was Chief Medical Officer at SELLAS Life Sciences Group from November 2015 to September 2016 and was Medical Director, Early Development Immuno-Oncology at BMS from October 2012 to November 2015, where he oversaw the development of translational and clinical development of immuno-oncology programs in solid tumors and hematological malignancies. Earlier, Dr. Gutierrez was Medical Director for several biotechnology companies, including Sunesis Pharmaceuticals, BioMarin Pharmaceutical, Proteolix and Oculus Innovative Sciences, leading key programs with talazoparib and carfilzomib, among others. Prior to Oculus, he served as Director of the Gene & Cell Therapy Unit at the National Institutes of Health in Mexico City and as a consultant physician at the Hospital Angeles del Pedregal.

Director Independence

Each of our incumbent non-employee directors is independent in accordance with the definition set forth in the rules of the Nasdaq Stock Market LLC, though our common stock is not currently listed on that exchange. Each nominated member of each of our Board committees is an independent director under the Nasdaq standards applicable to such committees. The Board considered the information included in transactions with related parties as outlined below along with other information the Board considered relevant, when considering the independence of each director.

Board Meetings and Committee Meetings; Attendance

All directors who served as directors at the time attended our 2022 Annual Meeting of Stockholders. Directors are expected, but not required, to attend the annual meeting of stockholders. Our Board holds meetings at least quarterly. Our Board held 20 meetings during fiscal year 2022.

Audit Committee

The Audit Committee of our Board of Directors is currently composed of three directors, all of whom satisfy the independence and other standards for Audit Committee members under the Nasdaq rules and the Exchange Act rules. The Audit Committee is responsible for recommending the engagement of auditors to the full Board, reviewing the results of the audit engagement with the independent registered public accounting firm, identifying irregularities in the management of our business in consultation with our independent accountants, and suggesting an appropriate course of action, reviewing the adequacy, scope, and results of the internal accounting controls and procedures, reviewing the degree of independence of the auditors, as well as the nature and scope of our relationship with our independent registered public accounting firm, and reviewing the auditors' fees. For fiscal year 2022, the Audit Committee was composed of Messrs. Berman and Appel and Dr. Patton, with Mr. Berman serving as the Audit Committee's financial expert as defined under Item 407 of Regulation S-K. The Audit Committee held five meetings during the most recent fiscal year.

Following the Merger, the Audit Committee is comprised of Mr. Goldberg, Mr. Appel and Dr. Bisker-Leib.

The Audit Committee operates under a written Audit Committee Charter, which is available to stockholders on our website at <https://www.ayalapharma.com/corporate-governance/governance-overview>.

Compensation Committee

The Compensation Committee of our Board of Directors as of October 31, 2022 consisted of Mr. Berman, and Drs. Khleif and Sidransky. The Compensation Committee determines the salaries, bonuses, and incentive and equity compensation of our officers subject to applicable employment agreements, provides recommendations for the salaries and incentive compensation of our other employees and consultants, and reviews and oversees our compensation programs and policies generally. For executives other than the Chief Executive Officer, the Compensation Committee receives and considers performance evaluations and compensation recommendations submitted to the Committee by the Chief Executive Officer. In the case of the Chief Executive Officer, the evaluation of his performance is conducted by the Compensation Committee, which determines any adjustments to his compensation as well as awards to be granted. The agenda for meetings of the Compensation Committee is usually determined by its Chairman, with the assistance of the Company's Chief Executive Officer. The Compensation Committee held one meeting and acted by unanimous written consent once during the 2022 fiscal year.

Following the Merger, the Compensation Committee is comprised of Mr. Appel, Dr. Bisker-Leib and Dr. Sidransky.

The Compensation Committee operates under a written Compensation Committee Charter, which is available to stockholders on our website at <https://www.ayalapharma.com/corporate-governance/governance-overview>.

Nominating and Corporate Governance Committee

The Nominating and Corporate Governance Committee of our Board of Directors as of October 31, 2022 consisted of Mr. Berman, and Drs. Patton, Khleif and Sidransky. The functions of the Nominating and Corporate Governance Committee include identifying and recommending to the Board individuals qualified to serve as members of the Board and on the committees of the Board, advising the Board with respect to matters of board composition, procedures and committees, developing and recommending to the Board a set of corporate governance principles applicable to us and overseeing corporate governance matters generally including review of possible conflicts and transactions with persons affiliated with directors or members of management, and overseeing the annual evaluation of the Board and our management. The Nominating and Governance Committees held 1 meeting during the 2022 fiscal year.

Following the Merger, the Nominating and Governance Committee is comprised of Drs. Sidransky, Spiegel and Khleif.

The Nominating and Corporate Governance Committee operates under a written Nominating and Corporate Governance Committee Charter, which is available to stockholders on our website at <https://www.ayalapharma.com/corporate-governance/governance-overview>.

Research and Development Committee

The Research and Development Committee was established in August 2013 with the purpose of providing advice and guidance to the Board on scientific and medical matters and development. The Research and Development Committee as of October 31, 2022 consisted of Drs. Sidransky, Khleif and Patton. The functions of the Research and Development Committee include providing advice and guidance to the Board on scientific matters and providing advice and guidance to the Board on medical matters. The Research and Development Committee held 1 meeting during the 2021 fiscal year.

Following the Merger, the Nominating and Governance Committee is comprised of Drs. Khleif, Sidransky and Spiegel.

Code of Ethics

We have adopted a Code Business Conduct and Ethics that applies to our employees, senior management and Board of Directors, including the Chief Executive Officer and Chief Financial Officer. The Code of Business Conduct and Ethics is available on our website at <https://www.ayalapharma.com/corporate-governance/governance-overview>.

Item 11: Executive Compensation.

The following table sets forth the compensation of our chief executive officer and chief financial officer, and our “named executive officers,” for the fiscal years ended October 31, 2022 and 2021:

Summary Compensation Table

Name and Principal Position	Fiscal Year	Salary	Bonus	Stock Award(s)	Option Award(s) (1)	All Other Compensation (2)	Total
Kenneth Berlin President, Chief Executive Officer	2022	\$ 643,427	\$ -	-	\$ -	\$ 60,341	\$ 703,768
	2021	\$ 569,670	\$ -	-	\$ -	\$ 55,728	\$ 625,398
Igor Gitelman ⁽³⁾ Executive VP, Interim Chief Finance Officer	2022	\$ 299,985	\$ -	-	\$ -	\$ 42,224	\$ 342,209
	2021	\$ 259,135	\$ -	-	\$ 15,777	\$ 38,733	\$ 313,645
Andres Gutierrez Senior VP, Chief Medical Officer	2022	\$ 494,944	\$ -	-	\$ -	\$ 38,683	\$ 533,627
	2021	\$ 438,208	\$ -	-	\$ -	\$ 33,824	\$ 472,032

(1) Reflects the aggregate grant date fair value of stock options determined in accordance with FASB ASC Topic 718. The assumptions used in determining the grant date fair values of the stock options are set forth in Note 7 to the Company’s financial statements.

(2) All Other Compensation is more fully described in the table under “All Other Compensation – Supplemental” below.

(3) Mr. Gitelman began his employment with the Company as VP of Finance in November 2020 and as Chief Accounting Officer since February 2021, and was named Interim Chief Financial Officer on May 1, 2022.

All Other Compensation – Supplemental

Name and Principal Position	Fiscal Year	Health Insurance Premiums \$	Life and AD&D Insurance \$	Matching Contributions to 401(k) Plan \$	Other \$	Total \$
Kenneth Berlin President, Chief Executive Officer	2022	35,179	536	24,026	600	60,341
	2021	32,526	696	21,906	600	55,728
Igor Gitelman Chief Accounting Officer, VP of Finance	2022	35,179	536	5,909	600	42,224
	2021	29,442	665	8,049	577	38,733
Andres Gutierrez Senior VP, Chief Medical Officer	2022	35,179	536	2,368	600	38,683
	2021	32,526	698	-	600	33,824

Employment Agreements with Named Executive Officers

The Company appointed Mr. Berlin as President and Chief Executive Officer, effective April 23, 2018. The Company and Mr. Berlin entered into an employment agreement, effective April 23, 2018, which provides for an initial three-year term, after which it will be automatically renewed for one-year periods, unless otherwise terminated by either party upon ninety (90) days’ written notice. The employment agreement provides that Mr. Berlin will receive a base salary of \$696,115 per year, as adjusted for annual increases by the Compensation Committee since entry of the agreement, and he is eligible for an annual bonus targeted at 55% of his base salary based on achievement of performance goals in the discretion of the Compensation Committee. Mr. Berlin also received a one-time lump-sum bonus equal to \$150,000 that was paid within fifteen (15) days following the effective date of the agreement. Mr. Berlin also received 625 stock options and 208 restricted stock units, which vest in equal instalments over the first three years of his employment. In May 2020, Mr. Berlin received an additional 625 stock options.

The Company appointed Mr. Gitelman as Chief Accounting Officer, effective February 11, 2021. Mr. Gitelman does not have an employment agreement with the Company. In November 2020, Mr. Gitelman received 625 stock options.

The Company appointed Mr. Gutierrez as Executive Vice President and Chief Medical Officer, effective April 23, 2018. The Company and Mr. Gutierrez entered into an employment agreement, effective April 23, 2018, which provides for an initial three-year term, after which it will be automatically renewed for one-year periods, unless otherwise terminated by either party upon ninety (90) days' written notice. The employment agreement provides that Mr. Gutierrez will receive a base salary of \$535,473 per year, as adjusted for annual increases by the Compensation Committee since entry of the agreement, and eligible for an annual bonus based on achievement of performance goals at the discretion of the Compensation Committee. Mr. Gutierrez also received a one-time lump-sum bonus equal to \$40,000 that was paid within the first ninety (90) days following the effective date of the agreement. Mr. Gutierrez also received 208 stock options, which vest annually on the first three anniversaries of his employment as an equity incentive award. In May 2020, Mr. Gutierrez received an additional 625 stock options.

In the event Mr. Gutierrez employment is terminated without Just Cause, or if he voluntarily resigns with Good Reason, or if his employment is terminated due to disability (all as defined in their respective employment agreements), and so long as he executes a confidential separation and release agreement, in addition to the applicable base salary, plus any accrued but unused vacation time and unpaid expenses that have been earned as of the date of such termination, he is entitled to the following severance benefits: (i) twelve months of base salary payable in equal monthly installments, (ii) a bonus payment for the year in which the employment is terminated equal to the target bonus percentage, multiplied by the base salary in effect at the time of termination, (iii) continued health and welfare benefits for 12 months, and (iv) full vesting of all stock options and stock awards (with extension of the exercise period for stock options by two years).

On September 12, 2022, the Company and Mr. Berlin entered into Amendment No. 1 to his employment agreement to revise certain terms related to if he was terminated without Just Cause or he terminated his employment for Good Reason. In the event Mr. Berlin's employment is terminated without Just Cause during the period beginning three months prior to a Change in Control and ending after the CIC Protection Period, or if Mr. Berlin voluntarily resigns with Good Reason, during the CIC Protection Period, and provided that Mr. Berlin continues to comply with certain covenants set forth in his employment agreement, in addition to the applicable base salary and any earned but unpaid bonus for the prior fiscal year, plus any accrued but unused vacation time and unpaid expenses that have been earned as of the date of such termination, Mr. Berlin is entitled to the following severance benefits: (i) an amount equal to 2 times the sum of the applicable base salary plus an amount equal to Mr. Berlin's target bonus, payable in a single lump sum within sixty (60) days of the termination, (ii) a bonus payment for the year in which the employment is terminated equal to the target bonus percentage, multiplied by the base salary in effect at the time of termination, multiplied by a fraction, the numerator of which is the number of calendar days Mr. Berlin was employed during such year and the denominator is 365, (iii) continued health and welfare benefits for 24 months, and (iv) full vesting and exercisability of all stock options and stock awards. Amendment No. 1 further provides, that in the event Mr. Berlin's employment were terminated without Just Cause, or he terminated his employment for Good Reason, other than during the CIC Protection Period, he would receive equal monthly installments of 1.25 times his applicable Base Salary (increased from 1.0 times), and that he would receive this amount for 15 months rather than 12. In addition, the number of months for which he would receive continued health and welfare benefits in this circumstance is increased from 12 months to 15 months. Mr. Berlin is also entitled to a bonus payment for the year in which his employment is terminated equal to the target bonus percentage, multiplied by the base salary in effect at the time of termination.

The named executive officer employment agreements contain customary covenants regarding non-solicitation, non-compete, confidentiality and works for hire.

Potential Payments Upon Termination or Change-in-Control

Termination of Employment

As described above under "Employment Agreements with Named Executive Officers," the Company has entered into employment agreements with two of the named executive officers that provide for certain severance payments and benefits in the event the named executive officer's employment with the Company is terminated under certain circumstances.

In addition, upon a Change in Control of the Company, unvested equity awards held by two of the executive officers will be accelerated as follows: (i) outstanding stock options and other awards in the nature of rights that may be exercised shall become fully vested and exercisable, (ii) time-based restrictions on restricted stock, restricted stock units and other equity awards shall lapse and the awards shall become fully vested, and (iii) performance-based equity awards, if any, shall become vested and shall be deemed earned based on an assumed achievement of all relevant performance goals at “target” levels, and shall payout pro rata to reflect the portion of the performance period that had elapsed prior to the Change in Control.

The table below shows the estimated value of benefits to each of the named executive officers if their employment had been terminated under various circumstances as of October 31, 2022. The amounts shown in the table exclude accrued but unpaid base salary, unreimbursed employment-related expenses, accrued but unpaid vacation pay, and the value of equity awards that were vested by their terms as of October 31, 2022.

	Involuntary Termination without a Change in Control (\$)	Involuntary Termination in connection with a Change in Control (\$)	Death (\$)	Disability (\$)	Termination for Cause; Voluntary Resignation (\$)
Kenneth Berlin					
<i>Cash severance</i>	870,144(1)	2,157,996(5)	-	870,144(1)	-
<i>Bonus</i>	382,863(7)	382,863(2)	382,863(2)	382,863(7)	-
<i>Health benefits</i>	45,813(3)	73,701(6)	-	45,813(3)	-
<i>Value of equity Acceleration</i>	-(4)	-(4)	-(4)	-(4)	-
Total	1,298,820	2,614,120	382,863	1,298,820	-
Andres Gutierrez					
<i>Cash severance</i>	535,473(1)	535,473(5)	-	535,473(1)	-
<i>Bonus</i>	214,189(7)	214,189(2)	214,189(7)	214,189(7)	-
<i>Health benefits</i>	36,651(3)	36,651(6)	-	36,651(3)	-
<i>Value of equity Acceleration</i>	-(4)	-(4)	-(4)	-(4)	-
Total	786,313	786,313	214,189	786,313	-
Igor Gitelman					
<i>Cash severance</i>	-	-	-	-	-
<i>Bonus</i>	-	-	-	-	-
<i>Health benefits</i>	-	-	-	-	-
<i>Value of equity Acceleration</i>	-	-	-	-	-
Total	-	-	-	-	-

- (1) For Mr. Berlin, reflects severance payment equal to 1.25 times base salary payable in equal monthly instalments for 15 months. For Mr. Gutierrez, reflects severance payment equal to one times base salary payable in equal monthly instalments for 12 months.
- (2) Reflects pro rata bonus determined by multiplying the target bonus amount for the year in which the termination occurs by a fraction, the numerator of which is the number of calendar days the executive is employed during such year and the denominator of which is 365. Because the amounts reflected in the table assume the named executive officer’s employment was terminated on October 31, 2022 (the last day of the 2022 fiscal year), the amounts reflected are not pro-rated.
- (3) For Mr. Berlin, reflects the Company’s cost of continued health coverage at active employee rates for 15 months. For Mr. Gutierrez, reflects the Company’s cost of continued health coverage at active employee rates for 12 months.
- (4) Reflects the value of unvested in-the-money stock options that vest upon the designated event.
- (5) For Mr. Berlin, reflects two times the sum of his base salary and target bonus, payable in equal monthly installments for 24 months. For Mr. Gutierrez, equals one times base salary, payable in equal monthly installments for 12 months.
- (6) Reflects the full cost of continued health coverage for 24 months for Mr. Berlin and 12 months for Mr. Gutierrez.
- (7) Represents a bonus payment equal to the executive’s target bonus.

