UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(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, 2025

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 001-40544

Jade Biosciences, Inc.

(Exact name of Registrant as specified in its Charter)

Nevada	**83-1377888**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
221 Crescent Street, Building 23, Suite 105 Waltham, Massachusetts	**02453**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: 781-312-3013

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

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, par value $0.0001 per share	JBIO	The Nasdaq Capital Market

Securities registered pursuant to Section 12(g) of the Act: **None**

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 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, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 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 ☒

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the Registrant, based on the closing price of the shares of common stock on The Nasdaq Capital Market on June 30, 2025, was approximately $289.4 million.

The number of shares of Registrant's Common Stock outstanding as of February 28, 2026 was 49,316,287.

DOCUMENTS INCORPORATED BY REFERENCE

List hereunder the following documents if incorporated by reference and the Part of the Form 10-K (e.g., Part I, Part II, etc.) into which the document is incorporated: (1) Any annual report to security holders; (2) Any proxy or information statement; and (3) Any prospectus filed pursuant to Rule 424(b) or (c) under the Securities Act of 1933. The listed documents should be clearly described for identification purposes (e.g., annual report to security holders for fiscal year ended December 24, 1980)

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PART I

Item 1. Business.

Company Overview

We are a clinical-stage biopharmaceutical company developing novel biologic therapies for patients living with autoimmune diseases. Our goal is to improve meaningfully upon the existing treatment paradigm through the delivery of improved dosing and convenience, a comparable safety profile, and potentially increased clinical activity. Our approach is to discover and efficiently develop biologics that address emerging targets supported by third-party clinical data and that overcome shortcomings of existing product candidates in development, such as potency, bioavailability, formulation, and pharmacokinetic properties.

Our lead product candidate, JADE101, is a monoclonal antibody ("mAb") targeting a cytokine called "A PRoliferation Inducing Ligand" ("APRIL") that modulates plasma cell survival and immunoglobulin production, which we plan to initially develop for the treatment of IgA nephropathy ("IgAN"). Our second product candidate is JADE201, a mAb targeting B cell activating factor receptor ("BAFF-R") for the treatment of multiple autoimmune disorders. Our third product candidate is JADE301, a mAb targeting an undisclosed pathway.

Our Pipeline

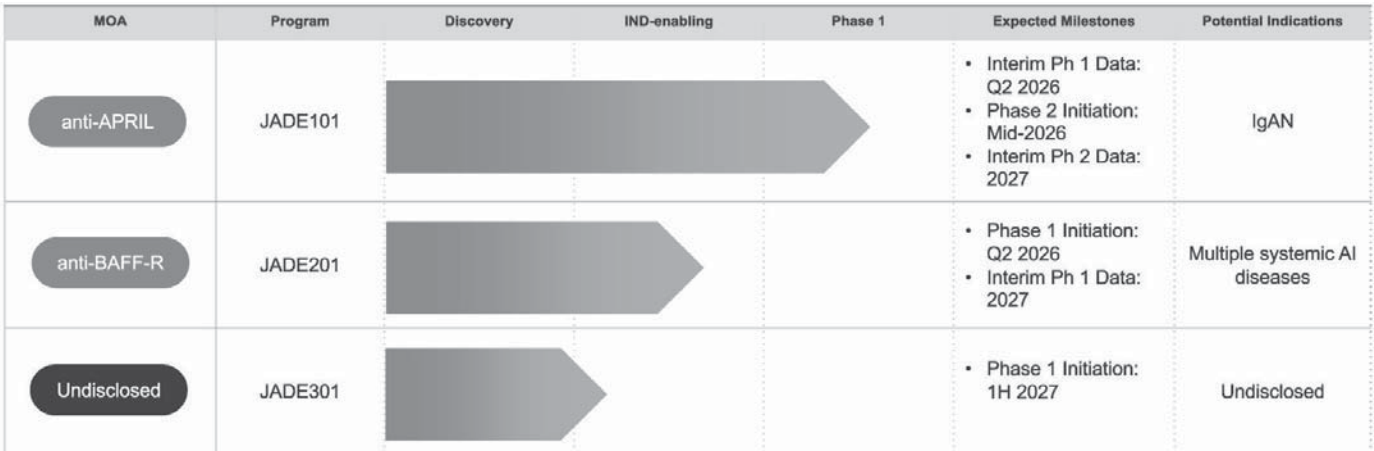

Figure 1. Our pipeline.

JADE101

JADE101 is a high affinity, half-life extended mAb targeting APRIL, which plays a critical role in the development of IgAN and other autoimmune disorders. JADE101 has been engineered to address two key limitations of anti-APRIL mAb candidates in clinical development: potency and pharmacokinetic half-life. Increased APRIL binding affinity, improved potency in *in vitro* functional assays and an extended pharmacokinetic half-life in non-human primates ("NHPs") have been observed in head-to-head preclinical studies of JADE101 compared to other therapeutics and product candidates in development that were manufactured based on public data. JADE101 is engineered with YTE half-life extension technology, an amino acid change in the fragment crystallizable ("Fc") domain to modify the pH-dependent binding to the neonatal Fc receptor ("FcRn") and increase serum half-life. As a result, it has a pharmacokinetic profile designed to support a subcutaneous ("SQ") injection every eight weeks or longer. We initiated a Phase 1 clinical trial of JADE101 in healthy volunteers in New Zealand in August 2025, with the aim of generating interim data, including mechanistic biomarker data, in the second quarter of 2026. We plan to initiate a Phase 2 clinical trial in IgAN patients in the middle of 2026, with interim data expected in 2027.

JADE201

JADE201 is a half-life extended, afucosylated mAb that targets BAFF-R. It has a dual mechanism of action.

First, via enhanced effector function, it directly kills B cells through antibody-dependent mechanisms, and second, by inhibiting BAFF signaling to block a critical activation and survival pathway for B cells. JADE201 incorporates half-life extension technology, which has the potential to significantly prolong its duration of action, by maintaining pharmacologic activity throughout the dosing interval. We plan to initiate a Phase 1 clinical trial evaluating JADE201 in patients with rheumatoid arthritis in the second quarter of 2026, with interim data expected in 2027.

JADE301

We have a third mAb program, JADE301 (formerly JADE-003), designed to target an undisclosed pathway, for which we are conducting preclinical research. We expect to initiate a Phase 1 clinical trial for this program in the first half of 2027.

Our Strategy

Our goal is to discover and develop differentiated biologic therapies for patients living with autoimmune diseases. Our strategy to accomplish this goal includes:

- ***Advance JADE101's clinical development in IgAN***. Preclinical studies indicate that JADE101 may have increased in vitro potency compared to other anti-APRIL product candidates in clinical development and improved pharmacokinetics in NHPs compared to sibeprenlimab. In August 2025, we initiated a Phase 1 clinical trial of JADE101 in healthy volunteers in New Zealand, and we anticipate mechanistic biomarker results regarding its anti-APRIL activity and pharmacokinetic properties in the second quarter of 2026. We believe that successful demonstration of anti-APRIL activity with 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. We expect to initiate an open-label Phase 2 clinical trial in IgAN patients in the middle of 2026, with interim data expected in 2027.
- ***Address the needs of patients with multiple autoimmune disorders by advancing JADE201 into the clinic.*** JADE201 is designed to work through a dual mechanism of action that directly addresses the key limitations of earlier B cell depletion strategies. First, it possesses enhanced cytotoxicity through increased effector function — afucosylation increases affinity between JADE201 and immune cell receptors, driving stronger antibody-dependent cellular cytotoxicity, ("ADCC") activity, which is expected to enable potent, deep and sustained depletion of BAFF-R–expressing B cells. Second, it pharmacologically inhibits BAFF signaling through the BAFF receptor, blocking an important B cell activation and survival signal, and cutting off the compensatory response to upregulation of BAFF that typically follows B cell depletion. We believe that more potent, durable B cell depletion in a convenient, infrequent subcutaneous injection could enable JADE201 to demonstrate meaningful patient benefit across numerous autoimmune disorders. We plan to initiate a Phase 1 clinical trial evaluating JADE201 in patients with rheumatoid arthritis in the second quarter of 2026, with interim data expected in 2027.
- ***Expand our pipeline by leveraging our expertise to bring additional product candidates into the clinic***. We have an exclusive option to license JADE301 and Paragon Therapeutics, Inc. ("Paragon") is conducting preclinical discovery services with respect to this program, including generating and testing potential antibody drug candidates directed to the JADE301 undisclosed target. We plan to initiate a Phase 1 clinical trial of JADE301 in the first half of 2027. We may also explore opportunities to in-license other candidates which fit our strategy.
- ***Maximize the value of JADE101 by exploring its potential in other autoimmune disorders***. We believe targeting APRIL may have patient benefit in other autoimmune disorders. We are evaluating the feasibility of initiating a clinical trial in 2027 to explore JADE101 in one or more of these disorders.

IgAN disease background

IgAN is the most common primary glomerular disease in the world. IgAN is a progressive disease that is most often diagnosed before age 40 and can result in kidney failure. IgAN has an estimated incidence of at least 2.5 cases in every 100,000 adults, in studies spanning multiple countries, an estimate that likely underestimates the true prevalence since confirmatory diagnosis requires a kidney biopsy. The U.S. Food and Drug Administration ("FDA") estimates a U.S. prevalence for IgAN of 169,000, the European Medicines Agency ("EMA") estimates a European Union prevalence of 205,000, and Novartis AG ("Novartis") estimates a Japan prevalence of 103,000 and China prevalence of 783,000, totaling a prevalence of over 1,000,000 globally. The prevalence of IgAN varies geographically with the highest prevalence in the Asia Pacific region.

Within 20 years of diagnosis, between 20 – 50% of patients with IgAN progress to end-stage kidney disease ("ESKD"), a disease state requiring dialysis or kidney transplant for survival due to insufficient kidney function.

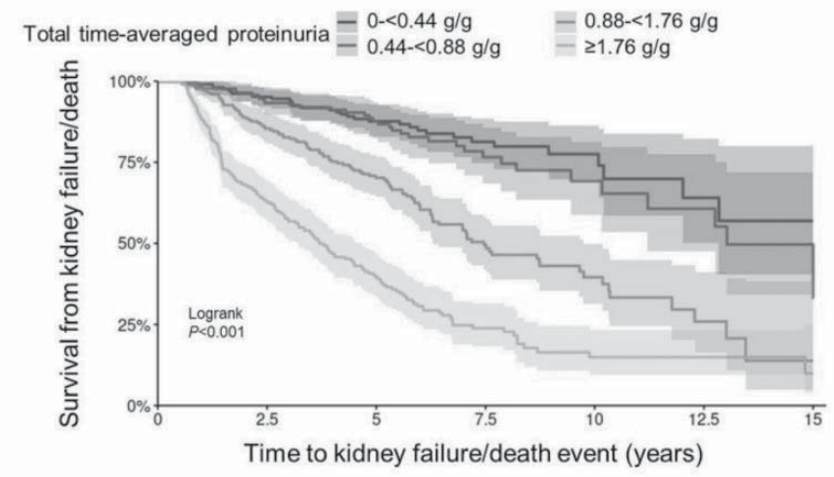

Figure 2. IgAN is a progressive disease that results in kidney failure in the majority of patients.

In addition to the morbidity and mortality associated with ESKD, treatment of patients with ESKD has a significant economic burden. The costs of dialysis for a patient in the United States are typically between $100,000 and $275,000 annually and the cost of a kidney transplant can be over $450,000.

Underlying molecular cause

IgAN is an autoimmune kidney disease that is caused by the deposition of immune complexes containing IgA in the glomerular mesangium, the cellular structures supporting the tiny blood vessels of the glomeruli of the kidney that filter waste from the blood, leading to kidney injury. IgAN is commonly diagnosed following a respiratory tract infection, and the initiating pathogenic event is considered to be an aberrant mucosal immune response that leads to the excess production of an abnormal form of IgA that is deficient in sugar residues, called galactose-deficient IgA1 ("Gd-IgA1"). APRIL is thought to be a key driver of Gd-IgA1 overproduction in IgAN. Gd-IgA1 acts as an autoantigen and is recognized by circulating autoantibodies resulting in the formation of immune complexes which deposit in the glomerular mesangium of the kidney and trigger complement activation and an inflammatory response, leading to kidney injury. This injury results in leakage of protein across the filtration barrier of the kidney, leading to increased protein levels in the urine (proteinuria), an important measure of disease severity and predictor of risk of progression in IgAN. Over time, progressive injury can lead to a loss in the number of functional filtration units in the kidney, impairing the kidney's ability to effectively filter the blood to clear waste products from the body, which can result in dialysis and/or kidney transplant in a subset of patients. Serum levels of creatinine are an important marker of this loss of filtration function and are used to calculate the estimated glomerular filtration rate ("eGFR"), a parameter that is used to assess the loss of kidney function over time in IgAN and other kidney diseases.

Current treatment guidelines for IgAN

New international treatment guidelines have recently been published (KDIGO, 2025), emphasizing the importance of early diagnosis and recommending kidney biopsies for all adults with proteinuria levels of 0.5 g/d or higher when IgAN is suspected. The updated guidelines recommend initiating treatment or adding additional treatments in IgAN patients with proteinuria > 0.5 g/day and also establish more rigorous proteinuria treatment goals to below 0.5 g/d and preferably to below 0.3 g/d to minimize the lifetime risk for progressive kidney function decline. The recommended treatment approach advises targeting the underlying autoimmune disease pathogenesis of IgAN while simultaneously managing the nephron loss associated with progressive IgAN. Managing nephron loss involves optimizing supportive therapy, including blood pressure control, a low-sodium diet, and smoking cessation. Pharmacological approaches to this include renin–angiotensin–aldosterone system ("RAAS") inhibitors, SGLT2 inhibitors and endothelin receptor antagonists. Current strategies recommended in the guidelines to reduce the formation of pathogenic immune complexes or the inflammatory injury in response to these immune complexes include delayed release or systemic steroids. However, these measures are not disease-modifying in the majority of patients. The updated guidelines direct the incorporation of treatments that have been proven to reduce pathogenic forms of IgA in the management of IgAN patients.

The FDA recently approved four small molecule drugs to treat IgAN: Tarpeyo, Filspari, Fabhalta, and Vanrafia. Tarpeyo, marketed by Calliditas Therapeutics, which was recently acquired by Asahi Kasei Corporation, is a delayed release formulation of budesonide, a corticosteroid. Filspari, or sparsentan, is a dual endothelin and angiotensin II receptor antagonist marketed by Travere Therapeutics, Inc.. Neither Tarpeyo nor Filspari are disease modifying. As a result, each provides only relatively modest reductions in proteinuria relative to control and neither has been shown to stabilize kidney function as eGFR has been observed to continue to decline while on treatment. Tarpeyo is only approved for a 9-month treatment course, due to the risk of significant adverse effects associated with long-term steroid use.

In August 2024, iptacopan, marketed as Fabhalta by Novartis, received accelerated approval for the treatment of IgAN based on interim results in high risk IgAN patients for whom iptacopan treatment was associated with a 38% decrease in urine protein creatinine ratio ("UPCR") compared to placebo. Iptacopan is an inhibitor of the immune complement system and is approved to treat paroxysmal nocturnal hemoglobinuria, a rare disease of red blood cell destruction or hemolysis. Results from iptacopan provide support for the ability of anti-inflammatory drugs to reduce the kidney damage in IgAN, as anti-inflammatory drugs do not target overproduction of pathologic IgA, the primary cause of the disease.

In August 2025, atrasentan, marketed as Vanrafia by Novartis, received accelerated approval for the treatment of IgAN based on interim results in high risk IgAN patients for whom atrasentan treatment was associated with a 36% decrease in urine protein creatinine ratio ("UPCR") compared to placebo. Atrasentan is an endothelin receptor antagonist.

In November 2025, the FDA granted accelerated approval to sibeprenlimab, marketed as Voyxact by Otsuka Pharmaceutical Co., Ltd. ("Otsuka") Sibeprenlimab is an APRIL inhibitor and is the first b-cell modulating, disease-modifying treatment to be approved for IgAN patients.

Emerging therapeutic approaches

Multiple emerging approaches attempt to address the underlying autoimmune nature of IgAN by targeting antibody-producing B cells. Therapies approved for other autoimmune indications that target B cells, such as rituximab, an anti-CD20 drug which depletes B cells, have been observed to have a minimal impact in IgAN. Specifically, B cell depletion with rituximab failed to reduce Gd-IgA1, anti-Gd-IgA1 autoantibody or proteinuria and did not preserve eGFR. This lack of activity is believed to be due to the loss of CD20 expression as B cells mature into antibody-producing plasma cells, which are thought to be the pathogenic cell type in IgAN. Furthermore, blisibimod, a BAFF-targeted peptibody, a type of fusion protein, was tested in IgAN and also observed to have a minimal impact in reducing either IgA or proteinuria from baseline through the first year of treatment in IgAN, which is directly comparable to the treatment duration available for other programs. Promising clinical results have been obtained, however, with therapies targeting plasma cell function and survival. Most notable are inhibitors of APRIL.

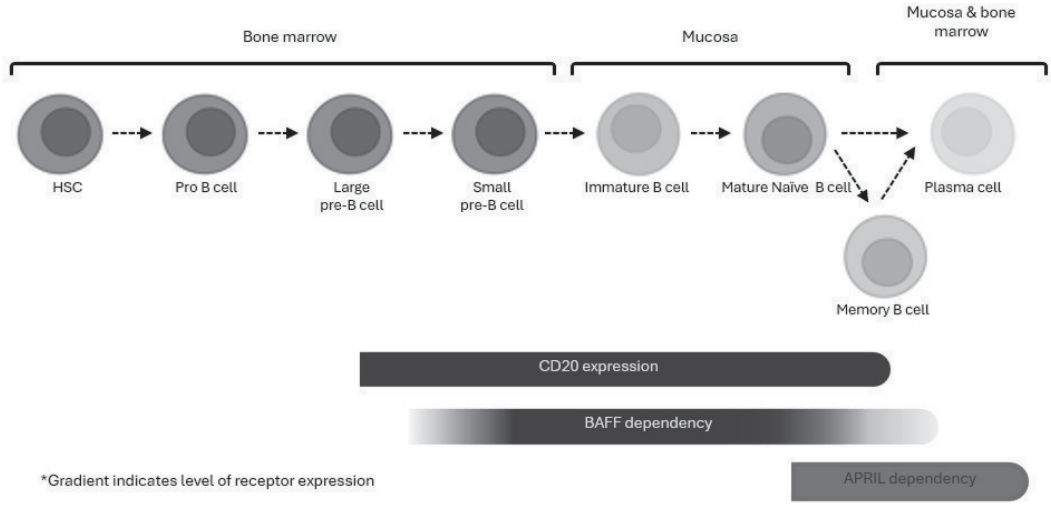

Figure 3. Antibody-producing plasma cells are dependent on APRIL.

Potential of APRIL inhibitors to treat IgAN

APRIL has been shown to regulate the development of plasma cells, which are specialized B cells that secrete large amounts of immunoglobulins. APRIL is produced by various immune cells, including macrophages, dendritic cells, and activated

T cells. APRIL exerts its effects through binding to its two receptors: B cell maturation antigen ("BCMA"), and transmembrane activator and calcium-modulating cyclophilin ligand interactor ("TACI"). These two receptors also bind to a related ligand called B cell activating factor from the tumor necrosis factor family, also known as "BAFF" or "BLyS." In addition to these two receptors, BAFF also binds to the BAFF receptor, a binding event that is essential for both survival and maturation of immature B cells. Although BAFF and APRIL are structurally related, they bind to their receptors with different affinities and have distinct biological roles in regulating B cell function.

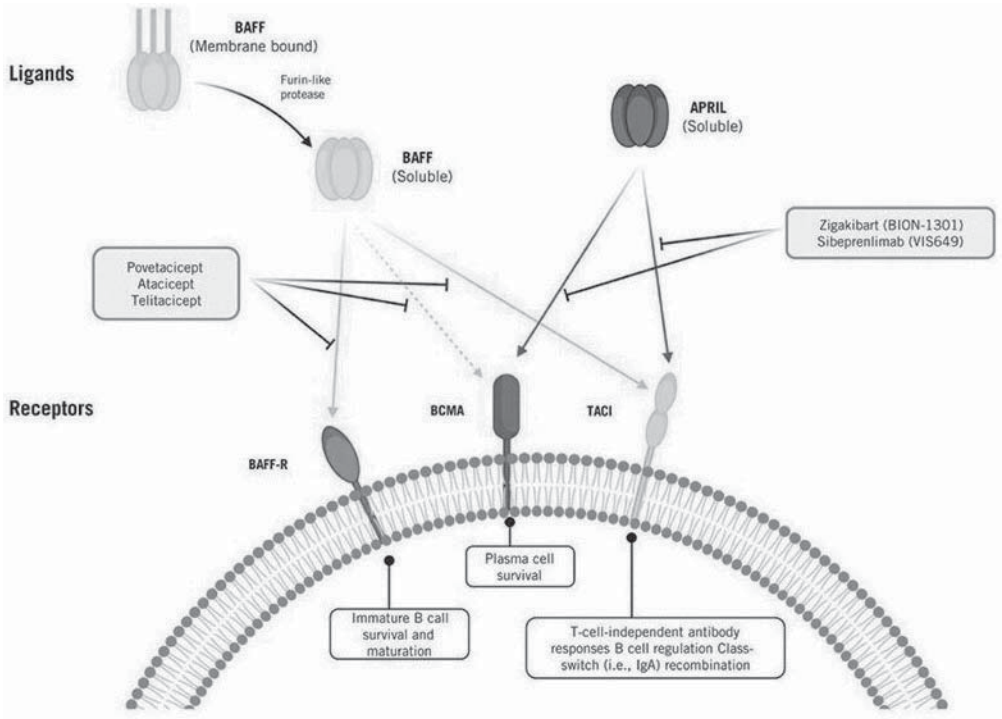

Figure 4. BAFF and APRIL stimulate overlapping but non-identical B cell pathways.

Multiple product candidates that block the activity of BAFF and APRIL are in clinical development for the treatment of IgAN. Atacicept, in development by Vera Therapeutics, Inc. ("Vera Therapeutics"), and telitacicept, a product from RemeGen approved in China for the treatment of systemic lupus erythematosus ("SLE"), are biologics called fusion proteins that fuse the cytokine binding domain of the TACI receptor to the fragment crystallizable portion of an antibody. These fusion proteins bind to both BAFF and APRIL to prevent B cell activation via BAFF and block pathological antibody production via APRIL. In IgAN patients in a Phase 2 trial treated with telitacicept, circulating levels of IgA antibodies were observed to decrease by approximately 50% and patients had reductions in certain IgA immune complexes of over 60%. In a double-blind Phase 3 trial, a once weekly subcutaneous dose of 150 mg of atacicept led to a statistically significant, placebo-adjusted reduction in UPCR of 42% at week 36.

Povetacicept is a more potent, engineered TACI receptor fusion protein in development by Vertex. In an ongoing open-label Phase 2 trial, subcutaneous doses of 80 mg administered every four weeks were observed to reduce UPCR from baseline by approximately 64% at 48 weeks in seventeen treated patients in which stable kidney function was also observed as assessed by eGFR. Povetacicept is currently being evaluated in a global phase 3 clinical trial in IgAN patients.

These clinical trial results are part of a large body of scientific and third-party clinical evidence that points to the inhibition of APRIL and not BAFF as the primary mechanism of action of TACI fusion proteins in the treatment of IgAN, including:

- An association of a genetic variant of APRIL with increased risk of developing IgAN has been identified by genome-wide association studies;
- Elevated levels of APRIL are found in IgAN patients;
- Elevated levels of APRIL are correlated with disease severity;
- APRIL promotes secretion of pathologic IgA from IgAN patient lymphocytes in ex vivo experiments;

- IgA class switching can be driven by APRIL in vivo;
- Knockout of the gene for APRIL decreases IgA levels in mice;
- Overexpression of APRIL is sufficient to cause glomerular IgA deposition in mice;
- Selective inhibitors of APRIL demonstrate activity in preclinical IgAN murine models and in IgAN patients; and
- Selective inhibition of BAFF demonstrated minimal activity in a preclinical IgAN murine model and in IgAN patients.

