

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

**FORM 10-K/A
(Amendment No. 1)**

(Mark One)

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

For the fiscal year ended December 31, 2023

or

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

For the transition period from _____ to _____

Commission File Number 001-36138

AYALA PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of
incorporation or organization)

02-0563870

(I.R.S. Employer
Identification No.)

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

(Address of principal executive offices)

08852

(Zip Code)

(609) 452-9813

(Registrant's telephone number, including area code)

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

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

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

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 June 30, 2023, the aggregate market value of the voting common equity held by non-affiliates was approximately \$3.7 million 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 42,633,400 shares of common stock, par value \$0.001 per share, outstanding as of April 8, 2024.

Documents Incorporated by Reference

None in this Amendment No. 1 on Form 10-K/A.

Audit Firm ID

1281

Auditor Name

Kost Forer Gabbay & Kasierer

Auditor Location

Tel-Aviv, Israel

EXPLANATORY NOTE

On April 16, 2024, Ayala Pharmaceuticals, Inc. (“New Ayala,” “Advaxis,” the “Company,” “we,” “us,” “our” and similar references) filed its Annual Report on Form 10-K for the year ended December 31, 2023 (the “Original Filing”), with the Securities and Exchange Commission (the “Commission”). The Company indicated that it would incorporate Part III of Form 10-K in the Original Filing by reference to the Company’s definitive proxy statement for its 2024 annual meeting of stockholders. Because the Company does not anticipate filing its definitive proxy statement by April 29, 2024, the Company is filing this Amendment No. 1 (this “Amendment”) on Form 10-K/A, which amends and restates items identified below with respect to the Original Filing and provides the disclosure required by Part III of Form 10-K.

This Form 10-K/A only amends information in Part III, Item 10 (Directors, Executive Officers and Corporate Governance), Item 11 (Executive Compensation), Item 12 (Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters), Item 13 (Certain Relationships and Related Transactions, and Director Independence), Item 14 (Principal Accounting Fees and Services) and Part IV, Item 15 (Exhibits, Financial Statement Schedules). All other items as presented in the Original Filing are unchanged. Except for the foregoing amended and restated information, this Amendment does not amend, update or change any other information presented in the Original Filing.

In addition, as required by Rule 12b-15 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), this Form 10-K/A contains new certifications by our principal executive officer and our principal financial and accounting officer, filed as exhibits hereto.

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PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Information about our Directors

| Name | Age | Position |
|-----------------------|-----|---|
| Dr. David Sidransky | 63 | Chairman of our Board of Directors |
| Dr. Vered Bisker-Leib | 53 | Vice Chairman of our Board of Directors |
| Roni A. Appel | 57 | Director |
| Kenneth Berlin | 59 | President and Chief Executive Officer, Director |
| Yuval Cabilly, Ph.D. | 43 | Director |
| Murray Goldberg | 79 | Director |
| Bridget Martell, M.D. | 58 | Director |
| Pini Orbach, Ph.D. | 59 | Director |
| Dr. Robert Spiegel | 74 | Director |

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.

Vered Bisker-Leib, Ph.D., M.B.A. Dr. Bisker-Leib has served as a member of our Board of Directors since January 2023. Dr. Bisker-Leib also served on the board of Old Ayala, Inc. from August 2023 to December 2022. 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.

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 Advaxis, 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.

Yuval Cabilly, Ph.D. Dr. Cabilly has served as a member of our Board of Directors since October 2023. Dr. Cabilly previously served as a director of Biosight. Dr. Cabilly is the Co-Founder and Managing Partner of Israel Biotech Fund. Dr. Cabilly received his PhD in molecular cell biology from Tel Aviv University, where his research focused on a neurodegenerative disease, and several of his articles have been published in well-known scientific journals. We believe that Dr. Cabilly's extensive experience identifying, funding and engaging in business development activities in the life-science industry qualifies him to serve on the Board.

Murray A. Goldberg, M.B.A. Mr. Goldberg has served as a member of our Board of Directors since January 2023. Mr. Goldberg also served on the board of Old Ayala, Inc. from December 2017 to December 2022. 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.

Pini Orbach, Ph.D. Dr. Orbach has served as a member of our Board of Directors since October 2023. Dr. Orbach previously served as a director of Biosight. Dr. Orbach is the Head of the Pharma Division of Arkin Holdings and a board member of several pharmaceutical companies, including UroGen Pharma and Quiet Therapeutics, from which he shares his extensive hands-on drug development and business experience. Dr. Orbach has experience with United States based pharmaceutical companies such as, Arisaph Pharmaceuticals and Epix Pharmaceuticals (NASDAQ, EPIX), as well as Israeli-based companies cCAM BioTherapeutics - a cancer immunotherapy company, which was sold to Merck in 2015 for \$605M. Dr. Orbach holds a PhD from the University of Florida, and was a postdoctoral fellow at Harvard Medical School – Massachusetts General Hospital. We believe that Dr. Orbach's extensive experience in the life-science industry qualifies him to serve on the Board.