Outstanding Equity Awards at 2022 Fiscal Year-End

The following table summarizes all outstanding equity awards held by our named executive officers at fiscal year-end. The market or payout value of unearned shares, units or rights that have not vested equals \$1.86, which was the closing price of New Ayala's common shares on Nasdaq on October 31, 2022 and for performance based restricted stock units presumes that the target performance goals are met.

Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price (\$)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Value of Shares or Units of Stock That Have Not Vested (\$)
Kenneth Berlin	625	-(1)	1,944.00	4/23/2028	-	-
	267	-(2)	648.00	11/5/2028	-	-
	625	-(3)	24.80	10/24/2029	-	-
	417	208(4)	52.80	5/4/2030	-	-
Igor Gitelman	209	416(6)	31.20	11/16/2030	-	-
Andres Gutierrez	208	-(5)	1,944.00	4/23/2028	-	-
	104	-(2)	648.00	11/05/2028	-	-
	313	-(3)	24.80	10/24/2029	-	-
	417	208(4)	52.80	5/4/2030	-	-

- (1) Of these options, one-third vested on December 31, 2018, one-third vested on April 23, 2020, and the award was fully vested on April 23, 2021.
- (2) Of these options, one-third vested on November 5, 2019, one-third vested on November 5, 2020, and the award was fully vested on November 5, 2021.
- (3) Of these options, one-third vested on October 24, 2020, one-third vested on October 24, 2021, and the award was fully vested on October 24, 2022.
- (4) Of these options, one-third vested on May 4, 2021, one-third will vest on May 4, 2022, and the award will be fully vested on May 4, 2023.
- (5) Of these options, one-third vested on April 23, 2019, one-third vested on April 23, 2020, and the award was fully vested on April 23, 2021.
- (6) Of these options, one-third vested on November 16, 2021, one-third was vested on November 16, 2022, and the award will be fully vested on November 16, 2023.

The table below summarizes the compensation that was earned by our non-employee directors for fiscal year 2022:

Name	Fees Earned or Paid in Cash (\$) (1)	Option Awards (\$) (2)	Total (\$)
Dr. David Sidransky	105,000	-	105,000
Dr. James Patton	87,500	-	87,500
Roni A. Appel	62,500	-	62,500
Richard J. Berman	72,500	-	72,500
Dr. Samir N. Khleif	67,500	-	67,500

(1) Represents the annual retainers paid in cash for director services in fiscal year 2022.

(2) Reflects the aggregate grant date fair value of stock options determined in accordance with FASB ASC Topic 718. The assumptions used in determining the grant date fair values of the stock options are set forth in Note 7 to the Company's financial statements.

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

The following table sets forth information regarding the beneficial ownership of our common stock by (a) each person who is known to us to be the owner of more than five percent (5%) of our common stock, (b) each of our directors, (c) each of the named executive officers, and (d) all directors and executive officers and executive employees as a group. For purposes of the table, a person or group of persons is deemed to have beneficial ownership of any shares that such person has the right to acquire within 60 days of October 31, 2022. The percentage of ownership is based on 1,815,951 shares outstanding as of October 31, 2022. Unless otherwise indicated by footnote, the address for each of the beneficial owners set forth in the table below is c/o Ayala Pharmaceuticals, Inc., 9 Deer Park Drive, Suite K-1, Monmouth Junction, NJ 08852.

Name of Beneficial Owner	Total # of Shares Beneficially Owned	Percentage of Ownership
Kenneth Berlin ⁽¹⁾	2,205	*0%
Igor Gitelman ⁽²⁾	417	*0%
David Sidransky ⁽³⁾	461	*0%
Roni Appel ⁽⁴⁾	508	*0%
Richard Berman ⁽⁵⁾	399	*0%
Samir Khleif ⁽⁶⁾	448	*0%
James Patton ⁽⁷⁾	598	*0%
Andres Gutierrez ⁽⁸⁾	1,089	*0%
All Current Directors and Officers as a Group (8 People) ⁽⁹⁾	6,125	*0%

* Constitutes less than 1% of our outstanding Common Stock.

- (1) Represents 271 issued shares of our Common Stock, and options to purchase 1,934 shares of our Common Stock exercisable within 60 days.
- (2) Represents options to purchase 417 shares of our Common Stock exercisable within 60 days.
- (3) Represents 93 issued shares of our Common Stock and options to purchase 368 shares of our Common Stock exercisable within 60 days.
- (4) Represents 133 issued shares of our Common Stock, options to purchase 351 shares of our Common Stock exercisable within 60 days and warrants to purchase 24 shares of our Common Stock exercisable within 60 days.
- (5) Represents 47 issued shares of our Common Stock and options to purchase 352 shares of our Common Stock exercisable within 60 days.
- (6) Represents 59 issued shares of our Common Stock and options to purchase 389 shares of our Common Stock exercisable within 60 days.
- (7) Represents 241 issued shares of our Common Stock and options to purchase 357 shares of our Common Stock exercisable within 60 days.
- (8) Represents 47 issued shares of our Common Stock and options to purchase 1,042 shares of our Common Stock exercisable within 60 days.
- (9) Represents 891 issued shares of our Common Stock and options to purchase 5,210 shares of our Common Stock exercisable within 60 days and warrants to purchase 24 shares of our Common Stock exercisable within 60 days.

Securities Authorized for Issuance under Equity Compensation Plans

Equity Compensation Plan Information

The following table includes information related to shares available and outstanding awards under our equity incentive plans as of October 31, 2022:

Plan Category	Number of Securities to be issued upon Exercise of outstanding Options, Warrants and Rights (#)	Weighted-average Exercise Price of Outstanding Options, Warrants and Rights (\$)	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (#)
Equity Compensation Plans approved by security holders	11,118	1,412.82	66,191
Equity Compensation Plans not approved by security holders	-	-	-
TOTAL:	11,118	1,412.82	66,191

Compensation Committee Interlocks and Insider Participation

The members of the Compensation Committee during the 2022 fiscal year were Mr. Berman, and Drs. Khleif and Sidransky. During the 2022 fiscal year, no member of our Compensation Committee was an officer, former officer or employee of the Company or had any direct or indirect material interest in a transaction with us or in a business relationship with the Company that would require disclosure under the applicable rules of the SEC. In addition, no interlocking relationship existed between any member of our Compensation Committee, any member of our Board, or one of our executive officers, and any member of the board of directors or compensation committee of any other company.

Compensation Committee Report

Our Compensation Committee has reviewed and discussed the Compensation Discussion and Analysis with management. Based on this review and discussion, our Compensation Committee recommended to our Board of Directors that the Compensation Discussion and Analysis be included in our Annual Report on Form 10-K.

The Compensation Committee

Dr. David Sidransky – Chair
Dr. Samir Khleif
Richard Berman

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

Certain Relationships and Related Transactions

Our policy is to enter into transactions with related parties on terms that, on the whole, are no more favorable, or no less favorable, than those available from unaffiliated third parties. Based on our experience in the business sectors in which we operate and the terms of our transactions with unaffiliated third parties, we believe that all transactions that we enter will meet this policy standard at the time they occur. Presently, we have no such related party transactions.

Director Independence

In accordance with the disclosure requirements of the SEC, we have adopted the Nasdaq listing standards for independence. Each of our non-employee directors is independent in accordance with the definition set forth in the Nasdaq rules. Each nominated member of each of our Board committees is an independent director under the Nasdaq standards applicable to such committees. The Board considered the information included in transactions with related parties as outlined below along with other information the Board considered relevant, when considering the independence of each director.

Item 14: Principal Accountant Fees and Services.

In December 2012, we engaged Marcum, LLP (“Marcum”) as our independent registered public accounting firm to audit our financial statements. Beginning with the fiscal year ended October 31, 2012, Marcum has audited our financial statements. The following table presents fees for professional services rendered by Marcum for the fiscal years ended October 31, 2022 and 2021:

	Fiscal 2022	Fiscal 2021
Audit Fees ⁽¹⁾	\$ 232,879	\$ 153,770
Tax Fees ⁽²⁾	-	-
All Other Fees ⁽³⁾	69,010	103,766
Total	\$ 301,889	\$ 257,536

(1) Audit Fees consisted primarily of annual audit fees and reviews of the Company’s quarterly reports on Form 10-Q.

(2) Tax Fees consisted primarily of services related to tax compliance, including the preparation, review and filing of tax returns.

(3) All Other Fees consisted primarily of services related to the review of securities registration documents and other non-audit reviews.

Policy on Audit Committee Pre-Approval of Audit and Permissible Non-Audit Services of Independent Auditors

The Audit Committee will pre-approve all auditing services and the terms thereof (which may include providing comfort letters in connection with securities underwriting) and non-audit services (other than non-audit services prohibited under Section 10A(g) of the Exchange Act or the applicable rules of the SEC or the Public Company Accounting Oversight Board) to be provided to us by the independent auditor; provided, however, the pre-approval requirement is waived with respect to the provisions of non-audit services for us if the “de minimis” provisions of Section 10A(i)(1)(B) of the Exchange Act are satisfied. This authority to pre-approve non-audit services may be delegated to one or more members of the Audit Committee, who shall present all decisions to pre-approve an activity to the full Audit Committee at its first meeting following such decision. The Audit Committee may review and approve the scope and staffing of the independent auditors’ annual audit plan.

PART IV

Item 15. Exhibits and Financial Statements Schedules.

(a) 1. Financial Statements.

For a list of the financial statements included herein, see Index to the Financial Statements on page F-1 of this Form 10-K.

2. Financial Statement Schedules.

No financial statement schedules have been submitted because they are not required or are not applicable or because the information required is included in the financial statements or the notes thereto.

3. List of Exhibits.

See the Exhibit Index in Item 15(b) below.

Exhibit Number	Description of Exhibits
2.1	<u>Agreement and Plan of Merger and Reorganization, by and among the Company, Merger Sub, and Ayala, dated as of October 18, 2022. Incorporated by reference to Exhibit 2.1 to Current Report on Form 8-K filed with the SEC on October 19, 2022.</u>
3.1*	<u>Restated Certificate of Incorporation of Ayala Pharmaceuticals, Inc., dated as of [January 27], 2023.</u>

- 3.2 [Second Amended and Restated By-Laws of Advaxis, Inc. Incorporated by reference to Exhibit 3.1 of the Current Report on Form 8-K filed with the SEC on March 5, 2021.](#)
- 3.3 [Amendment No. 1 to the Second Amended and Restated By-Laws of Advaxis, Inc. Incorporated by reference to Exhibit 3.1 of the Current Report on Form 8-K filed with the SEC on September 20, 2021.](#)
- 4.1 [Form of Warrant Agency Agreement, dated as of September 11, 2018 between Advaxis, Inc. and Continental Stock Transfer and Trust Company \(and Form of Warrant contained therein\), Incorporated by reference to Exhibit 4.1 to Current Report on Form 8-K filed with the SEC on September 11, 2018.](#)
- 4.2 [Form of Common Warrant dated July 25, 2019 Incorporated by reference to Exhibit 4.2 to the Current Report on Form 8-K filed with the SEC on July 25, 2019.](#)
- 4.3 [Form of Common Stock Warrant dated November 27, 2020. Incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K filed with the SEC on November 27, 2020.](#)
- 4.4 [Form of Pre-Funded Warrant. Incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K filed with the SEC on April 12, 2021.](#)
- 4.5 [Form of Accompanying Warrant. Incorporated by reference to Exhibit 4.2 to the Current Report on Form 8-K filed with the SEC on April 12, 2021.](#)
- 4.6 [Form of Private Placement Warrant. Incorporated by reference to Exhibit 4.3 to the Current Report on Form 8-K filed with the SEC on April 12, 2021.](#)

- 4.7 [Description of each class of securities registered under Section 12 of the Securities Exchange Act of 1934](#)
- 10.1 [License Agreement, between the Trustees of the University of Pennsylvania and the registrant dated as of June 17, 2002, as Amended and Restated on February 13, 2007. Incorporated by reference to Exhibit 10.11 to Annual Report on Form 10-KSB filed with the SEC on February 13, 2007.](#)
- 10.2 [Second Amendment to the Amended and Restated Patent License Agreement between the registrant and the Trustees of the University of Pennsylvania dated as of May 10, 2010. Incorporated by reference to Exhibit 10.1 to Quarterly Report on Form 10-Q filed with the SEC on June 3, 2010.](#)
- 10.3 [2011 Omnibus Incentive Plan of registrant. Incorporated by reference to Annex A to DEF 14A Proxy Statement filed with the SEC on August 29, 2011.](#)
- 10.4 [Amendment No. 1, dated as of March 26, 2007, to the License Agreement, between the Trustees of the University of Pennsylvania and Advaxis, Inc. dated as of June 17, 2002, as amended and restated on February 13, 2007. Incorporated by reference to Exhibit 10.1 to Quarterly Report on Form 10-Q filed with the SEC on June 14, 2012.](#)
- 10.5 [Amendment No. 3, dated as of December 12, 2011, to the License Agreement, between the Trustees of the University of Pennsylvania and Advaxis, Inc. dated as of June 17, 2002, as amended and restated on February 13, 2007. Incorporated by reference to Exhibit 10.5 to Quarterly Report on Form 10-Q filed with the SEC on June 14, 2012.](#)
- 10.6 [Amendment No. 1 to 2011 Omnibus Incentive Plan of registrant. Incorporated by reference to Annex B to DEF 14A Proxy Statement filed with the SEC on July 19, 2012.](#)
- 10.7 [Indemnification Agreement. Incorporated by reference to Exhibit 10.3 to Current Report on Form 8-K filed with the SEC on August 20, 2013.](#)
- 10.8 [Exclusive License and Technology Transfer Agreement by and between Advaxis, Inc. and Global BioPharma, Inc., dated December 9, 2013. Incorporated by reference to Exhibit 10.79 to Annual Report on Form 10-K/A filed with the SEC on February 6, 2014.](#)
- 10.9 [Distribution and Supply Agreement, dated as of January 20, 2014, by and between Advaxis, Inc. and Biocon, Limited. Incorporated by reference to Exhibit 10.7 to Quarterly Report on Form 10-Q filed with the SEC on March 17, 2014.](#)
- 10.10 [Exclusive License Agreement, dated March 19, 2014, by and between Advaxis, Inc. and Aratana Therapeutics, Inc. Incorporated by reference to Exhibit 10.1 to Quarterly Report on Form 10-Q filed with the SEC on June 10, 2014.](#)
- 10.11 [Clinical Trial Collaboration Agreement, dated July 21, 2014, by and between Advaxis, Inc. and MedImmune, LLC. Incorporated by reference to Exhibit 10.1 to Quarterly Report on Form 10-Q filed with the SEC on September 9, 2014.](#)
- 10.12 [5th Amendment to the Amended & Restated License Agreement, dated July 25, 2014, by and between Advaxis, Inc. and University of Pennsylvania. Incorporated by reference to Exhibit 10.2 to Quarterly Report on Form 10-Q filed with the SEC on September 9, 2014.](#)

