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Subject Company: Aerovate Therapeutics, Inc.
Commission File No.: 001-40544
Date: October 31, 2024

This filing relates to the proposed transaction pursuant to the terms of that certain Agreement and Plan of Merger, dated as of October 30, 2024, by and among Aerovate Therapeutics, Inc., an Delaware corporation ("Aerovate"), Jade Biosciences, Inc., a Delaware corporation ("Jade"), Caribbean Merger Sub I, Inc., a Delaware corporation and a wholly owned subsidiary of Aerovate ("Merger Sub I"), and Caribbean Merger Sub II, LLC, a Delaware limited liability company and a wholly owned subsidiary of Aerovate ("Merger Sub II" and together with Merger Sub I, "Merger Subs") (the "Merger Agreement"), pursuant to which, and subject to the satisfaction or waiver of the conditions set forth in the Merger Agreement, among other things, Merger Sub I will merge with and into Jade, with Jade surviving the merger as the surviving corporation (the "First Merger"), and as part of the same overall transaction, Jade will merge with and into Merger Sub II, with Merger Sub II continuing as a wholly owned subsidiary of Aerovate and the surviving corporation of the merger (the "Second Merger" and together with the First Merger, the "Merger").

The following is a transcript of the investor webcast hosted by Jade on October 31, 2024 to discuss the announcement of the proposed Merger transaction involving Aerovate and Jade. The slides that are referred to herein are furnished as Exhibit 99.2 of the Current Report on Form 8-K filed by Aerovate with the Securities and Exchange Commission on October 31, 2024.

Project Caribbean Investor Webcast Prepared Remarks

Live session: October 31, 2024, 8:30 AM ET / 5:30 AM PT

Operator

Good morning, and welcome to the Jade Biosciences conference call. Please note that this call is being recorded and will be available for replay. Now, I'd like to turn the call over to Tom Frohlich, Chief Executive Officer of Jade Biosciences.

Tom Frohlich – CEO, Jade Biosciences

Thank you, and good morning, everyone.

Before we continue, I'd like to remind you that today's call may include forward-looking statements. These statements reflect the expectations and beliefs of both Aerovate Therapeutics and Jade Biosciences regarding the potential outcomes of the merger and future business plans. They may include projections on clinical trial timelines, expected financial resources following the completion of the transaction, business milestones, and the potential benefits for stockholders.

It is important to understand that these forward-looking statements are subject to risks and uncertainties. These risks include, but are not limited to, the ability to close the merger, achieve clinical milestones, maintain adequate funding, and the receipt of required regulatory approvals. For a complete discussion of these risks, we encourage investors to review the latest Securities and Exchange Commission filings for Aerovate Therapeutics, including its most recent Form 10-K and quarterly reports. I will point out that our listeners can access additional information on Jade in our corporate presentation which is available on the Jade website at www dot Jade Biosciences dot com.

Joining me on today's call is Jade's Chief Scientific Officer and Head of R&D, Andrew King.

We're thrilled to have the opportunity to tell you about Jade Biosciences, and our plans to advance a pipeline of novel therapies that we believe could meaningfully advance the standard of care in autoimmune diseases.

Jade is a company dedicated to developing best-in-class therapeutics for high value inflammation and immunity indications including systemic autoimmune disease.

Jade is the fourth company founded on assets licensed from Paragon Therapeutics, a leader in antibody discovery and protein engineering. Paragon has a strong track record of discovering and optimizing highly potent and half-life extended monoclonal antibody therapeutics, enabling the development of potentially efficacious therapies that require less frequent dosing.

Jade's initial pipeline includes one program licensed from Paragon and two programs with an exclusive option to license from Paragon – all with the potential to be best-in-class therapeutics for serious autoimmune diseases.

In addition to a promising pipeline, Jade has assembled a world-class team, composed of experienced drug developers, company builders, and strategists. This team has the capability to not only move our programs rapidly into human trials but also the experience to advance our programs into late-stage clinical trials and beyond. We expect our exclusive focus on autoimmune diseases will allow us to build deep expertise and connections with the physicians and patients in the autoimmune disease community.

Jade's pipeline is supported by a strong financial foundation. Today we announced commitments for an oversubscribed private investment that is expected to result in total gross proceeds of approximately $300 million, including the conversion of the previously announced $95 million convertible notes, from a syndicate of healthcare investors led by Fairmount, Venrock Healthcare Capital Partners, and a large investment firm, along with participation from other leading investment management firms. This private placement is expected to fund operations through 2027, based on our current development plans for JADE-001, JADE-002, and JADE-003. This runway extends well beyond our expected disclosure of initial biomarker-rich clinical results from the JADE-001 Human Volunteer study.