Anti-APRIL products investigated for the treatment of IgAN provide proof-of-concept data

Zigakibart and sibeprenlimab, two selective anti-APRIL mAbs, have been investigated in clinical trials in IgAN patients. Zigakibart, under development by Novartis, was well-tolerated in IgAN patients in an open-label Phase 2 trial in which rapid and sustained reductions in APRIL levels were observed. Zigakibart treatment resulted in lower levels of pathologic IgA levels and reduced proteinuria that continued to decline through two years of treatment. Stabilization of eGFR was observed through 100 weeks of treatment. No treatment-related serious adverse events were observed. A Phase 3 trial is now enrolling patients.

Similarly, sibeprenlimab, marketed as Voyxact by Otsuka, led to significant reductions in pathogenic IgA and proteinuria in IgAN patients in a Phase 2 double-blind placebo-controlled trial. Initial UPCR reductions from baseline of over 60% in the 4 mg/kg and 8 mg/kg groups were observed following a 12-month treatment period with sibeprenlimab and were sustained for an additional four months following treatment discontinuation. No treatment-related serious adverse events were observed.

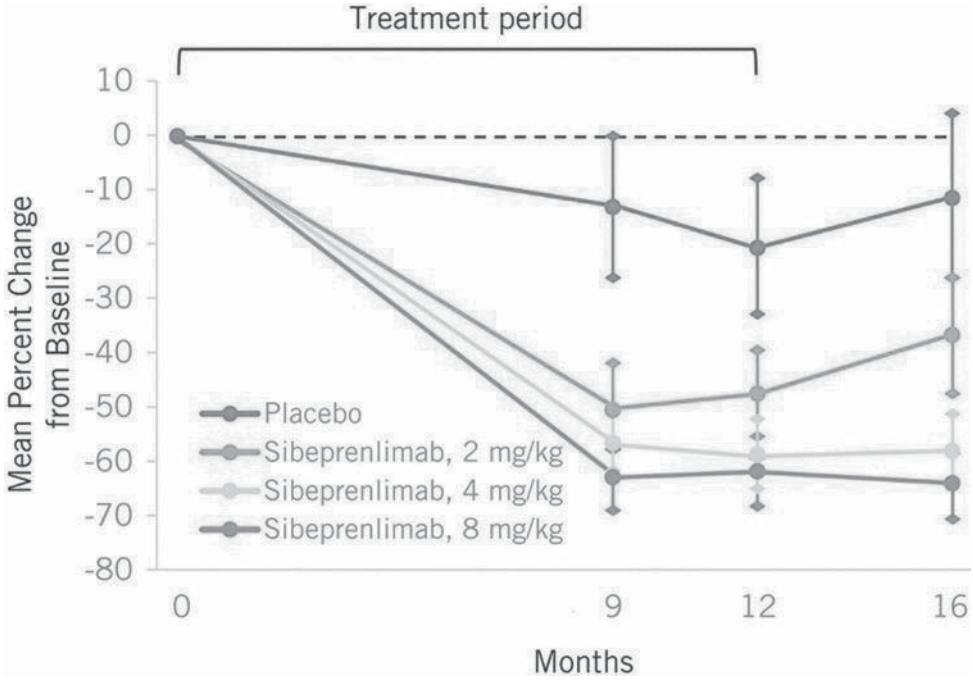

Figure 5. Intravenous doses of sibeprenlimab led to significant and sustained reductions in UPCR in a Phase 2 trial in IgAN.

At 12 months of treatment with 4 mg/kg or 8 mg/kg sibeprenlimab, eGFR was observed to stabilize, providing strong clinical validation of the potential for an anti-APRIL mAb to stabilize kidney function as measured by eGFR. In a Phase 3 clinical trial, Otsuka reported in June 2025 that sibeprenlimab achieved a statistically significant and clinically meaningful 51.2% ($P<0.0001$) reduction in UPCR at nine months of treatment when compared to placebo.

Clinical data from the most advanced anti-APRIL antibodies and TACI fusion proteins reveal that they have similar profiles with regard to pharmacodynamic biomarker responses, efficacy, tolerability, and dosing schedules. We believe that there

is potential for a differentiated anti-APRIL product candidate without potentially unnecessary immunosuppression (via BAFF inhibition) to capture a sizable portion of the highly competitive emerging IgAN market.

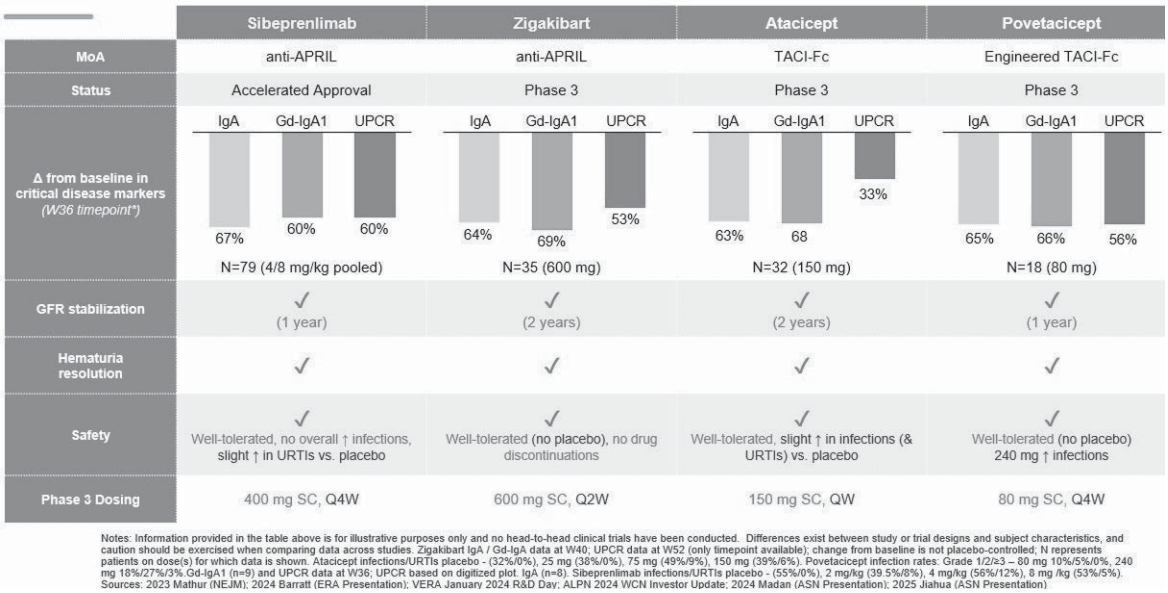

Figure 6. The most advanced anti-APRIL antibodies and TACI fusion proteins have similar activity in Phase 2 clinical trials. SC = subcutaneous; QW = once-weekly dosing; Q2W = once every other week dosing; Q4W = once-monthly dosing.

Our solution: JADE101

JADE101 is a selective fully human anti-APRIL mAb designed to build on the proof-of-concept validating data generated in clinical trials of sibeprenlimab and zigakibart in IgAN while addressing shortcomings which we believe will limit those antibodies' clinical and commercial impact. We believe that JADE101 has the potential to deliver improved dosing and convenience, a comparable safety profile and potentially increased clinical activity through antibody modifications that improve potency and extend its half-life, as compared to the existing product candidates in development.

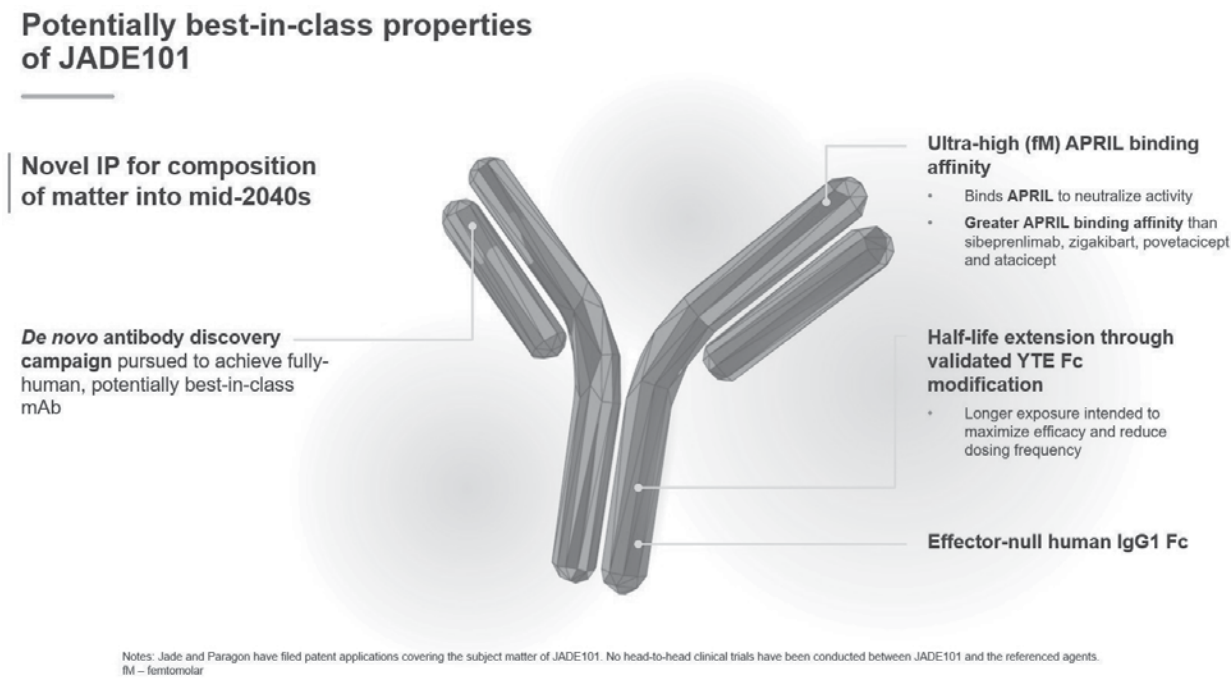

Figure 7. Design of JADE101.

Increased potency

Through a series of *in vitro* selection and protein engineering steps, JADE101 was designed by targeting a series of antibodies with an affinity for APRIL that were at least five-fold higher in the same assay than other anti-APRIL product candidates manufactured based on published data.

The binding affinity to APRIL of JADE101, was measured using surface plasmon resonance. Serial dilutions of test antibodies were flowed over APRIL immobilized on sensor chips to assess binding kinetics and affinity. Binding at various concentrations was measured by an increase in resonance units and the dependence of the rate of binding with the concentration allowed the equilibrium dissociation constant ("K_D") to be determined. The smaller the K_D value, the greater the binding affinity of the antibody for APRIL. JADE101 had a K_D value approximately 755 times lower than that observed for sibeprenlimab, indicating higher binding affinity to APRIL for JADE101 compared to sibeprenlimab.

The increased affinity of JADE101 for APRIL was observed to have high potency in a series of *in vitro* competition binding and reporter cell assays. JADE101 has been observed to be a potent inhibitor of APRIL binding to BCMA and TACI receptors, as assessed in BCMA and TACI competition ELISA assays. JADE101 was also observed to be potent in blocking APRIL signaling in BCMA and TACI cellular reporter assays. We believe that this increased potency as a result of the greater binding affinity will facilitate the ability to maximally suppress APRIL signaling in IgAN patients as JADE101 is evaluated in its ongoing Phase 1 clinical trial.

Improved pharmacokinetics in preclinical studies

High molecular weight biologics, such as antibodies, are routinely dosed via intravenous or subcutaneous administration. Subcutaneous administration enables the potential for convenient self-administration at home. We believe that the disease-modifying impact and tolerability profile observed with anti-APRIL product candidates under clinical development provide the opportunity for an anti-APRIL product candidate, such as JADE101, to gain a competitive advantage based on a less frequent and more convenient subcutaneous dosing regimen.

JADE101 has been engineered to have an extended half-life in the body based on specific modifications that have been shown to be effective in other therapies. One of these modifications, YTE substitution, significantly extends the half-life of antibodies by increasing their ability to be recycled.

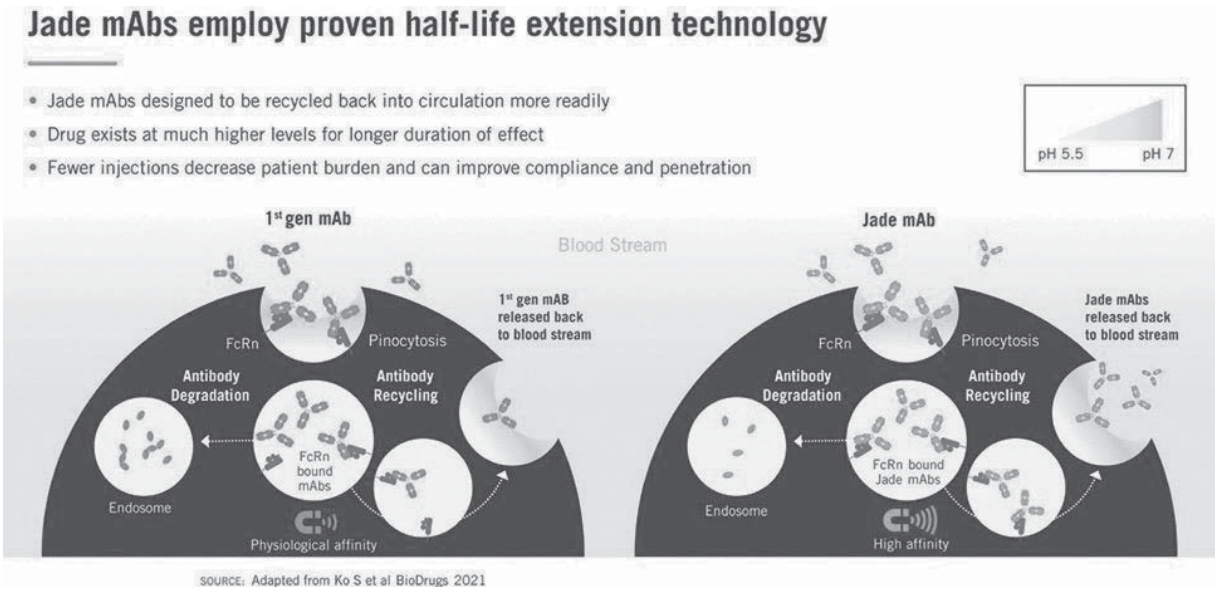

Figure 8. Illustration of a mAb without YTE half-life extension technology compared to Jade antibodies that employ YTE half-life extension technology.

While the half-life of an immunoglobulin G antibody is typically a few weeks, antibodies that are engineered with YTE half-life extension amino acid substitutions have half-lives that have been observed to be up to four-fold longer. Nirsevimab, a YTE-modified anti-RSV antibody marketed as Beyfortus by Sanofi, has a half-life of 59 days in infants. APG777, a YTE-modified anti-IL-13 antibody in development for atopic dermatitis, has shown a half-life of approximately 75 days in a Phase 1 clinical trial in healthy volunteers, compared to an approximately 25 day half-life shown by lebrikizumab in an earlier trial in healthy volunteers, a non-half-life extended anti-IL-13 antibody. ORKA-001, a YTE-modified mAb targeting IL-23p19 in development for plaque psoriasis, has an extended half-life of approximately 100 days in a Phase 1 trial in healthy volunteers, greater than three times that of riskankizumab.

In a single-dose study in NHPs dosed with JADE101, a more than three-fold increase in half-life was observed when compared to sibeprenlimab (manufactured based on published data).

We believe that the extended half-life observed in NHPs with JADE101 has the potential to carry over into clinical development, as the half-life of other antibodies in NHPs, including those engineered to have extended half-lives, correlates with that observed in humans.

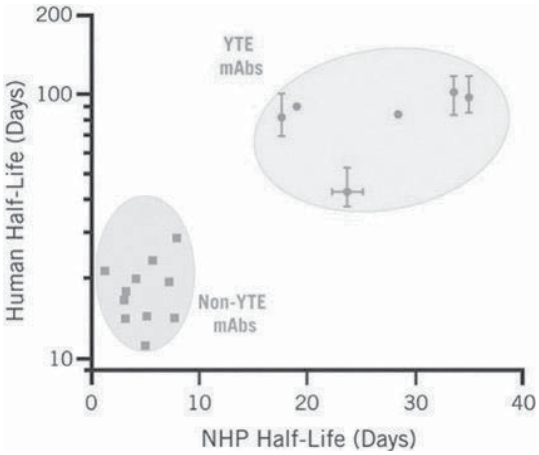

Figure 9. Clinical stage YTE mAbs and non-YTE mAbs demonstrate half-life extension in both NHPs and humans.

Opportunity for JADE101 to have differentiated clinical activity

Compared to existing anti-APRIL mAbs in clinical development, two features of JADE101, its increased potency and half-life extension, have the potential to deliver improved dosing and convenience, a comparable safety profile and potentially increased clinical activity in IgAN. In a third-party Phase 2 trial, a clear increase in clinical remission with higher doses of intravenously administered sibeprenlimab was observed. At the highest dose of 8 mg/kg, 26% of patients were observed to be in clinical remission at 12 months, defined as proteinuria of less than 0.3 g/day.

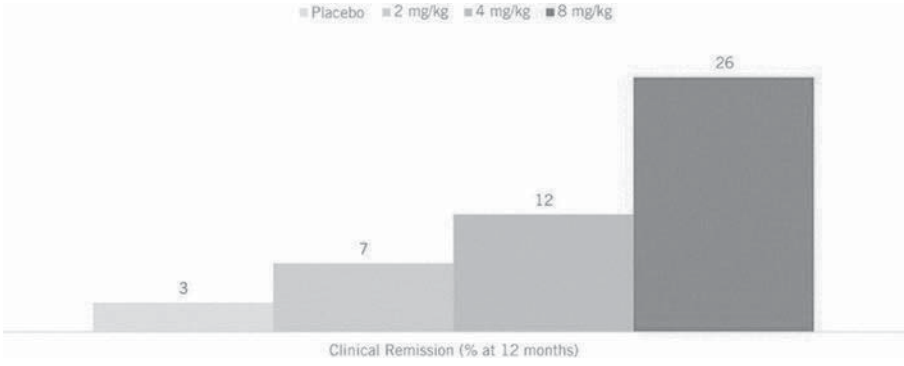

Figure 10. A dose-response in IgAN remission was observed in a Phase 2 trial of sibeprenlimab.

Furthermore, the highest rates of clinical remission at the highest 8 mg/kg intravenous dose were accompanied by the deepest levels of APRIL suppression.

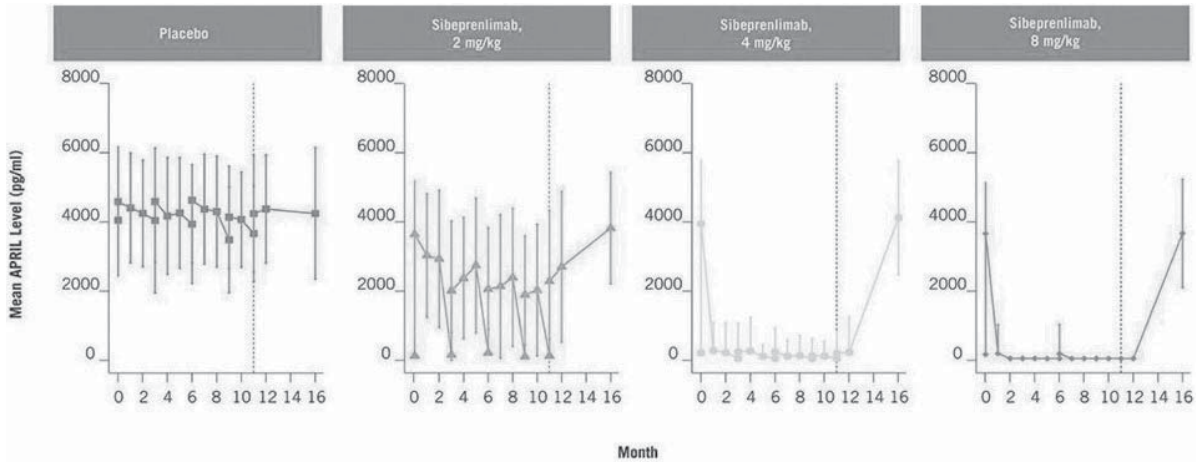

Figure 11. The 8 mg/kg dose of sibeprenlimab demonstrated the deepest level of APRIL suppression in a third-party Phase 2 trial.

In the Phase 3 clinical trial of sibeprenlimab, a trial known as VISIONARY, the dosing regimen was changed from weight-based intravenous administration to a fixed subcutaneous dose of 400 mg administered every four weeks. Based on a single ascending dose trial with subcutaneous administration, the bioavailability of sibeprenlimab was reported to be approximately 75% of that observed in intravenous administration. Based on the average adult IgAN weight of approximately 85 kg reported in third-party global Phase 3 IgAN trials, we estimate that a subcutaneous dose of 400 mg would roughly correspond to an intravenous dose of less than 4 mg/kg in an average IgAN patient, a dose that did not maximally suppress APRIL or provide the highest levels of clinical activity. A body weight range of approximately 45 to 125 kg (95% confidence interval) has been reported in global third-party Phase 3 IgAN trials. For the higher body weight patients, the Phase 3 dosing regimen for sibeprenlimab would correspond to well below 4 mg/kg. JADE101's increased potency, improved exposure through half-life extension and femtomolar affinity may provide an opportunity for patients to obtain incremental clinical benefit.

We believe that the longer half-life of JADE101 has the potential to require less frequent dosing and lead to potentially higher clinical activity as therapeutic levels of the antibody are expected to be maintained in a patient's body for longer periods of time, as compared to other existing agents. Delivering improved clinical benefit with less frequent dosing would be less burdensome for IgAN patients and may also ultimately result in improved outcomes through better adherence.

Potential mechanism of action validation in a Phase 1 trial in healthy volunteers

Third-party clinical data generated with both anti-APRIL antibodies and TACI fusion proteins provides strong support for the value of Phase 1 clinical data to signal the clinical activity of these product candidates in IgAN patients. The ability to suppress IgA production in healthy volunteers has been shown to closely correlate with the ability to reduce IgA levels in IgAN patients. Furthermore, the level of reduction in IgA levels in IgAN patients correlates with improvements in kidney function, as measured by parameters such as UPCR. Based on these observations, reduction in IgA levels in healthy volunteers may serve as an early surrogate for IgAN clinical efficacy; in addition, such reduction serves as a critical validation for clinical development of candidates in IgAN. UPCR in IgAN patients was the basis for accelerated approval of budesonide, sparsentan, iptacopan,

sibeprenlimab, and atrasentan. In addition, Phase 1 clinical data may also characterize other pharmacokinetic properties such as half-life extension, subcutaneous bioavailability and immunogenicity.