- 10.13 [Amendment No. 2 to the Advaxis, Inc. 2011 Omnibus Incentive Plan, effective July 9, 2014. Incorporated by reference to Annex A to Current Report on Schedule 14A filed with the SEC on May 20, 2014.](#)
- 10.14 [Amended and Restated 2011 Omnibus Incentive Plan, dated September 8, 2014. Incorporated by reference to Exhibit 10.4 to Quarterly Report on Form 10-Q filed with the SEC on September 9, 2014.](#)
- 10.15 [Master Services Agreement for Technical Transfer and Clinical Supply, dated February 5, 2014, by and between Advaxis, Inc. and SynCo Bio Partners B.V. Incorporated by reference to Exhibit 10.1 to Current Report to Form 8-K filed with the SEC on February 11, 2014.](#)
- 10.16 [Clinical Trial Collaboration and Supply Agreement by and between Advaxis, Inc. and Merck & Co. dated August 22, 2014. Incorporated by reference to Exhibit 10.101 to Annual Report on Form 10-K filed with the SEC on January 6, 2015](#)
- 10.17 [Co-Development and Commercialization Agreement between Advaxis, Inc. and Especificos Stendhal SA de CV dated February 3, 2016. Incorporated by reference to Exhibit 10.1 to Quarterly Report on Form 10-Q filed with the SEC on February 26, 2016.](#)
- 10.18 [2015 Incentive Plan of registrant. Incorporated by reference to Annex A to DEF 14A Proxy Statement filed with the SEC on April 7, 2015.](#)
- 10.19 [Amendment to the Advaxis, Inc. 2015 Incentive Plan. Incorporated by reference to Exhibit B to DEF 14A Proxy Statement filed with the SEC on February 11, 2016.](#)
- 10.20 [Amendment to the Advaxis, Inc. 2015 Incentive Plan. Incorporated by reference to Exhibit A to DEF 14A Proxy Statement filed with the SEC on February 10, 2017.](#)
- 10.21 [Amendment to the Advaxis, Inc. 2015 Incentive Plan. Incorporated by reference to Exhibit A to DEF 14A Proxy Statement filed with the SEC on March 20, 2020.](#)
- 10.22 [Sales Agreement, dated May 8, 2020, by and between Advaxis, Inc. and A.G.P./Alliance Global Partners. Incorporated by reference to Exhibit 1.1 to the Company's Current Report on Form 8-K filed with the SEC on May 8, 2020\)](#)
- 10.23 [Purchase Agreement, dated July 30, 2020, by and between Advaxis, Inc. and Lincoln Park Capital Fund, LLC. Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on August 3, 2020\)](#)
- 10.24 [Lease Agreement, dated March 25, 2021, by and between Advaxis, Inc. and Princeton Corporate Plaza, LLC. Incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the SEC on March 30, 2021.](#)
- 10.25 [Lease Termination and Surrender Agreement, dated March 26, 2021, by and between Advaxis, Inc. and 300 CR LLC. Incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed with the SEC on March 30, 2021](#)
- 10.26 [Securities Purchase Agreement dated April 12, 2021, by and among Advaxis, Inc. and the purchasers identified on the signature pages thereto. Incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the SEC on April 12, 2021.](#)
- 10.27 [Form of Investor Agreement. Incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed with the SEC on April 12, 2021.](#)

- 10.28 [Amendment to the Advaxis, Inc. 2015 Incentive Plan, dated as of February 11, 2021. Incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the SEC on June 4, 2021.](#)
- 10.29 [Employment Agreement between Advaxis, Inc. and Kenneth A. Berlin, dated April 23, 2018. Incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the SEC on April 23, 2018.](#)
- 10.30 [Employment Agreement between Advaxis, Inc. and Andres Gutierrez, M.D., dated April 23, 2018. Incorporated by reference to Exhibit 10.33 to the Annual Report on Form 10-K/A filed with the SEC on February 26, 2021.](#)
- 10.31 [Amended 2017 Stock Incentive Plan and form of agreements thereunder. Incorporated by reference to Exhibit 10.01 of the Old Ayala, Inc. \(f/k/a Ayala Pharmaceuticals, Inc.\) Annual Report on Form 10-K filed with the SEC on March 28, 2022 \(File No. 333-236942\).](#)
- 10.32 [Lease Agreement, dated January 24, 2019, between Ayala-Oncology Israel Ltd. and Ogen Real Estate Maniv Ltd. Incorporated by reference to Exhibit 10.08 of the Old Ayala, Inc. \(f/k/a Ayala Pharmaceuticals, Inc.\) Annual Report on Form 10-K filed with the SEC on March 28, 2022 \(333-236942\).](#)
- 10.33 [License Agreement, dated November 29, 2017, between the Registrant and Bristol-Myers Squibb Company, as amended. Incorporated by reference to Exhibit 10.01 of the Old Ayala, Inc. \(f/k/a Ayala Pharmaceuticals, Inc.\) Annual Report on Form 10-K filed with the SEC on March 28, 2022 \(File No. 333-236942\).](#)
- 10.34 [Evaluation, Option and License Agreement, dated December 19, 2018, between the Registrant and Novartis International Pharmaceutical Limited. Incorporated by reference to Exhibit 10.09 of the Old Ayala, Inc. \(f/k/a Ayala Pharmaceuticals, Inc.\) Annual Report on Form 10-K filed with the SEC on March 28, 2022 \(File No. 333-236942\).](#)
- 10.35 [Securities Purchase Agreement, dated February 19, 2021, by and among Ayala Pharmaceuticals, Inc. and the Investors named therein. Incorporated by reference to Exhibit 10.10 of the Old Ayala, Inc. \(f/k/a Ayala Pharmaceuticals, Inc.\) Annual Report on Form 10-K filed with the SEC on March 28, 2022 \(File No. 001-39279\).](#)
- 10.36 [Amendment No. 1 to the employment agreement between Advaxis, Inc. and Kenneth A. Berlin, dated September 12, 2022. Incorporated by reference to Exhibit 10.1 to the Quarterly Report on Form 10-Q filed with the SEC on September 12, 2022.](#)
- 14.1 [Code of Business Conduct and Ethics dated July 9, 2014. Incorporated by reference to Exhibit 14.1 to Current Report on Form 8-K filed with the SEC on July 10, 2014.](#)
- 23.1* [Consent of Independent Registered Public Accounting Firm](#)
- 31.1* [Certification of Chief Executive Officer pursuant to section 302 of the Sarbanes-Oxley Act of 2002](#)
- 31.2* [Certification of interim Chief Financial Officer pursuant to section 302 of the Sarbanes-Oxley Act of 2002](#)
- 32.1* [Certification of Chief Executive Officer pursuant to section 906 of the Sarbanes-Oxley Act of 2002](#)
- 32.2* [Certification of interim Chief Financial Officer pursuant to section 906 of the Sarbanes-Oxley Act of 2002](#)
- 99.1 [Definitive Proxy Statement of Old Ayala \(f/k/a Ayala Pharmaceuticals, Inc.\). Incorporated by reference to the description of the business of Old Ayala set forth in pages 233-273 of the Definitive Proxy Statement of Old Ayala for the Special Meeting of Stockholders of Old Ayala held on January 13, 2023, filed with the SEC on December 12, 2022 \(File No. 001-39279\).](#)
- 99.2 [Definitive Proxy Statement of Old Ayala \(f/k/a Ayala Pharmaceuticals, Inc.\). Incorporated by reference to description of the risk factors relating to Old Ayala set forth in pages 64-131 of the Old Ayala Merger Proxy, filed with the SEC on December 12, 2022 \(File No. 001-39279\).](#)
- 101.INS** Inline XBRL Instance Document
- 101.SCH** Inline XBRL Taxonomy Extension Schema Document
- 101.CAL** Inline XBRL Taxonomy Extension Calculation Linkbase Document
- 101.DEF** Inline XBRL Taxonomy Extension Definitions Linkbase Document
- 101.LAB** Inline XBRL Taxonomy Extension Label Linkbase Document
- 101.PRE** Inline XBRL Taxonomy Extension Presentation Linkbase Document
- 104 Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith.

** Furnished herewith.

‡ Denotes management contract or compensatory plan or arrangement.

ITEM 16. Form 10-K Summary

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this Annual Report to be signed on its behalf by the undersigned, thereunto duly authorized, in Princeton, Mercer County, State of New Jersey, on this 9th day of February 2023.

AYALA PHARMACEUTICALS, INC.

By: /s/ Kenneth Berlin
President, Chief Executive Officer

By: /s/ Igor Gitelman
Interim Chief Financial Officer

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Kenneth Berlin (with full power to act alone), as his true and lawful attorney-in-fact and agents, with full powers of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent full power and authority to do and perform each and every act and thing requisite or necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent, or his substitute or substitutes, lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this report has been signed by the following persons on behalf of the registrant and in the capacities and on the dates indicated:

<u>SIGNATURE</u>	<u>Title</u>	<u>DATE</u>
<u>/s/ Kenneth Berlin</u> Kenneth Berlin	President, Chief Executive Officer, Director (Principal Executive Officer)	February 9, 2023
<u>/s/ Igor Gitelman</u> Igor Gitelman	Interim Chief Financial Officer (Principal Financial Officer)	February 9, 2023
<u>/s/ David Sidransky</u> David Sidransky	Chairman of the Board	February 9, 2023
<u>/s/ Vered Bisker-Leib</u> Vered Bisker-Leib	Director	February 9, 2023
<u>/s/ Murray A. Goldberg</u> Murray A. Goldberg	Director	February 9, 2023
<u>/s/ Robert Spiegel</u> Robert Spiegel	Director	February 9, 2023
<u>/s/ Samir Khleif</u> Samir Khleif	Director	February 9, 2023
<u>/s/ Roni Appel</u> Roni Appel	Director	February 9, 2023

AYALA PHARMACEUTICALS, INC.

FINANCIAL STATEMENTS

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and Board of Directors of
Ayala Pharmaceuticals, Inc. (formerly known as Advaxis, Inc.)

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Ayala Pharmaceuticals, Inc. (formerly known as Advaxis, Inc.) (the “Company”) as of October 31, 2022 and 2021, the related consolidated statements of operations, stockholders’ equity and cash flows for each of the two years in the period ended October 31, 2022, and the related notes (collectively referred to as the “financial statements”). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of October 31, 2022 and 2021, and the results of its operations and its cash flows for each of the two years in the period ended October 31, 2022, in conformity with accounting principles generally accepted in the United States of America.

Explanatory Paragraph – Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As more fully described in Note 1, the Company has incurred significant losses and needs to raise additional funds to meet its obligations and sustain its operations. These conditions raise substantial doubt about the Company’s ability to continue as a going concern. Management’s plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

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

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

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

Critical Audit Matters

Critical audit matters are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. We determined that there are no critical audit matters.

/s/ Marcum LLP

Marcum LLP

We have served as the Company’s auditor since 2012.

New York, NY
February 9, 2023

AYALA PHARMACEUTICALS, INC.
(formerly known as Advaxis, Inc.)
CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share data)

	October 31,	
	2022	2021
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 25,208	\$ 41,614
Prepaid expenses and other current assets	551	1,643
Total current assets	25,759	43,257
Property and equipment (net of accumulated depreciation)	38	118
Intangible assets (net of accumulated amortization)	110	3,354
Operating right-of-use asset (net of accumulated amortization)	12	40
Other assets	11	11
Total assets	\$ 25,930	\$ 46,780
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 22	\$ 87
Accrued expenses	2,150	2,836
Current portion of operating lease liability	12	28
Common stock warrant liability	119	4,929
Total current liabilities	2,303	7,880
Operating lease liability, net of current portion	-	12
Total liabilities	2,303	7,892
Contingencies – Note 8		
Series D convertible preferred stock- \$0.001 par value; 0 shares authorized, 0 shares issued and outstanding at October 31, 2022 and October 31, 2021.	-	-
Stockholders' equity:		
Preferred stock, \$0.001 par value; 5,000,000 shares authorized, 0 shares issued and outstanding at October 31, 2022 and October 31, 2021.	-	-
Common stock - \$0.001 par value; 170,000,000 shares authorized, 1,815,951 and 1,820,452 shares issued and outstanding at October 31, 2022 and 2021.	2	2
Additional paid-in capital	466,584	467,486
Accumulated deficit	(442,959)	(428,600)
Total stockholders' equity	23,627	38,888
Total liabilities and stockholders' equity	\$ 25,930	\$ 46,780

The accompanying notes should be read in conjunction with the financial statements.

AYALA PHARMACEUTICALS, INC.
(formerly known as Advaxis, Inc.)
CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except share and per share data)

	Year Ended October 31,	
	2022	2021
Revenue	\$ 250	\$ 3,240
Operating expenses:		
Research and development expenses	7,616	10,562
General and administrative expenses	8,891	11,464
Intangible asset impairment	3,053	-
Total operating expenses	<u>19,560</u>	<u>22,026</u>
Loss from operations	(19,310)	(18,786)
Other income (expense):		
Interest income	157	5
Net changes in fair value of derivative liabilities	4,853	970
Other expense	(9)	(1)
Net loss before income taxes	<u>(14,309)</u>	<u>(17,812)</u>
Income tax expense	<u>50</u>	<u>50</u>
Net loss	(14,359)	(17,862)
Accretion of discount and redemption feature of convertible preferred stock	(1,025)	-
Income available to common stockholders	<u>\$ (15,384)</u>	<u>\$ (17,862)</u>
Net loss per common share, basic and diluted	<u>\$ (8.46)</u>	<u>\$ (11.07)</u>
Weighted average number of common shares outstanding, basic and diluted	1,818,639	1,613,634

The accompanying notes should be read in conjunction with the financial statements.

AYALA PHARMACEUTICALS, INC.
(formerly known as Advaxis, Inc.)
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(In thousands, except share and per share data)

	Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Shareholders' Equity
	Shares	Amount	Shares	Amount			
Balance at October 31, 2020	-	\$ -	975,897	\$ 1	\$ 440,917	\$ (410,738)	\$ 30,180
Stock-based compensation	-	-	69	-	566	-	566
Stock option exercises	-	-	4	-	-	-	-
Issuance of shares to employees under ESPP Plan	-	-	12	-	-	-	-
Warrant exercises	-	-	230,343	-	3,771	-	3,771
Public offerings, net of offering costs	-	-	614,127	1	22,232	-	22,233
Net Loss	-	-	-	-	-	(17,862)	(17,862)
Balance at October 31, 2021	-	-	1,820,452	2	467,486	(428,600)	38,888
Stock-based compensation	-	-	-	-	97	-	97
Accretion of discount and redemption feature of convertible preferred stock	-	-	-	-	(1,025)	-	(1,025)
Convertible preferred stock redemption	-	-	-	-	44	-	44
Fractional shares cashed out	-	-	(4,501)	-	(18)	-	(18)
Net Loss	-	-	-	-	-	(14,359)	(14,359)
Balance at October 31, 2022	-	\$ -	1,815,951	\$ 2	\$ 466,584	\$ (442,959)	\$ 23,627

The accompanying notes should be read in conjunction with the financial statements.