Bridget Martell, M.D. Dr. Martell has served as a member of our Board of Directors since October 2023. Dr. Martell is a seasoned biopharmaceutical corporate executive with a demonstrated track record in financing, building, and leading highly successful companies. She has served in numerous C-Suite, Venture, and Independent Board roles, most recently President and Chief Executive Officer of Artizan Biosciences, Inc., a part-time Healthcare Venture Partner with AlleyCorp, an early stage venture capital company, and as an independent board director of Achieve Life Sciences, Aligos Therapeutics, and POINT Biopharma (acquired by Lilly, September 2023). Under the auspice of her consulting practice, BAM Consultants LLC, Dr. Martell has held various leadership positions in early stage to late stage public and private companies, including Chief Medical Officer of three private and two publicly traded companies as well as at RRD International, a boutique Contract Research Organization (acquired by Unipharm in 2021). Dr. Martell began her Pharmaceutical career at Pfizer where she held leadership roles of increasing responsibility at from 2005 to 2011. Dr. Martell earned her B.S. in microbiology from Cornell University, her M.A. in molecular immunology from Boston University and her M.D. from the Chicago Medical School. She completed her internship and residency in internal medicine and was an internal medicine chief resident and RWJ Faculty Clinical Scholar at Yale University. Dr. Martell is board certified in both internal and addiction medicine. We believe that Dr. Martell's extensive experience in the life-science industry qualifies her to serve on the Board.

Robert Spiegel, M.D., F.A.C.P. Dr. Spiegel has served as a member of our Board of Directors since January 2023. Dr. Spiegel also served on the board of Old Ayala, Inc. from December 2017 to December 2022. 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.

Our Executive Officers

Information about our Executive Officers is set forth in Part I, Item 4 of the Original Filing.

Director Independence

Dr. Bisker-Leib, Mr. Appel, Mr. Goldberg, Dr. Martell and Dr. Spiegel are independent in accordance with the definition set forth in the OTCQX® Rules for U.S. Companies. Each member of each of our Board committees is an independent director under the OTCQX® rules 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 2023 Annual Meeting of Stockholders. Directors are expected, but not required, to attend the annual meeting of stockholders. We will encourage, but will not require, our directors to attend the Annual Meeting. Except for Drs. Bisker-Leib, Cabilly, Orbach and Sidransky, who recused themselves from meetings of the Board at which matters were considered as to which they may not have been disinterested directors, as defined under applicable law, each of our directors attended at least seventy-five percent (75%) of the aggregate of: (1) the total number of Board meetings; and (2) the total number of meetings of the committee(s) of which they were a member, if any. Our Board held 14 meetings during our fiscal year ended December 31, 2023.

Board Committees

Presently, the Board has the following standing committees: Audit Committee, Compensation Committee, Nominating and Corporate Governance Committee and Research and Development Committee. Each of the standing committees is comprised solely of independent directors.

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 OTCQX® Rules for U.S. Companies 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. The Audit Committee is comprised of Mr. Goldberg, Mr. Appel and Dr. Bisker-Leib, with Mr. Goldberg serving as the Audit Committee's financial expert as defined under Item 407 of Regulation S-K.

The Audit Committee held four meetings during our fiscal year ended December 31, 2023.

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

Compensation Committee

The Compensation Committee of our Board of Directors 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 is comprised of Mr. Appel, Dr. Bisker-Leib and Dr. Sidransky.

The Compensation Committee held one meeting during our fiscal year ended December 31, 2023.

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

Nominating and Corporate Governance Committee

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 Committee is comprised of Drs. Sidransky and Spiegel.

The Nominating and Governance Committees held one meeting during our fiscal year ended December 31, 2023.

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://ir.ayalapharma.com/corporate-governance/documents-charters>.

The Nominating and Corporate Governance Committee will consider director candidates recommended by eligible stockholders. Stockholders may recommend director nominees for consideration by the Nominating and Corporate Governance Committee by writing to the Nominating and Corporate Governance Committee, Attention: Chairman, Ayala Pharmaceuticals, Inc., 9 Deer Park Drive, Suite K-1, Monmouth Junction, NJ 08852. Any recommendations for director made to the Nominating and Corporate Governance Committee should include the nominee's name and qualifications for membership on our Board and must include the information required pursuant to the By-Laws with respect to the nominating stockholder and the director nominee.

The Company must receive the written nomination for an annual meeting not less than 90 days and not more than 120 days prior to the first anniversary of the previous year's annual meeting of stockholders, or, if no annual meeting was held the previous year or the date of the annual meeting is advanced more than 30 days before or delayed more than 60 days after the anniversary date, we must receive the written nomination not later than the later of 90 days prior to such annual meeting or the close of business on the tenth day following the day on which public announcement of the date of such annual meeting is made by the Company.

