

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

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): April 26, 2024

ARYA SCIENCES ACQUISITION CORP IV

(Exact name of registrant as specified in its charter)

Cayman Islands
(State or other jurisdiction of incorporation)

001-40122
(Commission File Number)

98-1574672
(I.R.S. Employer Identification No.)

51 Astor Place, 10th Floor
New York, NY
(Address of principal executive offices)

10003
(Zip Code)

(212) 284-2300
(Registrant's telephone number, including area code)

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the Registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Class A Ordinary Shares, par value \$0.0001 per share	ARYD	The Nasdaq Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 or Rule 12b-2 of the Securities Exchange Act of 1934.

Emerging growth company

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

Item 8.01 Other Events.

As previously announced, on February 13, 2024, ARYA Sciences Acquisition Corp IV, a Cayman Islands exempted company (“ARYA”), Aja Holdco, Inc., a Delaware corporation and wholly-owned subsidiary of ARYA (“ListCo”), Aja Merger Sub 1, a Cayman Islands exempted company and wholly-owned subsidiary of ListCo (“ARYA Merger Sub”), Aja Merger Sub 2, Inc., a Delaware corporation and wholly-owned subsidiary of ListCo (“Company Merger Sub”) and Adagio Medical, Inc., a Delaware corporation (“Adagio”), entered into a Business Combination Agreement (as it may be amended, supplemented or otherwise modified from time to time, the “Business Combination Agreement” and the transactions contemplated thereby, the “Business Combination”). On April 26, 2024, Adagio received a letter from the U.S. Food and Drug Administration (the “FDA Letter”) approving Adagio’s requests to increase the number of study sites and subjects in Adagio’s pivotal study (Cryoablation for Monomorphic Ventricular Tachycardia) for its vCLAS™ Cryoablation System and to modify the study documents and device design to support the pivotal phase of such study.

The FDA Letter is filed with this Current Report on Form 8-K (this “Current Report”) as Exhibit 99.1.

Forward-Looking Statements

Certain statements in this Current Report may be considered “forward-looking statements” within the meaning of the “safe harbor” provisions of the United States Private Securities Litigation Reform Act of 1995. Forward-looking statements generally relate to future events or ARYA’s, Adagio’s or New Adagio’s future financial or operating performance. For example, any statements that refer to expectations, projections or other characterizations of future events or circumstances, including post-Business Combination fully diluted equity value, the anticipated enterprise value of New Adagio, expected ownership in New Adagio, projections of market opportunity and market share, the capability of Adagio’s or New Adagio’s business plans including its plans to expand, the sources and uses of cash from the Business Combination, any benefits of Adagio’s partnerships, strategies or plans as they relate to the Business Combination, anticipated benefits of the Business Combination and expectations related to the terms and timing of the Business Combination, Adagio’s expected pro forma cash, Adagio’s or New Adagio’s expected cash runway through 2025 or statements related to Adagio’s or New Adagio’s funding gap, funded business plan or use of proceeds, or other metrics or statements derived therefrom, are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “forecast,” “future,” “intend,” “may,” “might,” “plan,” “possible,” “potential,” “predict,” “project,” “propose,” “seek,” “should,” “strive,” “will,” or “would” or the negatives of these terms or variations of them or similar terminology. Such forward-looking statements are subject to risks, uncertainties, and other factors which may be beyond the control of ARYA, Adagio or New Adagio and could cause actual results to differ materially from those expressed or implied by such forward-looking statements. These forward-looking statements are based upon estimates and assumptions that, while considered reasonable by ARYA and its management, Adagio and its management and New Adagio and its management, as the case may be, are inherently uncertain. Each of ARYA, Adagio and New Adagio caution you that these statements are based on a combination of facts and factors currently known and projections of the future, which are inherently uncertain. There will be risks and uncertainties described in the proxy statement/prospectus included in the Registration Statement relating to the Business Combination, which has been filed by ListCo with the U.S. Securities and Exchange Commission (the “SEC”), and described in other documents filed by ARYA or New Adagio from time to time with the SEC. These filings may identify and address other important risks and uncertainties that could cause actual events and results to differ materially from those contained in the forward-looking statements. Neither ARYA nor Adagio can assure you that the forward-looking statements in this Current Report will prove to be accurate.