AYALA PHARMACEUTICALS, INC.
(formerly known as Advaxis, Inc.)
CONSOLIDATED STATEMENT OF CASH FLOWS
(In thousands, except share and per share data)

	Year Ended October 31,	
	2022	2021
OPERATING ACTIVITIES		
Net loss	\$ (14,359)	\$ (17,862)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share based compensation	97	566
Gain on change in value of warrants	(4,810)	(970)
Gain on change in value of preferred stock redemption liability	(43)	-
(Gain) loss on disposal of property and equipment	(8)	1,439
Abandonment of intangible assets	159	94
Impairment charges on intangible assets	3,053	-
Depreciation expense	53	387
Amortization expense of intangible assets	233	273
Amortization of right-of-use assets	28	330
Net gain on write-off of right-of-use asset and lease liability	-	(116)
<u>Change in operating assets and liabilities:</u>		
Prepaid expenses, other current assets and deferred expenses	1,092	1,030
Other assets	-	171
Accounts payable and accrued expenses	(751)	776
Deferred revenue	-	(165)
Operating lease liabilities	(28)	(1,392)
Net cash used in operating activities	<u>(15,284)</u>	<u>(15,439)</u>
INVESTING ACTIVITIES		
Proceeds from disposal of property and equipment	35	449
Cost of intangible assets	(201)	(460)
Net cash used in investing activities	<u>(166)</u>	<u>(11)</u>
FINANCING ACTIVITIES		
Net proceeds of issuance of Series D preferred stock	4,312	-
Net proceeds of issuance of common stock and warrants	-	28,115
Fractional shares cashed out	(18)	-
Redemption of Series D preferred stock	(5,250)	-
Warrant exercises	-	3,771
Net cash provided by (used in) financing activities	<u>(956)</u>	<u>31,886</u>
Net (decrease) increase in cash and cash equivalents	(16,406)	16,436
Cash and cash equivalents at beginning of year	41,614	25,178
Cash and cash equivalents at end of year	<u>\$ 25,208</u>	<u>\$ 41,614</u>

The accompanying notes should be read in conjunction with the financial statements.

Supplemental Disclosures of Cash Flow Information

	Year Ended October 31,	
	2022	2021
Cash paid for taxes	\$ 50	\$ 50

Supplemental Schedule of Noncash Investing and Financing Activities

	Year Ended October 31,	
	2022	2021
Reclassification of preferred stock redemption liability into equity upon redemption of preferred stock	\$ 44	\$ -
Accretion of discount and redemption feature of convertible preferred stock	1,025	-
Reassessment of the lease term	-	43

The accompanying notes should be read in conjunction with the financial statements.

AYALA PHARMACEUTICALS, INC.
(formerly known as Advaxis, Inc.)
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. NATURE OF OPERATIONS AND BASIS OF PRESENTATION

In these financial statements, unless otherwise stated or the context otherwise indicates, references to “New Ayala,” “Advaxis,” the “Company,” “we,” “us,” “our” and similar references refer to Ayala Pharmaceuticals, Inc., a Delaware corporation, which prior to the change of its name effected on January 19, 2023, was known as Advaxis, Inc.

New Ayala was a clinical-stage biotechnology company focused on the development and commercialization of proprietary *Listeria monocytogenes* (“*Lm*”)–based antigen delivery products. The Company is using its *Lm* platform directed against tumor-specific targets in order to engage the patient’s immune system to destroy tumor cells. Through a license from the University of Pennsylvania, New Ayala has exclusive access to this proprietary formulation of attenuated *Lm* called *Lm* TechnologyTM. New Ayala’s proprietary approach is designed to deploy a mechanism of action that redirects the immune system to attack cancer in three distinct ways:

- Alerting and training the immune system by activating multiple pathways in Antigen-Presenting Cells (“APCs”) with the equivalent of multiple adjuvants;
- Attacking the tumor by generating a strong, cancer-specific T cell response; and
- Breaking down tumor protection through suppression of the protective cells in the tumor microenvironment (“TME”) that shields the tumor from the immune system. This enables the activated T cells to begin working to attack the tumor cells.

New Ayala’s proprietary *Lm* platform technology has demonstrated clinical activity in several of its programs and has been dosed in over 470 patients across multiple clinical trials and in various tumor types. The Company believes that *Lm* Technology immunotherapies can complement and address significant unmet needs in the current oncology treatment landscape. Specifically, its product candidates have the potential to work synergistically with other immunotherapies, including checkpoint inhibitors, while having a generally well-tolerated safety profile.

Merger with Ayala Pharmaceuticals, Inc.

On October 18, 2022, the Company entered into a Merger Agreement (the “Merger Agreement”), subject to shareholder approval, with Ayala Pharmaceuticals, Inc. (“Old Ayala”) and Doe Merger Sub, Inc. (“Merger Sub”), a direct, wholly-owned subsidiary of New Ayala. Under the terms of the agreement, the Merger Sub merged with and into Old Ayala, with Old Ayala continuing as the surviving company and a wholly-owned subsidiary of New Ayala (the “Merger”). Immediately after the Merger, New Ayala stockholders as of immediately prior to the Merger own approximately 37.5% of the outstanding shares of the combined company and former Old Ayala shareholders own approximately 62.5% of the outstanding shares of the combined company. The Merger was accounted for as a reverse acquisition pursuant to ASC 805-40.

At the effective time of the Merger (the “Effective Time”), each share of share capital of Ayala issued and outstanding immediately prior to the Effective Time was converted into the right to receive a number of shares of New Ayala common stock, par value \$0.001 per share, equal to the exchange ratio, 0.1874 shares of New Ayala common stock per Old Ayala share.

On January 13, 2023, the Ayala stockholders approved the Merger Agreement and the Merger closed on January 19, 2023. See Note 16.

Similar to other development stage biotechnology companies, the Company's products that are being developed have not generated significant revenue. As a result, the Company has suffered recurring losses and requires significant cash resources to execute its business plans. These losses are expected to continue for the foreseeable future. The aforementioned factors raise substantial doubt about the Company's ability to continue as a going concern within one year from the date of filing. The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The financial statements do not include any adjustments relating to the recoverability and classification of asset amounts or the classification of liabilities that might be necessary should the Company be unable to continue as a going concern within one year after the date the financial statements are issued.

As of October 31, 2022, the Company had approximately \$25.2 million in cash and cash equivalents. The Company does not believe it has sufficient capital to fund its obligations after the closing of the Merger, as they become due, in the ordinary course of business until at least one year from the issuance of these consolidated financial statements but will need to raise additional funds.

The Company recognizes it will need to raise additional capital in order to continue to execute its business plan in the future. There is no assurance that additional financing will be available when needed or that management will be able to obtain financing on terms acceptable to the Company or whether the Company will become profitable and generate positive operating cash flow. If the Company is unable to raise sufficient additional funds, it will have to further scale back its operations.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America ("U.S. GAAP") requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Estimates are used when accounting for such items as the fair value and recoverability of the carrying value of property and equipment and intangible assets (patents and licenses), determining the Incremental Borrowing Rate ("IBR") for calculating Right-Of-Use ("ROU") assets and lease liabilities, deferred expenses, the fair value of options, warrants and related disclosure of contingent assets and liabilities. The Company bases its estimates on historical experience and on various other assumptions that it believes are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. On an ongoing basis, the Company reviews its estimates to ensure that they appropriately reflect changes in the business or as new information becomes available. Actual results may differ from these estimates.

Principles of Consolidation

The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary. All significant intercompany accounts and transactions have been eliminated.

Revenue Recognition

Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, the Company assesses the goods or services promised within each contract, determines those that are performance obligations and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

The Company enters into licensing agreements that are within the scope of ASC 606, under which it may exclusively license rights to research, develop, manufacture and commercialize its product candidates to third parties. The terms of these arrangements typically include payment to the Company of one or more of the following: non-refundable, upfront license fees; reimbursement of certain costs; customer option exercise fees; development, regulatory and commercial milestone payments; and royalties on net sales of licensed products.

In determining the appropriate amount of revenue to be recognized as it fulfills its obligations under its agreements, the Company performs the following steps: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) the Company satisfies each performance obligation. As part of the accounting for these arrangements, the Company must use significant judgment to determine: (a) the number of performance obligations based on the determination under step (ii) above; (b) the transaction price under step (iii) above; and (c) the stand-alone selling price for each performance obligation identified in the contract for the allocation of transaction price in step (iv) above. The Company uses judgment to determine whether milestones or other variable consideration, except for royalties, should be included in the transaction price as described further below. The transaction price is allocated to each performance obligation on a relative stand-alone selling price basis, for which the Company recognizes revenue as or when the performance obligations under the contract are satisfied.

Amounts received prior to revenue recognition are recorded as deferred revenue. Amounts expected to be recognized as revenue within the 12 months following the balance sheet date are classified as current portion of deferred revenue in the accompanying consolidated balance sheets. Amounts not expected to be recognized as revenue within the 12 months following the balance sheet date are classified as deferred revenue, net of current portion.

Exclusive Licenses. If the license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenue from non-refundable, upfront fees allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. In assessing whether a performance obligation is distinct from the other performance obligations, the Company considers factors such as the research, development, manufacturing and commercialization capabilities of the collaboration partner and the availability of the associated expertise in the general marketplace. In addition, the Company considers whether the collaboration partner can benefit from a performance obligation for its intended purpose without the receipt of the remaining performance obligation, whether the value of the performance obligation is dependent on the unsatisfied performance obligation, whether there are other vendors that could provide the remaining performance obligation, and whether it is separately identifiable from the remaining performance obligation. For licenses that are combined with other performance obligation, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition. The measure of progress, and thereby periods over which revenue should be recognized, are subject to estimates by management and may change over the course of the research and development and licensing agreement. Such a change could have a material impact on the amount of revenue the Company records in future periods.

Milestone Payments. At the inception of each arrangement that includes research or development milestone payments, the Company evaluates whether the milestones are considered probable of being achieved and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. An output method is generally used to measure progress toward complete satisfaction of a milestone. Milestone payments that are not within the control of the Company or the licensee, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. The Company evaluates factors such as the scientific, clinical, regulatory, commercial, and other risks that must be overcome to achieve the particular milestone in making this assessment. There is considerable judgment involved in determining whether it is probable that a significant revenue reversal would not occur. At the end of each subsequent reporting period, the Company re-evaluates the probability of achievement of all milestones subject to constraint and, if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenue and earnings in the period of adjustment.

Collaborative Arrangements

The Company analyzes its collaboration arrangements to assess whether such arrangements involve joint operating activities performed by parties that are both active participants in the activities and exposed to significant risks and rewards dependent on the commercial success of such activities and therefore within the scope of ASC Topic 808, *Collaborative Arrangements* (ASC 808). This assessment is performed throughout the life of the arrangement based on changes in the responsibilities of all parties in the arrangement. For collaboration arrangements within the scope of ASC 808 that contain multiple elements, the Company first determines which elements of the collaboration are deemed to be within the scope of ASC 808 and which elements of the collaboration are more reflective of a vendor-customer relationship and therefore within the scope of ASC 606. For elements of collaboration arrangements that are accounted for pursuant to ASC 808, an appropriate recognition method is determined and applied consistently, generally by analogy to ASC 606. Amounts that are owed to collaboration partners are recognized as an offset to collaboration revenue as such amounts are incurred by the collaboration partner. For those elements of the arrangement that are accounted for pursuant to ASC 606, the Company applies the five-step model described above under ASC 606.

Cash and Cash Equivalents

The Company considers all highly liquid investments with an original maturity of three months or less from the date of purchase to be cash equivalents. As of October 31, 2022 and 2021, the Company had cash equivalents of approximately \$12.3 million and \$17.2 million, respectively.

Restricted Cash

On January 31, 2022, the Company transferred \$5,250,000 into an escrow fund to fund a potential Series D preferred stock redemption. On April 6, 2022, the Series D convertible preferred stock was redeemed utilizing the entire amount held in the escrow fund.

Concentration of Credit Risk

The Company maintains its cash in bank deposit accounts (checking) that at times exceed federally insured limits. Approximately \$25.0 million is subject to credit risk at October 31, 2022. The Company has not experienced any losses in such accounts.

Deferred Expenses

Deferred expenses consist of advanced payments made on research and development projects. Expense is recognized in the consolidated statement of operations as the research and development activity is performed.

Property and Equipment

Property and equipment are stated at cost. Additions and improvements that extend the lives of the assets are capitalized, while expenditures for repairs and maintenance are expensed as incurred. Leasehold improvements are amortized on a straight-line basis over the shorter of the asset's estimated useful life or the remaining lease term. Depreciation is calculated on a straight-line basis over the estimated useful lives of the assets ranging from three to ten years.

When depreciable assets are retired or sold the cost and related accumulated depreciation are removed from the accounts and any resulting gain or loss is recognized in operations.

Intangible Assets

Intangible assets are recorded at cost and include patents and patent application costs, licenses and software. Intangible assets are amortized on a straight-line basis over their estimated useful lives ranging from three to 20 years. Patent application costs are written-off if the application is rejected, withdrawn or abandoned.

Impairment of Long-Lived Assets

The Company periodically assesses the carrying value of intangible and other long-lived assets, and whenever events or changes in circumstances indicate that the carrying amount of an asset might not be recoverable. The assets are considered to be impaired if the Company determines that the carrying value may not be recoverable based upon its assessment, which includes consideration of the following events or changes in circumstances:

- the asset's ability to continue to generate income from operations and positive cash flow in future periods;
- loss of legal ownership or title to the asset(s);
- significant changes in the Company's strategic business objectives and utilization of the asset(s); and
- the impact of significant negative industry or economic trends.

If the assets are considered to be impaired, the impairment recognized is the amount by which the carrying value of the assets exceeds the fair value of the assets. Fair value is determined by the application of discounted cash flow models to project cash flows from the assets. In addition, the Company bases estimates of the useful lives and related amortization or depreciation expense on its subjective estimate of the period the assets will generate revenue or otherwise be used by it. Assets to be disposed of are reported at the lower of the carrying amount or fair value, less selling costs. The Company also periodically reviews the lives assigned to long-lived assets to ensure that the initial estimates do not exceed any revised estimated periods from which the Company expects to realize cash flows from its assets.

Leases

At the inception of an arrangement, the Company determines whether an arrangement is or contains a lease based on the facts and circumstances present in the arrangement. An arrangement is or contains a lease if the arrangement conveys the right to control the use of an identified asset for a period of time in exchange for consideration. Most leases with a term greater than one year are recognized on the consolidated balance sheet as operating lease right-of-use assets and current and long-term operating lease liabilities, as applicable. The Company has elected not to recognize on the consolidated balance sheet leases with terms of 12 months or less. The Company typically only includes the initial lease term in its assessment of a lease arrangement. Options to extend a lease are not included in the Company's assessment unless there is reasonable certainty that the Company will renew.