The Nominating and Corporate Governance Committee expects, as minimum qualifications, that nominees to our Board of Directors (including incumbent directors) will enhance our Board of Director's management, finance and/or scientific expertise, will not have a conflict of interest and will have a high ethical standard. A director nominee's knowledge and/or experience in areas such as, but not limited to, the medical, biotechnology, or life sciences industry, equity and debt capital markets and financial accounting are likely to be considered both in relation to the individual's qualification to serve on our Board of Directors and the needs of our Board of Directors as a whole. Other characteristics, including but not limited to, the director nominee's material relationships with us, time availability, service on other boards of directors and their committees, or any other characteristics that may prove relevant at any given time as determined by the Nominating and Corporate Governance Committee shall be reviewed for purposes of determining a director nominee's qualification.

Candidates for director nominees are evaluated by the Nominating and Corporate Governance Committee in the context of the current composition of our Board, our operating requirements and the long-term interests of our stockholders. The Nominating and Corporate Governance Committee then uses its network of contacts to compile a list of potential candidates, but may also engage, if it deems appropriate, a professional search firm. The Nominating and Corporate Governance Committee conducts any appropriate and necessary inquiries into the backgrounds and qualifications of possible candidates after considering the function and needs of our Board. In the case of incumbent directors whose terms of office are set to expire, the Nominating and Corporate Governance Committee reviews such directors' overall service to us during their term, including the number of meetings attended, level of participation, quality of performance, and any other relationships and transactions that might impair such directors' independence. The Nominating and Corporate Governance Committee meets to discuss and consider such candidates' qualifications and then selects a nominee for recommendation to our Board by majority vote. To date, the Nominating and Corporate Governance Committee has not paid a fee to any third party to assist in the process of identifying or evaluating director candidates.

In identifying candidates for membership on the Board, the Nominating and Corporate Governance Committee takes into account all factors it considers appropriate and will seek to ensure that its membership consists of sufficiently diverse backgrounds, meaning a mix of backgrounds and experiences that will enhance the quality of the Board's deliberations and decisions. In considering candidates for the Board, the independent directors will consider, among other factors, diversity with respect to viewpoints, skills, experience and other demographics. In February 2020, the Nominating and Corporate Governance Committee instituted a policy whereby diversity, including diversity of gender, origin and background, became a key consideration when identifying candidates for membership on the Board. The Nominating and Corporate Governance Committee also may consider the extent to which the candidate would fill a present need on the Board.

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 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 Nominating and Governance Committee is comprised of Drs. Sidransky and Spiegel.

The Research and Development Committee did not meet during our fiscal year ended December 31, 2023.

Board Leadership Structure

On May 27, 2015, David Sidransky was appointed Chairman 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, customers 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.

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://ir.ayalapharma.com/corporate-governance/documents-charters>.

Risk Oversight

The Board has an active role in overseeing our risk management and is responsible for discussing with management and the independent auditors our major financial risk exposures, the guidelines and policies by which risk assessment and management is undertaken, and the steps management has taken to monitor and control risk exposure. The Board regularly engages in discussions of the most significant risks that we are facing and how those risks are being managed. The Board believes that its work and the work of the Chairman and the principal executive officer, enables the Board to effectively oversee our risk management function.

Stockholder Communications to the Board

Stockholders may contact an individual director, the Board as a group, or a specified Board committee or group, including the non-employee directors as a group, by writing to the following address:

Ayala Pharmaceuticals, Inc.
9 Deer Park Drive, Suite K-1
Monmouth Junction, NJ 08852
Attn: Board of Directors

Each communication should specify the applicable addressee or addressees to be contacted as well as the general topic of the communication. We will initially receive and process communications before forwarding them to the addressee. We generally will not forward to the directors a stockholder communication that we determine to be primarily commercial in nature or relates to an improper or irrelevant topic, or that requests general information about us.

Delinquent Section 16(a) Reports

Section 16(a) of the Exchange Act requires the Company's directors, executive officers and persons who beneficially own more than 10 percent of the Company's common stock (collectively, "Reporting Persons") to file with the Commission initial reports of ownership and changes in ownership of the Company's common stock. Based solely on its review of the copies of such reports received or written representations from certain Reporting Persons that no other reports were required, the Company believes that during its fiscal year ended December 31, 2023 all filing requirements applicable to the Reporting Persons were timely met except (i) Israel Biotech Fund filed its Form 3 late and thereafter was late in filing two Form 4s listing a total of four transactions and (ii) each of Drs. Martell and Orbach, as well as Mr. Golan, filed his or her Form 3 six days late, and Dr. Cabilly filed his 11 days late.