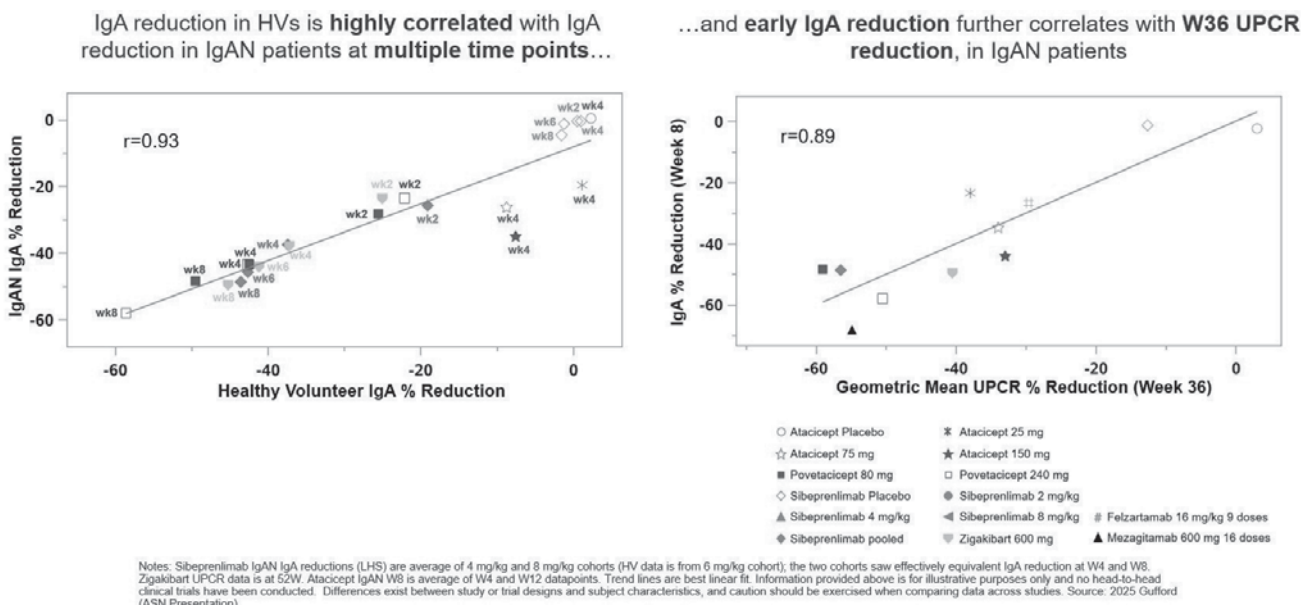

Figure 12. IgA reduction in healthy volunteers is a critical event for clinical development in IgAN.

JADE101 Development

Phase 1 Trial in Healthy Volunteers

In August 2025, we initiated a Phase 1 clinical trial of JADE101 in healthy volunteers in New Zealand. The JADE101 Phase 1 trial is a double-blind, placebo-controlled trial in healthy volunteers consisting of four cohorts in a single-ascending dose ("SAD") design. Eight healthy volunteers, six treated with JADE101 and two treated with placebo, were enrolled in each cohort, for a total of 32 healthy adult subjects in the trial. The primary endpoints are safety and tolerability, and secondary endpoints include pharmacokinetics, pharmacodynamics, including APRIL, IgA, and other immunoglobulin levels, and immunogenicity. We expect interim results to be available in the second quarter of 2026.

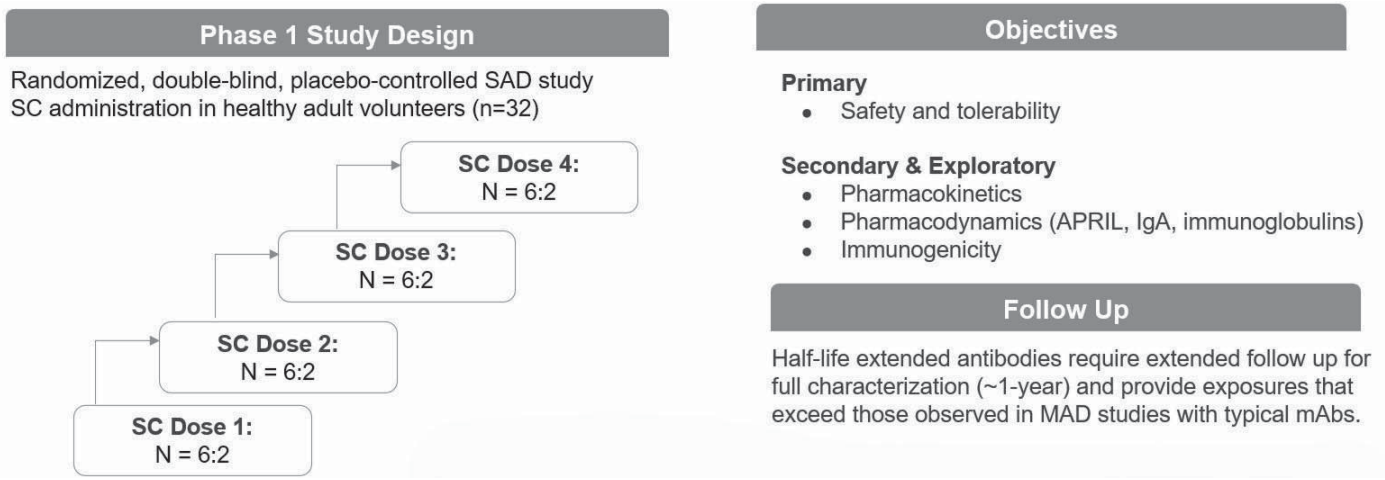

Figure 13. JADE101 Phase 1 healthy volunteer trial design. SAD = single ascending dose, SC = subcutaneous, MAD = multiple ascending dose.

We expect to initiate an open-label Phase 2 clinical trial in IgAN patients in the middle of 2026, with interim data expected in 2027.

IgAN market opportunity

A retrospective study of over 2,200 biopsy-confirmed IgAN patients in the United Kingdom found that, in over 70% of cases, decline in kidney function was not well-controlled, putting patients at risk for developing ESKD. Given the number of supportive care therapies prescribed to patients off-label, and the commercial success of only recently launched, non-disease modifying branded agents Tarpeyo and Filspari that have yet to achieve full market penetration, we believe that there is a meaningful market opportunity for a safe and effective therapeutic in IgAN in the United States. Much like other autoimmune markets, the IgAN market is expected to grow rapidly as new, more effective, potentially disease-modifying products are approved. We estimate a U.S. total addressable market opportunity of approximately $20 billion based on the current estimated number of approximately 169,000 IgAN patients, 60 - 75% of which have persistent proteinuria and would be eligible for new, disease-modifying therapies, and pricing that is comparable to existing therapies. As a reference, Voyxact, which was approved by the FDA in November 2025, is estimated to cost between $360,000 and $390,000 annually.

Expansion opportunities for JADE101

We believe targeting APRIL may have patient benefit in other autoimmune disorders. We are evaluating the feasibility of initiating a clinical trial in 2027 to explore JADE101 in one or more of these disorders.

JADE201

Background on B Cell Depletion in Autoimmune Disease

B cell depletion has been shown to be a validated approach in multiple autoimmune diseases. However, these therapies have important limitations:

- They often achieve incomplete B cell depletion, sparing pathogenic autoreactive B cells in circulation and lymphoid and target organ tissues.
- Residual B cells in secondary lymphoid tissues and/or ineffective depletion of B cells in ectopic lymphoid tissues after treatment.
- Resistance and relapse risk as a result of elevated BAFF signaling that drives B cell repopulation and autoreactivity. Resistance mechanisms, particularly elevated BAFF after anti-CD20 therapy, enable autoreactive B cells to repopulate, undermining durability.
- Some B cell depleting therapies, such as rituximab, are administered through intravenous infusions, which are inconvenient for patients.

Our Solution: JADE201

JADE201 is a half-life extended, afucosylated, anti-BAFF-R mAb designed to work through a dual mechanism of action that directly addresses the key limitations of earlier B cell depletion strategies:

- ***Direct cytotoxicity through enhanced effector function***. Afucosylation increases affinity between JADE201 and immune cell receptors, driving stronger antibody-dependent cellular cytotoxicity (“ADCC”) activity, which is expected to enable potent, deep and sustained depletion of BAFF-R–expressing B cells.
- ***Pharmacologically blocking BAFF signaling by blocking the BAFF receptor***. This process cuts off the compensatory response to upregulation of BAFF that typically follows B cell depletion. This additional mechanism is anticipated to be impactful where ADCC cannot be effectively engaged due to low receptor expression or in settings with sparse availability of effector cells, including NK cells. Blockade of BAFF will act to reduce B cell activation, proliferation, and inflammatory responses, and can ultimately drive B cell death, through starvation from this important pro-survival signal.

We believe this dual mechanism may enable JADE201 to be well-suited for targeting tissue-resident B cells in lymphoid tissues and ectopic germinal centers, where autoreactivity is established and drives disease. Ianalumab, an afucosylated anti-

BAFF-R being developed by Novartis, provided proof-of-concept in multiple clinical trials for overcoming these barriers, including clinical tissue B cell depletion.

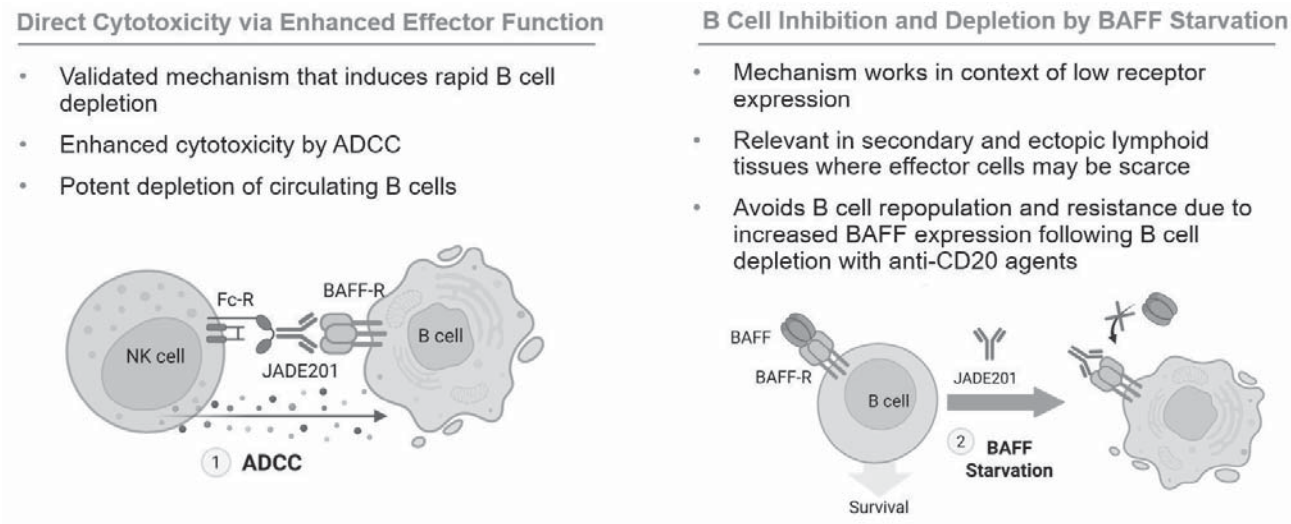

Figure 14. JADE201 mechanism of action.

JADE201 was designed to exhibit the pharmacologic properties of ianalumab, such as its high BAFF-R affinity and enhanced ADCC activity to deplete BAFF-R expressing B cell sub-populations. However, ianalumab has a relatively short human half-life of only ten days. We designed JADE201 to incorporate half-life extension to mitigate this limitation. These attributes provide the opportunity for extended receptor occupancy with the goal of delivering deeper, more durable B cell depletion with less frequent subcutaneous dosing. JADE201 incorporates glycoengineering to generate an afucosylated mAb to increase affinity between JADE201 and immune cell receptors, enabling enhanced ADCC mediated B cell depletion. JADE201 also contains the half-life extending LS modification in the Fc region to increase affinity to FcRN, promoting antibody recycling and an extended pharmacokinetic exposure.

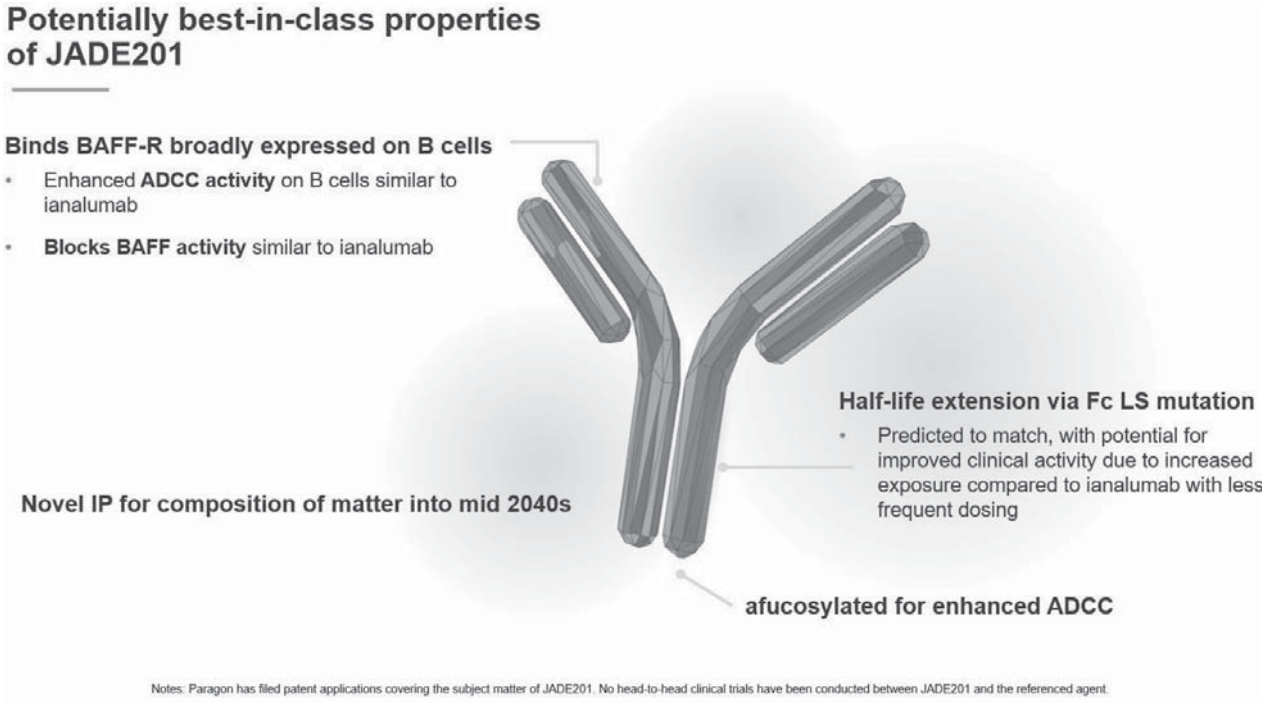

Figure 15. Design of JADE201.

JADE201 Preclinical profile

High BAFF-R binding affinity and functional activity in preclinical studies

Our preclinical data show that JADE201 successfully retained the desirable pharmacologic attributes of ianalumab, including its high affinity BAFF-R binding and blockade, with EC_{50} values in line with ianalumab across multiple assays, suggesting that the addition of half-life extension did not compromise target binding or potency.

JADE201 also maintained effector function mediated B cell depletion in preclinical studies. We observed robust ADCC in both primary human B cells and the Raji B cell line. Importantly, binding to Fc receptors and C1q was preserved, ensuring effector functions were retained, despite the LS Fc modification.

Taken together, these data validate JADE201 as a high affinity anti-BAFF-R mAb with enhanced ADCC activity that is designed to preserve ianalumab's proven biology, while successfully incorporating half-life extension into the antibody design. We believe this results in an optimized next-generation molecule designed to maintain potency and activity while potentially improving durability and patient convenience.

As shown in Figure 16 below, JADE201 successfully retained the high affinity BAFF-R binding of ianalumab, with EC_{50} values in line with ianalumab in human embryonic kidney ("HEK") cells.

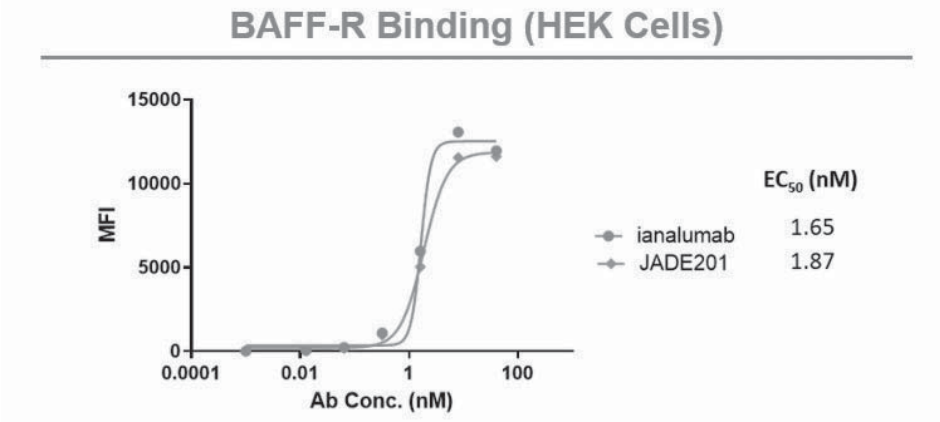

Figure 16. Preclinical BAFF-R binding in HEK cells. MFI = mean fluorescence intensity, Ab Conc. = antibody concentration

As shown in Figure 17 below, JADE201 successfully retained its high affinity BAFF-R blockade in a competition ELISA assay, with IC_{50} values in line with ianalumab.

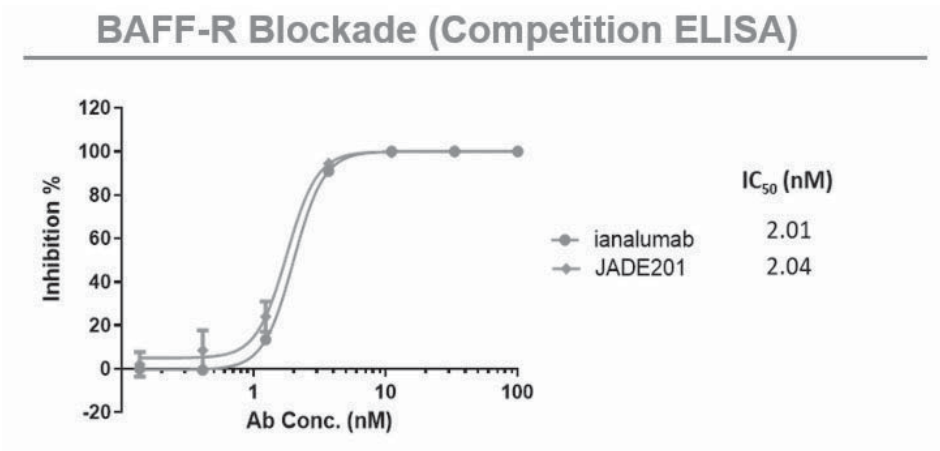

Figure 17. Preclinical BAFF-R blockade in a competition ELISA assay.

As shown in Figure 18 below, JADE201 also maintained effector function mediated B cell depletion. We observed robust ADCC in primary human B cells.

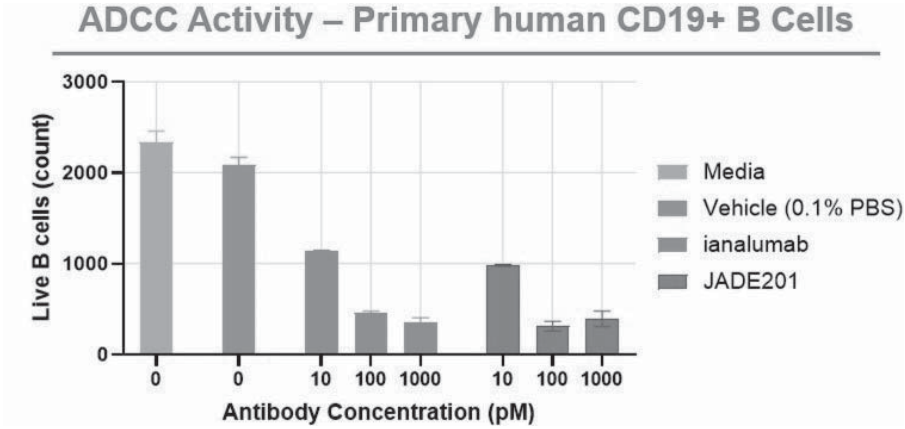

Figure 18. Preclinical ADCC activity in human CD19+ B cells.

Proof of concept of JADE201 in pharmacokinetic and pharmacodynamic results from NHPs

As shown in Figure 19, pharmacokinetics in NHPs were roughly dose-proportional across a wide range of doses from 0.001 to 10 mg/kg intravenously.

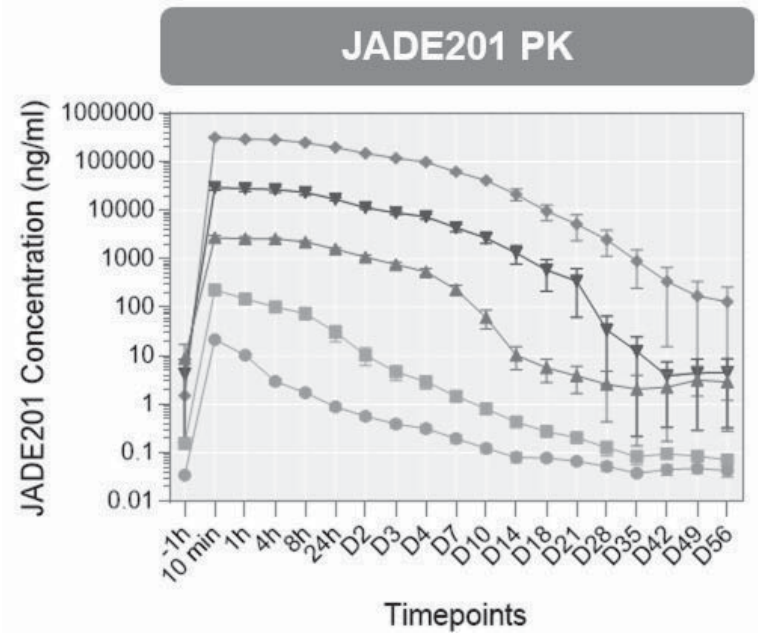

Figure 19. Preclinical pharmacokinetic results of JADE201 in NHPs.

As shown in Figure 20 below, measures of BAFF-R occupancy were assessed, showing dose-dependent BAFF-R occupancy, both in terms of magnitude and duration of receptor coverage. Doses of one milligram per kilogram and higher approached complete BAFF-R occupancy.

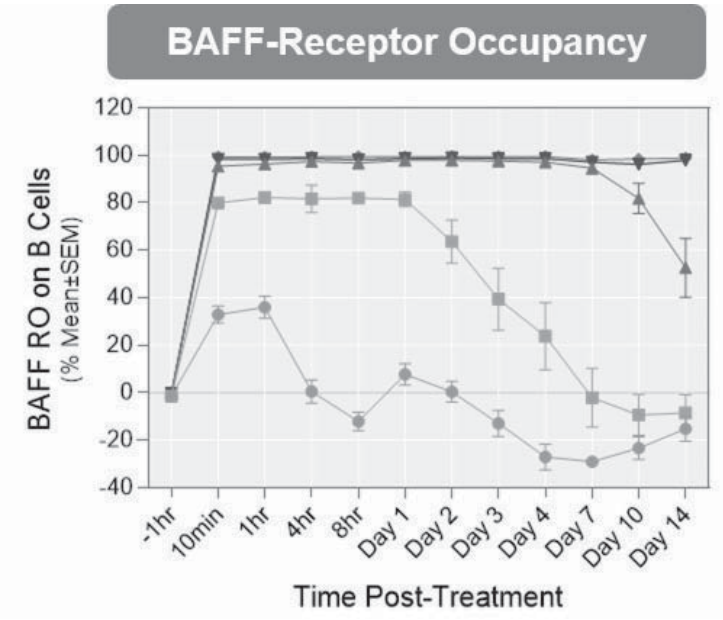

Figure 20. Preclinical BAFF-receptor occupancy in NHPs. RO = receptor occupancy, SEM = standard error of the mean.

As shown in Figure 21 below, a single subcutaneous dose of JADE201 achieved dose-dependent, deep and sustained B cell depletion in NHPs.

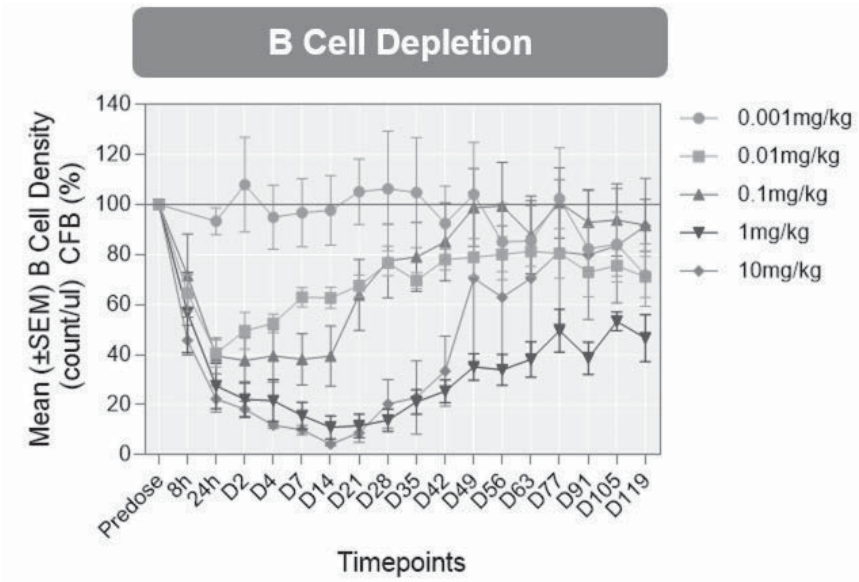

Figure 21. Preclinical B cell depletion in NHPs.