Next, I'd like to briefly walk you through the details of the merger agreement and the expected ownership structure of the combined company.

Under the terms of the merger agreement, pre-merger Aerovate stockholders are expected to own approximately 1.6% of the combined company, while pre-merger Jade stockholders, including investors participating in the pre-closing private placement, are expected to own approximately 98.4% These ownership percentages are subject to adjustment based on Aerovate's net cash prior to the stockholder meeting, which is expected to be shortly before closing. Aerovate expects to distribute a dividend of approximately $65 million to its pre-merger stockholders shortly prior to closing.

The merger is subject to approval by the stockholders of both companies, as well as other customary closing conditions, including regulatory approvals. We expect the transaction to close in the first half of 2025. Upon completion, the combined company is expected to operate under the name Jade Biosciences and trade on Nasdaq under the ticker symbol JBIO.

We believe this merger will enable Jade to rapidly advance its portfolio of therapies focused on autoimmune diseases. Jade's lead program, JADE-001, is a monoclonal antibody targeting the cytokine, A Proliferation Inducing Ligand, or APRIL, for the treatment of Immunoglobulin A nephropathy, also known as IgAN.

IgAN is a serious, chronic autoimmune kidney disease that affects approximately 169,000 patients in the United States, several hundred thousand in Europe, and over a million patients in Asia. IgAN is most commonly diagnosed in young adults who have relatively few comorbidities beyond their chronic kidney disease. IgAN requires long-term, lifelong treatment to preserve kidney function and prevent progression to kidney failure, requiring dialysis or transplant, emphasizing the need for effective therapeutics with convenient dosing.

Despite its prevalence and impact, none of the currently approved therapies are disease-modifying or can stabilize kidney function as measured by eGFR. This unmet medical need represents a significant market opportunity, with the U.S. total addressable market alone expected to surpass $10 billion.

The importance of innovative, disease modifying therapies has been further underscored by the recently proposed updates to the KDIGO treatment guidelines for the management of IgAN.

The guidelines emphasize the importance of early diagnosis, recommending kidney biopsies for all adults with proteinuria levels of 0.5 g/d or higher when IgAN is suspected, which we believe will increase diagnosis rates over time.

The guidelines also establish more rigorous proteinuria targets for IgAN patient management. Specifically, patients exhibiting proteinuria of 0.5 g/d or higher are considered at risk for progressive kidney function decline, whether they are currently receiving treatment or not. In these cases, treatment should be initiated or adjusted accordingly. Proteinuria remains the only validated early biomarker available for guiding clinical decisions, with recommended target levels below 0.5 g/d, and preferably below 0.3 g/d.

Furthermore, the guidelines direct that management of IgAN patients incorporate treatments that have been proven to reduce pathogenic forms of IgA. This focus on pathogenic IgA depletion represents a key focus for future therapeutic development in IgAN.

The anti-APRIL class of drugs has the potential to fill the treatment gap in the current guidelines and provide disease modifying impact in patients with IgAN. Agents in this class have demonstrated significant and sustained depletion of pathogenic IgA, which has been accompanied by robust proteinuria reduction and stabilization of kidney function as measured by eGFR in early clinical trials.

Based on this, we believe selective APRIL-inhibition will become the predominantly used class of therapeutic agents in IgAN.

JADE-001, which has been licensed from Paragon Therapeutics, is an anti-APRIL monoclonal antibody engineered to have best-in-class potential.

JADE-001 has been designed and selected, with the goal to provide full inhibition of APRIL throughout the dosing interval, which we believe can translate into best-in-class clinical activity. Through the incorporation of YTE half-life extension technology, JADE-001 is engineered to maintain an extended duration of action. We anticipate this will enable an at least eight-week dosing interval, significantly reducing treatment burden in this young patient population requiring long-term, life-long therapy, while maintaining optimized disease control. This combination of potent APRIL inhibition and convenient dosing schedule represents a significant advancement in therapeutic design, potentially offering patients improved efficacy, enhanced quality of life and improved treatment compliance, through reduced treatment frequency.

We anticipate initiating a healthy volunteer trial with JADE-001 in the second half of 2025 and expect to disclose initial results in the first half of 2026. We believe the Phase 1 healthy volunteer results will be meaningful as APRIL neutralization could provide a biomarker-rich response.

The magnitude of IgA reduction achieved by APRIL inhibition in healthy volunteers correlates strongly with the degree of IgA reduction observed in IgAN patients. We believe that successful demonstration of free-APRIL and IgA reductions in healthy volunteers, along with an extended half-life, has the potential to translate into clinical activity in IgAN patients in subsequent clinical trials.