ITEM 11. EXECUTIVE COMPENSATION

The Compensation Committee of the Board has responsibility for establishing, implementing and continually monitoring adherence with the Company's compensation philosophy. The Compensation Committee seeks to ensure that the total compensation paid to the executives is fair, reasonable and competitive. Our named executive officers for our fiscal year ended December 31, 2023 are Mr. Berlin, Dr. Gutierrez and Mr. Igor Gitelman, who served as our Interim Chief Executive Officer until October 18, 2023, when Mr. Golan assumed that role. Mr. Golan's compensation from the Company for 2023 was less than \$100,000, and he is thus omitted from the following table based on Instruction 2 to Item 402(m)(2) of Regulation S-K.

The following table summarizes all compensation awarded to, earned by or paid to our Named Executive Officers for our last fiscal year ended December 31, 2023, as well as the “stub” period from November 1, 2022 through December 31, 2022, and our last full fiscal year, which ended October 31, 2022. As previously disclosed, our fiscal year end was changed from October 31 to December 31, effective on January 26, 2023.

| Name and Principal Position | Year | Salary | Bonus | Stock Awards | Option Awards | All Other Compensation⁽¹⁾ | Total |
|--|-------------|---------------|--------------|---------------------|----------------------|---|--------------|
| Kenneth Berlin President, Chief Executive Officer | 2023 | \$ 693,438 | \$ - | \$ - | \$ - | \$ 42,852 | \$ 736,290 |
| | Stub | \$ 107,095 | \$ - | \$ - | \$ - | \$ 4,539 | \$ 111,634 |
| | 2022 | \$ 643,427 | \$ - | \$ - | \$ - | \$ 60,341 | \$ 703,768 |
| Andres Gutierrez Senior VP, Chief Medical Officer | 2023 | \$ 533,414 | \$ - | \$ - | \$ - | \$ 44,533 | \$ 577,947 |
| | Stub | \$ 82,380 | \$ - | \$ - | \$ - | \$ 9,605 | \$ 91,985 |
| | 2022 | \$ 494,944 | \$ - | \$ - | \$ - | \$ 38,683 | \$ 533,627 |
| Igor Gitelman (2) Former Interim Chief Financial Officer and VP of Finance | 2023 | \$ 315,182 | \$ - | \$ - | \$ - | \$ 44,659 | \$ 359,841 |
| | Stub | \$ 48,865 | \$ - | \$ - | \$ - | \$ 6,310 | \$ 55,175 |
| | 2022 | \$ 299,985 | \$ - | \$ - | \$ - | \$ 42,224 | \$ 342,209 |

(1) These amounts primarily represent:

- premiums paid for health insurance on each of the officers named in this table, as follows: 2023, Mr. Berlin \$17,678, Dr. Gutierrez \$31,640 and Mr. Gitelman \$31,640; stub, Mr. Berlin \$3,472, Dr. Gutierrez \$6,108 and Mr. Gitelman \$6,108; and 2022, Mr. Berlin \$35,179, Dr. Gutierrez \$35,179 and Mr. Gitelman \$35,179.
- premiums paid for life and AD&D insurance on each of the officers named in this table, as follows: 2023, Mr. Berlin \$536, Dr. Gutierrez \$536 and Mr. Gitelman \$536; stub, Mr. Berlin \$110, Dr. Gutierrez \$110 and Mr. Gitelman \$110; and 2022, Mr. Berlin \$536, Dr. Gutierrez \$536 and Mr. Gitelman \$536.
- matching contributions to 401(k) plan to each of the officers named in this table, as follows: 2023, Mr. Berlin \$24,639, Dr. Gutierrez \$12,357 and Mr. Gitelman \$12,483; stub, Mr. Berlin \$865, Dr. Gutierrez \$3,295 and Mr. Gitelman \$0; and 2022, Mr. Berlin \$24,026, Dr. Gutierrez \$2,368 and Mr. Gitelman \$5,909.

(2) Mr. Gitelman served as the Company’s Chief Financial Officer through October 18, 2023.

Outstanding Equity Awards at Fiscal Year-End

The following table summarizes all outstanding equity awards held by our named executive officers as of December 31, 2023.

| Name | Number of Securities Underlying Unexercised Options (#) Exercisable | Number of Securities Underlying Unexercised Options (#) Unexercisable | Option Exercise Price (\$) | Option Expiration Date |
|------------------|--|--|-----------------------------------|-------------------------------|
| Kenneth Berlin | 625 | — | 1,944.00 | 4/23/2028 |
| | 267 | — | 648.00 | 11/5/2028 |
| | 625 | — | 24.80 | 10/24/2029 |
| | 625 | — | 52.80 | 5/4/2030 |
| Andres Gutierrez | 208 | — | 1,944.00 | 4/23/2028 |
| | 104 | — | 648.00 | 11/5/2028 |
| | 313 | — | 24.80 | 10/24/2029 |
| | 625 | — | 52.80 | 5/4/2030 |
| Igor Gitelman | 625 | — | 31.20 | 11/16/2030 |

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 was subsequently amended by Amendment No. 1 thereto entered into as of September 1, 2022. The employment agreement, as so amended, 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 \$576,493 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 50,000 stock options and 16,667 restricted stock units (both as adjusted to account for our 1 for 15 reverse stock split effective March 29, 2019), which vest in equal instalments over the first three years of his employment. In May 2020, Mr. Berlin received an additional 50,000 stock options, which vest in equal instalments of 16,667 options on the first three anniversary dates of the grant.