JADE201 has demonstrated extended half-life in NHPs

In head-to-head NHP studies, JADE201 demonstrated an approximately two-fold increase in half-life relative to ianalumab (manufactured based on published data). Ianalumab has a relatively short half-life in humans of approximately 10-days, and

therefore the two-fold half-life increase in JADE201 has the potential to extend the duration of BAFF-R coverage with less frequent dosing.

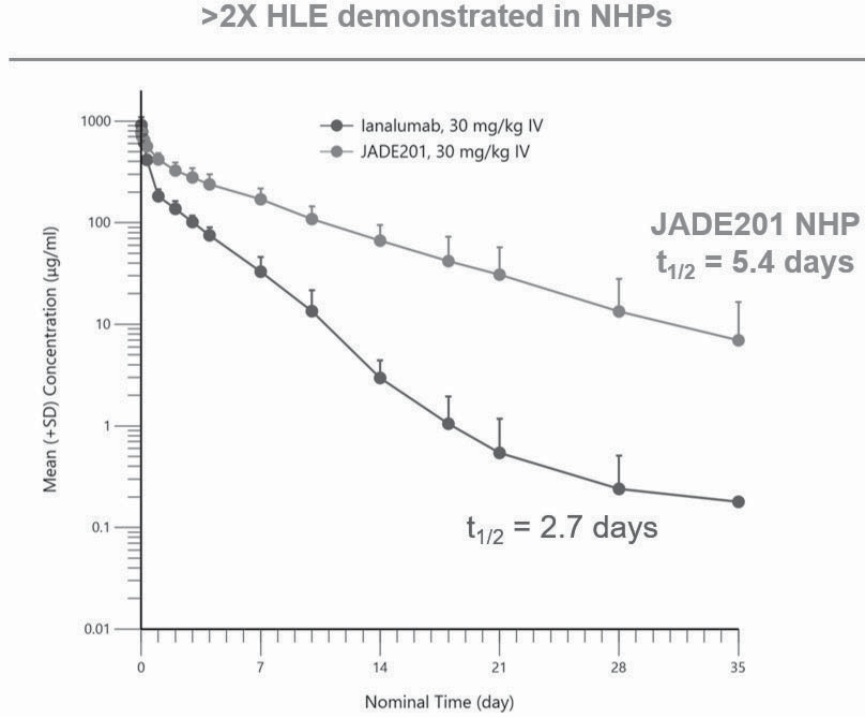

Figure 22. Pharmacokinetic data of JADE201 and ianalumab in NHPs.

JADE201 Development

Planned JADE201 Phase 1 trial in rheumatoid arthritis patients

In the second quarter of 2026, we plan to initiate a Phase 1 trial of JADE201 in rheumatoid arthritis patients. This Phase 1 trial will be a randomized, placebo-controlled, single ascending dose design. The trial aims to establish safety, tolerability, and pharmacokinetics. We will also measure biomarkers such as BAFF-R occupancy, soluble BAFF levels, and immunophenotype B cell subpopulations by flow cytometry to assess the depth and duration of depletion. Because rheumatoid arthritis patients respond rapidly to B cell depletion, we will also incorporate exploratory efficacy measures, such as Disease Activity Score-28

("DAS28") which may provide additional insight into JADE201's therapeutic potential even at this early stage. We expect to report initial clinical data from this trial in 2027.

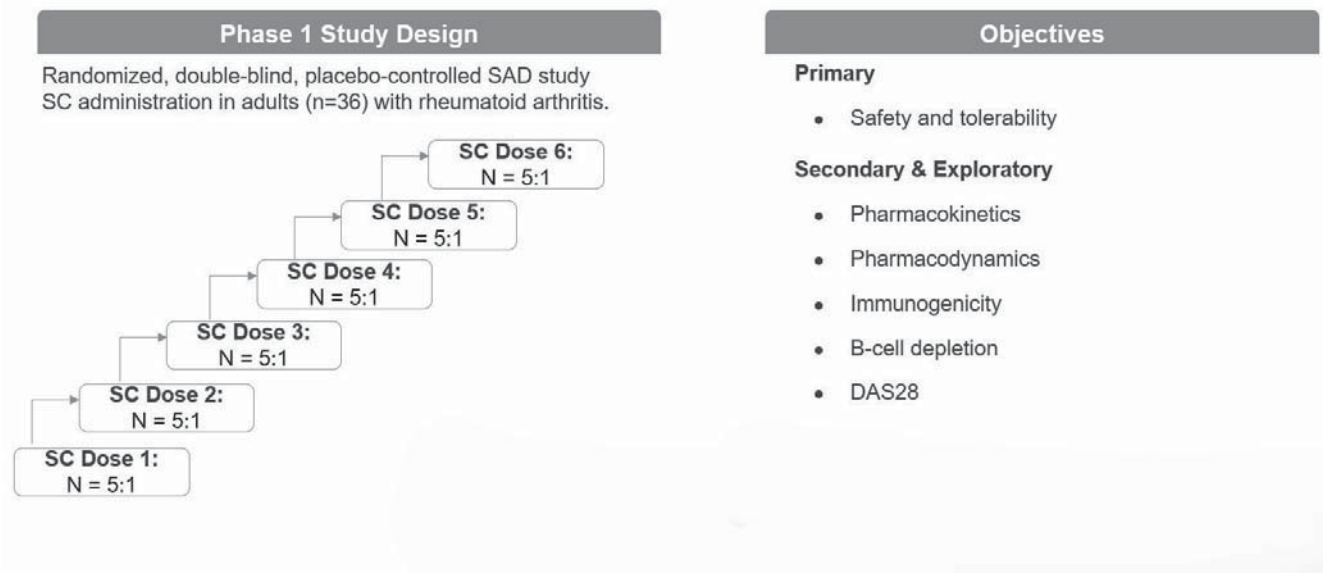

Figure 23. JADE201 Phase 1 trial design. SAD = single ascending dose, SC = subcutaneous

JADE201 future development

As shown in Figure 24, there are many indications across multiple therapeutic areas where B cell dependence is well-validated. We will focus on executing on our Phase 1 trial in patients with rheumatoid arthritis, and assuming positive data from our Phase 1 trial, we will prioritize indications where we believe we can demonstrate the most significant patient benefit. We believe that the total potential addressable market for JADE201 exceeds 17 million patients and $80 billion.

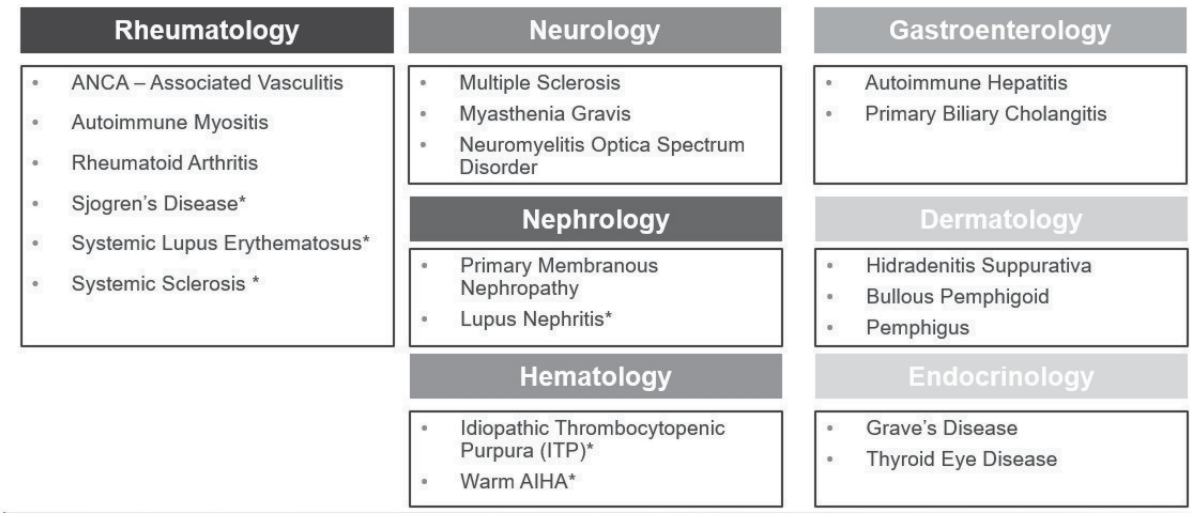

*Figure 24: Potential indications for JADE201. *Ianalumab ongoing phase 3 trial; primary endpoint met in ianalumab Phase 3 trials in Sjogren's Disease and ITP.*

Our pipeline beyond JADE101 and JADE201

In selecting programs to add to our pipeline, we are focused on:

- The potential for a product profile to be best-in-class and best-in-indication.
- The potential for the product to rapidly demonstrate clinical proof-of-concept.

- High unmet need within the indications of interest.

We have an option to exclusively license certain Paragon intellectual property with respect to JADE301, which is a monoclonal antibody against an undisclosed target. We have commenced preclinical development of the JADE301 program, nominated a development candidate and anticipate initiating a Phase 1 clinical trial in healthy volunteers in the first half of 2027. While our initial and primary focus is to in-license product candidates from Paragon, we may also from time to time explore the acquisition or in-licensing of product candidates from other third parties or identify and develop our own product candidates.

Our Collaboration, License and Services Agreements

Paragon Option Agreement

In July 2024, we entered into an Antibody Discovery and Option Agreement (the "Paragon Option Agreement") with Paragon and Parade Biosciences Holding LLC ("Parade"). Under the terms of the agreement, Paragon agreed to perform certain research activities to discover, generate, identify, and characterize antibodies directed to certain mutually agreed therapeutic targets of interest to us (each, a "Research Program"). The Paragon Option Agreement initially included one selected target for JADE101: APRIL. From time to time, we can choose to add additional targets by mutual agreement with Paragon and Parade. The Paragon Option Agreement was amended in September 2024 to, among other things, include a target for each of JADE201 and JADE301.

We, Paragon, and Parade have developed a research plan for each target that includes design, modeling, synthesis, evaluation, and other mutually agreed activities (each, a "Research Plan"). Under the Paragon Option Agreement, we have an exclusive option, on a Research Program-by-Research Program basis, to enter into a separate agreement with Paragon (a "License Agreement") that will include an exclusive, worldwide license to all of Paragon's right, title, and interest in and to the intellectual property resulting from the applicable Research Program to develop, manufacture, and commercialize the monospecific antibodies and products directed to the selected target(s) (an "Option"). The Option with respect to each Research Program is exercisable at our sole discretion at any time during the period beginning on the initiation of activities under the associated Research Program and ending a specified number of days following the delivery of the data package from Paragon related to the results of the Research Program (an "Option Period"). There is no payment due upon exercise of an Option pursuant to the Paragon Option Agreement. We have exercised the Options to acquire the intellectual property rights with respect to JADE101 and JADE201, and we have entered into license agreements with Paragon relating to these candidates. Our Option to acquire the intellectual property rights to JADE301 currently remains unexercised.

Unless terminated earlier, the Paragon Option Agreement shall continue in force on a Research Program-by-Research Program basis until the later of: (i) the end of the Option Period for such Research Program, as applicable, if such Option is not exercised by us; (ii) if we exercise our Option with respect to a Research Program, but the parties are unable to finalize and execute a License Agreement within 30 days, the expiration of such 30-day period (subject to any mutually agreed extension of such period); and (iii) the expiration of the applicable Research Term (as defined under the Paragon Option Agreement). We may terminate the Paragon Option Agreement or any Research Program at any time for any or no reason upon 30 days' prior written notice to Paragon; provided that we must pay certain unpaid fees due to Paragon upon such termination, as well as any non-cancellable obligations reasonably incurred by Paragon in connection with its activities under any terminated Research Program. Paragon may terminate the Paragon Option Agreement or a Research Program immediately upon written notice to us if, as a result of any action or failure to act by us or our affiliates, such Research Program or all material activities under the applicable Research Plan are suspended, discontinued or otherwise delayed for a certain consecutive number of months. Each party has the right to terminate the Paragon Option Agreement or any Research Program upon (i) 30 days' prior written notice of the other party's material breach that remains uncured for the 30-day period and (ii) the other party's bankruptcy.

Upon entering into the Paragon Option Agreement, we were required to pay Paragon an upfront amount of $5.6 million. This amount reflected the actual historical direct costs incurred by Paragon as well as a 20% mark-up on the direct costs to approximate the indirect costs incurred by Paragon from the inception of the APRIL program to the entry into the Paragon Option Agreement. Substantially all of the costs reflected in the upfront amount were incurred by Paragon between January 1, 2024 and the parties' entry into the Paragon Option Agreement, and the remainder of the costs were incurred in the year ended December 31, 2023. Such direct costs were related to research and development activities. Of these upfront research and development costs, a total of $5.5 million was included in our consolidated statement of operations as research and development expense during the period from June 18, 2024 (inception) to December 31, 2024. Paragon had no investments, intangibles, debt, or other assets or liabilities related to the APRIL program aside from standard operating liabilities that were included in the upfront amount we paid to Paragon. Paragon's cash flows related to the APRIL program were operating cash flows and this categorization is consistent with the presentation of R&D expense related cash flows, as presented on our consolidated statement of cash flows.

We are also required to pay Paragon for certain development fees and costs on a Research Program-by-Research Program

basis. Under the Paragon Option Agreement, we are required to pay Paragon a one-time, non-refundable research initiation fee within 30 days following finalization of a Research Plan in the amount of $1.3 million for JADE101 and $1.0 million for each of JADE201 and JADE301. Under the Paragon Option Agreement, on a Research Program-by-Research Program basis, we are required to make one-time non-refundable milestone payments to Paragon of up to a total of $22.0 million upon the achievement of certain clinical development and regulatory milestones. The JADE101, JADE201, and JADE301 respective research plans were all finalized in November 2024. The total amount of $3.3 million of one-time nonrefundable research initiation fees related to our programs was recognized as research and development expense in our consolidated statement of operations and comprehensive loss during the period June 18, 2024 (inception) to December 31, 2024.

We are also required to pay Paragon for certain development fees and costs on a Research Program-by-Research Program basis. Under the Paragon Option Agreement, on a Research Program-by-Research Program basis, we are required to make one-time non-refundable milestone payments to Paragon of up to a total of $22.0 million upon the achievement of certain clinical development and regulatory milestones. For amounts incurred during the periods presented please refer to Note 12 in our financial statements included elsewhere in this Annual Report on Form 10-K.

Upon exercise of the Option with respect to a Research Program, the parties are obligated to use reasonable efforts to finalize and execute a License Agreement within 30 days. Any License Agreement entered into with respect to a given Research Program is expected to be consistent with pre-negotiated terms attached to the Paragon Option Agreement and shall contain the same milestone payment obligations as the Paragon Option Agreement, provided that any milestone set in the Paragon Option Agreement that has not yet been achieved and is duplicated in such License Agreement shall no longer be achievable and payable under the terms of the Paragon Option Agreement and shall only be achievable under the terms of the License Agreement. For the avoidance of doubt, if a milestone is achieved and paid by us pursuant to the Paragon Option Agreement for a certain Research Program, then there shall be no milestone payment due for the achievement of such milestone under a subsequently executed License Agreement for such Research Program. Further, under a License Agreement, we would also be required to make royalty payments to Paragon in the low to mid-single-digit percentage range based on net sales of products, subject to certain reductions. The royalty term will terminate on a product-by-product and country-by-country basis upon the later of the expiration of the last-to-expire valid claim within the relevant patent rights or the twelfth anniversary of the first commercial sale of such product in such country.

Additionally, as part of the Paragon Option Agreement, on December 31, 2025 we granted and on December 31, 2026, we will grant Parade warrants to purchase a number of shares equal to 1.00% of our outstanding capital stock as of the date of the grant on a fully-diluted basis, with an exercise price equal to the fair market value of the underlying shares of our common stock on each respective grant date. Parade is an entity formed by Paragon as a vehicle to hold equity in our company in order to share profits with certain employees of Paragon and will not perform any substantive role under the Paragon Option Agreement other than to receive such warrants.

JADE101 License Agreement

In October 2024, we entered into a License Agreement with Paragon (the "JADE101 License Agreement"), pursuant to which Paragon granted us a royalty-bearing, worldwide, exclusive and sublicensable license to use, make, sell, import, export and otherwise exploit certain monospecific antibodies and products targeting APRIL in the field of prophylaxis, palliation, treatment and diagnosis of human disease and disorders in all therapeutic areas (the "field"). Among other rights, Paragon specifically granted us a royalty-bearing, worldwide, exclusive and sublicensable license in the field to Paragon's patents covering the antibodies generated under the APRIL Research Plan performed by Paragon under the Option Agreement, and their method of use and method of manufacture. Under the terms of the JADE101 License Agreement, we are obligated to pay Paragon up to $22.0 million based on specific development and regulatory milestones, including a $1.5 million fee for nomination of a development candidate, which was paid in December 2024, and a further milestone payment of $2.5 million upon the first dosing of a human patient in a Phase 1 trial, which was paid in September 2025. On a product-by-product basis, we are obligated to pay sublicensing fees of up to approximately $20.1 million, mainly upon the achievement of commercial milestones. We will pay Paragon a low to mid-single-digit percentage royalty based on annual net sales of monospecific products in the field and in the territory, and a mid-single-digit percentage royalty based on annual net sales of multispecific products in the field and in the territory, subject to a 30% reduction if there is no valid patent covering the product in the country of sale. On a country-by-country basis, the royalty term for a product ends on the later of (i) the twelfth anniversary of the date of first sale of a Company product or (ii) the expiration of the last-to-expire valid patent covering the product in the country at issue.

Paragon will not conduct any new campaigns that generate APRIL monospecific antibodies in the field for at least five years. We and Paragon may pursue the development and commercialization of multispecific antibodies and products directed to APRIL in the field, and we have a right of first negotiation for any such multispecific antibodies and products proposed by Paragon for a period of five years from the execution of the JADE101 License Agreement. The JADE101 License Agreement

may be terminated on 60 days' notice by us; on material breach without cure; and to the extent permitted by law, on a party's insolvency or bankruptcy.

JADE201 License Agreement

In October 2025, we and Paragon entered into a License Agreement (the "JADE201 License Agreement"), pursuant to which Paragon granted us a royalty-bearing, worldwide, exclusive and sublicensable license to use, make, sell, import, export and otherwise exploit certain antibodies and products targeting BAFF-R in the field. Among other rights, Paragon specifically granted us a royalty-bearing, worldwide, exclusive and sublicensable license in the field to Paragon's patents covering the antibodies generated under the BAFF-R Research Plan performed by Paragon under the Option Agreement, and their method of use and method of manufacture. Under the terms of the JADE201 License Agreement, we are obligated to pay Paragon up to $22.0 million based on specific development, regulatory and clinical milestones for our first monospecific product to reach such milestones, including a $1.5 million fee for nomination of a development candidate, which was paid in April 2025, and a further milestone payment of $2.5 million upon the first dosing of a human patient in a Phase 1 trial. We will pay Paragon a low to mid-single-digit percentage royalty based on annual net sales of monospecific products in the field, subject to a 30% reduction if there is no valid patent covering the product in the country of sale. On a country-by-country basis, the royalty term for a monospecific product ends on the later of (i) the twelfth anniversary of the date of first sale of the monospecific product or (ii) the expiration of the last-to-expire valid patent covering the monospecific product in the country at issue.

Paragon will not conduct any new campaigns that generate anti-BAFF-R monospecific antibodies in the field for at least 5 years. Paragon may pursue the development and commercialization of multispecific antibodies and products directed at the BAFF-R target in the field, subject to certain rights held by us, and we have a right of first negotiation for any such multispecific antibodies and products proposed by Paragon for a period of five years from the execution of the JADE201 License Agreement. . Jade is obligated to pay Paragon up to $24.0 million based on specific development, regulatory and clinical milestones for each Jade multispecific product to reach such milestones and will pay Paragon a mid-single-digit percentage royalty based on annual net sales of all Jade multispecific products in the field, subject to a 30% reduction if there is no valid patent covering the product in the country of sale. On a country-by-country basis, the royalty term for a multispecific product ends on the later of (i) the twelfth anniversary of the date of first sale of the multispecific product or (ii) the expiration of the last-to-expire valid patent covering the multispecific product in the country at issue. The JADE201 License Agreement may be terminated on 60 days' notice by us; on material breach without cure; and to the extent permitted by law, on a party's insolvency or bankruptcy.

Wuxi Master Services Agreement

In February 2025, we entered into an amended and restated biologics master services agreement (the "WuXi Biologics MSA") with WuXi Biologics (Hong Kong) Limited ("WuXi Biologics (Hong Kong)"). The WuXi Biologics MSA governs certain development activities and current good manufacturing practice ("cGMP") manufacturing and testing for our programs, on a non-exclusive, work order basis. Under the WuXi Biologics MSA, we are obligated to pay WuXi Biologics (Hong Kong) a service fee and all non-cancellable obligations in the amount specified in each work order associated with the agreement for the provision of services. WuXi Biologics (Hong Kong) is obligated to, among other things, (i) perform manufacturing services in accordance with applicable standards and law using personnel with appropriate qualifications, and to manufacture product in accordance with cGMP, (ii) comply with confidentiality and invention assignment provisions, (iii) notify us of regulatory visits or inspections and provide redacted copies of any report or written communication received from such authorities in connection therewith and (iv) assign to us all right, title and interest in to all intellectual property created or developed in connection with the provision of the services, and all intellectual property relating to such inventions, subject to certain exceptions.

The WuXi Biologics MSA terminates on the later of (i) February 3, 2030, or (ii) the completion of services under all work orders executed by the parties prior to February 3, 2030, unless terminated earlier. The term of each work order terminates upon completion of the services under such work order, unless terminated earlier. We can terminate the WuXi Biologics MSA or any work order (i) at any time upon 30 days' prior written notice, (ii) immediately upon written notice if WuXi Biologics (Hong Kong) fails to obtain or maintain required material governmental licenses or approvals or (iii) immediately upon written notice in the event that any law is enacted that has, or could be reasonably expected to have, a material adverse effect on us or any product of ours that is the subject of the WuXi Biologics MSA, in each case, as a result of WuXi Biologics (Hong Kong) providing services under the WuXi Biologics MSA or us being a party to the WuXi Biologics MSA. Either party may terminate a work order (i) at any time upon six months' prior notice with reasonable cause, provided however that if WuXi Biologics (Hong Kong) terminates a work order in such manner, no termination or cancellation fees shall be paid by us and (ii) immediately for cause upon (a) the other party's material breach that remains uncured for 30 days after notice of such breach, (b) the other party's bankruptcy or (c) a force majeure event that prevents performance for a period of at least 90 days.