Operating lease liabilities and their corresponding right-of-use assets are recorded based on the present value of lease payments over the expected remaining lease term. Certain adjustments to the right-of-use asset may be required for items such as prepaid or accrued rent. The interest rate implicit in the Company's leases is typically not readily determinable. As a result, the Company utilizes its incremental borrowing rate, which reflects the fixed rate at which the Company could borrow on a collateralized basis the amount of the lease payments in the same currency, for a similar term, in a similar economic environment.

Net Income (Loss) per Share

Basic net income or loss per common share is computed by dividing net income or loss available to common stockholders by the weighted average number of common shares outstanding during the period. Diluted earnings per share give effect to dilutive options, warrants, restricted stock units and other potential common stock outstanding during the period. In the case of a net loss, the impact of the potential common stock resulting from warrants, outstanding stock options and convertible debt are not included in the computation of diluted loss per share, as the effect would be anti-dilutive. In the case of net income, the impact of the potential common stock resulting from these instruments that have intrinsic value are included in the diluted earnings per share. The table sets forth the number of potential shares of common stock that have been excluded from diluted net loss per share:

	As of October 31,	
	2022	2021
Warrants	377,818	377,818
Stock options	11,118	11,192
Total	388,936	389,010

Research and Development Expenses

Research and development costs are expensed as incurred and include but are not limited to clinical trial and related manufacturing costs, payroll and personnel expenses, lab expenses, and related overhead costs.

Stock Based Compensation

The Company has an equity plan which allows for the granting of stock options to its employees, directors and consultants for a fixed number of shares with an exercise price equal to the fair value of the shares at date of grant. The Company measures the cost of services received in exchange for an award of equity instruments based on the fair value of the award. The fair value of the award is measured on the grant date and is then recognized over the requisite service period, usually the vesting period, in both research and development expenses and general and administrative expenses on the consolidated statement of operations, depending on the nature of the services provided by the employees or consultants.

The process of estimating the fair value of stock-based compensation awards and recognizing stock-based compensation cost over their requisite service period involves significant assumptions and judgments. The Company estimates the fair value of stock option awards on the date of grant using the Black Scholes Model for the remaining awards, which requires that the Company makes certain assumptions regarding: (i) the expected volatility in the market price of its common stock; (ii) dividend yield; (iii) risk-free interest rates; and (iv) the period of time employees are expected to hold the award prior to exercise (referred to as the expected holding period). As a result, if the Company revises its assumptions and estimates, stock-based compensation expense could change materially for future grants.

The Company accounts for stock-based compensation using fair value recognition and records forfeitures as they occur. As such, the Company recognizes stock-based compensation cost only for those stock-based awards that vest over their requisite service period, based on the vesting provisions of the individual grants.

Fair Value of Financial Instruments

The carrying value of financial instruments, including cash and cash equivalents and accounts payable, approximated fair value as of the balance sheet date presented, due to their short maturities.

Convertible Preferred Stock

Preferred shares subject to mandatory redemption are classified as liability instruments and are measured at fair value. The Company classifies conditionally redeemable preferred shares, which includes preferred shares that feature redemption rights that are either within the control of the holder or subject to redemption upon the occurrence of uncertain events not solely within the Company's control, as temporary equity ("mezzanine") until such time as the conditions are removed or lapse.

Derivative Financial Instruments

The Company does not use derivative instruments to hedge exposures to cash flow, market or foreign currency risks. The Company evaluates all of its financial instruments to determine if such instruments are derivatives or contain features that qualify as embedded derivatives. For derivative financial instruments that are accounted for as liabilities, the derivative instrument is initially recorded at its fair value and is then re-valued at each reporting date, with changes in the fair value reported in the statements of operations. For share-based derivative financial instruments, the Company used the Monte Carlo simulation model, the Black Scholes model and a binomial model to value the derivative instruments at inception and on subsequent valuation dates. The classification of derivative instruments, including whether such instruments should be recorded as liabilities or as equity, is evaluated at the end of each reporting period. Derivative liabilities are classified in the consolidated balance sheet as current or non-current based on whether or not net-cash settlement of the instrument could be required within 12 months after the balance sheet date.

Income Taxes

The Company uses the asset and liability method of accounting for income taxes in accordance with ASC Topic 740, “*Income Taxes*.” Under this method, income tax expense or benefit is recognized for the amount of: (i) taxes payable or refundable for the current year and (ii) deferred tax consequences of temporary differences resulting from matters that have been recognized in an entity’s financial statements or tax returns. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in the results of operations in the period that includes the enactment date. A valuation allowance is provided to reduce the deferred tax assets reported if based on the weight of the available positive and negative evidence, it is more likely than not some portion or all of the deferred tax assets will not be realized.

On August 16, 2022, the Inflation Reduction Act (IRA) was signed into law. The legislation imposes new taxes, including a 15% corporate alternative minimum tax (CAMT) on adjusted financial statement income of corporations with profits over \$1 billion, which is effective for tax years beginning after December 31, 2022, and a 1% surcharge on corporate stock buybacks of public US companies, which applies to repurchases of stock after December 31, 2022. The tax provisions of the Inflation Reduction Act do not have a material impact on the Company’s financial statements.

Reverse Stock Split

On March 31, 2022, the Company’s stockholders voted to approve an amendment to allow the Company to execute a reverse stock split of common stock within a range of 1 for 20 to 1 for 80, without reducing the authorized number of shares of the common stock, at the discretion of the Board of Directors. On June 3, 2022, the Board of Directors approved a 1 for 80 reverse stock split, which became effective on June 6, 2022. All references in this Report to number of shares, price per share and weighted average number of shares of common stock outstanding prior to this reverse stock split have been adjusted to reflect the reverse stock split on a retroactive basis, unless otherwise noted.

Recent Accounting Standards

Business Combinations

In October 2021, the FASB issued ASU 2021-08, Business Combinations (Topic 805): Accounting for Contract Assets and Contract Liabilities from Contracts with Customers which amended guidance on accounting for contract assets and contract liabilities from contracts with customers in a business combination. The guidance is intended to address inconsistency related to recognition of an acquired contract liability and payment terms and their effect on subsequent revenue recognized. At the acquisition date, an entity should account for the related revenue contracts in accordance with existing revenue recognition guidance generally by assessing how the acquiree applied recognition and measurement in their financial statements. The amended guidance is effective for the Company as of November 1, 2023 on a prospective approach. Early adoption is permitted. This guidance is not expected to have a material effect on the Company’s financial statements.

Management does not believe that any recently issued, but not yet effective accounting pronouncements, if adopted, would have a material impact on the accompanying consolidated financial statements.

3. PROPERTY AND EQUIPMENT

Property and equipment consist of the following (in thousands):

	October 31,	
	2022	2021
Laboratory Equipment	\$ 94	\$ 179
Computer equipment	24	241
Total property and equipment	118	420
Accumulated depreciation and amortization	(80)	(302)
Net property and equipment	\$ 38	\$ 118

Depreciation expense for the years ended October 31, 2022 and 2021 was approximately \$53,000 and \$387,000, respectively. During the year ended October 31, 2022, the Company incurred a gain on disposal of equipment of approximately \$8,000, all of which is reflected in the research and development expenses in the consolidated statement of operations. During the year ended October 31, 2021, the Company incurred a loss on disposal of equipment of approximately \$1,439,000, \$891,000 of which is reflected in the research and development expenses and \$548,000 of which is reflected in the general and administrative expenses in the consolidated statement of operations.

4. INTANGIBLE ASSETS

Intangible assets consist of the following (in thousands):

	October 31,	
	2022	2021
Patents	\$ 95	\$ 4,836
License	15	777
Software	-	98
Total intangibles	110	5,711
Accumulated amortization	-	(2,357)
Net intangible assets	\$ 110	\$ 3,354

The expiration dates of the existing patents range from 2022 to 2039 but the expiration dates can be extended based on market approval if granted and/or based on existing laws and regulations. Capitalized costs associated with patent applications that are abandoned without future value are charged to expense when the determination is made not to further pursue the application. Patent applications having a net book value of approximately \$159,000 and \$94,000 were abandoned and were charged to general and administrative expenses in the consolidated statement of operations for the years ended October 31, 2022 and 2021, respectively. Amortization expense for intangible assets that was charged to general and administrative expense in the consolidated statement of operations aggregated approximately \$233,000 and \$273,000 for the years ended October 31, 2022 and 2021, respectively.

Management reviews its long-lived assets for impairment whenever events and circumstances indicate that the carrying value of an asset might not be recoverable. Net assets are recorded on the balance sheet for patents related to ADXS-HER2 and the *Lm* technology licensed from the University of Pennsylvania. There are various scenarios under which an impairment charge may be recorded, which include if a competitor were to gain FDA approval for a similar treatment before the Company, if future clinical trials fail to meet the targeted endpoints, or if a drug application is rejected or fails to be issued. Lastly, if the Company is unable to raise enough capital to continue funding its studies and developing its intellectual property, the Company would likely record an impairment to these assets.

During the year ended October 31, 2022, the Company identified the following indicators of impairment under ASC 360 indicating that the patents and license carrying amounts might not be recoverable:

- Adverse changes in the business climate for biotechnology companies, particularly raising capital; and
- A significant reduction in the Company's market capitalization during the year ended October 31, 2022.

The Company performed an impairment test under ASC 350 on its patents owned and in-licensed intellectual property. Under this test a fair value of the relevant asset is compared with the carrying amount of such asset. Fair value is calculated using a discounted cash flow analysis. Cash flows are discounted using a weighted average cost of capital derived from comparable companies, which reflects the costs of borrowing as well as the associated risk. The results of the impairment test indicated that the carrying value of the patents owned and in-licensed intellectual property exceeded the fair value. During the year ended October 31, 2022, the Company recorded an impairment charge for patents owned and in-licensed intellectual property of approximately \$3,052,000 in its consolidated statement of operations.

At October 31, 2022, the estimated amortization expense by fiscal year based on the current carrying value of intangible assets is as follows (in thousands):

2023	\$	66
2024		44
Total	\$	<u>110</u>

5. ACCRUED EXPENSES:

The following table represents the major components of accrued expenses (in thousands):

	October 31,	
	2022	2021
Salaries and other compensation	\$ 92	\$ 55
Vendors	1,151	1,968
Professional fees	707	613
Other	200	200
Total accrued expenses	<u>\$ 2,150</u>	<u>\$ 2,836</u>

6. LEASES

The Company previously leased a corporate office and manufacturing facility in Princeton, New Jersey under an operating lease that was set to expire in November 2025. On March 26, 2021, the Company entered into a Lease Termination and Surrender Agreement with respect to this lease agreement. The Lease Termination and Surrender Agreement provides for the early termination of the lease, which became effective on March 31, 2021. In connection with the early termination of the lease, the Company was required to pay a \$1,000,000 termination payment. The unapplied security deposit totaling approximately \$182,000 was credited against the termination fee for a net payment of approximately \$818,000. The Company wrote off of the remaining right-of-use asset of approximately \$4,512,000 and lease liability of approximately \$5,628,000. After consideration of the termination payment and write off the remaining right-of-use asset and lease liability, the Company recorded a net gain of approximately \$116,000.

On March 25, 2021, the Company entered into a new one-year lease agreement for its corporate office/lab with base rent of approximately \$29,000 per year, plus other expenses. This lease was accounted for as a short-term lease at inception, and the Company elected not to recognize a right-of-use asset and lease liability. In September 2021, the Company exercised its option to renew the lease, extending the lease term until March 25, 2023. Since the renewed lease term exceeded one-year, the lease no longer qualified for the short-term lease exception, resulting in the recognition of a right-of-use asset and operating lease liability of approximately \$43,000.

Supplemental balance sheet information related to leases was as follows (in thousands):

	October 31, 2022	October 31, 2021
Operating leases:		
Operating lease right-of-use assets	\$ 12	\$ 40
Operating lease liability	\$ 12	\$ 28
Operating lease liability, net of current portion	-	12
Total operating lease liabilities	<u>\$ 12</u>	<u>\$ 40</u>

Supplemental lease expense related to leases was as follows (in thousands):

Lease Cost (in thousands)	Statements of Operations Classification	For the Fiscal Year Ended October 31, 2022	For the Fiscal Year Ended October 31, 2021
Operating lease cost	General and administrative	\$ 29	\$ 1,302
Short-term lease cost	General and administrative	-	14
Variable lease cost	General and administrative	47	180
Total lease expense		<u>\$ 76</u>	<u>\$ 1,496</u>

Other information related to leases where the Company is the lessee is as follows:

	October 31, 2022	October 31, 2021
Weighted-average remaining lease term	0.4 years	1.4 years
Weighted-average discount rate	3.79%	3.79%

Supplemental cash flow information related to operating leases was as follows:

	For the Fiscal Year Ended October 31, 2022	For the Fiscal Year Ended October 31, 2021
Cash paid for operating lease liabilities	<u>\$ 29</u>	<u>\$ 547</u>

Future minimum lease payments under non-cancellable leases as of October 31, 2022 were as follows:

Fiscal Year ending October 31,	
2023	\$ 13
Less: Imputed interest	(1)
Total	<u>\$ 12</u>

7. COMMON STOCK PURCHASE WARRANTS AND WARRANT LIABILITY

Warrants

As of October 31, 2022 and 2021, there were outstanding and exercisable warrants to purchase 377,818 shares of our common stock with exercise prices ranging from \$20.00 to \$224.00 per share. Information on the outstanding warrants is as follows:

Exercise Price	Number of Shares Underlying Warrants	Expiration Date	Type of Financing
\$ 20.00	879	September 2024	September 2018 Public Offering
\$ 224.00	4,092	July 2024	July 2019 Public Offering
\$ 28.00	57,230	November 2025	November 2020 Public Offering
\$ 56.00	140,552	April 2026	April 2021 Registered Direct Offering (Accompanying Warrants)
\$ 56.00	175,065	5 years after the date such warrants become exercisable, if ever	April 2021 Private Placement (Private Placement Warrants)
Grand Total	<u><u>377,818</u></u>		

As of October 31, 2022 and 2021, the Company had 201,874 of its total 377,818 outstanding warrants classified as equity (equity warrants). At issuance, equity warrants are recorded in Additional Paid-In Capital in the shareholders equity section of the consolidated balance sheets.

A summary of warrant activity was as follows (In thousands, except share and per share data):

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life In Years	Aggregate Intrinsic Value
Outstanding and exercisable warrants at October 31, 2020	4,971	\$ 6.40	3.76	\$ 110,640
Issued	603,190	38.40		
Exercised	(230,343)	16.00		
Outstanding and exercisable warrants at October 31, 2021	377,818	\$ 53.49	4.63	\$ 631,089
Outstanding and exercisable warrants at October 31, 2022	377,818	\$ 53.49	4.09	\$ -

Shares Issued for Warrants Exercises

During the year ended October 31, 2021, warrant holders from the Company's November 2020 offering exercised 134,437 warrants in exchange for 134,437 shares of the Company's common stock and warrant holders from the Company's April 2021 Offering exercised 95,899 pre-funded warrants in exchange for 95,899 shares of the Company's common stock. Pursuant to these warrant exercises, the Company received aggregate proceeds of approximately \$3.8 million which were payable upon exercise.