In the event Mr. Berlin's employment is terminated without Just Cause during the period beginning three months prior to a Change in Control (as defined in Mr. Berlin's employment agreement) and ending 18 months after the Change in Control (such period, 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 2.0 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.

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

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

Security Ownership of Certain Beneficial Owners

The following table lists the persons we know to be beneficial owners of at least five percent of our common stock as of April 26, 2024.

| <u>Name and Address of Beneficial Owner</u> | <u>Number of Shares</u> | <u>Approximate Percentage of Outstanding Common Stock⁽¹⁾</u> |
|--|-------------------------|---|
| I.B.F Management Ltd. ⁽²⁾ HaOgen Tower, 4 Oppenheimer St. Rehovot 7670104, Israel | 24,492,541 | 57.4% |
| Arkin Bio Ventures Limited Partnership ⁽³⁾ Hamonofim 11 St Hertzlia, 4672537 Israel | 8,940,448 | 21% |

(1) Based on 42,633,400 shares of common stock outstanding as of April 26, 2024.

(2) Based on Amendment No. 3 to Schedule 13D filed with the Commission on February 12, 2024. The filing states that I.B.F Management Ltd. has shared voting and dispositive power over all such shares. I.B.F Management Ltd. is the management company of each of Israel Biotech Fund I, L.P. and Israel Biotech Fund II, L.P., which are noted in such filing as having shared voting and dispositive power over 20,661,639 and 25,130,903 shares of common stock, respectively. The general partners of Israel Biotech Fund I, L.P. and Israel Biotech Fund II, L.P., which are Israel Biotech Fund GP Partners, L.P. and Israel Biotech Fund GP Partners II, L.P., respectively, also have shared voting and dispositive power over such shares.

(3) Based on the records of the Company in connection with transactions engaged in by the Company since November 2023, Arkin Bio Ventures Limited Partnership together with Arkin Media Ltd. (collectively "Arkin") are the beneficial owners of 8,940,448 shares of common stock issued or issuable upon the exercise or conversion of convertible notes, and warrants that are or were held by Arkin.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS (CONTINUED)

Security Ownership of Management

The following table lists the number of shares of our common stock beneficially owned, as of April 26, 2024, by each director and director nominee, each of our executive officers, certain members of our senior management, and by our directors, nominees and executive officers as a group. In general, beneficial ownership includes those shares a person has the power to vote or transfer, as well as shares owned by immediate family members who live with that person.

| Name | Number of Shares | Approximate Percentage of Outstanding Common Stock ⁽¹⁾ |
|---|------------------|---|
| Ken Berlin ⁽²⁾ | 2,413 | * |
| Roy Golan | - | * |
| Dr. David Sidransky ⁽³⁾ | 5,145 | * |
| Dr. Vered Bisker-Leib ⁽⁴⁾ | 3,981 | * |
| Roni A. Appel ⁽⁵⁾ | 508 | * |
| Yuval Cabilly, Ph.D. ⁽⁶⁾ | - | * |
| Murray Goldberg ⁽⁷⁾ | 7,963 | * |
| Bridget Martell, M.D. ⁽⁸⁾ | - | * |
| Pini Orbach, Ph.D. ⁽⁹⁾ | - | * |
| Dr. Robert Spiegel ⁽¹⁰⁾ | 7,963 | * |
| Dr. Andres Gutierrez ⁽¹¹⁾ | 1,297 | * |
| Igor Gitelman ⁽¹²⁾ | 417 | * |
| All Current Directors and Officers as a Group (10 People) ⁽¹³⁾ | 29,687 | * |

* Represents less than one percent of our outstanding common stock.

(1) Based on 42,633,400 shares of common stock outstanding as of April 26, 2024.

(2) Represents 271 issued shares of our Common Stock, and options to purchase 2,142 shares of our Common Stock exercisable within 60 days.

(3) Represents 93 issued shares of our Common Stock and options to purchase 5,052 shares of our Common Stock exercisable within 60 days.

(4) Represents options to purchase 3,981 shares of our Common Stock exercisable within 60 days.

(5) 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. (7) Represents options to purchase 7,963 shares of our Common Stock exercisable within 60 days.

(10) Represents options to purchase 7,963 shares of our Common Stock exercisable within 60 days.

(11) Represents 47 issued shares of our Common Stock and options to purchase 1,250 shares of our Common Stock exercisable within 60 days.

(12) Represents options to purchase 417 shares of our Common Stock exercisable within 60 days.

(13) Represents 544 issued shares of our Common Stock, options to purchase 29,119 shares of our Common Stock exercisable within 60 days and warrants to purchase 24 shares of our Common Stock exercisable within 60 days.