Furthermore, the degree of IgA reduction achieved by agents that block APRIL in IgAN patients has been found to be correlated with reduction of proteinuria, a key kidney disease biomarker that is recognized by the FDA as a surrogate endpoint to support accelerated approval in IgAN.

Pending positive results with JADE-001 in a Phase 1 trial, and with this biomarker-driven strategy, we are well-positioned to efficiently advance JADE-001 through key development phases.

With that, I'll now pass it over to Andrew King, our Chief Scientific Officer and Head of R&D, to take us through the JADE-001 program and our broader scientific strategy.

Andrew King – Chief Scientific Officer, Jade Biosciences

Thank you, Tom, and good morning, everyone. I am excited to walk you through the science behind JADE-001 and its potential to provide disease modifying impact to patients with IgAN.

IgAN is a chronic autoimmune kidney disease caused by deposits of immunoglobulin A, or IgA containing immune complexes in the kidneys. These deposits trigger inflammation and injury in the kidney that can result in progressive loss of kidney function over time. IgAN is a leading cause of end-stage kidney disease in young adults, which requires dialysis or a kidney transplant to manage.

A series of IgAN clinical trials across a variety of B cell targeting agents have revealed that modulating plasma cells, specifically by blocking APRIL, to reduce pathogenic IgA production is a potentially disease modifying treatment for IgAN. Broad B cell depletion with rituximab or selective BAFF inhibition, which both spare plasma cells, fail to impact the key biomarkers in IgAN patients and show minimal clinical benefit.

In contrast, agents that block the cytokine APRIL, either selective anti-APRIL monoclonal antibodies or the TACI-Fc fusion proteins that inhibit both APRIL and BAFF, have been shown to effectively target the plasma cell compartment, significantly deplete pathogenic IgA, and reduce proteinuria, and most importantly, have shown a kidney function stabilizing benefit.

With the disclaimers and known limitations that apply to cross trial comparisons, currently available data across IgAN clinical trials indicate that the anti-APRIL mAbs at least match the impact of TACI-Fcs on all relevant biomarkers including pathogenic IgA as well as across clinically meaningful endpoints including proteinuria reduction, kidney function stabilization and resolution of hematuria. Therefore, we believe that selectively blocking APRIL represents a potentially disease modifying treatment in IgAN, targeted to the plasma cell to block pathogenic IgA production, without broadly impacting B-cell development and maturation, to minimize immunosuppression in IgAN patients who require long-term therapy potentially for decades.

JADE-001 is a potentially best-in-class anti-APRIL monoclonal antibody with novel CDRs supporting provisional composition of matter patent filings. These antibodies are engineered on the human IgG1 effector null backbone with the clinically validated YTE mutation incorporated into the Fc to promote human half-life extension.

In preclinical testing, we observe higher affinity binding of our antibody clones to APRIL than that observed in the anti-APRIL mAbs currently in clinical development – though cross-trial comparisons have limitations. The goal of JADE-001 is to combine superior potency with extended pharmacokinetic exposures to potentially provide greater clinical activity, with a dosing interval of at least every eight weeks. Less frequent administration has the potential to reduce the treatment burden, making it easier for patients to stay on therapy and improve compliance.

We are encouraged by early pharmacokinetic and pharmacodynamic results from non-human primates, with a representative JADE-001 antibody, which shows, both an extended half-life and prolonged IgA reductions, compared to sibeprenlimab, an anti-APRIL monoclonal antibody currently in Phase 3 development. This profile aligns with our goal of delivering transformative outcomes for IgAN patients while minimizing disruptions to their daily lives by providing a convenient dosing schedule.

We expect to initiate first-in-human trials for JADE-001 in the second half of 2025, with early data from healthy volunteers anticipated in the first half of 2026.

In addition to JADE-001, we are advancing two other undisclosed antibody programs to which we have exclusive rights from Paragon Therapeutics, JADE-002 and JADE-003, which are currently in preclinical development. These programs target serious, systemic autoimmune diseases, broadening our pipeline and positioning Jade to address unmet needs across multiple important indications. We anticipate initiating first in human studies for these programs in the first half of 2026 and first half of 2027, respectively.

I’ll now hand the call back to Tom.

Tom Frohlich – CEO, Jade Biosciences

Thank you, Andrew.

This merger marks an exciting moment for both Aerovate Therapeutics and Jade Biosciences, and positions Jade to develop innovative therapies that address critical unmet needs in autoimmune diseases.