Patheon Master Services Agreement

In June 2025, we entered into a master services agreement (the "Patheon MSA") with Patheon Biologics LLC, a brand of Thermo Fisher Scientific, Inc. ("Patheon"). The Patheon MSA governs certain development activities and cGMP manufacturing and testing for JADE101, as well as future Company programs, on a non-exclusive, project agreement basis. Under the Patheon MSA, the Company is obligated to pay Patheon certain service fees and non-cancellable obligations in the amount specified in each project agreement executed under the Patheon MSA for the provision of services. Patheon is obligated to, among other things, (i) perform manufacturing services in accordance with applicable standards, laws, and instructions, including cGMP where applicable, (ii) comply with confidentiality and invention assignment provisions, (iii) notify the Company of regulatory visits or inspections and (iv) assign to the Company all right, title and interest in and to intellectual property created or developed in connection with the provision of the services, and intellectual property relating to such inventions, subject to certain exceptions. The Patheon MSA has an initial term of five years and automatically renews for additional three year periods unless either party gives notice of non-renewal before the end of the then-existing term. The term will extend (even if notice of non-renewal has been given) to allow for completion of services under any active project agreement. Unless the parties otherwise agree in a particular project agreement, the term of each project agreement shall commence on execution by both parties and terminate upon completion of the services thereunder. Notwithstanding the foregoing, the Company can terminate any project agreement upon prior written notice to Patheon for any business reason, subject to certain specified cancellation fees if applicable. In addition, either may terminate a project agreement in the event of bankruptcy or insolvency, uncured material breach or a force majeure event that prevents performance of a pending project agreement.

Cell Line License Agreement

On February 3, 2025, we entered into an amended and restated cell line license agreement (the "Cell Line License Agreement") with WuXi Biologics Ireland Limited ("WuXi Biologics Ireland"). Under the Cell Line License Agreement, we received a non-exclusive, worldwide, sublicensable license to certain of WuXi Biologics Ireland's patent rights, know-how, cell line, biological materials and media and feeds to develop, manufacture, have manufactured, make, have made, import, sell, keep, commercialize and otherwise deal in, use and exploit certain therapeutic products produced through the use of the cell lines licensed by WuXi Biologics Ireland under the Cell Lines License Agreement (the "WuXi Biologics Ireland Licensed Products"). JADE101 is, and we anticipate that JADE201 will be, manufactured using a cell line licensed under the Cell Line License Agreement. A cell line has not yet been selected for JADE301.

In consideration for the license, we incurred a non-refundable license fee of $0.2 million and may incur additional non-refundable license fees of up to $0.1 million. Additionally, if we manufacture all of our commercial supplies of bulk drug product for a particular product with a manufacturer other than WuXi Biologics Ireland or its affiliates, we are required to make royalty payments to WuXi Biologics Ireland in an amount equal to a fraction of a single digit percentage of global net sales of the WuXi Biologics Ireland Licensed Products manufactured by a third-party manufacturer (the "Royalty"). If we manufacture part of our commercial supplies of the WuXi Biologics Ireland Licensed Products with WuXi Biologics Ireland or its affiliates, then the Royalty will be reduced accordingly on a pro rata basis. We have the option, at any time, to pay WuXi Biologics Ireland a non-refundable lump-sum royalty buyout payment on a drug product-by-drug product basis to extinguish future Royalty obligations with respect to such drug product.

The Cell Line License Agreement will continue indefinitely unless terminated (i) by us upon six months' prior written notice and our payment of all undisputed amounts due to WuXi Biologics Ireland through the effective date of termination, (ii) by either party for a material breach by the other party that remains uncured for 60 days after written notice, (iii) by WuXi Biologics Ireland if we fail to make a payment and such failure continues for 30 days after receiving notice of such failure, or (iv) by either party upon the other party's bankruptcy.

Competition

The biotechnology and biopharmaceutical industries are characterized by continuing technological advancement and significant competition. While we believe that our programs, technology, development experience and scientific knowledge provide us with competitive advantages, we face competition from major pharmaceutical and biotechnology companies, academic institutions, governmental agencies and public and private research institutions, among others. Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies currently in clinical development or that may become available in the future. Many of the companies with which we are currently competing or will compete against in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industry may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors,

particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites, patient enrollment for clinical trials as well as in acquiring technologies complementary to, or necessary for, our programs.

Key competitive factors affecting the success of all our product candidates, if approved, are likely to be efficacy, safety, convenience, dosing frequency, presentation, price, the level of competition and generic competition and the availability of reimbursement from government and other third-party payors. Some competitors have obtained regulatory approval for products and they or others may in the future also obtain regulatory approvals for products with similar or different mechanisms of action as compared with our product candidates more rapidly than we may obtain approval for our product candidates, which may result in our competitors establishing a strong market position before we are able to enter the market.

Specifically, there are several companies developing or marketing treatments that may be approved for the same indications and/or disease as our most advanced product candidate, JADE101, including major pharmaceutical companies, some of which use the same mechanism of action as JADE101. We have not yet completed clinical trials for any of our programs and there can be no assurance that our programs will have similar or superior results.

There is one biologic approved for the treatment of IgAN, sibeprenlimab, which is marketed as Voyxact by Otsuka. There are four small molecule drugs that have been approved: Tarpeyo, Filspari, Fabhalta and Vanrafia. None of these small molecule drugs are disease modifying. As a result, each provides only relatively modest reductions in proteinuria relative to control and neither has been shown to stabilize kidney function as eGFR continues to decline while on treatment. Tarpeyo is approved for a 9-month treatment course, due to the risk of significant adverse effects associated with long-term steroid use. While results from Fabhalta provide support for the ability of anti-inflammatory drugs to reduce the rate of IgAN kidney damage, anti-inflammatory drugs do not target overproduction of pathologic IgA, the primary cause of the disease. The treatment paradigm in IgAN is rapidly evolving and several companies, including Novartis, Vera Therapeutics, and Vertex, are developing therapeutics for IgAN currently in late-stage clinical development that are expected to be disease modifying in IgAN and direct competitors with JADE101. Climb Bio is also developing a therapeutic for IgAN that is currently in early clinical development and that is also a direct competitor with JADE101.

We do not yet have clinical data for JADE101 for the treatment of IgAN and there can be no assurance that our programs will have similar or superior results to those offered by the existing and evolving treatment landscape.

Manufacturing and Supply

We do not own or operate, and currently have no plans to establish, any manufacturing facilities. All of our preclinical and clinical drug supply development, manufacturing, storage, distribution and testing are outsourced to third-party manufacturers and facilities. We believe our manufacturing strategy enables us to more efficiently direct financial resources to the research, development and commercialization of programs rather than diverting resources to internally develop and maintain manufacturing facilities. As our programs advance through development, we expect to enter into longer-term commercial supply agreements with key suppliers and manufacturers to fulfill and secure our supply needs.

Intellectual Property

Overview

We strive to protect the proprietary programs and technologies that we believe are important to our business, including seeking and maintaining patent protection intended to cover the composition of matter of our programs, our methods of use and manufacture, and other inventions.

We and Paragon have filed patent applications directed to anti-APRIL antibodies and Paragon has filed patent applications directed to antibodies targeting BAFF-R and provisional patent applications directed to the target of JADE301, including applications covering composition of matter. We hold a license from Paragon to the patent applications directed to JADE101 and JADE201, and an exclusive option to license the patent applications Paragon has filed with respect to JADE301. A provisional patent application is an application filed in the USPTO for the purpose of securing a date of priority for the applicant's invention. The provisional application must include a written description of what the inventor has discovered, along with a drawing of the invention, but need not include patent claims, statements concerning or disclosing the prior art, or certain other formalities. A provisional patent application allows for an effective filing date to be established with regard to an invention, but once a provisional patent application is filed, either a corresponding non-provisional patent application or a petition to convert the provisional patent application into a non-provisional patent application must be filed within 12 months or such effective filing date will be lost.

The maximum term of a U.S. patent, excluding extensions and adjustments, begins on the effective filing date of the first non-provisional application claiming the patented invention and ending 20 years from that date. In essence, a provisional patent application provides a patent applicant two principal advantages over filing a non-provisional application. First, it allows the applicant to secure an earlier priority date for its invention than that of an equivalent non-provisional application — up to one year earlier than the filing date of a related non-provisional application. Second, since the term of a patent runs from the effective filing date of the first non-provisional application but does not begin upon filing a provisional application, filing a provisional application provides the applicant an additional year's time to refine that invention before filing a related non-provisional application without surrendering the earlier priority date. Securing an earlier priority date both ensures that later inventors cannot obtain a patent to the same invention and provides protection against certain arguments that developments in the field arising after the priority date should prevent or invalidate the applicant's invention.

If the non-provisional patent applications filed with respect to JADE101 and JADE201 result in issued patents, such patents are expected to expire in 2045 and 2046, respectively, without taking potential patent term adjustment or patent term extension into consideration and assuming payment of appropriate maintenance, renewal, annuity and other governmental fees. If we or Paragon timely file non-provisional patent applications in the United States and in countries outside of the United States with regard to the JADE301 provisional patent applications and these non-provisional patent applications result in issued patents, such patents are expected to expire in 2046, without taking potential patent term adjustment or patent term extension into consideration and assuming payment of appropriate maintenance, renewal, annuity and other governmental fees.

Patent Term Extension

In the United States, after a BLA is approved, owners of relevant drug patents may apply for up to a five-year patent extension, which permits patent term restoration as compensation for the patent term lost during the FDA regulatory process. The allowable patent term extension is typically calculated as one-half the time between (1) the later of (a) the effective date of an Investigational New Drug Applicable ("IND") and (b) issue date of the patent for which extension is sought, and (2) the submission date of a BLA, plus the time between BLA submission date and the BLA approval date, up to a maximum of five years. The time can be shortened if the FDA determines that the applicant did not pursue licensure with due diligence. The total patent term after the extension may not exceed 14 years from the date of product licensure. Only one patent applicable to a licensed biological product is eligible for extension and only those claims covering the product, a method for using it, or a method for manufacturing it may be extended, and the application for the extension must be submitted prior to the expiration of the patent in question. However, we may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Some, but not all, foreign jurisdictions possess patent term extension or other additional patent exclusivity mechanisms that may be more or less stringent and comprehensive than those of the United States.

Other IP Rights

In addition to patents, we rely upon unpatented trade secrets, know-how and continuing technological innovation to develop and maintain our competitive position. However, trade secrets and know-how can be difficult to protect. We seek to protect our proprietary information, in part by executing confidentiality agreements with our collaborators and scientific advisors, and non-competition, non-solicitation, confidentiality and invention assignment agreements with our employees and consultants. We have also executed agreements requiring assignment of inventions with selected scientific advisors and collaborators. The confidentiality agreements we enter into are designed to protect our proprietary information and the agreements or clauses requiring assignment of inventions to us are designed to grant us ownership of technologies that are developed through our relationship with the respective counterparty. We cannot guarantee, however, that we have executed such agreements with all applicable counterparties, that such agreements will not be breached, or that these agreements will afford us adequate protection of our intellectual property and proprietary rights. For more information, please see the section titled "*Risk Factors—Risks Related to Our Intellectual Property*" in this Annual Report on Form 10-K.

Employees and Human Capital Resources

As of December 31, 2025, we had 55 full-time employees, 15 of whom have Ph.D. or M.D. degrees and are engaged in research and development. We also retain independent contractors, as needed, to support our organization's needs. None of our employees are represented by labor unions or covered under collective bargaining agreements. We consider our relationship with our employees to be good.

We believe our employees are critical to our success and ability to achieve our business objectives. To that end, we are focused on retaining, developing and engaging our existing employees, and attracting high performing talent to join our team. Our

rewards package (cash and equity-based compensation and 401(k) and health and welfare benefits plans) is a key tool in retaining, engaging and rewarding our team. We are also committed to the continued learning and development of our employees, which we believe will enable us to do our best work for patients. We encourage our team members to attend conferences and seminars and take continuing education courses to further their development.

We expect to continue to build our team to ensure we can effectively execute against our business plans.

Government Regulation

The FDA and other regulatory authorities at federal, state and local levels, as well as in foreign countries, extensively regulate, among other things, the research, development, testing, manufacture, quality control, import, export, safety, effectiveness, labeling, packaging, storage, distribution, record keeping, approval, advertising, promotion, marketing, post-approval monitoring and post-approval reporting of biologics such as those we are developing. We, along with our third-party contractors, will be required to navigate the various preclinical, clinical and commercial approval requirements of the governing regulatory authorities of the countries in which we conduct studies or seek approval or licensure of our product candidates. Generally, before a new therapeutic product can be marketed, considerable data demonstrating a biological product candidate's quality, safety, purity and potency, must be obtained, organized into a format specific for each regulatory authority, submitted for review and approved by the regulatory authority. For biological product candidates, potency is similar to efficacy and is interpreted to mean the specific ability or capacity of the product, as indicated by appropriate laboratory tests or by adequately controlled clinical data obtained through the administration of the product in the manner intended, to effect a given result.

U.S. Biologics Regulation

In the United States, biological products (or "biologics") are subject to regulation under the Federal Food, Drug, and Cosmetic Act ("FDCA"), the Public Health Service Act ("PHSA") and other federal, state, local, and foreign statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, and local statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or following approval may subject an applicant to administrative action and judicial sanctions.

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

- completion of certain preclinical laboratory tests and animal studies performed in accordance with the FDA's current Good Laboratory Practices ("GLP") regulations;
- submission to the FDA of an IND, which must become effective before clinical trials may begin and must be updated annually or when certain changes are made;
- approval by an independent institutional review board ("IRB"), or ethics committee at each clinical site before the trial is commenced;
- manufacture of the proposed biologic candidate in accordance with cGMPs;
- performance of adequate and well-controlled human clinical trials in accordance with good clinical practice ("GCP") requirements to establish the safety, purity and potency of the proposed biologic product candidate for its intended purpose;
- preparation of and submission to the FDA of a biologics license application ("BLA"), after completion of all pivotal clinical trials;
- a determination by the FDA within 60 days of its receipt of a BLA to file the application for review;
- satisfactory completion of an FDA Advisory Committee review, if applicable;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the proposed product is produced to assess compliance with cGMPs, and to assure that the facilities, methods and controls are adequate to preserve the biological product's continued safety, purity and potency;
- satisfactory completion of potential inspection of selected clinical investigation sites to assess compliance with GCPs; and
- FDA review and approval of a BLA to permit commercial marketing of the product for particular indications for use in the United States.

Preclinical and Clinical Development

Once a product candidate is identified for development, it enters the preclinical testing stage. Preclinical tests generally include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies. Prior to beginning any clinical trial of a product candidate in the United States, we must submit an IND to the FDA. An IND is a request for allowance from the FDA to administer an investigational drug product to humans. The central focus of an IND submission is on the general investigational plan and the protocol or protocols for preclinical studies and clinical trials. The IND also includes results of animal and in vitro studies assessing the toxicology, pharmacokinetics, pharmacology and pharmacodynamic characteristics of the product, chemistry, manufacturing and controls information, and any available human data or literature to support the use of the investigational product. An IND must become effective before human clinical trials in the U.S. may begin. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day period, raises safety concerns or questions about the proposed clinical trial. In such a case, the IND may be placed on partial or full clinical hold and the IND sponsor, and the FDA must resolve any outstanding concerns or questions before the clinical trial can begin. Submission of an IND therefore may or may not result in FDA authorization to begin a clinical trial. Clinical holds also may be imposed by the FDA at any time before or during clinical trials in response to safety concerns or due to non-compliance with specific FDA requirements.

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCPs, which among other things, include the requirement that all research subjects provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol amendments. Furthermore, an independent IRB representing each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and its informed consent form before the clinical trial begins at that site, and must monitor the trial until completed. While the IND is active, progress reports summarizing the results of the clinical trials and nonclinical studies performed since the last progress report, among other information, must be submitted at least annually to the FDA, and written IND safety reports must be submitted to the FDA and investigators for serious and unexpected suspected adverse events, findings from other studies suggesting a significant risk to humans exposed to the same or similar drugs, findings from animal or in vitro testing suggesting a significant risk to humans, and any clinically important increased incidence of a serious suspected adverse reaction compared to that listed in the protocol or investigator brochure.

Regulatory authorities, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk or that the trial is unlikely to meet its stated objectives. Some studies also include oversight by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board, which provides authorization for whether or not a trial may move forward at designated check points based on access to certain data from the trial and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. There are also requirements governing the reporting of ongoing preclinical studies and clinical trials and clinical trial results to public registries.

For purposes of BLA approval, human clinical trials are typically conducted in three sequential phases that may overlap.

- Phase 1. The investigational product is initially introduced into healthy human subjects or patients with the target disease or condition. These studies are designed to test the safety, dosage tolerance, absorption, metabolism and distribution of the investigational product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness.
- Phase 2. The investigational product is administered to a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages and dosing schedule and to identify possible adverse side effects and safety risks.
- Phase 3. The investigational product is administered to an expanded patient population to further evaluate dosage, to provide substantial evidence of clinical efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product labeling.

In some cases, the FDA may require, or companies may voluntarily pursue, additional clinical trials after a product is approved to gain more information about the product within the intended indication. These so-called Phase 4 studies may be made a condition to approval of the BLA.

Concurrent with clinical trials, companies may complete additional animal studies and develop additional information about the biological characteristics of the product candidate, and must finalize a process for manufacturing the product in

commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, must develop methods for testing the identity, strength, quality and purity of the final product, or for biologics, the safety, purity and potency. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

BLA Submission and Review

The results of product development, including results from nonclinical studies and clinical trials, are submitted to the FDA as part of a BLA requesting approval to market the product for one or more indications. The BLA must include all relevant data available from pertinent preclinical studies and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls, and proposed labeling, among other things. Data can come from company-sponsored clinical studies intended to test the safety and effectiveness of the product, or from a number of alternative sources, including studies initiated and sponsored by investigators. The submission of a BLA requires payment of a substantial application user fee to the FDA, unless a waiver or exemption applies.

Within 60 days following submission of the application, the FDA reviews a BLA to determine if it is substantially complete before the FDA accepts it for filing. The FDA may refuse to file any BLA that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the BLA must be resubmitted with the additional information. Once an original BLA has been accepted for filing, the FDA's goal is to review the applications within 10 months after the filing date, or, if the application qualifies for priority review, six months after the FDA accepts the application for filing. In both standard and priority reviews, the review process may also be extended by the FDA to review information deemed a major amendment to the application. The FDA reviews a BLA to determine, among other things, whether a product is safe, pure and potent and the facility in which it is manufactured, processed, packed or held meets standards designed to assure the product's continued safety, purity and potency. During the review, the FDA may convene an advisory committee to provide clinical insight on application review questions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving a BLA, the FDA will typically inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure compliance with GCPs.

After the FDA evaluates a BLA and conducts any required inspections of manufacturing facilities where the investigational product and/or its drug substance will be produced, the FDA may issue an approval letter or a Complete Response letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A Complete Response letter will describe all of the deficiencies that the FDA has identified in the BLA, except that where the FDA determines that the data supporting the application are inadequate to support approval, the FDA may issue the Complete Response letter without first conducting required inspections, testing submitted product lots and/or reviewing proposed labeling. In issuing the Complete Response letter, the FDA may recommend actions that the applicant might take to place the BLA in condition for approval, including requests for additional information or clarification, or requirements to conduct additional clinical studies. If a Complete Response letter is issued, the sponsor must resubmit the BLA addressing all of the deficiencies identified in the letter or withdraw the application. Even if such data and information are submitted, the FDA may decide that the resubmitted application does not satisfy the criteria for approval.

If regulatory approval of a product is granted, such approval will be granted for particular indications and may entail limitations on the indicated uses for which such product may be marketed. For example, the FDA may approve the BLA with a risk evaluation and mitigation strategy ("REMS") to ensure the benefits of the product outweigh its risks. A REMS is a safety strategy to manage a known or potential serious risk associated with a product and to enable patients to have continued access to such medicines by managing their safe use, and could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling or the development of adequate controls and specifications. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing requirements is not maintained or if problems occur after the product reaches the marketplace. The FDA may require one or more

post-market studies and surveillance to further assess and monitor the product's safety and effectiveness after commercialization, and may limit further marketing of the product based on the results of these post-marketing studies.

Expedited Development and Review Programs

The FDA has a number of programs intended to expedite the development or review of a marketing application for an investigational biologic. For example, the fast track designation program is intended to expedite or facilitate the process for developing and reviewing product candidates that meet certain criteria. Specifically, investigational biologics are eligible for fast track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. The sponsor of a fast track product candidate has opportunities for more frequent interactions with the applicable FDA review team during product development and, once a BLA is submitted, the application may be eligible for priority review. With regard to a fast track product candidate, the FDA may consider for review sections of the BLA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the BLA, the FDA agrees to accept sections of the BLA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the BLA.

A product candidate intended to treat a serious or life-threatening disease or condition may also be eligible for breakthrough therapy designation to expedite its development and review. A product candidate can receive breakthrough therapy designation if preliminary clinical evidence indicates that the product candidate, alone or in combination with one or more other drugs or biologics, may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The designation includes all of the fast track program features, as well as more intensive FDA interaction and guidance beginning as early as Phase 1 and an organizational commitment to expedite the development and review of the product candidate, including involvement of senior managers.

A BLA may also be eligible for priority review if the product candidate is designed to treat a serious condition, and if approved, would provide a significant improvement in safety or efficacy compared to available therapies. The FDA will attempt to direct additional resources to the evaluation of a BLA designated for priority review. The FDA endeavors to review applications with priority review designations within six months of the filing date as compared to ten months for review of original BLAs under its current PDUFA review goals.

In addition, depending on the design of the applicable clinical trials, a product candidate may be eligible for accelerated approval. Specifically, biologics intended to treat serious or life-threatening diseases or conditions may be eligible for accelerated approval upon a determination that the product candidate has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA generally requires that a sponsor of a drug or biologic receiving accelerated approval perform adequate and well-controlled confirmatory clinical trials, and may require that such confirmatory trials be underway prior to granting accelerated approval. Biologics receiving accelerated approval may be subject to expedited withdrawal procedures if the sponsor fails to conduct the required confirmatory trials in a timely manner or if such trials fail to verify the predicted clinical benefit. In addition, the FDA requires as a condition of accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

Fast track designation, breakthrough therapy designation, priority review, and accelerated approval do not change the standards for approval but may expedite the development or approval process. Even if a product candidate qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition, which is a disease or condition that affects fewer than 200,000 individuals in the United States or, if it affects more than 200,000 individuals in the United States, there is no reasonable expectation that the cost of developing and making the product available in the United States for this type of disease or condition will be recovered from sales of the product. Orphan designation must be requested before submitting an BLA. After the FDA grants orphan designation, the identity of the therapeutic

agent and its potential orphan use are disclosed publicly by the FDA. Orphan designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications –including full BLAs– to market the same drug for the same approved indication or use within such disease or condition for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity in the relevant indication or inability to manufacture the product in sufficient quantities to meet the needs related to the approved indication or use of the relevant patient population. The designation of such biologic also entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. However, competitors, may receive approval of different products for the indication or use for which the orphan product has exclusivity, or obtain approval for the same product but for any indication or use within a different disease or condition for which the orphan product has exclusivity. Orphan exclusivity also could block the approval of a competing product for the relevant orphan indication or use for seven years if a competitor obtains approval of the "same drug," as defined by the FDA, or if the active ingredient of the product candidate is determined to be contained within the competitor's product. In addition, if an orphan designated product receives marketing approval for a disease or condition broader than what is designated, it may not be entitled to orphan exclusivity.

Post-Approval Requirements

Any products manufactured or distributed by us pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of the product. As part of the manufacturing process, the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. After a BLA is approved for a biological product, the product also may be subject to official lot release. If the product is subject to official release by the FDA, the manufacturer submits samples of each lot of product to the FDA together with a release protocol showing a summary of the history of manufacture of the lot and the results of all of the manufacturer's tests performed on the lot. The FDA also may perform certain confirmatory tests on lots of some products before releasing the lots for distribution by the manufacturer. In addition, the FDA conducts laboratory research related to the regulatory standards on the safety, purity, and potency or effectiveness of biologics.

After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing user fee requirements, under which the FDA assesses an annual program fee for each product identified in an approved BLA. Biologic manufacturers and their subcontractors are required to register their establishments with the FDA and certain state authorities, and are subject to periodic unannounced inspections by the FDA and certain state authorities for compliance with cGMPs, which impose certain procedural and documentation requirements upon product sponsors and their third-party manufacturers. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMPs and impose reporting requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMPs and other aspects of regulatory compliance.