The table below presents certain information as of December 31, 2023 concerning securities issuable in connection with equity compensation plans that have been approved by the Company's stockholders.

| Plan category | Number of securities to be potentially issued upon realization of restricted stock awards] | Weighted-average exercise price of outstanding options, warrants and rights | Number of securities remaining available for issuance under equity compensation plans, excluding securities reflected in column (a) |
|--|--|---|---|
| | (a) | (b) | (c) |
| Equity compensation plans approved by security holders | — | N/A | 2,981,248 |
| Equity compensation plans not approved by security holders | — | — | — |
| Total | — | N/A | 2,981,248 |

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

As the Company has disclosed in its prior filings under the Exchange Act, the Company has entered into several transactions with entities associated with Israel Biotech Fund (with which Dr. Cabilly is associated) and Arkin Holdings (with which Dr. Orbach is associated). These transactions are described as follows:

On August 7, 2023, the Company issued a Senior Secured Convertible Promissory Note (the “Note”) to Israel Biotech Fund I, L.P. with a principal amount of up to \$2,000,000, which amount was funded soon thereafter. In connection with the Note, the Company also entered into or provided a Security Agreement concurrent with the issuance of the Note. The Company’s obligations under the Note were guaranteed by its subsidiary, Old Ayala, Inc. The Note was convertible into shares of the Company’s common stock under the terms described in the Note, with the expected mandatory conversion in the event of a PIPE (Private Investment into a Public Entity) with the minimum of \$15 million investment at a price equal to 65% of the lowest price offered in the PIPE.

On September 15, 2023, the Company entered into a Side Letter Agreement for Conversion (the “Side Letter Agreement”) with Israel Biotech Fund I, L.P., Israel Biotech Fund II, L.P. and certain other investors named therein (the “Investors”). The Side Letter Agreement references (i) the merger contemplated by the Agreement and Plan of Merger and Reorganization, dated as of July 26, 2023, between the Company, Biosight Ltd. (“Biosight”) and a wholly owned subsidiary of the Company (the “Merger Agreement”), pursuant to which such subsidiary shall merge with and into Biosight, with Biosight surviving as a wholly owned subsidiary of the Company (the “Merger”), (ii) that certain Senior Secured Convertible Promissory Note entered into between the Company and the investors named therein for an original principal amount of up to \$2,000,000 (the “Promissory Note”), which was previously disclosed by the Company in its Quarterly Report on Form 10-Q for the quarter ended June 30, 2023, and (iii) a Simple Agreement for Future Equity by and between Biosight and the Investors, pursuant to which the Investors agreed to invest in Biosight up to \$2,500,000, and Biosight agreed to issue equity interests in Biosight to the Investors in certain circumstances (the “SAFE”).

Pursuant to the Side Letter Agreement, the Company and the Investors agreed that should the contemplated merger between the Company, Biosight Ltd. (“Biosight”) and a wholly owned subsidiary of the Company (the “Biosight Merger”), pursuant to which such subsidiary shall merge with and into Biosight, be consummated prior to the termination of the SAFE, then the Investors shall be entitled to receive, in consideration for amounts actually invested in Biosight up to \$2,500,000, shares of the Company’s common stock in a number equal to the amounts actually invested by the Investors in Biosight, divided by a conversion price equal to sixty-five percent (65%) of an amount determined in accordance with such Side Letter Agreement

On November 17, 2023, the Company issued Senior Convertible Promissory Notes (collectively, the “Senior Convertible Notes”), in an aggregate amount of \$4.0 million, to several existing lenders and investors in the Company, including Israel Biotech Fund I, L.P., Israel Biotech Fund II, L.P., Arkin Bio Ventures L.P. and Biotel Limited. The Company and Israel Biotech Fund I, L.P. and Israel Biotech Fund II, L.P. also agreed to amend and restate the terms of the Senior Secured Convertible Promissory Notes issued by the Company on August 7, 2023 (the “Existing Secured Notes”), to conform to the terms of the Senior Convertible Notes. The Senior Convertible Notes and the amended and restated Existing Secured Notes were convertible into shares of the Common Stock at any time at the option of the noteholders, and subject to mandatory conversion upon certain events, at a conversion price equal to the lower of (i) 50% of the Common Stock’s price per share as of market close on November 16, 2023 and (ii) 50% of the Common Stock’s price per share as of the close of market on the Trading Day immediately prior to the date of the Notice of Conversion, subject to certain adjustments. In connection with the issuance of the Senior Convertible Note and the amendment and restatement of the Existing Secured Notes, the Company also issued to the noteholders warrants (the “Warrants”) to purchase an aggregate of 22,500,000 shares of the Common Stock with an exercise price equal to the lower of (A) 50% of the Common Stock’s price per share as of market close on November 16, 2023 and (ii) 50% of the Common Stock’s price per share as of the close of market on the Trading Day immediately prior to the date of the Notice of Exercise of the warrant, subject to adjustment, which exercise may be on a cashless basis.