The substantial financing we announced today is expected to provide resources for the advancement of Jade's pipeline. With JADE-001 on track to enter the clinic in the second half 2025 and two additional pre-clinical programs advancing steadily, we are well-positioned to deliver meaningful value to our investors and, most importantly, deliver potentially transformative therapies to patients.

Before concluding, I'd like to take a moment to thank the teams at both companies for their efforts on behalf of patients. We are excited about the road ahead and confident in our ability to execute on our strategy.

With that, I'll now hand the call back to the operator. Thank you for joining.

Operator

Ladies and gentlemen, this concludes today's conference call. All parties may now disconnect.

Forward-Looking Statements

Certain statements in this communication, other than purely historical information, may constitute "forward-looking statements" within the meaning of the federal securities laws, including for purposes of the "safe harbor" provisions under the Private Securities Litigation Reform Act of 1995, concerning Aerovate, Jade, the proposed concurrent investment and the proposed Merger (collectively, the "Proposed Transactions") and other matters. These forward-looking statements include, but are not limited to, express or implied statements relating to Aerovate's and Jade's management teams' expectations, hopes, beliefs, intentions or strategies regarding the future including, without limitation, statements regarding: the Proposed Transactions and the expected effects, perceived benefits or opportunities of the Proposed Transactions, including investment amounts from investors and expected proceeds, and related timing with respect thereto; expectations related to Aerovate's contribution and payment of the cash dividends in connection with the proposed Merger, including the anticipated timing of the Closing of the proposed transactions (the "Closing"); the expectations regarding the ownership structure of the combined company; and the expected trading of the combined company's stock on Nasdaq under the ticker symbol "JBIO" after the Closing. In addition, any statements that refer to projections, forecasts or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements. The words "opportunity," "potential," "milestones," "pipeline," "can," "goal," "strategy," "target," "anticipate," "achieve," "believe," "contemplate," "continue," "could," "estimate," "expect," "intends," "may," "plan," "possible," "project," "should," "will," "would" and similar expressions (including the negatives of these terms or variations of them) may identify forward-looking statements, but the absence of these words does not mean that a statement is not forward-looking. These forward-looking statements are based on current expectations and beliefs concerning future developments and their potential effects. There can be no assurance that future developments affecting Aerovate, Jade or the Proposed Transactions will be those that have been anticipated. These forward-looking statements involve a number of risks, uncertainties (some of which are beyond Aerovate's control) or other assumptions that may cause actual results or performance to be materially different from those expressed or implied by these forward-looking statements. These risks and uncertainties include, but are not limited to, the risk that the conditions to the Closing or consummation of the Proposed Transactions are not satisfied, including Aerovate's failure to obtain stockholder approval for the proposed Merger; the risk that the proposed concurrent investment is not completed in a timely manner or at all; uncertainties as to the timing of the consummation of the Proposed Transactions and the ability of each of Aerovate and Jade to consummate the transactions contemplated by the Proposed Transactions; risks related to Aerovate's continued listing on Nasdaq until closing of the Proposed Transactions and the combined company's ability to remain listed following the Proposed Transactions; risks related to Aerovate's and Jade's ability to correctly estimate their respective operating expenses and expenses associated with the Proposed Transactions, as applicable, as well as uncertainties regarding the impact any delay in the closing of any of the Proposed Transactions would have on the anticipated cash resources of the resulting combined company upon closing and other events and unanticipated spending and costs that could reduce the combined company's cash resources; the failure or delay in obtaining required approvals from any governmental or quasi-governmental entity necessary to consummate the Proposed Transactions; the occurrence of any event, change or other circumstance or condition that could give rise to the termination of the business combination between Aerovate and Jade; the effect of the announcement or pendency of the Merger on Aerovate's or Jade's business relationships, operating results and business generally; costs related to the Merger; the risk that as a result of adjustments to the exchange ratio, Jade stockholders and Aerovate stockholders could own more or less of the combined company than is currently anticipated; the outcome of any legal proceedings that may be instituted against Aerovate, Jade or any of their respective directors or officers related to the Merger Agreement or the transactions contemplated thereby; the ability of Aerovate and Jade to protect their respective intellectual property rights; competitive responses to the Proposed Transactions; unexpected costs, charges or expenses resulting from the Proposed Transactions; potential adverse reactions or changes to business relationships resulting from the announcement or completion of the Proposed Transactions; failure to realize certain anticipated benefits of the Proposed Transactions, including with respect to future financial and operating results; the risk that Aerovate stockholders receive more or less of the cash dividend than is currently anticipated; legislative, regulatory, political and economic developments; and those uncertainties and factors more fully described in periodic filings with the SEC, including under the heading "Risk Factors" and "Business" in Aerovate's most recent Annual Report on Form 10-K for the year ended December 31, 2023, filed with the SEC on March 25, 2024, subsequent Quarterly Reports on Form 10-Q filed with the SEC, as well as discussions of potential risks, uncertainties, and other important factors included in other filings by Aerovate from time to time, any risk factors related to Aerovate or Jade made available to you in connection with the Proposed Transactions, as well as risk factors associated with companies, such as Jade, that operate in the biopharma industry. Should one or more of these risks or uncertainties materialize, or should any of Aerovate's or Jade's assumptions prove incorrect, actual results may vary in material respects from those projected in these forward-looking statements. Nothing in this communication should be regarded as a representation 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. You should not place undue reliance on forward-looking statements in this communication, which speak only as of the date they are made and are qualified in their entirety by reference to the cautionary statements herein. Neither Aerovate nor Jade undertakes or accepts any duty to release publicly any updates or revisions to any forward-looking statements. This communication does not purport to summarize all of the conditions, risks and other attributes of an investment in Aerovate or Jade.