In addition, new risks and uncertainties may emerge from time to time, and it may not be possible to identify and accurately predict the potential impacts of any such risks and uncertainties that may arise in the future. Factors that may cause actual results to differ materially from current expectations include, but are not limited to: (1) the occurrence of any event, change or other circumstances that could give rise to the termination of negotiations and any subsequent definitive agreements with respect to the Business Combination; (2) the outcome of any potential litigation, government or regulatory proceedings that may be instituted against ARYA, Adagio, New Adagio or others; (3) the inability to complete the Business Combination due to the failure to obtain approval of the shareholders of ARYA, to obtain financing to complete the Business Combination or to satisfy other conditions to closing; (4) the amount of redemption requests made by ARYA's public shareholders; (5) changes to the proposed structure of the Business Combination that may be required or appropriate as a result of applicable laws or regulations or as a condition to obtaining regulatory approval of the Business Combination; (6) delays in obtaining, adverse conditions in, or the inability to obtain regulatory approvals, or delays in completing regulatory reviews, required to complete the Business Combination; (7) the ability to meet stock exchange listing standards prior to or following the consummation of the Business Combination; (8) the risk that the Business Combination disrupts current plans and operations of Adagio or New Adagio as a result of the announcement and consummation of the Business Combination; (9) Adagio's ability to remain compliant with the covenants of its existing debt, including any convertible or bridge financing notes; (10) New Adagio's ability to remain compliant with the covenants of, and other obligations under, the senior secured convertible notes that will be issued in connection with the closing of the Business Combination; (11) the ability to recognize the anticipated benefits of the Business Combination, which may be affected by, among other things, competition, the ability of New Adagio to grow and manage growth profitably, maintain relationships with customers and suppliers and retain its management and key employees; (12) costs related to the Business Combination; (13) risks associated with changes in applicable laws or regulations and Adagio's or New Adagio's international operations and operations in a regulated industry; (14) the possibility that Adagio or New Adagio may be adversely affected by other economic, business, and/or competitive factors; (15) Adagio's or New Adagio's use of proceeds, post-Business Combination fully diluted equity value or fully diluted enterprise value, expected pro forma cash, expected cash runway or funding gap, estimates of expenses and profitability; and (16) the other risks and uncertainties set forth in the sections entitled "Risk Factors" and "Cautionary Note Regarding Forward-Looking Statements" in ARYA's Annual Report on Form 10-K for the year ended December 31, 2023, its Quarterly Reports on Form 10-Q, and other documents filed, or to be filed, with the SEC by ARYA or New Adagio. There may be additional risks that ARYA, Adagio or New Adagio do not presently know or that ARYA, Adagio or New Adagio currently believe are immaterial that could also cause actual results to differ from those contained in the forward-looking statements. Actual events and circumstances are difficult or impossible to predict and may materially differ from assumptions. Many actual events and circumstances are beyond the control of ARYA, Adagio and New Adagio.

Nothing in this Current Report should be regarded as a representation or warranty by any person that the forward-looking statements set forth herein will be achieved or that any of the contemplated results of such forward-looking statements will be achieved, in any specified time frame, or at all. You should not place undue reliance on forward-looking statements, which speak only as of the date they are made in this Current Report. Subsequent events and developments may cause those views to change. Neither ARYA, Adagio nor New Adagio undertakes any duty to update these forward-looking statements.