On February 7, 2024, the noteholders and warrant holders exercised in full their conversion right under the Senior Convertible Notes, the Existing Secured Notes and the Warrants (the latter on a cashless basis), utilizing a conversion price equal to 50% of the Common Stock’s price per share as of market close on November 16, 2023. As a result, an aggregate of 30,736,555 shares of Common Stock were issued by the Company to the noteholders and warrant holders.

On March 1, 2024, the Company issued Senior Convertible Promissory Notes (collectively, the “March 1 Convertible Notes”), in an aggregate amount of \$2.0 million, to several existing lenders and investors in the Company, including Israel Biotech Fund I, L.P., Israel Biotech Fund II, L.P., Arkin Bio Ventures L.P. and Biotel Limited. The March 1 Convertible Notes were convertible into shares of the Company’s common stock, at any time at the option of the noteholders, and subject to mandatory conversion upon certain events, including a Change of Control Transaction, as defined in the March 1 Convertible Notes, at a conversion price equal to the lower of (i) 50% of the Common Stock’s price per share as of market close on November 16, 2023 and (ii) 50% of the Common Stock’s price per share as of the close of market on the Trading Day immediately prior to the date of the Notice of Conversion, subject to certain adjustments. In connection with the issuance of the March 1 Convertible Notes, the Company also issued to the noteholders warrants (the “March 1 Warrants”) to purchase an aggregate of 7,500,000 shares of the Common Stock with an exercise price equal to the lower of (A) 50% of the Common Stock’s price per share as of market close on November 16, 2023 and (ii) 50% of the Common Stock’s price per share as of the close of market on the Trading Day immediately prior to the date of the Notice of Exercise of the warrant, subject to adjustment, which exercise may be on a cashless basis.

On March 25, 2024, March 1 Convertible Notes were automatically converted in full utilizing a conversion price equal to 50% of the Common Stock's price per share as of market close on March 22, 2024. As a result, an aggregate of 6,666,666 shares of Common Stock were issued by the Company to the noteholders.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Our Audit Committee has selected Kost, Forer, Gabbay & Kasierer, a Member of EY Global ("KFGK"), to act in the capacity of independent accountants for the current fiscal year ending December 31, 2024. KFGK also acted in such capacity with respect to our audited financial statements as of and for the fiscal year ended December 31, 2023, during which year it replaced our prior independent registered public accounting firm, Marcum LLP. The information below sets forth the aggregate amount of fees billed for professional services rendered by KFGK to the Company during the fiscal year ended December 31, 2023. Since KFGK was appointed in the fiscal year ended December 31, 2023, there were no fees billed for professional services rendered by KFGK during the prior fiscal year.

Fees Billed by KFGK during the fiscal year ended December 31, 2023

Audit Fees. Fees billed to the Company by KFGK for audit services rendered by KFGK for the audit of the Company's 2023 annual financial statements (including the audit of internal control over financial reporting), for the review of those financial statements included in the Company's Quarterly Reports on Form 10-Q, and for services that are normally provided by KFGK in connection with statutory and regulatory filings or engagements, totaled approximately \$365,000.

Audit-Related Fees. Fees billed to the Company by KFGK during 2023 for audit-related services that were reasonably related to the performance of the audit or review of the Company's financial statements and are not reported under the preceding paragraph totaled \$80,000.

Tax Fees. Fees billed to the Company by KFGK during 2023 for professional services rendered for tax compliance, tax advice and tax planning \$10,000.

All Other Fees. Other fees billed to the Company by KFGK were \$20,000 for 2023.

The Audit Committee has considered whether KFGK's provision of services other than professional services rendered for the audit and review of our financial statements is compatible with maintaining KFGK's independence and has determined that it is so compatible.

All audit, audit-related, tax and other services were pre-approved by the Audit Committee pursuant to applicable regulations. The Audit Committee currently pre-approves all engagements of the Company's accountants to provide both audit and non-audit services and has not established formal pre-approval policies or procedures. The Audit Committee did not approve any non-audit services pursuant to Rule 2-01 (c) (7) (i) (C) of Regulation S-X during fiscal 2023.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

(a)(1) Financial Statements.

The financial statements required by this item are listed in Item 8, “Financial Statements and Supplementary Data” herein.

(a)(2) Financial Statement Schedules.

All financial statement schedules have been omitted because they are not applicable, not required or the information required is shown in the financial statements or the notes thereto.

(a)(3) Exhibits.

The following is a list of exhibits filed as part of this Annual Report on Form 10-K.