Warrant Liability

As of October 31, 2022 and 2021, the Company had 175,944 of its total 377,818 outstanding warrants from April 2021 Private Placement Offering and September 2018 Public Offering classified as liabilities (liability warrants).

The warrants issued in the April 2021 Private Placement will become exercisable only on such day, if ever, that is 14 days after the Company files an amendment to the Company's Amended and Restated Certificate of Incorporation to increase the number of authorized shares of common stock, \$0.001 par value per share from 170,000,000 shares to 300,000,000 shares. These warrants expire five years after the date they become exercisable. As of October 31, 2022, the Company did not have sufficient authorized common stock to allow for the issuance of common stock underlying these warrants. The Company did not receive stockholder authorization to increase the authorized shares from 170,000,000 to 300,000,000 shares at the stockholder's meeting commenced on June 3, 2021. The Company was subsequently required to file a proxy to seek an increase in the number of authorized shares and did not file such a proxy but rather elected to seek a reverse stock split to, among other things, increase the shares available. Accordingly, based on certain indemnification provisions of the securities purchase agreement, the Company concluded that liability classification is warranted. The Company utilized the Black Scholes model to calculate the fair value of these warrants at issuance and at each subsequent reporting date.

In measuring the warrant liability for the warrants issued in the April 2021 Private Placement at October 31, 2022 and 2021, the Company used the following inputs in its Black Scholes model:

	October 31, 2022	October 31, 2021
Exercise Price	\$ 56.00	\$ 56.00
Stock Price	\$ 1.86	\$ 38.80
Expected Term	5.00 years	5.00 years
Volatility %	114%	106%
Risk Free Rate	4.45%	1.18%

The September 2018 Public Offering warrants contain a down round feature, except for exempt issuances as defined in the warrant agreement, in which the exercise price would immediately be reduced to match a dilutive issuance of common stock, options, convertible securities and changes in option price or rate of conversion. As of October 31, 2022, the down round feature was triggered four times and the exercise price of the warrants were reduced from \$1,800.00 to \$20.00. The warrants require liability classification as the warrant agreement requires the Company to maintain an effective registration statement and does not specify any circumstances under which settlement in other than cash would be permitted or required. As a result, net cash settlement is assumed and liability classification is warranted. For these liability warrants, the Company utilized the Monte Carlo simulation model to calculate the fair value of these warrants at issuance and at each subsequent reporting date.

In measuring the warrant liability for the September 2018 Public Offering warrants at October 31, 2022 and 2021, the Company used the following inputs in its Monte Carlo simulation model:

	October 31, 2022	October 31, 2021
Exercise Price	\$ 20.00	\$ 24.00
Stock Price	\$ 1.86	\$ 38.80
Expected Term	1.86 years	2.87 years
Volatility %	113%	123%
Risk Free Rate	4.66%	0.77%

At October 31, 2022 and 2021, the fair value of the warrant liability was approximately \$119,000 and \$4,929,000, respectively. For the years ended October 31, 2022 and 2021, the Company reported income of approximately \$4,810,000 and \$970,000, respectively, due to changes in the fair value of the warrant liability.

8. COMMITMENTS AND CONTINGENCIES

Arbitration

On November 15, 2021, a purported stockholder of the Company commenced an action against the Company and certain of its directors in the U.S. District Court for the District of New Jersey, entitled *Atachbarian v. Advaxis, Inc., et al.*, No. 3:21-cv-20006. The plaintiff alleges that the defendants breached their fiduciary duties and violated Section 14(a) and Rule 20(a) of the Securities Exchange Act of 1934 and Rule 14a-9 promulgated thereunder by allegedly failing to disclose certain matters in its Registration Statement on Form S-4 (Commission File No. 333-259065 (the "Registration Statement")) filed in connection with a proposed merger with Biosight Ltd. (the "Previously Proposed Merger"). On December 15, 2021, pursuant to an understanding reached with the plaintiff, the Company made certain other additional disclosures that mooted the demands asserted in the complaint. On December 17, 2021, the plaintiff filed a notice of voluntary dismissal with prejudice. On February 7, 2022, the Company and the plaintiff reached a settlement agreement, which is recorded in general and administrative expenses in the consolidated statement of operations.

Purported Stockholder Claims Related to Biosight Transaction

Between September 16, 2021, and November 4, 2021, the Company received demand letters on behalf of six purported stockholders of the Company, alleging that the Company failed to disclose certain matters in the Registration Statement, and demanding that the Company disclose such information in a supplemental disclosure filed with the SEC. On October 14, 2021, the Company filed an amendment to the Registration Statement and on November 8, 2021, the Company made certain other additional disclosures that mooted the demands asserted in the above-referenced letters. The six plaintiffs have made settlement demands. On May 20, 2022, the Company and one of the plaintiffs have reached a settlement agreement, which is recorded in general and administrative expenses in the consolidated statement of operations. At this time, the Company is unable to predict the likelihood of an unfavorable outcome.

In addition, the Company received certain additional demands from stockholders asserting that the proxy materials filed by the Company in connection with the Previously Proposed Merger contained alleged material misstatements and/or omissions. Certain stockholders also demanded books and records of the Company pursuant to Delaware law. In response to these demands, the Company agreed to make, and did make, certain supplemental disclosures to the proxy materials. The stockholders have made settlement demands. On July 18, 2022, the Company and the plaintiffs consummated settlement agreements, which is recorded in general and administrative expenses in the consolidated statement of operations.

Purported Stockholder Claims Related to Series D Convertible Preferred Stock Offering

On February 17, 2022, the Company received a letter on behalf of purported stockholders of the Company, demanding certain books and records pursuant to Delaware law regarding the proposed issuance of super voting preferred stock. The Company agreed to provide certain books and records to the stockholders and agreed to make, and did make, a supplemental disclosure to the proxy materials. The stockholders have made settlement demands. On July 18, 2022, the Company and the plaintiffs consummated settlement agreements, which is recorded in general and administrative expenses in the consolidated statement of operations.

Purported Stockholder Claims Related to Merger with Old Ayala

On December 15, 2022, a purported stockholder of Old Ayala filed a complaint in the U.S. District Court for the Southern District of New York against Old Ayala and the members of its Board, captioned Stephen Bushansky v. Ayala Pharmaceuticals, Inc., Case No.1:22-cv-10621 (S.D.N.Y.) (the “Complaint”).

The Complaint asserts claims against all defendants under Section 14(a) of the Securities Exchange Act of 1934, as amended (the “Exchange Act”) and Rule 14a-9 promulgated thereunder for omitting or misrepresenting material information from Old Ayala’s Proxy Statement and against the individual defendants under Section 20(a) of the Exchange Act for alleged “control person” liability with respect to such alleged omissions and misrepresentations. The allegations in the Complaint include that the Proxy Statement omitted material information regarding Old Ayala’s financial projections and the financial analyses of Old Ayala’s financial advisor for the Merger. The Complaint seeks, among other relief, (1) to enjoin defendants from consummating the Merger; (2) to enjoin a vote on the Merger; (3) to rescind the Merger Agreement or recover damages, if the Merger is completed; (4) a declaration that defendants violated Sections 14(a) or 20(a) and Rule 14a-9 of the Exchange Act; and (5) attorneys’ fees and costs.

In addition, approximately nine purported stockholders of Old Ayala sent letters to those noted in the above-referenced Complaint alleging similar deficiencies in Old Ayala’s Proxy Statement (collectively, the “Demand Letters”).

At this time, the Company is unable to predict the likelihood of an unfavorable outcome with respect to the Complaint and the Demand Letters.

9. TEMPORARY EQUITY

Series D Convertible Preferred Stock Offering

On January 31, 2022, the Company consummated an offering with certain institutional investors for the private placement of 1,000,000 shares of Series D convertible redeemable preferred stock (the “Series D Preferred Stock”). The shares, which have since been redeemed in accordance with their terms as described below, and are thus no longer outstanding as of July 31, 2022, had an aggregate stated value of \$5,000,000. Each share of the Series D preferred stock had a purchase price of \$4.75, representing an original issue discount of 5% of the stated value. The shares of Series D Preferred Stock were convertible into shares of the Company’s common stock, upon the occurrence of certain events, at a conversion price of \$20.00 per share. The conversion, at the option of the stockholder, could occur at any time following the receipt of the stockholders’ approval for a reverse stock split. The Company was permitted to compel conversion of the Series D Preferred Stock after the fulfillment of certain conditions and subject to certain limitations. The Series D Preferred Stock also had a liquidation preference over the shares of common stock, and could be redeemed by the investors, in accordance with certain terms, for a redemption price equal to 105% of the stated value, or in certain circumstances, 110% of the stated value. Total net proceeds from the offering, after deducting the financial advisor’s fees and other estimated offering expenses, were approximately \$4.3 million.

Since the Series D preferred stock had a redemption feature at the option of the holder, it was classified as temporary equity. At the January 31, 2022 issuance date, the Series D preferred stock was recorded on the balance sheet at approximately \$4,225,000, which is the \$4,312,000 net proceeds less the \$87,000 value of the bifurcated preferred stock redemption liability (see below).

On April 6, 2022, the holders of all 1,000,000 outstanding shares of the Series D Preferred Stock exercised their right to cause the Company to redeem all of such shares at a price per share equal to 105% of the stated value per share of \$5.00, and such shares were redeemed accordingly. The \$1,025,000 accretion of the Series D convertible preferred stock to its redemption value was recorded as a reduction in additional paid-in capital.

Preferred Stock Redemption Liability

The Company evaluated the preferred stock redemption feature under ASC 815. Since the preferred stock redemption feature is not considered to be clearly and closely related to the preferred stock host and the redemption feature meets the four characteristics of a derivative under ASC 815, the preferred stock redemption feature is required to be bifurcated from the preferred stock host and valued as a liability. The Company utilized a binomial model to calculate the fair value of the preferred stock redemption feature at issuance.

In measuring the preferred stock redemption liability at April 6, 2021 (redemption date) and January 31, 2022 (issuance date), the Company used the following inputs in its binomial model:

	April 6, 2022	January 31, 2022
Exercise Price	\$ 20.00	\$ 20.00
Stock Price	\$ 9.04	\$ 10.88
Volatility %	96%	105%
Risk Free Rate	1.25%	1.00%

At April 6, 2022 and January 31, 2022, the fair value of the preferred stock redemption liability was approximately \$44,000 and \$87,000, respectively. On April 6, 2022, the Series D convertible preferred stock was redeemed, and the \$44,000 preferred stock redemption liability was reclassified into other paid-in capital. For the year ended October 31, 2022, the Company reported income \$43,000 due to a change in the fair value of the preferred stock redemption liability.

10. STOCKHOLDERS' EQUITY

Public Offerings

In April 2021, the Company entered into a securities purchase agreement (the "Purchase Agreement") with certain investors. The Purchase Agreement provided for the sale and issuance by the Company of an aggregate of 219,718 shares (the "Shares") of the Company's common stock, \$0.001 par value (the "Common Stock"), at an offering price of \$63.37 per Share and 95,899 pre-funded warrants to certain purchasers whose purchase of additional Shares would otherwise result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 9.99% of the Company's outstanding Common Stock immediately following the consummation of the offering (the "Pre-Funded Warrants"). The Shares and Pre-Funded Warrants were sold together with warrants to purchase up to 140,552 shares of Common Stock (the "Accompanying Warrants" and together with the Shares and the Pre-Funded Warrants, the "Securities"). The Pre-Funded Warrants were sold for a purchase price of \$63.29 per share and have an exercise price of \$0.001 per share. The Pre-Funded Warrants were immediately exercisable and may be exercised at any time until all of the Pre-Funded Warrants are exercised in full. Each Accompanying Warrant has an exercise price per share of \$56.00, became exercisable immediately and will expire on the fifth anniversary of the original issuance date.

The Purchase Agreement also provided for a concurrent private placement (the "Private Placement") of 175,065 warrants to purchase the Company's Common Stock (the "Private Placement Warrants") with the purchasers in the Registered Offering. The Private Placement Warrants will be exercisable for an aggregate of 175,065 shares of Common Stock at any time on or after such date, if ever, that is 14 days after the Company files an amendment (the "Authorized Shares Amendment") to the Company's Amended and Restated Certificate of Incorporation to increase the number of authorized shares of Common Stock, \$0.001 par value per share from 170,000,000 shares to 300,000,000 shares with the Delaware Secretary of State and on or prior to the date that is five years after such date. The Private Placement Warrants have an exercise price of \$56.00 per share.

In May 2020, the Company entered into a sales agreement related to an ATM equity offering program pursuant to which the Company may sell, from time to time, common stock with an aggregate offering price of up to \$40 million through A.G.P./Alliance Global Partners, as sales agent. In March 2021, the Company sold 11,076 shares of its common stock under the ATM program for \$762,000, or an average of \$68.80 per share, and received net proceeds of \$737,000, net of commissions of \$25,000.

In November 2020, the Company closed on a public offering of 383,333 shares of its common stock at a public offering price of \$24.00 per share, for gross proceeds of approximately \$9.2 million, which gives effect to the exercise of the underwriter's option in full. In addition, the Company also undertook a concurrent private placement of warrants to purchase up to 191,677 shares of common stock. The warrants have an exercise price per share of \$28.00, are exercisable immediately and will expire five years from the date of issuance. The warrants also provide that if there is no effective registration statement registering, or no current prospectus available for, the issuance or resale of the warrant shares, the warrants may be exercised via a cashless exercise. After deducting the underwriting discounts and commissions and other offering expenses, the net proceeds from the offering were approximately \$8.5 million.

11. SHARE BASED COMPENSATION

The following table summarizes share-based compensation expense included in the consolidated statement of operations by expense category for the years ended October 31, 2022 and 2021 (in thousands):

	Year Ended October 31,	
	2022	2021
Research and development	\$ 47	\$ 164
General and administrative	50	402
Total	<u>\$ 97</u>	<u>\$ 566</u>

Amendments

The Advaxis, Inc. 2015 Incentive Plan (the “2015 Plan”) was originally ratified and approved by the Company’s stockholders on May 27, 2015. Subject to proportionate adjustment in the event of stock splits and similar events, the aggregate number of shares of common stock that may be issued under the 2015 Plan is 79,165 shares, plus a number of additional shares (not to exceed 542) underlying awards outstanding as of the effective date of the 2015 Plan under the prior plan that thereafter terminate or expire unexercised, or are cancelled, forfeited or lapse for any reason.

On January 1, 2021, 2,083 shares were added to the 2015 Plan. On January 1, 2022, 2,083 shares were added to the 2015 Plan.

As of October 31, 2022, there were 66,191 shares available for issuance under the 2015 Plan.

Restricted Stock Units (RSUs)

A summary of the Company’s RSU activity and related information for the fiscal year ended October 31, 2022 and 2021 is as follows:

	Number of RSU’s	Weighted- Average Grant Date Fair Value
Balance at October 31, 2020	69	\$ 1,946
Vested	(69)	1,944
Balance at October 31, 2021	-	\$ -
Balance at October 31, 2022	-	\$ -

The fair value of the RSUs as of the vesting date was approximately \$3,000 for the year ended October 31, 2021.