Additional Information

In connection with the Business Combination, ListCo has filed with the SEC a Registration Statement on Form S-4 containing a preliminary proxy statement of ARYA and a preliminary prospectus of ListCo, and after the Registration Statement is declared effective, ARYA expects to mail a definitive proxy statement/prospectus related to the Business Combination to its shareholders. The proxy statement/prospectus contains important information about the Business Combination and the other matters to be voted upon at ARYA's shareholder meeting to be held to approve the Business Combination. ARYA and ListCo may also file other documents with the SEC regarding the Business Combination. This Current Report does not contain all the information that should be considered concerning the Business Combination and is not intended to form the basis of any investment decision or any other decision in respect of the Business Combination. Before making any voting or other investment decisions, shareholders of ARYA and other interested persons are advised to read, the preliminary proxy statement/prospectus and any amendments thereto, the definitive proxy statement/prospectus and other documents filed in connection with the Business Combination, as these materials contain important information about ARYA, Adagio and the Business Combination. After the Registration Statement becomes effective, the definitive proxy statement/prospectus and other relevant materials for the Business Combination will be mailed to shareholders of ARYA as of a record date to be established for voting on the Business Combination. Shareholders will also be able to obtain copies of the definitive proxy statement/prospectus and other documents filed with the SEC, without charge, once available, at the SEC's website at www.sec.gov, or by directing a request to: ARYA Sciences Acquisition Corp IV, 51 Astor Place, 10th Floor, New York, New York, 10003, Attention: Secretary, ARYA4@perceptivelife.com.

INVESTMENT IN ANY SECURITIES DESCRIBED HEREIN HAS NOT BEEN APPROVED OR DISAPPROVED BY THE SEC OR ANY OTHER REGULATORY AUTHORITY NOR HAS ANY AUTHORITY PASSED UPON OR ENDORSED THE MERITS OF THE OFFERING OR THE ACCURACY OR ADEQUACY OF THE INFORMATION CONTAINED HEREIN. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.

Participants in the Solicitation

ARYA and its respective directors and executive officers may be deemed to be participants in the solicitation of proxies from ARYA's shareholders with respect to the Business Combination. A list of the names of ARYA's directors and executive officers and a description of their interests in ARYA is contained in ARYA's Annual Report on Form 10-K, which was filed with the SEC and is available free of charge at the SEC's web site at www.sec.gov, or by directing a request to ARYA Sciences Acquisition Corp IV, 51 Astor Place, 10th Floor, New York, New York, 10003, Attention: Secretary, ARYA4@perceptivelife.com. Additional information regarding the interests of such participants is contained in the proxy statement/prospectus for the Business Combination. Investors, security holders and other interested persons of ARYA, Adagio and New Adagio are urged to carefully read in their entirety the proxy statement/prospectus and other relevant documents that have been filed or will be filed with the SEC because they contain important information about the Business Combination. Also see above under the heading "Additional Information."

Adagio and New Adagio, and its directors and executive officers may also be deemed to be participants in the solicitation of proxies from the shareholders of ARYA in connection with the Business Combination. A list of the names of such directors and executive officers and information regarding their interests in the Business Combination is included in the proxy statement/prospectus for the Business Combination.

No Offer and Non-Solicitation

This Current Report does not constitute (i) a solicitation of a proxy, consent or authorization with respect to any securities or in respect of the Business Combination or (ii) an offer to sell, a solicitation of an offer to buy, or a recommendation to purchase any securities of ARYA, Adagio or New Adagio, nor shall there be any sale of any such securities in any state or jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of such state or jurisdiction. No offer of securities shall be made except by means of a prospectus meeting the requirements of Section 10 of the Securities Act, or an exemption therefrom.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit

Number Description

99.1	FDA Letter, dated April 26, 2024
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: May 2, 2024

ARYA Sciences Acquisition Corp IV

By: /s/ Adam Stone

Name: Adam Stone

Title: Chief Executive Officer



April 26, 2024

Adagio Medical Inc.
Nabil Jubran
Chief Compliance Officer
26051 Merit Circle, Suite 102
Laguna Hills, California 92653