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

- restrictions on the marketing or manufacturing of a product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical studies;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of existing product approvals;
- product seizure or detention, or refusal of the FDA to permit the import or export of products;
- consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs;

- mandated modification of promotional materials and labeling and the issuance of corrective information;
- the issuance of safety alerts, Dear Healthcare Provider letters, press releases and other communications containing warnings or other safety information about the product; or
- injunctions or the imposition of civil or criminal penalties.

The FDA closely regulates the marketing, labeling, advertising and promotion of biologics. A company can make only those claims relating to safety and efficacy, purity and potency that are approved by the FDA and in accordance with the provisions of the approved label. The FDA and other governmental regulatory authorities actively enforce the laws and regulations prohibiting the promotion of off-label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use of their products.

Biosimilars and Reference Product Exclusivity

The BPCIA created an abbreviated approval pathway for biological products that are highly similar, or "biosimilar," to or interchangeable with an FDA-approved reference biological product. The FDA has issued several guidance documents outlining an approach to review and approval of biosimilars.

Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, is generally shown through analytical studies, animal studies, and a clinical trial or trials. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product in any given patient and, for products that are administered multiple times to an individual, the biologic and the reference biologic may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. A product shown to be biosimilar or interchangeable with an FDA-approved reference biological product may rely in part on the FDA's previous determination of safety and effectiveness for the reference product for approval, which can potentially reduce the cost and time required to obtain approval to market the product.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing that applicant's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of its product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products.

A reference biologic is granted 12 years of exclusivity from the time of first licensure of the reference product. The first biologic product submitted under the abbreviated approval pathway that is determined to be interchangeable with the reference product has exclusivity against other biologics submitted under the abbreviated approval pathway for the lesser of (i) one year after the first commercial marketing, (ii) 18 months after approval if there is no legal challenge, (iii) 18 months after the resolution in the applicant's favor of a lawsuit challenging the biologics' patents if an application has been submitted, or (iv) 42 months after the application has been approved if a lawsuit is ongoing within the 42-month period. A biological product can also obtain pediatric market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued "Written Request" for such a study.

Other U.S. Healthcare Laws

Pharmaceutical companies are subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which they conduct their business, which may constrain the financial arrangements and relationships through which we conduct research, as well as sell, market and distribute any products for which we obtain marketing approval. Such laws include, without limitation, federal and state anti-kickback, fraud and abuse, false

claims, and physician and other health care provider transparency laws and regulations. Violation of any of these laws or any other governmental regulations that apply include, without limitation, civil, criminal and administrative penalties, damages, fines, exclusion from government-funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations to resolve allegations of non-compliance, disgorgement, individual imprisonment, contractual damages, reputational harm, diminished profits and the curtailment or restructuring of operations.

Data Privacy and Security Laws

Numerous state, federal, and foreign laws govern the collection, dissemination, use, access to, confidentiality, and security of personal information, including health-related information that could apply now or in the future to our operations or the operations of our partners. In the United States, numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws and regulations, govern the collection, use, disclosure, and protection of health-related and other personal information. In addition, certain foreign laws govern the privacy and security of personal data. Privacy and security laws, regulations, and other obligations are constantly evolving, may conflict with each other to complicate compliance efforts, and can result in investigations, proceedings, or actions that lead to significant civil and/or criminal penalties and restrictions on data processing.

Coverage and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any pharmaceutical or biological product for which we obtain regulatory approval. Sales of any product, if approved, depend, in part, on the extent to which such product will be covered by third-party payors, such as federal, state, and foreign government healthcare programs, commercial insurance and managed healthcare organizations, and the level of reimbursement, if any, for such product by third-party payors. Decisions regarding whether to cover any of our product candidates, if approved, the extent of coverage and amount of reimbursement to be provided are made on a plan-by-plan basis. Further, no uniform policy for coverage and reimbursement exists in the United States, and coverage and reimbursement can differ significantly from payor to payor. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement rates, but also have their own methods and approval process apart from Medicare determinations. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

Third-party payors are increasingly challenging the prices charged for medical products and services, examining the medical necessity and reviewing the cost effectiveness of pharmaceutical or biological products, medical devices and medical services, in addition to questioning safety and efficacy. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit sales of any product that receives approval. Decreases in third-party reimbursement for any product or a decision by a third-party not to cover a product could reduce physician usage and patient demand for the product.

In addition, companion diagnostic tests require coverage and reimbursement separate and apart from the coverage and reimbursement for their companion pharmaceutical or biological products. Similar challenges to obtaining coverage and reimbursement, applicable to pharmaceutical or biological products, will apply to companion diagnostics.

In addition, the U.S. government, state legislatures and foreign governments have continued implementing cost-containment programs, including price controls, restrictions on coverage and reimbursement and requirements for substitution of generic products. The IRA provides CMS with significant new authorities intended to curb drug costs and to encourage market competition, including the ability to directly negotiate prescription drug prices and to cap out-of-pocket costs. Each year, CMS will select and negotiate a preset number of high-spend drugs and biologics that are covered under Medicare Part B and Part D that do not have generic or biosimilar competition, although the Medicare drug price negotiation program is currently subject to legal challenges. CMS has announced the agreed-upon reimbursement prices of the first 10 drugs that were subject to price negotiations, which went into effect in January 2026, and the subsequent 15 drugs, which will first be effective in 2027.The IRA also provides a new “inflation rebate” covering Medicare patients that took effect in 2023 and is intended to counter certain price increases in prescriptions drugs. The inflation rebate provision requires drug manufacturers to pay a rebate to the federal government if the price for a drug or biologic under Medicare Part B and Part D increases faster than the rate of inflation. To support biosimilar competition, beginning in October 2022, qualifying biosimilars may receive a Medicare Part B payment increase for a period of five years. Separately, if a biologic drug for which no biosimilar exists delays a biosimilar’s market entry beyond two years, CMS will be authorized to subject the biologics manufacturer to price negotiations intended to ensure fair

competition. Notwithstanding these provisions, the IRA's impact on commercialization and competition remains largely uncertain.

Healthcare Reform

The United States and some foreign jurisdictions are considering or have enacted a number of reform proposals to change the healthcare system. There is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by federal and state legislative initiatives, including those designed to limit the pricing, coverage, and reimbursement of pharmaceutical and biopharmaceutical products, especially under government-funded health care programs, and increased governmental control of drug pricing.

For example, the ACA, which was enacted in March 2010, substantially changed the way healthcare is financed by both governmental and private insurers in the United States, and significantly affected the pharmaceutical industry. The ACA contains a number of provisions of particular import to the pharmaceutical and biotechnology industries, including, but not limited to, those governing enrollment in federal healthcare programs, a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, and annual fees based on pharmaceutical companies' share of sales to federal health care programs. Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. For example, the IRA, among other things, extended enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and creating a new manufacturer discount program.

Other legislative changes have been proposed and adopted since the ACA was enacted, including automatic aggregate reductions of Medicare payments to providers as part of the federal budget sequestration under the Budget Control Act of 2011. These reductions went into effect in April 2013 and, due to subsequent legislative amendments, will remain in effect until 2032 unless additional action is taken by Congress. In addition, the American Rescue Plan Act of 2021 eliminated the statutory Medicaid drug rebate cap, which began on January 1, 2024.

The One Big Beautiful Bill Act (the "OBBBA") also included significant reforms to Medicaid, including an estimated $1 trillion in reduced federal Medicaid spending from 2025 through 2034, the imposition of work requirements for certain adult enrollees, more frequent eligibility redeterminations, and increased cost-sharing for beneficiaries. These changes are expected to reduce overall Medicaid enrollment and access to care. Although the effect on our business is currently unknown, any decrease in the number of insured patients or reimbursement levels for our products, if approved, could adversely affect our revenue and commercial prospects.

Moreover, there has recently been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state measures designed to, among other things, reduce the cost of prescription drugs, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. In addition to the IRA, the Trump administration is pursuing a two-fold strategy to reduce drug costs in the U.S. While it is unclear whether and how the Trump proposals will be implemented, the Trump policies are likely to have a negative impact on the pharmaceutical industry and on our ability to receive adequate revenues for our product candidates, if approved. On the one hand, President Trump has threatened to impose significant tariffs on pharmaceutical manufacturers that do not adopt pricing policies such as most favored nation pricing, which would tie the price for drugs in the U.S. to the lowest price in a group of other countries. In response, multiple manufacturers have reportedly entered into confidential pricing agreements with the federal government. On the other hand, the Trump administration is pursuing traditional regulatory pathways to impose drug pricing policies and published two proposed regulations in December 2025, referred to as Globe and Guard. If finalized, these regulations would implement mandatory payment models under which manufacturers of eligible drugs would be required to pay rebates to the federal government on a portion of the units of their drugs that are reimbursed by Medicare, with the rebate amount based on most favored nation pricing. Imposing a rebate in the United States that is based on drug prices outside the United States would mark a drastic and unprecedented shift in the U.S. pharmaceutical market, and while the impact of the Globe and Guard proposed regulations, if finalized, cannot yet be determined, it is likely to be significant. Even regulatory proposals or executive actions that are ultimately deemed unlawful could negatively impact the U.S. pharmaceutical sector and our business. In addition, pharmaceutical pricing and marketing has long been the subject of considerable discussion in Congress and among policymakers, and it is possible that Congress could enact additional laws that negatively affect the pharmaceutical industry.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access, and marketing cost disclosure, drug price reporting and other transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Some states have enacted legislation creating so-called prescription drug affordability boards with the goal of imposing price limits on certain drugs in these states, and at least one state board is imposing an upper payment limit. States while some states are also seeking to implement general, across the board price caps for pharmaceuticals, or are seeking to regulate drug distribution. Some measures are designed to encourage importation from other countries. These types of initiatives may result in additional reductions in Medicare, Medicaid, and other healthcare funding, and may otherwise affect the prices we may obtain for our product candidates, if approved. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, results of operations, financial condition and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our product candidates, if approved, or put pressure on our product pricing, which could negatively affect our business, results of operations, financial condition and prospects.

Similar political, economic and regulatory developments are occurring in the European Union ("EU") and may affect the ability of pharmaceutical companies to profitably commercialize their products. In addition to continuing pressure on prices and cost containment measures, legislative developments at the EU or member state level may result in significant additional requirements or obstacles. The delivery of healthcare in the EU, including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national, rather than EU, law and policy. National governments and health service providers have different priorities and approaches to the delivery of health care and the pricing and reimbursement of products in that context. In general, however, the healthcare budgetary constraints in most EU member states have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. Coupled with ever-increasing EU and national regulatory burdens on those wishing to develop and market products, this could restrict or regulate post-approval activities and affect the ability of pharmaceutical companies to commercialize their products. In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies.

Health Technology Assessment ("HTA") of medicinal products in the EU is an essential element of the pricing and reimbursement decision-making process in a number of EU member states. The outcome of HTA has a direct impact on the pricing and reimbursement status granted to the medicinal product. A negative HTA by a leading and recognized HTA body concerning a medicinal product could undermine the prospects to obtain reimbursement for such product not only in the EU member state in which the negative assessment was issued, but also in other EU member states.

In 2011, Directive 2011/24/EU was adopted at the EU level. This Directive establishes a voluntary network of national authorities or bodies responsible for HTA in the individual EU member states. The network facilitates and supports the exchange of scientific information concerning HTAs. Further to this, on December 13, 2021, Regulation No 2021/2282 on HTA, amending Directive 2011/24/EU, was adopted. The Regulation entered into force in January 2022 and has been applicable since January 2025, with phased implementation based on the type of product, i.e. oncology and advanced therapy medicinal products as of 2025, orphan medicinal products as of 2028, and all other new medicinal products by 2030. The Regulation intends to boost cooperation among EU member states in assessing health technologies, including new medicinal products, and provide the basis for cooperation at the EU level for joint clinical assessments in these areas. It will permit EU member states to use common HTA tools, methodologies, and procedures across the EU, working together in four main areas, including joint clinical assessment of the innovative health technologies with the highest potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EU member states will continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technology, and making decisions on pricing and reimbursement.

We expect that additional state, federal and foreign healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal, state and foreign governments will pay for healthcare products and services, which could result in reduced demand for our product candidates, if approved, or additional pricing pressures.

Other Government Regulation Outside of the United States

In addition to regulations in the United States, we are subject to a variety of regulations in other jurisdictions governing, among other things, research and development, clinical trials, testing, manufacturing, safety, efficacy, quality control, labeling, packaging, storage, record keeping, distribution, reporting, export and import, advertising, marketing and other promotional practices involving biological products as well as authorization, approval as well as post-approval monitoring and reporting of our

products. Because biologically sourced raw materials are subject to unique contamination risks, and their use may be restricted in some countries.

Whether or not we obtain FDA approval for a product, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. Certain countries outside of the United States have a similar process that requires the submission of a clinical trial application ("CTA") much like the IND prior to the commencement of human clinical trials.

The requirements and process governing the conduct of clinical trials, including requirements to conduct additional clinical trials, product licensing, safety reporting, post-authorization requirements, marketing and promotion, interactions with healthcare professionals, pricing and reimbursement may vary widely from country to country. No action can be taken to market any product in a country until an appropriate approval application has been approved by the regulatory authorities in that country. The current approval process varies from country to country, and the time spent in gaining approval varies from that required for FDA approval. In certain countries, the sales price of a product must also be approved. The pricing review period often begins after market approval is granted. Even if a product is approved by a regulatory authority, satisfactory prices may not be approved for such product, which would make launch of such products commercially unfeasible in such countries.

Regulation in the European Union

European Data Laws

The collection and use of personal health data and other personal data in the EU is governed by the provisions of the European General Data Protection Regulation (EU) 2016/679 (GDPR), which came into force in May 2018, and related data protection laws in individual member states of the EU ("EU Member States"). The GDPR imposes a number of strict obligations and restrictions on the ability to process, including collecting, analyzing and transferring, personal data of individuals, in including with respect to health data from clinical trials and adverse event reporting. The GDPR includes requirements relating to the legal basis of the processing (such as consent of the individuals to whom the personal data relates), the information provided to the individuals prior to processing their personal data, the notification obligations to the national data protection authorities and data subjects, the measures to be taken when engaging processors, and the security and confidentiality of the personal data. EU Member States may also impose additional requirements in relation to health, genetic and biometric data through their national legislation.

In addition, the GDPR imposes specific restrictions on the transfer of personal data to countries outside of the EU and in Iceland, Norway and Liechtenstein (together the European Economic Area ("EEA")) that are not considered by the European Commission ("EC") to provide an adequate level of data protection. Appropriate safeguards are required to enable such transfers. Among the appropriate safeguards that can be used, the data exporter may use the standard contractual clauses ("SCCs"). When relying on SCCs, data exporters are also required to conduct a transfer risk assessment to verify if anything in the law and/or practices of the third country may impinge on the effectiveness of the SCCs in the context of the transfer at stake and, if so, to identify and adopt supplementary measures that are necessary to bring the level of protection of the data transferred to the EU standard of essential equivalence. Where no supplementary measure is suitable, the data exporter should avoid, suspend or terminate the transfer With regard to the transfer of data from the EEA to the United States, on July 10, 2023, the EC adopted its adequacy decision for the EU-US Data Privacy Framework. On the basis of the new adequacy decision, personal data can flow from the EEA to U.S. companies participating in the framework. With regard to the transfer of data from EU to the United Kingdom ("UK"), personal data may freely flow from the EEA to the UK since the UK is deemed to have an adequate data protection level. However, the adequacy decisions for the UK include a "sunset clause" which entails that the decisions will automatically expire on 27 December 2031, unless renewed.

Furthermore, specific requirements relating to processing health data from clinical trials, including public disclosure obligations are provided in the EU Clinical Trial Regulation No. 536/2014 ("CTR"), EMA disclosure initiatives and voluntary commitments by industry.

On February 11, 2025, the European Union adopted Regulation (EU) 2025/327 establishing the European Health Data Space ("EHDS"), which imposes new obligations and liabilities on companies that handle electronic health data in the EU, including mandatory interoperability, logging, security and cross-border exchange requirements for electronic health record systems, expanded individual rights of access and control, and conditions and prohibitions on secondary uses of health data (e.g., for research or regulatory purposes), with staged implementation beginning in late 2025 and 2026. Compliance may require significant investments in technology, processes and governance, as well as engagement with national health data access bodies, and could limit companies' ability to collect, process, transfer, or commercialize health data or delay product development and post-market activities.

Additionally, following the UK's withdrawal from the EU and the EEA, companies also have to comply with the UK's data protection laws (including the UK GDPR (as defined in section 3(10) (as supplemented by section 205(4)) of the Data Protection Act 2018 (the DPA 2018)), the DPA 2018, and related data protection laws in the UK).

Companies are subject to specific transfer rules under the UK regime which broadly mirror the GDPR rules. On February 2, 2022, the UK Secretary of State laid before the UK Parliament the international data transfer agreement ("IDTA") and the international data transfer addendum to the EC's standard contractual clauses for international data transfers (the "IDTA Addendum") and a document setting out transitional provisions. The IDTA and IDTA Addendum came into force on March 21, 2022 and replaced the old SCCs for the purposes of the UK regime.

With regard to the transfer of personal data from the UK to the United States, the UK government has adopted an adequacy decision for the United States (the "UK-US Data Bridge"), which came into force on October 12, 2023. The UK-US Data Bridge recognizes the United States as offering an adequate level of data protection where the transfer is to a U.S. company participating in the EU-US Data Privacy Framework and the UK Extension to the EU-US Data Privacy Framework.

Non-clinical Studies and Clinical Trials

Similarly to the United States, the various phases of non-clinical and clinical research in the EU are subject to significant regulatory controls. Non-clinical studies are performed to demonstrate the health or environmental safety of new chemical or biological substances. Non-clinical (pharmaco-toxicological) studies must be conducted in compliance with the principles of good laboratory practice ("GLP") as set forth in EU Directive 2004/10/EC (unless otherwise justified for certain particular medicinal products, e.g., radio-pharmaceutical precursors for radio-labeling purposes). In particular, non-clinical studies, both in vitro and in vivo, must be planned, performed, monitored, recorded, reported and archived in accordance with the GLP principles, which define a set of rules and criteria for a quality system for the organizational process and the conditions for non-clinical studies. These GLP standards reflect the Organization for Economic Co-operation and Development requirements.

Clinical trials of medicinal products in the EU must be conducted in accordance with EU and national regulations and the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use ("ICH") guidelines on Good Clinical Practices ("GCP") as well as the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki. Additional GCP guidelines from the EC, focusing in particular on traceability, apply to clinical trials of advanced therapy medicinal products ("ATMPs"). If the sponsor of the clinical trial is not established within the EU, it must appoint an EU entity to act as its legal representative. The sponsor must take out a clinical trial insurance policy, and in most EU member states, the sponsor is liable to provide 'no fault' compensation to any study subject injured in the clinical trial.

The regulatory landscape related to clinical trials in the EU has been subject to recent changes. The EU Clinical Trials Regulation ("CTR") which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022. Unlike directives, the CTR is directly applicable in all EU member states without the need for member states to further implement it into national law. The CTR notably harmonizes the assessment and supervision processes for clinical trials throughout the EU via a Clinical Trials Information System, which contains a centralized EU portal and database.

While the EU Clinical Trials Directive required a separate CTA to be submitted in each member state in which the clinical trial takes place, to both the competent national health authority and an independent ethics committee, much like the FDA and IRB respectively, the CTR introduces a centralized process and only requires the submission of a single application for multi-center trials. The CTR allows sponsors to make a single submission to both the competent authority and an ethics committee in each member state, leading to a single decision per member state. The CTA must include, among other things, a copy of the trial protocol and an investigational medicinal product dossier containing information about the manufacture and quality of the medicinal product under investigation. The assessment procedure of the CTA has been harmonized as well, including a joint assessment by all member states concerned, and a separate assessment by each member state with respect to specific requirements related to its own territory, including ethics rules. Each member state's decision is communicated to the sponsor via the centralized EU portal. Once the CTA is approved, clinical study development may proceed.

The CTR transition period ended on January 31, 2025, and all clinical trials (and related applications) are now fully subject to the provisions of the CTR.

Medicines used in clinical trials must be manufactured in accordance with Good Manufacturing Practice, or GMP. Other national and EU-wide regulatory requirements may also apply.

During the development of a medicinal product, the EMA and national regulators within the EU provide the opportunity for dialogue and guidance on the development program. At the EMA level, this is usually done in the form of scientific advice, which is given by the Committee for Medicinal Products for Human Use ("CHMP") on the recommendation of the Scientific Advice Working Party. A fee is incurred with each scientific advice procedure but is significantly reduced for designated orphan medicines. Advice from the EMA is typically provided based on questions concerning, for example, quality (chemistry, manufacturing and controls testing), nonclinical testing and clinical studies, and pharmacovigilance plans and risk-management programs. Advice is not legally binding with regard to any future marketing authorization application ("MAA") of the product concerned.

Marketing Authorization

In the EU, after completion of all required clinical testing, pharmaceutical products may only be placed on the market after obtaining a MA. To obtain an MA, an applicant must submit an MAA. The process for doing this depends, among other things, on the nature of the medicinal product. There are two types of MAs: "Centralized MAs" are issued by the EC through the centralized procedure based on the opinion of the EMA's CHMP, and are valid throughout the EU. The centralized procedure is compulsory for certain types of medicinal products, including for (i) medicines developed by means of certain biotechnological processes, (ii) products designated as orphan medicinal products, (iii) ATMPs (gene therapy, somatic cell therapy, or tissue engineered medicines) and (iv) medicinal products with a new active substance indicated for the treatment of certain diseases (HIV/AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and viral diseases). For medicinal products containing a new active substance not yet authorized in the EU before May 20, 2004 and indicated for the treatment of other diseases, medicinal products that constitute significant therapeutic, scientific or technical innovations or for which the grant of a MA through the centralized procedure would be in the interest of public health at EU level, an applicant may voluntarily submit an application for a MA through the centralized procedure.

- Under the centralized procedure, the EMA's CHMP, is responsible for conducting the initial assessment of a product candidate. The CHMP is also responsible for several post-authorization and maintenance activities, such as the assessment of modifications or extensions to an existing MA. Under the centralized procedure, the maximum timeframe for the evaluation of an MAA by the EMA's CHMP is 210 days from receipt of a valid MAA. However, this timeline excludes clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the CHMP. Accelerated evaluation might be granted by the CHMP in exceptional cases, when a medicinal product is expected to be of a major public health interest, particularly from the point of view of therapeutic innovation. Upon request, the CHMP can reduce the time frame to 150 days if the applicant provides sufficient justification for an accelerated assessment. The CHMP will provide a positive opinion regarding the application only if it meets certain quality, safety and efficacy requirements. This opinion is then transmitted to the EC, which has the ultimate authority for granting MA.
- The Committee for Advanced Therapies "CAT" is responsible in conjunction with the CHMP for the evaluation of ATMPs. The CAT is primarily responsible for the scientific evaluation of ATMPs and prepares a draft opinion on the quality, safety and efficacy of each ATMP for which a MAA is submitted. The CAT's opinion is then taken into account by the CHMP when giving its final recommendation regarding the authorization of a product in view of the balance of benefits and risks identified. Although the CAT's draft opinion is submitted to the CHMP for final approval, the CHMP may depart from the draft opinion, if it provides detailed scientific justification. The CHMP and CAT are also responsible for providing guidelines on ATMPs and have published numerous guidelines, including specific guidelines on gene therapies and cell therapies. These guidelines provide additional guidance on the factors that the EMA will consider in relation to the development and evaluation of ATMPs and include, among other things, the preclinical studies required to characterize ATMPs; the manufacturing and control information that should be submitted in a MAA; and post-approval measures required to monitor patients and evaluate the long term efficacy and potential adverse reactions of ATMPs

- "National MAs" are issued by the competent authorities of the EU member states, only cover their respective territory, and are available for product candidates not falling within the mandatory scope of the centralized procedure. Where a product has already been authorized for marketing in an EU member state, this national MA can be recognized in another member state through the mutual recognition procedure. If the product has not received a national MA in any member state at the time of application, it can be approved simultaneously in various member states through the decentralized procedure. Under the decentralized procedure an identical dossier is submitted to the competent

authorities of each of the member states in which the MA is sought, one of which is selected by the applicant as the reference member state.