Employee Stock Awards

Common stock issued to executives and employees related to vested incentive retention awards and employment inducements totaled 0 shares and 69 shares during the years ended October 31, 2022 and 2021, respectively. Total stock compensation expense associated with these awards for the years ended October 31, 2022 and 2021 was approximately \$0 and \$67,000, respectively.

Stock Options

A summary of changes in the stock option plan for the years ended October 31, 2022 and 2021 is as follows (in thousands, except share and per share data):

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life In Years	Aggregate Intrinsic Value
Outstanding as of October 31, 2020	12,669	\$ 2,676.78	8.04	\$ 4
Granted	625	31.20		
Exercised	(4)	24.00		
Cancelled or expired	(2,098)	7,903.21		
Outstanding as of October 31, 2021	11,192	\$ 1,550.26	7.80	\$ 27
Cancelled or expired	(74)	22,200.00		
Outstanding as of October 31, 2022	11,118	1,412.82	6.81	-
Vested and exercisable at October 31, 2022	8,689	\$ 1,795.09	6.55	\$ -

During the year ended October 31, 2021, the Company granted stock options to purchase 625 shares of its common stock to an employee. The stock options have a ten-year term, vest over three years from the date of grant, and have an exercise price of \$31.20.

The weighted average grant date fair value of options granted during the fiscal year ended October 31, 2021 was \$24.80.

The total intrinsic value of options exercised during the fiscal years ended October 31, 2021 was \$162.

Total compensation cost related to the Company's outstanding stock options, recognized in the consolidated statement of operations for the years ended October 31, 2022 and 2021 was approximately \$97,000 and \$499,000, respectively.

As of October 31, 2022, there was approximately \$54,000 of unrecognized compensation cost related to non-vested stock option awards, which is expected to be recognized over a remaining weighted average vesting period of approximately 0.73 years.

The following table summarizes information about the outstanding and exercisable stock options at October 31, 2022:

Options Outstanding					Options Exercisable				
Exercise Price Range	Number Outstanding	Weighted Average Remaining Contractual	Weighted Average Exercise Price	Intrinsic Value	Number Exercisable	Weighted Average Remaining Contractual	Weighted Average Exercise Price	Intrinsic Value	
\$ 24.00-\$50.00	4,241	7.61	\$ 32.53	\$ -	3,162	7.47	\$ 31.31	\$ -	
\$ 50.01-100.00	4,174	7.49	\$ 53.33	\$ -	2,824	7.48	\$ 53.58	\$ -	
\$ 100.01-20,664.00	2,703	4.50	\$ 5,677.84	\$ -	2,703	4.50	\$ 5,677.84	\$ -	

The fair value of each option granted from the Company's stock option plans during the year ended October 31, 2021 was estimated on the date of grant using the Black-Scholes option-pricing model. Using this model, fair value is calculated based on assumptions with respect to (i) expected volatility of the Company's common stock price, (ii) the periods of time over which employees and Board Directors are expected to hold their options prior to exercise (expected lives), (iii) expected dividend yield on the Company's common stock, and (iv) risk-free interest rates, which are based on quoted U.S. Treasury rates for securities with maturities approximating expected lives of the options. The Company used their own historical volatility in determining the volatility to be used. The expected term of the stock option grants was calculated using the "simplified" method in accordance with the SEC Staff Accounting Bulletin 107. The "simplified" method was used since the Company believes its historical data does not provide a reasonable basis upon which to estimate expected term and the Company does not have enough option exercise data from its grants issued to support its own estimate as a result of vesting terms and changes in the stock price. The expected dividend yield is zero as the Company has never paid dividends to common shareholders and does not currently anticipate paying any in the foreseeable future.

The following table provides the weighted average fair value of stock options granted to directors and employees and the related assumptions used in the Black-Scholes model:

	Year Ended October 31, 2021
Expected term	6 years
Expected volatility	103.27%
Expected dividends	0%
Risk free interest rate	0.53%

Employee Stock Purchase Plan

The Advaxis, Inc. 2018 Employee Stock Purchase Plan (ESPP) was approved by the Company's shareholders on March 21, 2018. The 2018 ESPP allows employees to purchase common stock of the Company at a 15% discount to the market price on designated exercise dates. Employees were eligible to participate in the 2018 ESPP beginning May 1, 2018. 12,500 shares of the Company's Common stock were reserved for issuance under the 2018 ESPP.

During the fiscal years ended October 31, 2022 and 2021, the Company issued 0 and 12 shares, respectively, under the 2018 ESPP. In July 2021, the ESPP was terminated.

12. LICENSING AGREEMENTS

OS Therapies LLC

On September 4, 2018, the Company entered into a development, license and supply agreement with OS Therapies ("OST") for the use of ADXS31-164, also known as ADXS-HER2, for evaluation in the treatment of osteosarcoma in humans. Under the terms of the license agreement, as amended, OST is responsible for the conduct and funding of a clinical study evaluating ADXS-HER2 in recurrent, completely resected osteosarcoma. Under the most recent amendment to the licensing agreement, OST agreed to pay New Ayala \$25,000 per month ("Monthly Payment") starting on April 30, 2020 until OST achieves its funding milestone of \$2,337,500. Upon receipt of the first Monthly Payment, New Ayala will initiate the transfer of the intellectual property and licensing rights of ADXS31-164, which were licensed pursuant to the Penn Agreement, back to the University of Pennsylvania. Contemporaneously, OST will enter negotiations with the University of Pennsylvania to establish a licensing agreement for ADXS31-164 to OST for clinical and commercial development of the ADXS31-164 technology.

Provided that OST meets its ongoing obligation to make its Monthly Payments to New Ayala for six consecutive months, New Ayala agrees to transfer, and OST agrees to take full ownership of, the IND application for ADXS31-164 in its entirety to OST, along with agreements and promises contained therein, as well as all obligations associated with this IND or any HER2 product/program development. Until OST makes its Monthly Payments to New Ayala for six consecutive months, New Ayala will continue to bear the costs of the regulatory filing services related to the IND application for ADXS31-164.

Within five business days of achieving the funding milestone of \$2,337,500 for the performance of the Children's Oncology Group study (known as the "License Commencement Date"), OST will make a non-refundable and non-creditable payment to New Ayala of \$1,550,000 less the cumulative Monthly Payments previously made (the "License Commencement Payment"). Within five days following the License Commencement Date, New Ayala will provide existing drug supply "as is" to OST, and until the drug supply is supplied to OST, New Ayala will bear the storage costs for the drug product. Pursuant to the agreement, the Company is also to receive sales-based milestone payments and royalties on future product sales. In addition, the Company and OST will establish a Joint Steering Committee to oversee the R&D activities.

The promises to (1) Maintain the HER2 product until transfer to OST, (2) Provide the IND application ownership for ADX321-164 to OST, (3) Participate in the Joint Steering Committee, (4) Transfer of IP & licensing rights of ADXS31-164 and related Patents, and (5) Provide Clinical Drug Supply represent one combined performance obligation for revenue recognition purposes. The Company concluded that the transfer of the IP and licensing rights provides OST with a functional, or “right to use,” license, and thus the Company will recognize the upfront fees of \$1,550,000 from the license at a point in time. The revenue from the transfer of the license cannot be recognized until the transfer of the corresponding IP to OST has occurred and OST has the ability to benefit from the right to use the license. As the right to use the license begins when OST makes the upfront payment within five days of the License Commencement Date and the IP transfers to OST at that time, the upfront fees from the license will be recognized upon the transfer of the intellectual property to OST.

Since OST is making \$25,000 monthly payments that will be creditable against the \$1,550,000, as well as additional upfront payments not specified in the contract, the Company will receive payments prior to the performance of the single distinct performance obligation. Due to this, the Company will defer any of the monthly payments until the IP and licensing rights are transferred to OST. However, if OST terminates the contract, which they are able to do with 60-day notice, the Company would recognize any of the payments received when the contract terminates.

In December 2020 and January 2021, the Company received an aggregate of \$1,615,000 from OS Therapies upon achievement of the funding milestone set forth in the license agreement and recorded \$1,615,000 in revenue. The Company therefore transferred, and OST took full ownership of, the IND application for ADXS31-164 in its entirety along with agreements and promises contained therein, as well as all obligations associated with this IND or any HER2 product/program development.

In April 2021, the Company achieved the second milestone set forth in the license agreement for evaluation in the treatment of osteosarcoma in humans and recorded \$1,375,000 in revenue. The Company received the amount due from OS Therapies of \$1,375,000 in May 2021.

Global BioPharma Inc.

On December 9, 2013, the Company entered into an exclusive licensing agreement for the development and commercialization of axalimogene filolisbac with Global BioPharma, Inc. (GBP), a Taiwanese based biotech company funded by a group of investors led by Taiwan Biotech Co., Ltd (TBC). During each of the years ended October 31, 2022 and 2021, the Company recorded \$0.25 million in revenue for the annual license fee renewal. Since New Ayala has no significant obligation to perform after the license transfer and has provided GBP with the right to use its intellectual property, performance is satisfied when the license renews.

13. INCOME TAXES

The income tax provision (benefit) consists of the following (in thousands):

	October 31, 2022	October 31, 2021
Federal		
Current	\$ -	\$ -
Deferred	(3,990)	141
State and Local		
Current	-	-
Deferred	(1,289)	131
Foreign		
Current	50	50
Deferred	-	-
Change in valuation allowance	5,279	(272)
Income tax provision (benefit)	<u>\$ 50</u>	<u>\$ 50</u>

The Company has U.S. federal net operating loss carryovers (“NOLs”) of approximately \$333.6 million and \$314.8 million at October 31, 2022 and 2021, respectively, available to offset taxable income. The Company has \$75.3 million of NOLs which do not expire, the remainder of which are subject to expiration through 2038. The Company conducted an Internal Revenue Code Section 382 analysis through October 31, 2019. Based on that analysis, some NOLs incurred through October 31, 2019 are subject to limitation and will expire. Subsequent period NOLs have not been studied for the Internal Revenue Code Section 382 limitation. The Company also has New Jersey State Net Operating Loss carryovers of approximately \$172.9 million and \$153.7 million as of October 31, 2022 and 2021, respectively, available to offset future taxable income through 2042. Utilization of New Jersey NOLs may be similarly limited.

In assessing the realization of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon future generation for taxable income during the periods in which temporary differences representing net future deductible amounts become deductible. Management considers the scheduled reversal of deferred tax liabilities, projected future taxable income and tax planning strategies in making this assessment. After consideration of all the information available, management believes that significant uncertainty exists with respect to future realization of the deferred tax assets and has therefore established a full valuation allowance.

The Company evaluated the provisions of ASC 740 related to the accounting for uncertainty in income taxes recognized in an enterprise's financial statements. ASC 740 prescribes a comprehensive model for how a company should recognize, present, and disclose uncertain positions that the company has taken or expects to take in its tax return. For those benefits to be recognized, a tax position must be more-likely-than-not to be sustained upon examination by taxing authorities. Differences between tax positions taken or expected to be taken in a tax return and the net benefit recognized and measured pursuant to the interpretation are referred to as "unrecognized benefits." A liability is recognized (or amount of net operating loss carry forward or amount of tax refundable is reduced) for unrecognized tax benefit because it represents an enterprise's potential future obligation to the taxing authority for a tax position that was not recognized as a result of applying the provisions of ASC 740.

If applicable, interest costs related to the unrecognized tax benefits are required to be calculated and would be classified as other expense in the consolidated statement of operations. Penalties would be recognized as a component of general and administrative expenses in the consolidated statement of operations.

No interest or penalties on unrecognized tax benefits were recorded during the years ended October 31, 2022 and 2021, respectively. As of October 31, 2022, and 2021, no liability for unrecognized tax benefits was required to be reported. The Company does not expect any significant changes in its unrecognized tax benefits in the next year.

The Company files tax returns in the U.S. federal and state jurisdictions and is subject to examination by tax authorities beginning with the fiscal year ended October 31, 2019.

The Company's deferred tax assets (liabilities) consisted of the effects of temporary differences attributable to the following (in thousands):

	Years Ended	
	October 31, 2022	October 31, 2021
Deferred Tax Assets		
Net operating loss carryovers	\$ 38,294	\$ 32,971
Stock-based compensation	4,160	4,566
Research and development credits	11,721	11,371
Capitalized R&D costs	13,590	14,536
Adoption of ASC 842 – Lease Liability	3	11
Other deferred tax assets	129	92
Total deferred tax assets	\$ 67,897	\$ 63,547
Valuation allowance	(67,852)	(62,573)
Deferred tax asset, net of valuation allowance	\$ 45	\$ 974
Deferred Tax Liabilities		
Adoption of ASC 842 – ROU Asset	(3)	(11)
Patent cost	(31)	(943)
Other deferred tax liabilities	(11)	(20)
Total deferred tax liabilities	\$ (45)	\$ (974)
Net deferred tax asset (liability)	\$ -	\$ -

The expected tax (expense) benefit based on the statutory rate is reconciled with actual tax expense benefit as follows:

	Years Ended	
	October 31, 2022	October 31, 2021
US Federal statutory rate	21.00%	21.00%
State income tax, net of federal benefit	9.02	(0.73)
Merger costs	0.55	(1.68)
Other permanent differences	-	(0.02)
Research and development credits	2.31	3.09
Warrant Liability	7.12	1.14
Foreign taxes	(0.35)	(0.28)
Change in valuation allowance	(36.90)	1.52
Stock option expirations	(3.10)	(24.32)
Income tax (provision) benefit	(0.35)%	(0.28)%

The "Foreign taxes" income tax expense in the consolidated statement of operations for both the years ended October 31, 2022 and 2021 pertain to a Taiwan Excise tax of \$50,000 levied in connection with the GBP Revenue.

14. FAIR VALUE

The authoritative guidance for fair value measurements defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or the most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Market participants are buyers and sellers in the principal market that are (i) independent, (ii) knowledgeable, (iii) able to transact, and (iv) willing to transact. The guidance describes a fair value hierarchy based on the levels of inputs, of which the first two are considered observable and the last unobservable, that may be used to measure fair value which are the following:

- Level 1 — Quoted prices in active markets for identical assets or liabilities.
- Level 2— Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or corroborated by observable market data or substantially the full term of the assets or liabilities.
- Level 3 — Unobservable inputs that are supported by little or no market activity and that are significant to the value of the assets or liabilities.

The following table provides the assets and liabilities carried at fair value measured on a recurring basis as of October 31, 2022 and October 31, 2021 (in thousands):

Fair Value Measured at October 31, 2022				
	Level 1	Level 2	Level 3	Total
Financial assets at fair value:				
Cash equivalents (money market funds)	\$ 12,268	\$ -	\$ -	\$ 12,268
Total Financial Assets at Fair Value	\$ 12,268	\$ -	\$ -	\$ 12,268

Financial liabilities at fair value:				
Common stock warrant liability, warrants exercisable at \$20.00 through September 2024	\$ -	\$ -	\$ -	\$ -
Common stock warrant liability, warrants exercisable at \$56.00 through 5 years after the date such warrants become exercisable, if ever (Private Placement Warrants)	-	-	119	119
Total financial liabilities at fair value	\$ -	\$ -	\$ 119	\$ 119

Fair Value Measured at October 31, 2021				
	Level 1	Level 2	Level 3	Total
Financial assets at fair value:				
Cash equivalents (money market funds)	\$ 17,153	\$ -	\$ -	\$ 17,153
Total Financial Assets at Fair Value	\$ 17,153	\$ -	\$ -	\$ 17,153

Financial liabilities at fair value:				
Common stock warrant liability, warrants exercisable at \$24.00 through September 2024	\$ -	\$ -	\$ 27	\$ 27
Common stock warrant liability, warrants exercisable at \$56.00 through 5 years after the date such warrants become exercisable, if ever (Private Placement Warrants)	-	-	4,902	4,902
Total financial liabilities at fair value	\$ -	\$ -	\$ 4,929	\$ 4,929

The following table presents changes in Level 3 liabilities measured at fair value (in thousands) for the years ended October 31, 2022 and 2021. Unobservable inputs were used to determine the fair value of positions that the Company has classified within the Level 3 category.