Re: G220229/S002/A001
Trade/Device Name: vCLAS™ Cryoablation System (vCLAS™ Cryoablation Catheter, VT Cryoablation Console)
Dated: March 27, 2024
Received: March 28, 2024
CMS Category: B
Annual Report Due: December 8, 2024

Dear Nabil Jubran:

The Food and Drug Administration (FDA) has reviewed the supplement to your Investigational Device Exemption (IDE) application regarding your pivotal study (Cryoablation for Monomorphic Ventricular Tachycardia (VT)) for a significant risk device. You requested an increase in the number of study sites from 5 to 20 and an increase in the number of subjects from 20 to 206. You also requested modifications to the study documents and device design to support the pivotal phase of the study. FDA has determined you have provided sufficient data to support continuation of your human clinical study; this means that there are no subject protection concerns that preclude continuation of the investigation. Your supplement is therefore approved, and you may implement that change in your study. Your investigation is limited to 20 US institutions and 206 US subjects.

You must also obtain institutional review board (IRB) approval before implementing this change in your investigation as required by 21 CFR 812.35(a) because FDA believes this change affects the rights, safety, or welfare of subjects.

In order for your study to serve as the primary clinical support for a future marketing approval or clearance, FDA has provided additional study design considerations as an attachment to this letter. These recommendations do not relate to the safety, rights or welfare of study subjects and they do not need to be addressed in order for you to conduct your study. You are reminded that prior to implementing any significant modifications to the approved investigational protocol you must obtain FDA approval, and, if appropriate, IRB approval for the changes.

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

We note that you have designed this protocol to collect safety and effectiveness data to support submission of a future PMA application. Regarding the statistics to be presented in the PMA, we expect analysis of the primary dataset to contain one line per unit (e.g., person, sample, observation) with clinical outcomes and baseline covariates. You should also provide the statistical program code which produces the above analyses and which clearly documents variable definitions and coding schemes, as well as the data, in an electronic format (e.g., SAS, S-Plus or R, Excel, ASCII).

If approved, it is likely that a post-approval study (PAS) may be requested as a Condition of Approval (CoA). As the original IDE cohort can sometimes be used to gather long-term safety and effectiveness data after market approval, we suggest you consider obtaining patient informed consent and IRB approval at the initiation of the study so that enrolled subjects will be followed for a period of at least 5 years. FDA believes this may reduce patient loss to follow-up during the marketing application review process and keep many subjects available to participate in such a PAS if ordered. In addition, please note that other clinical studies apart from continued follow-up of IDE subjects, including prospective studies which enroll new patients, may also be required as CoA should a future marketing application be approved.

Future correspondence concerning this application should be identified as an IDE supplement referencing the IDE number above, and must be submitted following eCopy guidelines to:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
IDE Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

The Federal Food, Drug, and Cosmetic Act (the Act), as amended by section 1136 of the Food and Drug Administration Safety and Innovation Act (FDASIA), authorizes FDA to require an electronic copy (eCopy) for certain types of submissions. An eCopy is an exact duplicate of a paper submission, created and submitted on a CD, DVD, or other electronic media, accompanied by a single paper copy of your signed cover letter. This authorization applies to the original, amendments, supplements, and reports, as applicable, for your submission type.

For more information about FDA's eCopy program, including the technical standards for an eCopy, refer to the guidance document, "eCopy Program for Medical Device Submissions" at <https://www.fda.gov/media/83522/download>. In addition, we strongly encourage you to visit FDA's eSubmitter website at <https://www.fda.gov/industry/fda-esubmitter/cdrh-esubmitter-program> in order to develop an eCopy in accordance with the technical standards prior to sending it to FDA.

If you have any minor clarification questions concerning the contents of the letter, please contact Vincent Do at 240-402-4584 or Vincent.Do@fda.hhs.gov.

Sincerely,

Hetal Odobasic
Director
Division of Cardiac Electrophysiology, Diagnostics and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure
Additional Recommendations and Considerations