Innovative products that target an unmet medical need and are expected to be of major public health interest may be eligible for a number of expedited development and review programs, such as the PRIority MEdicines ("PRIME") scheme, which provides incentives similar to the breakthrough therapy designation in the U.S. In March 2016, the EMA launched an initiative, the PRIME scheme, a voluntary scheme aimed at enhancing the EMA's support for the development of medicines that target unmet medical needs. It is based on increased interaction and early dialogue with companies developing promising medicines, to optimize their product development plans and speed up their evaluation to help them reach patients earlier. Product developers that benefit from PRIME designation can expect to be eligible for accelerated assessment but this is not guaranteed. Many benefits accrue to sponsors of product candidates with PRIME designation, including but not limited to, early and proactive regulatory dialogue with the EMA, frequent discussions on clinical trial designs and other development program elements, and accelerated MAA assessment once a dossier has been submitted. Importantly, a dedicated contact and rapporteur from the CHMP is appointed early in the PRIME scheme facilitating increased understanding of the product at EMA's committee level. An initial meeting initiates these relationships and includes a team of multidisciplinary experts at the EMA to provide guidance on the overall development and regulatory strategies.

Moreover, in the EU, a "conditional" MA may be granted in cases where all the required safety and efficacy data are not yet available. The conditional MA is subject to conditions to be fulfilled for generating the missing data or ensuring increased safety measures. It is valid for one year and has to be renewed annually until fulfillment of all the conditions. Once the pending studies are provided, it can become a "standard" MA. However, if the conditions are not fulfilled within the timeframe set by the EMA, the MA ceases to be renewed.

Furthermore, MA may also be granted "under exceptional circumstances" when the applicant can show that it is unable to provide comprehensive data on the efficacy and safety under normal conditions of use even after the product has been authorized and subject to specific procedures being introduced. This may arise in particular when the intended indications are very rare and, in the present state of scientific knowledge, it is not possible to provide comprehensive information, or when generating data may be contrary to generally accepted ethical principles. This MA is close to the conditional MA as it is reserved to medicinal products to be approved for rare diseases or unmet medical needs and the applicant does not hold the complete data set legally required for the grant of a MA. However, unlike the conditional MA, the applicant does not have to provide the missing data and will never have to. Although the MA "under exceptional circumstances" is granted definitively, the risk-benefit balance of the medicinal product is reviewed annually and the MA is withdrawn in case the risk-benefit ratio is no longer favorable.

Under the above described procedures, in order to grant the MA, the EMA or the competent authorities of the EU member states make an assessment of the risk benefit balance of the product on the basis of scientific criteria concerning its quality, safety, and efficacy. MA have an initial duration of five years. After these five years, the authorization may subsequently be renewed on the basis of a reevaluation of the risk-benefit balance. Once renewed, the MA is valid for an unlimited period unless the EC or the national competent authority decides, on justified grounds relating to pharmacovigilance, to proceed with only one additional five-year renewal.

Any authorization which is not followed by the actual placing of the drug on the EU market (in case of centralized procedure) or on the market of the authorizing member state within three years after authorization ceases to be valid.

Advanced Therapy Classification

Based on legislation adopted in 2007, the EMA established an additional regulatory designation for products classified as an ATMP. The ATMP designation offers sponsors a variety of benefits similar to those associated with the PRIME scheme, including scientific and regulatory guidance, additional opportunities for dialogue with regulators, and pre-submission review and certification of the chemistry, manufacturing and controls, and nonclinical data proposed for submission in a forthcoming MAA for micro-,small-, or medium-sized enterprises. To qualify for this designation, product candidates intended for human use must be based on gene therapy, somatic cell therapy, or tissue engineered therapy.

Data and Market Exclusivity

In the EU, new products authorized for marketing (i.e., reference products) generally receive eight years of data exclusivity and an additional two years of market exclusivity upon MA. If granted, the data exclusivity period prevents generic and biosimilar applicants from relying on the preclinical and clinical trial data contained in the dossier of the reference product when applying for a generic or biosimilar MA in the EU during a period of eight years from the date on which the reference product was first authorized in the EU. The market exclusivity period prevents a successful generic or biosimilar applicant from

commercializing its product in the EU until ten years have elapsed from the initial MA of the reference product in the EU. The overall ten-year market exclusivity period can be extended to a maximum of eleven years if, during the first eight years of those ten years, the MA holder obtains an authorization for one or more new therapeutic indications, which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. However, there is no guarantee that a product will be considered by the EU's regulatory authorities to be a new chemical or biological entity, and products may not qualify for data exclusivity.

There is a special regime for biosimilars, or biological medicinal products that are similar to a reference medicinal product but that do not meet the definition of a generic medicinal product, for example, because of differences in raw materials or manufacturing processes. For such products, the results of appropriate preclinical or clinical trials must be provided, and guidelines from the EMA detail the type of quantity of supplementary data to be provided for different types of biological product. There are no such guidelines for complex biological products, such as gene or cell therapy medicinal products, and so it is unlikely that biosimilars of those products will currently be approved in the EU. However, guidance from the EMA states that they will be considered in the future in light of the scientific knowledge and regulatory experience gained at the time.

Orphan Medicinal Products

The criteria for designating an "orphan medicinal product" in the EU are similar in principle to those in the United States. A medicinal product can be designated as an orphan if its sponsor can establish that: (1) the product is intended for the diagnosis, prevention or treatment of a life threatening or chronically debilitating condition (2) either (a) such condition affects not more than five in 10,000 persons in the EU when the application is made, or (b) the product, without the benefits derived from the orphan status, would not generate sufficient return in the EU to justify the necessary investment; and (3) there exists no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorized for marketing in the EU or, if such method exists, the product will be of significant benefit to those affected by that condition.

Orphan designation must be requested before submitting an MAA. An EU orphan designation entitles a party to incentives such as reduction of fees or fee waivers, protocol assistance, and access to the centralized procedure. Upon grant of a MA, orphan medicinal products are entitled to ten years of market exclusivity for the approved indication, which means that the competent authorities cannot accept another MAA, or grant a MA, or accept an application to extend a MA for a similar medicinal product for the same indication for a period of ten years. The period of market exclusivity is extended by two years for orphan medicinal products that have also complied with an agreed pediatric investigation plan ("PIP"). No extension to any supplementary protection certificate can be granted on the basis of pediatric studies for orphan indications. Orphan designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

The orphan exclusivity period may be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for which it received orphan designation, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity or where the prevalence of the condition has increased above the threshold. Additionally, MA may be granted to a similar product for the same indication at any time if (i) the second applicant can establish that its product, although similar, is safer, more effective or otherwise clinically superior; (ii) the applicant consents to a second orphan medicinal product application; or (iii) the applicant cannot supply enough orphan medicinal product.

Pediatric Development

In the EU, MAAs for new medicinal products candidates have to include the results of studies conducted in the pediatric population, in compliance with a PIP agreed with the EMA's Pediatric Committee ("PDCO").The PIP sets out the timing and measures proposed to generate data to support a pediatric indication of the product candidate for which MA is being sought. The PDCO can grant a deferral of the obligation to implement some or all of the measures of the PIP until there are sufficient data to demonstrate the efficacy and safety of the product in adults. Further, the obligation to provide pediatric clinical trial data can be waived by the PDCO when these data are not needed or appropriate because the product is likely to be ineffective or unsafe in children, the disease or condition for which the product is intended occurs only in adult populations, or when the product does not represent a significant therapeutic benefit over existing treatments for pediatric patients. Once the MA is obtained in all the EU member states and study results are included in the product information, even when negative, the product is eligible for six months' supplementary protection certificate extension (if any is in effect at the time of approval) or, in the case of orphan medicinal products, a two year extension of the orphan market exclusivity is granted.

Post-Approval Regulation

Similar to the United States, both MA holders and manufacturers of medicinal products are subject to comprehensive regulatory oversight by the EMA, the EC and/or the competent regulatory authorities of the EU member states. The holder of a MA must establish and maintain a pharmacovigilance system and appoint an individual qualified person for pharmacovigilance ("QPPV"), who is responsible for the establishment and maintenance of that system, and oversees the safety profiles of medicinal products and any emerging safety concerns. Key obligations include expedited reporting of suspected serious adverse reactions and submission of periodic safety update reports ("PSURs").

All new MAA must include a risk management plan, or RMP, describing the risk management system that the company will put in place and documenting measures to prevent or minimize the risks associated with the product. The regulatory authorities may also impose specific obligations as a condition of the MA. Such risk-minimization measures or post-authorization obligations may include additional safety monitoring, more frequent submission of PSURs, or the conduct of additional clinical trials or post-authorization safety studies.

The advertising and promotion of medicinal products is also subject to EU laws concerning promotion of medicinal products, interactions with physicians, misleading and comparative advertising and unfair commercial practices. In addition, other national legislation of individual member states may apply to the advertising and promotion of medicinal products and may differ from one country to another. These laws require that promotional materials and advertising in relation to medicinal products comply with the product's summary of product characteristics ("SmPC") as approved by the competent regulatory authorities. All advertising and promotional activities for the product must be consistent with the approved SmPC and therefore all off-label promotion is prohibited. Direct-to-consumer advertising of prescription-only medicines is also prohibited in the EU. Violations of the rules governing the promotion of medicinal products in the EU could be penalized by administrative measures, fines and imprisonment. These laws may further limit or restrict the advertising and promotion of our products to the general public and may also impose limitations on our promotional activities with healthcare professionals.

In the EU, interactions between pharmaceutical companies and physicians are also governed by strict laws, regulations, industry self-regulation codes of conduct and physicians' codes of professional conduct both at EU level and in the individual EU member states. The provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is prohibited in the European Union. The provision of benefits or advantages to healthcare professionals and organizations is also governed by the national anti-bribery laws of the EU member states. Violation of these laws could result in substantial fines and imprisonment.

Payments made to healthcare professionals and organizations in certain EU member states also must be publicly disclosed. Moreover, agreements with healthcare professionals and organizations must often be the subject of prior notification and/or approval. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

Pharma Package Reform

The EU pharmaceutical legislation has been undergoing a complete review process, in the context of the Pharmaceutical Strategy for Europe initiative, launched by the EC in November 2020. The EC's proposal for revision of several legislative instruments related to medicinal products was published on April 26, 2023. The proposed changes were since discussed and negotiated by the European Parliament and the Council of the EU as part of the EU ordinary legislative process. A provisional agreement has been reached by the European Parliament and Council of the EU on the proposed revisions on December 11, 2025. The proposed revisions (affecting the duration of regulatory data protection and market protection, including for orphan medicinal products, revising the eligibility for expedited pathways, etc.) remain to be formally adopted by the two institutions, which is not anticipated before early 2026. The proposed changes are not expected to enter into application before 2028.

The aforementioned EU rules are generally applicable in the European Economic Area ("EEA") which consists of the 27 EU member states plus Norway, Liechtenstein and Iceland.

Failure by us or by any of our third-party partners, including suppliers, manufacturers and distributors to comply with EU laws and the related national laws of individual EU member states governing the conduct of clinical trials, manufacturing approval, MA of medicinal products and marketing of such products, both before and after grant of MA, statutory health insurance, bribery and anti-corruption or other applicable regulatory requirements may result in administrative, civil or criminal penalties. These penalties could include delays or refusal to authorize the conduct of clinical trials or to grant MA, product withdrawals and recalls, product seizures, suspension, withdrawal or variation of the MA, total or partial suspension of production, distribution, manufacturing or clinical trials, operating restrictions, injunctions, suspension of licenses, fines and criminal penalties.

Regulations in the UK

Following the end of the Brexit transition period on January 1, 2021 and the implementation of the Windsor Framework on January 1, 2025, the UK is not generally subject to EU laws in respect of medicines. The EU laws that have been transposed into UK law through secondary legislation remain applicable in the UK, however, new legislation such as the (EU) CTR is not applicable in the UK.

As of January 1, 2021, the Medicines and Healthcare products Regulatory Agency ("MHRA") is the UK's standalone medicines and medical devices regulator. As a result of the Northern Ireland Protocol, different rules applied in Northern Ireland than in England, Wales, and Scotland (together, "Great Britain"), which continued to follow the EU regulatory regime for a period of time after Brexit. However, on January 1, 2025 a new arrangement called the "Windsor Framework" came into effect and reintegrated Northern Ireland under the regulatory authority of the MHRA with respect to medicinal products. The Windsor Framework removes EU licensing processes and EU labeling and serialization requirements in relation to Northern Ireland and introduces a UK-wide licensing process for medicines.

The UK regulatory framework in relation to clinical trials is governed by the Medicines for Human Use (Clinical Trials) Regulations 2004, as amended, which is derived from the EU Clinical Trials Directive, as implemented into UK national law through secondary legislation. In April 2025, the UK introduced the Medicines for Human Use (Clinical Trials) (Amendment) Regulations. These changes, which will take full effect from April 2026, aim to create a streamlined, risk-proportionate system that accelerates approvals while maintaining robust safety standards.

Marketing authorizations in the UK are governed by the Human Medicines Regulations (SI 2012/1916), as amended. In order to use the centralized procedure to obtain a marketing authorization that will be valid throughout the EEA, companies must be established in the EEA. Therefore, after Brexit, companies established in the UK can no longer use the EU centralized procedure and instead an EEA entity must hold any centralized marketing authorizations. In order to obtain a UK marketing authorization to commercialize products in the UK, an applicant must follow one of the UK national authorization procedures or one of the remaining post-Brexit international cooperation procedures. The MHRA has introduced changes to national licensing procedures, including procedures to prioritize access to new medicines that will benefit patients, a 150-day assessment (subject to clock-stops) and a rolling review procedure. In addition, since January 1, 2024, the MHRA may rely on the International Recognition Procedure ("IRP") when reviewing certain types of MAAs. Pursuant to the IRP, the MHRA will take into account the expertise and decision-making of trusted regulatory partners (e.g. the medicines regulatory authorities in Australia, Canada, Switzerland, Singapore, Japan, the US and the EMA in the EU). The MHRA will conduct a targeted assessment of IRP applications but retain the authority to reject applications if the evidence provided is considered insufficiently robust.

In the UK, the initial duration of a marketing authorization is five years and following renewal will be valid for an unlimited period unless the MHRA decides on justified grounds relating to pharmacovigilance to proceed with only one additional five-year renewal. Any authorization which is not followed by the actual placing of the medicine on the market in the UK within three years shall cease to be in force.

There is no pre-marketing authorization orphan designation in the UK. Instead, the MHRA reviews applications for orphan designation in parallel to the corresponding MAA. The criteria are essentially the same as in the EU, but have been tailored for the market, i.e., the prevalence of the condition in the UK, rather than the EU, must not be more than five in 10,000. Should an orphan designation be granted, the period of market exclusivity will be set from the date of first approval of the product in the UK.

Rest of the World Regulation

For other countries outside of the EU, such as countries in Eastern Europe, Asia and Latin America, the requirements governing the conduct of clinical trials, data protection, product licensing, pricing and reimbursement vary from country to country. In all cases, the clinical trials must be conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension of clinical trials, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Corporate History and Background

We were initially incorporated as Aerovate Therapeutics, Inc., a Delaware corporation ("Aerovate"), on July 27, 2018. On April 28, 2025, we consummated a transaction (the "Closing") pursuant to that certain Agreement and Plan of Merger, dated as of October 30, 2024, by and among Jade Biosciences, Inc., a private Delaware corporation ("Pre-Merger Jade"), Aerovate, Caribbean Merger Sub I, Inc., a Delaware corporation and wholly-owned subsidiary of Aerovate ("First Merger Sub"), and Caribbean Merger Sub II, LLC, a Delaware limited liability company and wholly-owned subsidiary of Aerovate ("Second Merger Sub"). As part of the Closing, First Merger Sub merged with and into Pre-Merger Jade, with Pre-Merger Jade continuing as a wholly owned subsidiary of Aerovate and the surviving corporation of the merger (the "First Merger"), and Pre-Merger Jade merged with and into Second Merger Sub, with Second Merger Sub being the surviving entity of the merger (the "Second Merger" and, together with the First Merger, the "Merger"). In connection with the Merger, Second Merger Sub changed its name to "Jade Biosciences, LLC" and Aerovate changed its name to "Jade Biosciences, Inc." Subsequently, Jade Biosciences, LLC merged with and into Jade Biosciences, Inc. We are led by Pre-Merger Jade's management team and focus on developing differentiated biologic therapies for patients living with autoimmune diseases. On April 28, 2025, we changed our jurisdiction of incorporation from the State of Delaware to the State of Nevada (the "Redomestication") pursuant to a plan of conversion. The Redomestication became effective on April 28, 2025.

Unless the context otherwise requires, "we," "us," "our," and the "Company" refer to Jade Biosciences, Inc., a Nevada corporation, and its subsidiaries following the Closing.

Available Information

Our website address is www.jadebiosciences.com. The investor relations portion of our website is located at https://jadebiosciences.com/investors. We make available free of charge on the investor relations portion of our website under "SEC Filings" certain reports and other information we file with or furnish to the U.S. Securities and Exchange Commission (the "SEC"), including our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, our directors' and officers' Section 16 reports, and any amendments to those reports, as soon as reasonably practicable after we electronically file such materials with, or furnish them to, the SEC. They are also available for free on the SEC's website at www.sec.gov.

We intend to use the investor relations portion of our website as a means of disclosing material non-public information and for complying with our disclosure obligations under Regulation FD. Investors should monitor such website, in addition to following our press releases, SEC filings and public conference calls and webcasts. Information relating to our corporate governance is also included in the investor relations portion of our website. The information found on or accessible through our website and the SEC website is not incorporated into, and is not considered part of, this report. We have included these website addresses as inactive textual references only.

Item 1A. Risk Factors.

Investing in our common stock involves a high degree of risk. Before you decide to invest in our common stock, you should consider carefully the risks described below, together with the other information contained in this Annual Report on Form 10-K. We believe the risks described below are the risks that are material to us as of the date of this Annual Report. Some of the factors, events and contingencies discussed below may have occurred in the past, but the disclosures below are not representations as to whether or not the factors, events or contingencies have occurred in the past and instead reflect our beliefs and opinions as to the factors, events, or contingencies that could materially and adversely affect us in the future. If any of the following risks actually occur, our business, financial condition, results of operations and future growth prospects could be materially and adversely affected.

Risk Factor Summary

The summary below is not exhaustive and is qualified by reference to the full set of risk factors set forth in the "Risk Factors" section below. Please carefully consider all the information in this Form 10-K, including the full set of risks set forth in the "Risk Factors" section below, and in our other filings with the U.S. Securities and Exchange Commission (the "SEC") before making an investment decision regarding our company.

- We are a clinical stage biotechnology company with a limited operating history on which to assess our business; we have not completed any clinical trials, and we have no products approved for commercial sale, which may make it difficult to evaluate our current business and likelihood of success and viability.

- We will require substantial additional capital to finance our operations in the future. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce and/or eliminate one or more of our development programs or future commercialization efforts.

- We expect to continue to incur losses for the foreseeable future and may not be able to achieve or sustain profitability in the future. We have no products approved for sale, have not generated any revenue from our product candidates and may never generate revenue or become profitable.

- We face competition from entities that have developed or may develop products for the diseases addressed by our product candidates.

- Our programs are in the clinical and preclinical stages of development and may fail in development or suffer delays that materially and adversely affect our viability. If we or our current or future collaborators are unable to complete development of or commercialize our product candidates, or experience significant delays in doing so, our business will be materially harmed.

- We are substantially dependent on the success of JADE101, and our current and anticipated future clinical trials of such product candidate may not be successful.

- If we do not achieve our projected development objectives in the time frames we announce and expect, the commercialization of our product candidates may be delayed, which may harm our reputation and prospects, increase our expenses and cause our stock price to decline.

- Our approach to the discovery and development of our product candidates is unproven, and we may not be successful in our efforts to build a pipeline of product candidates with commercial value.

- Preclinical and clinical development involves a lengthy and expensive process that is subject to delays and with uncertain outcomes, and results of earlier studies and trials may not be predictive of future clinical trial results. If our preclinical studies and clinical trials are not sufficient to support regulatory approval of any of our product candidates, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development of such product candidate.

- We may find it difficult to enroll participants in our clinical trials, particularly given the relatively small patient population and significant competition for patients who have the diseases for which JADE101 is being developed. If we encounter difficulties enrolling participants in our current clinical trial of JADE101 or future clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

- Preliminary, "topline" or interim data from our clinical trials that we announce or publish from time to time may change as more participant data become available and are subject to audit and verification procedures.

- We rely on collaborations and licensing arrangements with third parties, including Paragon Therapeutics, Inc. ("Paragon"). If we are unable to maintain these collaborations or licensing arrangements, or if these collaborations or licensing arrangements are not successful, our business could be negatively impacted.

- We currently rely, and plan to rely in the future, on third parties to conduct and support our preclinical studies and clinical trials. If these third parties do not properly and successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval of or commercialize our product candidates.

- We rely on the use of third-party contract manufacturing organizations ("CMOs") to manufacture our product candidates, and we expect to continue to rely on third-party CMOs to produce our products, if approved. Our business could be adversely affected if we are unable to use third-party manufacturing suites or if the third-party manufacturers encounter difficulties in production.

- In order to successfully implement our plans and strategies, we will need to grow the size of our organization, and we may experience difficulties in managing this growth.

- We may be subject to intellectual property lawsuits or may need to file lawsuits to protect our intellectual property, which could result in substantial costs and liability and prevent us from commercializing our potential products.

- The regulatory approval processes of the U.S. Food and Drug Administration ("FDA") and other comparable foreign regulatory authorities are lengthy, time-consuming and inherently unpredictable. If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals for our product candidates, we will not be able to commercialize, or will be delayed in commercializing, our product candidates, and our ability to generate revenue will be materially impaired.

- Litigation costs and the outcome of litigation could have a material adverse effect on our business.

- The market price of our common stock has been and is expected to continue to be volatile.

- We are governed by Nevada law and our articles of incorporation and bylaws, provisions of which have anti-takeover implications.

- Because our articles of incorporation and bylaws limit the court in which you may bring an action against us, you may have difficulty obtaining a favorable judicial forum or you may incur more expense enforcing any rights which you may claim.

- Conflicts of interest may arise between us and Paragon or us and Fairmount Funds Management LLC ("Fairmount").

- Our executive officers, directors and principal stockholders have the ability to control or significantly influence all matters submitted to our stockholders for approval.

Risk Factors

Risks Related to Our Limited Operating History, Financial Position and Capital Requirements

We are a clinical stage biotechnology company with a limited operating history on which to assess our business; we have not completed any clinical trials, and we have no products approved for commercial sale, which may make it difficult to evaluate our current business and likelihood of success and viability.

We are a clinical stage biotechnology company with limited operating history. Since our inception, we have incurred operating losses with no corresponding revenue and have utilized substantially all of our resources to identify, license and develop our product candidates, organize and staff our company and provide other general and administrative support for our operations. We have no significant experience as a company in initiating, conducting or completing preclinical studies or clinical trials. In part because of this lack of experience, we cannot be certain that our preclinical studies or clinical trials will begin or be completed on time, if at all. In addition, we have not yet demonstrated an ability to obtain regulatory approvals, manufacture a commercial-scale product or arrange for a third party to do so on our behalf, or conduct sales, marketing and distribution

activities necessary for successful product commercialization. Consequently, any predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history.

In addition, as our business grows, we may encounter unforeseen expenses, restrictions, difficulties, complications, delays and other known and unknown factors. We will need to transition at some point from a company with an early research and development focus to a company capable of supporting larger scale clinical trials and eventually commercial activities. We may not be successful in such a transition.

We will require substantial additional capital to finance our operations in the future. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce and/or eliminate one or more of our development programs or future commercialization efforts.