No Offer or Solicitation

This communication and the information contained herein is not intended to and does not constitute (i) a solicitation of a proxy, consent or approval with respect to any securities or in respect of the Proposed Transactions or (ii) an offer to sell or the solicitation of an offer to subscribe for or buy or an invitation to purchase or subscribe for any securities pursuant to the Proposed Transactions or otherwise, nor shall there be any sale, issuance or transfer of securities in any jurisdiction in contravention of applicable law. No offer of securities shall be made except by means of a prospectus meeting the requirements of the Securities Act of 1933, as amended, or an exemption therefrom. Subject to certain exceptions to be approved by the relevant regulators or certain facts to be ascertained, the public offer will not be made directly or indirectly, in or into any jurisdiction where to do so would constitute a violation of the laws of such jurisdiction, or by use of the mails or by any means or instrumentality (including without limitation, facsimile transmission, telephone and the internet) of interstate or foreign commerce, or any facility of a national securities exchange, of any such jurisdiction.

NEITHER THE SEC NOR ANY STATE SECURITIES COMMISSION HAS APPROVED OR DISAPPROVED OF THE SECURITIES OR DETERMINED IF THIS COMMUNICATION IS TRUTHFUL OR COMPLETE.

Important Additional Information about the Proposed Transaction Will be Filed with the SEC

This communication is not a substitute for the registration statement or for any other document that Aerovate may file with the SEC in connection with the Proposed Transactions. In connection with the Proposed Transactions, Aerovate intends to file relevant materials with the SEC, including a registration statement on Form S-4 that will contain a proxy statement/prospectus of Aerovate. AEROVATE URGES INVESTORS AND STOCKHOLDERS TO READ THE REGISTRATION STATEMENT, PROXY STATEMENT/PROSPECTUS AND ANY OTHER RELEVANT DOCUMENTS THAT MAY BE FILED WITH THE SEC, AS WELL AS ANY AMENDMENTS OR SUPPLEMENTS TO THESE DOCUMENTS, CAREFULLY AND IN THEIR ENTIRETY IF AND WHEN THEY BECOME AVAILABLE BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION ABOUT AEROVATE, JADE, THE PROPOSED TRANSACTIONS AND RELATED MATTERS. Investors and stockholders will be able to obtain free copies of the proxy statement/prospectus and other documents filed by Aerovate with the SEC (when they become available) through the website maintained by the SEC at www.sec.gov. Stockholders are urged to read the proxy statement/prospectus and the other relevant materials when they become available before making any voting or investment decision with respect to the Proposed Transactions. In addition, investors and stockholders should note that Aerovate communicates with investors and the public using its website (https://ir.aerovatetx.com/).

Participants in the Solicitation

Aerovate, Jade and their respective directors and executive officers may be deemed to be participants in the solicitation of proxies from stockholders in connection with the Proposed Transactions. Information about Aerovate's directors and executive officers, including a description of their interests in Aerovate, is included in Aerovate's most recent Annual Report on Form 10-K for the year ended December 31, 2023, filed with the SEC on March 25, 2024, subsequent Quarterly Reports on Form 10-Q filed with the SEC, including any information incorporated therein by reference, as filed with the SEC, and other documents that may be filed from time to time with the SEC. Additional information regarding these persons and their interests in the transaction will be included in the proxy statement/prospectus relating to the Proposed Transactions when it is filed with the SEC. These documents can be obtained free of charge from the sources indicated above.