	Preferred Stock Redemption Liability	Warrant Liabilities	Total
Fair value at October 31, 2020	\$ -	\$ 17	\$ 17
Additions	-	5,882	5,882
Exercises	-	-	-
Change in fair value	-	(970)	(970)
Fair value at October 31, 2021	\$ -	\$ 4,929	\$ 4,929
Additions	87	-	87
Change in fair value	(43)	(4,810)	(4,853)
Redemption	(44)	-	(44)
Fair value at October 31, 2022	\$ -	\$ 119	\$ 119

15. EMPLOYEE BENEFIT PLAN

The Company sponsors a 401(k) Plan. Employees become eligible for participation upon the start of employment. Participants may elect to have a portion of their salary deferred and contributed to the 401(k) Plan up to the limit allowed under the Internal Revenue Code. The Company makes a matching contribution to the plan for each participant who has elected to make tax-deferred contributions for the plan year. The Company made matching contributions which amounted to approximately \$92,000 and \$78,000 for each of the years ended October 31, 2022 and 2021, respectively. These amounts were charged to the consolidated statement of operations. The employer contributions vest immediately.

16. SUBSEQUENT EVENTS

On December 1, 2022, the Company entered into a Subscription and Investment Representation Agreement (the “Subscription Agreement”) with Kenneth A. Berlin, its President and Chief Executive Officer, who is an accredited investor (the “Purchaser”), pursuant to which the Company agreed to issue and sell ten (10) shares of the Company’s Series E Preferred Stock, par value \$0.001 per share (the “Preferred Stock”), to the Purchaser for \$1,000 per share in cash. The sale closed on December 1, 2022.

Also on December 1, 2022, the Company filed a certificate of designation (the “Certificate of Designation”) with the Secretary of State of Delaware, effective as of the time of filing, designating the rights, preferences, privileges and restrictions of the shares of Preferred Stock. The Certificate of Designation provides that ten (10) shares of Preferred Stock will have 200,000,000 votes each and will vote together with the outstanding shares of the Company’s common stock as a single class exclusively with respect to any proposal to amend the Company’s Restated Certificate of Incorporation to change the name of the Company and to effect a reverse stock split of the Company’s common shares. The Preferred Stock will be voted, without action by the holder, on any such proposal in the same proportion as shares of common stock are voted. The Preferred Stock otherwise has no voting rights except as otherwise required by the General Corporation Law of the State of Delaware.

The Preferred Stock is not convertible into, or exchangeable for, shares of any other class or series of stock or other securities of the Company. The Preferred Stock has no rights with respect to any distribution of assets of the Company, including upon a liquidation, bankruptcy, reorganization, merger, acquisition, sale, dissolution or winding up of the Company, whether voluntarily or involuntarily. The holder of the Preferred Stock will not be entitled to receive dividends of any kind.

The outstanding shares of Preferred Stock shall be redeemed in whole, but not in part, at any time (i) if such redemption is ordered by the Board of Directors in its sole discretion or (ii) automatically upon the effectiveness of the amendment to the Certificate of Incorporation implementing a reverse stock split. Upon such redemption, the holder of the Preferred Stock will receive consideration of \$1,000 per share in cash.

As disclosed in Note 1, on October 18, 2022, the Company entered into a Merger Agreement with Old Ayala including terms that Old Ayala will continue as the surviving company and a wholly-owned subsidiary of New Ayala.

On January 13, 2023, the OldAyala stockholders approved the Merger Agreement and the Merger closed on January 19, 2023.

Also on January 13, 2023, the Company’s stockholders approved a reverse stock split of the common stock at a ratio to be determined by the Board of Directors within a range of one-for-two to one-for-ten (or any number in between), without reducing the authorized number of shares of the common stock, to be effected in the sole discretion of the Board of Directors at any time within one year of the date of the Special Meeting without further approval or authorization of our stockholders. The Company’s stockholders also approved an amendment to the Charter to change the corporate name from “Advaxis, Inc.” to “Ayala Pharmaceuticals, Inc.”.

**Amended and Restated Certificate of Incorporation
of
Ayala Pharmaceuticals, Inc.**

(as amended)

Ayala Pharmaceuticals, Inc. (the "Corporation"), a corporation duly organized and existing under the General Corporation Law of the State of Delaware (the "GCL"), does hereby certify that:

1. The present name of the Corporation is Ayala Pharmaceuticals, Inc.

2. The Corporation was originally incorporated under the name Advaxis, Inc., and its original Certificate of Incorporation was filed with the Secretary of State of the State of Delaware on February 28, 2002. On January 19, 2023, the Corporation filed an amendment to its Certificate of Incorporation to change its name from Advaxis, Inc. to Ayala Pharmaceuticals, Inc.

3. This Restated Certificate of Incorporation was duly adopted by the Board of Directors of the Corporation in accordance with the provisions of Section 245 of the General Corporation Law of the State of Delaware. This Restated Certificate of Incorporation only restates and integrates and does not further amend the provisions of the Corporation's Certificate of Incorporation, as theretofore amended or supplemented or restated, and there is no discrepancy between those provisions and the provisions of this Restated Certificate of Incorporation.

4. The text of the Corporation's Certificate of Incorporation, as heretofore amended or supplemented or restated, is hereby restated to read in its entirety as follows:

First: The name of the corporation is Ayala Pharmaceuticals, Inc. (the "Corporation").

Second: The address of the registered office of the Corporation is located at 160 Greentree Drive, Suite 101, Dover, Delaware 19904 in the county of Kent. The name of its registered agent at that address is National Registered Agents, Inc.

Third: The purposes for which the Corporation is formed are to engage in any lawful act or activity for which a corporation may be organized under the General Corporation Law of the State of Delaware.

Fourth:

A. The total number of shares which the Corporation shall have the authority to issue is One Hundred and Seventy Five Million (175,000,000) shares of which One Hundred and Seventy Million (170,000,000) shares shall be designated "Common Stock" and have a par value of \$0.001 per share, and Five Million (5,000,000) shares shall be "blank check" preferred stock and have a par value of \$0.001.

B. Subject to the provisions of the General Corporation Law of the State of Delaware, the Board of Directors of the Corporation is authorized to issue the shares of Preferred Stock in one or more series and determine the number of shares constituting each such series, the voting powers of shares of each such series and the designations, preferences and relative, participating, optional or other special rights, and qualifications, limitations or restrictions as set forth in a resolution or resolutions of the Board of Directors providing for the issue of such stock.

C. Effective as of March 29, 2019 (the “First Effective Time”), each fifteen (15) shares of the Corporation’s Common Stock, par value \$0.001 per share (“Common Stock”), then issued and outstanding or held by the Corporation in treasury stock immediately prior to the First Effective Time shall automatically be combined, reclassified and changed into one (1) validly issued, fully paid and non-assessable share of Common Stock without any further action by the Corporation or the holder thereof, subject to the treatment of fractional interests as described below. Notwithstanding the immediately preceding sentence, no fractional shares will be issued in connection with the combination effected by the preceding sentence. Stockholders of record who otherwise would be entitled to receive fractional shares in connection with such combination will instead be entitled to receive, in lieu of such fractional shares, an amount in cash equal to the product of (i) the closing sales price of the Common Stock as reported on The Nasdaq Global Select Market as of the First Effective Time, multiplied by (ii) the number of shares of Common Stock held by the stockholder immediately prior to the First Effective Time that would otherwise have been exchanged for such fractional shares.

D. Effective as of June 6, 2022 (the “Second Effective Time”), each eighty (80) shares of the Corporation’s Common Stock then issued and outstanding or held by the Corporation in treasury stock immediately prior to the Second Effective Time (the “Old Common Stock”) shall automatically be combined, reclassified and changed into one (1) validly issued, fully paid and non-assessable share of Common Stock without any further action by the Corporation or the holder thereof, subject to the treatment of fractional interests as described below (the “Reclassification”). Notwithstanding the immediately preceding sentence, no fractional shares will be issued in connection with the combination effected by the preceding sentence. Stockholders of record who otherwise would be entitled to receive fractional shares in connection with such combination will instead be entitled to receive, in lieu of such fractional shares, an amount in cash equal to the fraction to which the stockholder would otherwise be entitled multiplied by the closing price of our Common Stock on the OTCQX on the date on which the Second Effective Time occurs. Each stock certificate or book-entry position that, immediately prior to the Second Effective Time, represented shares of Old Common Stock shall, from and after the Second Effective Time, automatically and without the necessity of presenting the same for exchange, represent that number of shares of Common Stock after the Second Effective Time into which the shares of Old Common Stock have been reclassified pursuant to this paragraph, until the same shall be surrendered to the Corporation. The Reclassification shall also apply to any outstanding securities or rights convertible into, or exchangeable or exercisable for, Old Common Stock of the Corporation and all references to the Old Common Stock in agreements, arrangements, documents and plans relating thereto or any option or right to purchase or acquire shares of Old Common Stock shall be deemed to be references to the Common Stock or options or rights to purchase or acquire shares of Common Stock, as the case may be.

Fifth: The Corporation is to have perpetual existence.

Sixth: In furtherance and not in limitation of the powers conferred by statute and except as otherwise provided herein, the Board of Directors is expressly authorized to make, alter, amend or repeal the bylaws of the Corporation.

Seventh: The number of directors which constitute the whole Board of Directors of the Corporation shall be as specified in the bylaws of the Corporation.

Eighth: Meetings of stockholders may be held within or without the State of Delaware, as the bylaws of the Corporation may provide. The books of the Corporation may be kept outside the State of Delaware at such place or places as may be designated from time to time by the Board of Directors or in the bylaws of the Corporation.

Ninth:

A. The Corporation shall indemnify each of the Corporation's directors and officers in each and every situation where, under Section 145 of the General Corporation Law of the State of Delaware, as amended from time to time ("Section 145"), the Corporation is permitted or empowered to make such indemnification, and to the fullest extent permitted by law. The Corporation may, in the sole discretion of the Board of Directors of the Corporation, indemnify any other person who may be indemnified pursuant to Section 145 to the extent the Board of Directors deems advisable, as permitted by Section 145.

B. No person shall be personally liable to the Corporation or its stockholders for monetary damages for breach of fiduciary duty as a director; provided, however, that the foregoing 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 General Corporation Law of the State of Delaware or (iv) for any transaction from which the director derived an improper personal benefit. If the General Corporation Law of the State of Delaware is subsequently amended to further eliminate or limit the liability of a director, then a director of the Corporation, in addition to the circumstances in which a director is not personally liable as set forth in the preceding sentence, shall not be liable to the fullest extent permitted by the amended General Corporation Law of the State of Delaware. For purposes of this Article, "fiduciary duty as a director" shall include any fiduciary duty arising out of serving at the Corporation's request as a director of another corporation, partnership, joint venture, trust or other enterprise, and "personal liability to the Corporation or its stockholders" shall include any liability to such other corporation, partnership, joint venture, trust or other enterprise, and any liability to the Corporation in its capacity as a security holder, joint venturer, partner, beneficiary, creditor or investor of or in any such other corporation, partnership, joint venture, trust or other enterprise. Neither any amendment nor repeal of this Article Ninth (B), nor the adoption of any provision of this Certificate of Incorporation inconsistent with this Article Ninth (B), shall eliminate or reduce the effect of this Article Ninth (B) in respect of any matter occurring, or any cause of action, suit or claim that, but for this Article Ninth (B), would accrue or arise, prior to such amendment, repeal or adoption of an inconsistent provision.

Tenth: The directors of the Corporation need not be elected by written ballot unless the by-laws of the Corporation so provide.

Eleventh: The Corporation has opted out of Section 203 of the General Corporation Law of the State of Delaware.

INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM'S CONSENT

We consent to the incorporation by reference in the Registration Statement of Ayala Pharmaceuticals, Inc. (formerly known as Advaxis, Inc.) on Form S-8 (File Nos. 333-130080, 333-193007, 333-197465, 333-204939, 333-210285, 333-217218, 333-222483, 333-223851, and 333-239469) of our report dated February 9, 2023, which includes an explanatory paragraph as to the Company's ability to continue as a going concern, with respect to our audits of the consolidated financial statements of Ayala Pharmaceuticals, Inc. (formerly known as Advaxis, Inc.) as of October 31, 2022 and 2021 and for each of the two years in the period ended October 31, 2022, which report is included in this Annual Report on Form 10-K of Ayala Pharmaceuticals, Inc. for the year ended October 31, 2022.

/s/ Marcum LLP

Marcum LLP
New York, NY
February 9, 2023

**CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO 18.U.S.C. 7350
(SECTION 302 OF THE SARBANES OXLEY ACT OF 2002)**

I, Kenneth Berlin, certify that:

1. I have reviewed this annual report on Form 10-K for the fiscal year ended October 31, 2022 of Ayala Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

February 9, 2023

By: /s/ Kenneth Berlin

Name: Kenneth Berlin

Title: President, Chief Executive Officer

**CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO 18. U.S.C. 7350
(SECTION 302 OF THE SARBANES OXLEY ACT OF 2002)**

I, Igor Gitelman, certify that:

1. I have reviewed this annual report on Form 10-K for the fiscal year ended October 31, 2022 of Ayala Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 9, 2023

By: /s/ Igor Gitelman

Name: Igor Gitelman

Title: Interim Chief Financial Officer and VP of Finance

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

In connection with the Annual Report of Ayala Pharmaceuticals, Inc., a Delaware corporation (the "Company"), on Form 10-K for the fiscal year ended October 31, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, the Chief Executive Officer, hereby certifies pursuant to 18 U.S.C. Sec. 1350 as adopted pursuant to Section 906 of the Sarbanes Oxley Act of 2002 that, to the undersigned's knowledge:

- (1) the Report of the Company filed today fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operation of the Company.

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

Date: February 9, 2023

By: /s/ Kenneth Berlin

Name: Kenneth Berlin

Title: President, Chief Executive Officer

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

In connection with the Annual Report of Ayala Pharmaceuticals, Inc., a Delaware corporation (the "Company"), on Form 10-K for the fiscal year ended October 31, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, the Chief Financial Officer, hereby certifies pursuant to 18 U.S.C. Sec. 1350 as adopted pursuant to Section 906 of the Sarbanes Oxley Act of 2002 that, to the undersigned's knowledge:

- (1) the Report of the Company filed today fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operation of the Company.

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

Date: February 9, 2023

By: /s/ Igor Gitelman

Name: Igor Gitelman

Title: Interim Chief Financial Officer