Exhibit Index

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 Old 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> |
| 2.2 | <u>Agreement and Plan of Merger and Reorganization, by and among the Company, Merger Sub, and Biosight, Ltd., dated as of July 26, 2023. Incorporated by reference to Exhibit 2.1 to Current Report on Form 8-K filed with the SEC on August 1, 2023.</u> |
| 2.3+ | <u>Asset Purchase Agreement, dated as of February 5, 2024, by and between Ayala Pharmaceuticals, Inc. and Immunome, Inc. Incorporated by Reference to Exhibit 2.1 to the Current Report on Form 8-K of the Registrant, filed with the SEC on February 6, 2024.</u> |
| 3.1 | <u>Restated Certificate of Incorporation of Ayala Pharmaceuticals, Inc., dated as of January 27, 2023. Incorporated by reference to Exhibit 2.1 to Annual Report on Form 10-K filed with the SEC on February 10, 2023.</u> |
| 3.2 | <u>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.</u> |
| 3.3 | <u>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.</u> |
| 4.1 | <u>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.</u> |
| 4.2 | <u>Form of Common Warrant dated July 25, 2019 Incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K filed with the SEC on July 25, 2019.</u> |
| 4.3 | <u>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.</u> |
| 4.4 | <u>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.</u> |
| 4.5 | <u>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.</u> |
| 4.6 | <u>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.</u> |
| 4.7(1) | <u>Common Stock Purchase Warrant (Convertible Note), dated March 1, 2024, issued by Ayala Pharmaceuticals, Inc. to Israel Biotech Fund I, L.P. Incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed with the SEC on March 5, 2024.</u> |

- 4.8 [Description of each class of securities registered under Section 12 of the Securities Exchange Act of 1934. Incorporated by reference to Exhibit 4.7 to the Annual Report on Form 10-K filed with the SEC on February 10, 2023.](#)
- 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 | 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. |
| 10.23 | 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. |
| 10.24 | 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. |
| 10.25 | 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. |
| 10.26† | 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. |
| 10.27† | 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. |
| 10.28 | Securities Purchase Agreement, dated as of February 19, 2021, by and among Ayala Pharmaceuticals, Inc. and the Investors identified on Exhibit A named therein. Incorporate by reference to Exhibit 10.1 of the Old Ayala, Inc. (f/k/a Ayala Pharmaceuticals, Inc.) Current Report on Form 8-K filed with the SEC on February 22, 2021 (File No. 001-39279). |
| 10.29† | 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. |
| 10.30 | Registration Rights Agreement, dated November 17, 2023, by and among Ayala Pharmaceuticals, Inc., Israel Biotech Fund I, L.P., Israel Biotech Fund II, L.P., Arkin Bio Ventures L.P., Biotel Limited and Arkin Communication Ltd. Incorporated by reference to Exhibit 10.7 to the Quarterly Report on Form 10-Q filed with the SEC on November 20, 2023. |
| 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. |
| 31.1* | Certification of Chief Executive Officer pursuant to section 302 of the Sarbanes-Oxley Act of 2002 |
| 31.2* | Certification of 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 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). |
| 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.

@ Previously filed.

‡ Denotes management contract or compensatory plan or arrangement.

+ Certain schedules and exhibits to this agreement have been omitted in accordance with Item 601(a)(5) of Regulation S-K. A copy of any omitted schedule and/or exhibit will be furnished to the Securities and Exchange Commission on request.

Pursuant to Instruction 2 to Item 601 of Regulation S-K, the Company has filed a copy of one Common Stock Purchase Warrant (Convertible Note), and has set forth as follows the other documents omitted. The Company acknowledges that the Commission may at any time in its discretion require filing of copies of any documents so omitted.

- (1) 1. Common Stock Purchase Warrant (Convertible Note), dated March 1, 2024, issued by Ayala Pharmaceuticals, Inc. to Israel Biotech Fund II, L.P.
2. Common Stock Purchase Warrant (Convertible Note), dated March 1, 2024, issued by Ayala Pharmaceuticals, Inc. to Arkin Bio Ventures L.P.
3. Common Stock Purchase Warrant (Convertible Note), dated March 1, 2024, issued by Ayala Pharmaceuticals, Inc. to Biotel Limited.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

Ayala Pharmaceuticals, Inc.

Date: April 26, 2024

By: */s/ Kenneth Berlin.*

Kenneth Berlin
President and Chief Executive Officer

Date: April 26, 2024

By: */s/ Roy Golan.*

Roy Golan
Chief Financial Officer

CERTIFICATION

I, Kenneth Berlin, certify that:

1. I have reviewed this Amendment No. 1 to Annual Report on Form 10-K of Ayala Pharmaceuticals, Inc.; and
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
2. statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report.

Date: April 26, 2024

By: */s/ Kenneth Berlin*

Kenneth Berlin
Chief Executive Officer
(principal executive officer)

CERTIFICATION

I, Roy Golan, certify that:

1. I have reviewed this Amendment No. 1 to Annual Report on Form 10-K of Ayala Pharmaceuticals, Inc.; and
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
2. statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report.

Date: April 26, 2024

By: */s/ Roy Golan.*

Roy Golan
Chief Financial Officer
(principal financial and accounting officer)