Developing biotechnology products is a long, time-consuming, expensive and uncertain process that takes years to complete. We expect our expenses to increase in connection with our ongoing activities, particularly as we conduct preclinical studies and clinical trials of, and seek regulatory approval for our product candidates, advance discovery efforts with respect to our research and development programs, and advance any future programs and product candidates that we may license. Even if one or more of the programs that we develop is approved for commercial sale, we anticipate incurring significant costs associated with sales, marketing, manufacturing and distribution activities to launch any such product. Our expenses could increase beyond expectations if we are required by the FDA or other regulatory authorities to perform preclinical studies or clinical trials in addition to or more expansive than those that we currently anticipate. Because the design and outcome of our planned and anticipated clinical trials are highly uncertain, we cannot reasonably estimate the actual amount of funding that will be necessary to successfully complete the development and commercialization of any program we develop. Our future capital requirements depend on many factors, including but not limited to:

- the scope, design, progress, results and costs of discovery, preclinical and clinical development for our product candidates;
- the cost and timing of completion of clinical and commercial-scale manufacturing activities;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining, defending and enforcing our intellectual property and proprietary rights, and defending intellectual property-related claims, including claims of infringement, misappropriation or other violations of third-party intellectual property;
- the costs, timing and outcome of the regulatory review of our product candidates and obtaining the requisite regulatory approvals;
- the costs of our future commercialization activities, either on our own or in collaboration with others, including product sales, marketing, manufacturing, and distribution for any product candidate for which we receive regulatory approval;
- the revenue, if any, received from commercial sales of product candidates for which we receive regulatory approval;
- the success of our current or future collaborations, including our collaboration with Paragon pursuant to the Antibody Discovery and Option Agreement (as amended, the “Paragon Option Agreement”) with Paragon and Parade Biosciences Holding LLC (“Parade”) and our current and any future license agreements we enter into with Paragon;
- Our ability to establish and maintain additional collaborations on favorable terms, if at all;
- the extent to which we acquire or in-license products, intellectual property and technologies;
- the costs of operational, financial and management information systems and associated personnel; and
- the costs of operating as a public company.

As a result, we will require substantial additional funding to continue our operations. We expect that our existing cash and cash equivalents, and investments, will be sufficient to fund our operating expenses and capital expenditure requirements for at least twelve months from the date of our consolidated financial statements for the year ended December 31, 2025 were issued. We will still need to raise additional capital to continue to fund our operations in the future. If we are unable to raise additional capital when needed, that could raise substantial doubt about our ability to continue as a going concern.

We may be required to seek additional funds sooner than planned through public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources, and adequate additional financing may not be available to us on acceptable terms, or at all. Even if we believe we have sufficient capital for our current or future operating plans, we may

seek additional capital if market conditions are favorable or if we have specific strategic opportunities. Such financing may dilute our stockholders or the failure to obtain such financing may restrict our operating activities. Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our business. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be diluted, and the terms may include liquidation or other preferences and anti-dilution protections that adversely affect the rights of our stockholders. Debt financing may result in the imposition of debt covenants, increased fixed payment obligations or other restrictions that may affect our business. If we raise additional funds through upfront payments or milestone payments pursuant to current or future collaborations with third parties, we may have to relinquish valuable rights to our product candidates, or grant licenses on terms that are not favorable to us. Our ability to raise additional capital may be adversely impacted by global macroeconomic conditions and volatility in the credit and financial markets in the United States and worldwide. Our failure to raise capital as and when needed or on acceptable terms would have a negative impact on our financial condition and our ability to pursue our business strategy, and we may have to delay, reduce the scope of, suspend or eliminate one or more of our product candidates, clinical trials or future commercialization efforts or cease our operations.

We expect to continue to incur losses for the foreseeable future and may not be able to achieve or sustain profitability in the future. We have no products approved for sale, have not generated any revenue from our product candidates and may never generate revenue or become profitable.

Investment in biotechnology product development is a highly speculative undertaking and entails substantial upfront capital expenditures and significant risks that any product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval and become commercially viable. We have no products approved for commercial sale, have not generated any revenue from product sales to date, and continue to incur significant research and development and other expenses related to our ongoing operations. We do not expect to generate product revenue unless or until we successfully complete preclinical and clinical development and obtain regulatory approval of, and then successfully commercialize, at least one of our product candidates. We may never succeed in these activities and, even if we do, may never generate revenues that are significant or large enough to achieve profitability. If we are unable to raise sufficient additional capital to advance a product candidate to commercialization or generate sufficient revenue through the sale of any approved products, we may be unable to continue operations without additional funding.

We have incurred significant net losses in each period since we commenced operations in June 2024. We generated net losses of $127.4 million for the year ended December 31, 2025. As of December 31, 2025, we had an accumulated deficit of $174.4 million. We expect to continue to incur losses for the foreseeable future. Our operating expenses and net losses may fluctuate significantly from quarter to quarter and year to year. We anticipate that our expenses will increase substantially if and as we:

- advance our existing and future product candidates through preclinical and clinical development, including potential expansion into additional indications;
- seek to identify additional product candidates;
- maintain, expand, enforce, defend and protect our intellectual property portfolio;
- seek, obtain and maintain regulatory approvals for our product candidates;
- seek to identify, establish and maintain additional collaborations and license agreements;
- make milestone payments to Paragon under the Paragon Option Agreement and the license agreements with Paragon relating to JADE101 and JADE201 (together, the “Paragon License Agreements”), and under any additional future collaboration or license agreements that we enter into;
- ultimately establish a sales, marketing and distribution infrastructure to commercialize any drug products for which we may obtain regulatory approval, either on our own or in collaboration with others;
- generate revenue from commercial sales of product candidates for which we receive regulatory approval, if any;
- hire additional personnel including research and development, clinical and commercial personnel;
- adds operational, financial and management information systems and personnel, including personnel to support our product development;
- acquire or in-licenses products, intellectual property and technologies;
- establish clinical and commercial-scale current good manufacturing practices (“cGMP”) capabilities through a third-party or our own manufacturing facility; and

- operate as a public company.

In addition, our expenses will increase if, among other things, we are required by the FDA or other regulatory authorities to perform clinical trials or studies in addition to, or different than, those that we currently anticipate, there are any delays in completing our clinical trials or the development of any of our product candidates, or there are any third-party challenges to our intellectual property or we need to defend against any intellectual property-related claim.

Even if we obtain regulatory approval for, and are successful in commercializing, one or more of our product candidates, we expect to incur substantial additional research and development and other expenditures to develop and market additional product candidates and/or to expand the approved indications of any marketed product. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue.

Our failure to become profitable would decrease our value and could impair our ability to raise capital, maintain our research and development efforts, expand our business and/or continue our operations. A decline in the value of our stock could also cause stockholders to lose all or part of their investment.

Risks Related to Our Discovery, Development and Commercialization

We face competition from entities that have developed or may develop products for the diseases addressed by our product candidates.

The development and commercialization of drugs is highly competitive. Our product candidates, if approved, will face significant competition and our failure to effectively compete may prevent us from achieving significant market penetration. We compete with a variety of multinational biopharmaceutical companies, specialized biotechnology companies and emerging biotechnology companies, including Biogen Inc., Biohaven, Ltd., Calliditas Therapeutics AB, Climb Bio, Inc., Novartis AG, Otsuka Pharmaceutical Co., Ltd., Takeda Pharmaceutical Company Limited, Travere Therapeutics, Inc., Vera Therapeutics, Inc., Vertex Pharmaceuticals Incorporated, and Vor Biopharma Inc. as well as academic institutions, governmental agencies, and public and private research institutions, among others. Many of the companies with which we are currently competing or will compete against in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals, and regulatory approved products than we do, and are further along in the clinical development and/or commercialization process. Mergers and acquisitions in the pharmaceutical and biotechnology industry may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites, raising capital, patient registration for clinical trials, establishing and defending rights to intellectual property, as well as in acquiring technologies complementary to, or necessary for, our product candidates.

Our competitors have developed or are developing, and may in the future develop, product candidates or products competitive with our product candidates. Competitive therapeutic treatments include those that have already been approved and accepted by the medical community and any potential new treatments, including those currently under clinical development. Our success will depend partially on our ability to develop and commercialize products that have a competitive safety, efficacy, dosing and/or presentation profile. Our commercial opportunity and success will be reduced or eliminated if competing products are safer, more effective, have a more attractive dosing profile or presentation or are less expensive than the products we develop, or if our competitors develop competing products or biosimilars that enter the market more quickly than we do and are able to gain market acceptance. Conversely, the lack of commercial success of other competing therapies may raise concerns about the financial viability of our product candidates.

In addition, because of the competitive landscape for autoimmune indications, including IgA nephropathy (“IgAN”), we may also face competition for establishing trial sites and clinical trial enrollment. Participant Enrollment will depend on many factors, including if potential clinical trial participants choose to undergo treatment with approved products or enroll in competitors’ ongoing clinical trials for product candidates that are under development for the same indications as our product candidates. An increase in the number of approved products for the indications we are targeting with our product candidates will likely further exacerbate this competition. Our inability to enroll a sufficient number of participants could, among other impacts, delay our development timeline, which may further harm our competitive position.

Our programs are in the clinical and preclinical stages of development and may fail in development or suffer delays that materially and adversely affect our viability. If we or our current or future collaborators are unable to complete development of or commercialize our product candidates, or experience significant delays in doing so, our business will be materially harmed.

We have no commercially approved products. Our programs are in the clinical and preclinical stages of development, and we have not completed any clinical trials. As a result, we expect it will be many years before we commercialize any product candidate, if ever. Our ability to achieve and sustain profitability depends on obtaining regulatory approvals for, and successfully commercializing, our product candidates, either alone or with third parties, and we cannot guarantee you that we will ever obtain regulatory approval for any of our product candidates. We have not yet demonstrated our ability to complete any clinical trials, obtain regulatory approvals, manufacture a commercial-scale product or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Before obtaining regulatory approval for the commercial distribution of any product candidate, we or an existing or future collaborator must conduct extensive preclinical tests and clinical trials to demonstrate the safety, purity, potency (and efficacy) in humans of the product candidate.

Preclinical and clinical drug development is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the preclinical study or clinical trial process. Despite promising preclinical or clinical results, any product candidate can unexpectedly fail at any stage of preclinical or clinical development. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in clinical development even after achieving promising results in earlier studies, and the historical failure rate for product candidates in our industry is high. Such setbacks have occurred and may occur for many reasons, including, but not limited to: clinical sites and investigators may deviate from clinical trial protocols and we may fail to detect any such deviations in a timely manner; trial participants may fail to adhere to any required clinical trial procedures, including any requirements for post-treatment follow-up; our product candidates may fail to demonstrate effectiveness or safety in certain patient subpopulations, which has not been observed in earlier trials due to limited sample size, lack of analysis, or otherwise; or our clinical trials may not adequately represent the patient populations we intend to treat, whether due to limitations in our trial designs or otherwise, such as where one patient subgroup is overrepresented in the clinical trial

The results from preclinical studies or early clinical trials of a product candidate may not predict the results of later clinical trials of the product candidate, and interim results of a clinical trial are not necessarily indicative of final results. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy characteristics despite having progressed through preclinical studies and initial clinical trials. In particular, we do not know whether our product candidates will perform adequately in future clinical trials. It is not uncommon to observe results in clinical trials that are unexpected based on preclinical studies and early clinical trials, and many product candidates fail in clinical trials despite very promising early results. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses.

For the foregoing reasons, we cannot be certain that our ongoing and planned clinical trials and preclinical studies will be successful. Any safety concerns observed in any one of our clinical trials in our targeted indications could limit the prospects for regulatory approval of our product candidates in those and other indications, which could have a material adverse effect on our business, financial condition and results of operations.

We or our collaborators may experience delays in initiating or completing preclinical studies or clinical trials or reporting data readouts for such trials. We or our collaborators also may experience numerous unforeseen events during, or as a result of, any future preclinical studies or clinical trials that we could conduct that could delay or prevent our ability to receive regulatory approval or commercialize our product candidates, including:

- regulators, such as the FDA, comparable foreign regulatory authorities, institutional review boards (“IRBs”) or ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may experience delays in reaching, or fail to reach, agreement on acceptable terms with prospective trial sites and prospective clinical research organizations (“CROs”), the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- clinical trial sites may deviate from the trial protocol, fail to conduct trials in a compliant manner or drop out of a trial, which may require that we add new clinical trial sites or investigators or otherwise negatively impact the timing or integrity of our clinical trial(s);
- clinical trials of any product candidates may fail to show safety, purity, potency or efficacy, or may produce negative or inconclusive results and we may decide, or regulators may require us, to conduct additional preclinical studies or clinical trials or we may decide to abandon a product development program;

- the number of subjects required for clinical trials of any product candidates may be larger than we anticipate, especially if regulatory bodies require completion of non-inferiority or superiority trials, enrollment in these clinical trials may be slower than we anticipate or subjects may drop out of these clinical trials or fail to return for post-treatment follow-up at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, or may deviate from the clinical trial protocol or suffer other quality or performance issues that negatively impact the timing or integrity of our clinical trial(s);
- we may elect to, or regulators, IRBs or ethics committees may require that we or our investigators, suspend or terminate clinical research or trials for various reasons, including noncompliance with regulatory requirements or a finding that the participants in our clinical trials are being exposed to unacceptable health risks;
- the cost of clinical trials of any of our product candidates may be greater than we anticipate;
- the quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be inadequate to initiate or successfully complete a given clinical trial;
- we may be unable to manufacture sufficient quantities of our product candidates for use in clinical trials;
- we may be required to transfer manufacturing processes for our product candidates to other sites, which may require additional preclinical or clinical development;
- subjects in our trials may experience severe or serious unexpected drug-related adverse effects;
- serious adverse events may occur in trials of the same class of agents conducted by other companies that could be considered similar to our product candidates;
- we may select clinical endpoints that require prolonged periods of clinical observation or extended analysis of the resulting data;
- the FDA or other regulatory authorities may require us to submit additional data, such as long-term toxicology studies, or impose other requirements before permitting us to initiate a clinical trial.

Commencing clinical trials in the United States is subject to allowance by the FDA of an Investigational New Drug Applicable ("IND") and finalizing the trial design based on discussions with the FDA. Commencing clinical trials in jurisdictions outside of the United States is similarly subject to acceptance by the applicable regulatory authority of clinical trial documentation following discussions with such authority. In the event that the FDA or other applicable regulatory authority requires us to complete additional clinical or preclinical studies or we are required to satisfy other FDA or foreign regulatory authority requests, respectively, prior to commencing clinical trials, the start of our first clinical trial for a product candidate may be delayed. Even after we receive and incorporate advice from these regulatory authorities, the FDA or other regulatory authorities could disagree as to whether we have satisfied their requirements to commence any clinical trial or change their position on the acceptability of our trial design or the clinical endpoints selected, which may require us to complete additional preclinical studies or clinical trials, delay the enrollment of our clinical trials or impose stricter approval conditions than we currently expect. There are analogous processes and risks applicable to clinical trial applications in other countries, including New Zealand, Australia, countries in Europe and countries in Asia. Conducting clinical trials in multiple countries, as we have with respect to our product candidates, creates further risks, including the failure of enrolled subjects in foreign countries to adhere to clinical protocols as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with foreign regulatory schemes, and political and economic risks, including war, relevant to such foreign countries.

In addition, many of the factors that cause, or lead to, the termination suspension of, or a delay in the commencement or completion of, clinical trials may also ultimately lead to the denial of regulatory approval of a product candidate. Any resulting delays to our clinical trials could shorten any period during which we may have the exclusive right to commercialize our product candidates. In such cases, our competitors may be able to bring products to market before we do, and the commercial viability of our product candidates could be significantly reduced. Any of these occurrences may harm our business, financial condition and prospects.

We are substantially dependent on the success of JADE101, and our current and anticipated future clinical trials of such product candidate may not be successful.

Our future success is substantially dependent on our ability to timely obtain regulatory approval for, and then successfully commercialize, JADE101. We are initially investing a majority of our efforts and financial resources into the research and

development of this program. We initiated a Phase 1 clinical trial of JADE101 in healthy volunteers in New Zealand in August 2025. The success of JADE101 is dependent on observing suppression of IgA levels and improved pharmacokinetic properties compared to other anti-APRIL monoclonal antibody product candidates in clinical development. This is based in part on the assumption that the increased *in vitro* potency and improved pharmacokinetics observed in non-human primates ("NHPs") will translate into a suppression of IgA levels and improved pharmacokinetic properties of JADE101 in humans, resulting in a more convenient dosing regimen. To the extent we do not observe this suppression of IgA levels or improved pharmacokinetic properties in our Phase 1 clinical trial of JADE101 or in additional clinical trials, it would significantly and adversely affect the clinical and commercial potential of JADE101.

Our product candidates will require additional clinical development, evaluation of clinical, preclinical and manufacturing activities, regulatory approval in multiple jurisdictions, substantial investment and significant marketing efforts before we generate any revenues from product sales. We are not permitted to market or promote these product candidates, or any other product candidates, before we receive regulatory approval from the FDA and comparable foreign regulatory authorities, and we may never receive such regulatory approvals.

The success of our product candidates will depend on a variety of factors. We do not have complete control over many of these factors, including certain aspects of clinical development and the regulatory submission process, potential threats to our intellectual property rights, potential threats from the intellectual property rights of third parties and the manufacturing, marketing, distribution and sales efforts of any current or future collaborator. Accordingly, we cannot assure you that we will ever be able to generate revenue through the sale of these product candidates, even if approved. If we are not successful in obtaining regulatory approval and commercializing JADE101, or our other current or future product candidates, or are significantly delayed in doing so, our business will be materially harmed.

If we do not achieve our projected development objectives in the time frames we announce and expect, the commercialization of our product candidates may be delayed which may harm our reputation and prospects, increase our expenses and cause our stock price to decline.

From time to time, we estimate the timing of the anticipated accomplishment of various scientific, clinical, regulatory and other product development goals, which we sometimes refer to as milestones. These milestones may include the commencement or completion of scientific studies and clinical trials, such as the expected timing for the initiation of our Phase 2 clinical trial of JADE101 or our Phase 1 clinical trials of JADE201 and JADE301, the timing for clinical data, such as mechanistic clinical proof-of-concept data and data from the Phase 1 clinical trial of JADE101 in healthy volunteers, and the timing for the submission of regulatory filings. From time to time, we may publicly announce the expected timing of some of these milestones. All of these milestones are and will be based on numerous assumptions. The actual timing of these milestones can vary dramatically compared to our estimates, in many cases for reasons beyond our control. If we do not meet these milestones as publicly announced, or at all, our prospects and reputation may be adversely affected and our stock price may decline. Additionally, delays relative to our projected timelines are likely to cause overall expenses to increase, which may require us to raise additional capital sooner than expected and prior to achieving targeted development milestones.

The target patient population for the treatment of IgAN is small and has not been definitively determined, and if our estimates of the number of treatable patients is lower than expected, our potential revenues from sales of our product candidates, if approved, and our ability to achieve profitability would be compromised.

Our estimates of both the number of patients who have IgAN, as well as the subset of patients with the disease in a position to receive treatment from JADE101 (i.e., those with proteinuria > 0.5g/day), if approved, are based on our beliefs, and these estimates may prove to be incorrect. These estimates have been derived from a variety of sources, including scientific literature, input from physicians that treat patients with the diseases we are targeting, patient foundations and secondary market research databases. For example, our estimates of the prevalence of IgAN in certain geographies are based in part on the published prevalence of IgAN among patient populations in the United States split across ethnicities, and our own analyses of prevalence in Europe, and on published disease incidence rates for certain geographies and estimated for the populations of such geographies. Further, new studies may change the estimated incidence or prevalence of IgAN, and any regulatory approvals that we may receive for JADE101 may include limitations for use or contraindications that decrease the addressable patient population. Similar considerations would apply to estimates of patient population for target indications we select for JADE201, JADE301 and any future product candidates. Accordingly, our target patient populations may turn out to be lower than expected, in which case the potential revenues from sales of our product candidates, if approved, would be lower than expected.

Our approach to the discovery and development of our product candidates is unproven, and we may not be successful in our efforts to build a pipeline of product candidates with commercial value.

Our approach to the discovery and development of our product candidates leverages well-established mechanisms of action and incorporates advanced antibody engineering to optimize half-life and other properties designed to overcome limitations of existing therapies, such as by increasing binding affinity. Our product candidates are purposefully designed to improve upon existing product candidates and products while maintaining the same, well-established mechanisms of action. However, the scientific research that forms the basis of our efforts to develop product candidates using half-life extension technologies and to enhance efficacy through improved binding affinity, including monoclonal antibodies, is ongoing and may not result in viable product candidates. We have limited clinical data on product candidates utilizing monoclonal antibody half-life extension technologies, especially in autoimmune indications, demonstrating whether they are safe or effective for long-term treatment in humans. We also have no clinical data to indicate whether our modifications to enhance binding affinity translate into improved efficacy in humans. The long-term safety and efficacy of our product candidates compared to currently approved products is unknown.

We may ultimately discover that utilizing half-life extension technologies for our specific targets and indications and any product candidates resulting therefrom do not possess certain properties required for therapeutic effectiveness. Even with preclinical data regarding the increased half-life properties of our product candidates, and the same results may not be seen in humans. In addition, product candidates using half-life extension technologies may demonstrate different chemical and pharmacological properties in patients than they do in laboratory studies. This technology and any product candidates resulting therefrom may not demonstrate the same chemical and pharmacological properties in humans and may interact with human biological systems in unforeseen, ineffective or harmful ways. Many product candidates that appeared highly promising in preclinical studies or in early-stage clinical trials have failed when advanced into, or further in, clinical development.

In addition, other companies are developing drug products that utilize half-life extension technology in other targets and indications. The failure of those companies to demonstrate the safety and efficacy of their product candidates may be harmful to our business, financial condition, results of operations and prospects.

In addition, we may in the future seek to discover and develop product candidates that are based on novel targets and technologies that are unproven. If our discovery or business development activities fail to identify novel targets or technologies for drug development, or such targets or technologies prove to be unsuitable for treating human disease, we may not be able to develop viable additional product candidates. We and our existing or future collaborators may never receive approval to market and commercialize any product candidate. Even if we or an existing or future collaborator obtains regulatory approval, the approval may be for targets, disease indications or patient populations that are not as broad as we intended or desired or may require labeling that includes significant use or distribution restrictions or safety warnings. If the products resulting from our product candidates prove to be ineffective, unsafe or commercially unviable, our product candidates and pipeline would have little, if any, value, which would have a material and adverse effect on our business, financial condition, results of operations and prospects.

Preclinical and clinical development involves a lengthy and expensive process that is subject to delays and with uncertain outcomes, and results of earlier studies and trials may not be predictive of future clinical trial results. If our preclinical studies and clinical trials are not sufficient to support regulatory approval of any of our product candidates, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development of such product candidate.

Before obtaining regulatory approval from regulatory authorities for the sale of any product candidate, we must complete preclinical studies and then conduct extensive clinical trials to demonstrate the safety, potency and/or and efficacy of our product candidate in humans. Our clinical trials may not be conducted as planned or completed on schedule, if at all, and failure can occur at any time during the preclinical study or clinical trial process. For example, we depend on the availability of NHPs to conduct certain preclinical studies that we are required to complete prior to submitting an IND and initiating clinical development. There is currently a global shortage of NHPs available for drug development. While we currently do not anticipate that this shortage will materially impact our costs or timelines, a continuing or future shortage could cause the cost of obtaining NHPs for our future preclinical studies to increase significantly or result in delays to our development timelines. Furthermore, a failure of one or more clinical trials can occur at any clinical trial phase. The outcome of preclinical studies and early-stage clinical trials may not be predictive of the success of later clinical trials. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain regulatory approval of their product candidates. In addition, we expect to rely on patients to provide feedback on measures such as measures of disease and quality of life, which are subjective and inherently difficult to evaluate. These measures can be influenced by factors outside of our control and can vary widely from day to day for a particular patient, and from patient to patient and from site to site within a clinical trial.

We cannot be sure that the FDA or comparable foreign regulatory authorities will agree with our clinical development plans. We plan to use the data from our Phase 1 trial of JADE101 in healthy volunteers to support additional clinical trials. However, there is no guarantee the data from such Phase 1 trial will support additional trials. If the FDA or comparable foreign regulatory authorities require us to conduct additional trials or enroll additional participants, our development timelines may be delayed. We cannot be sure that submission of an IND or similar foreign application will result in the FDA or comparable foreign regulatory authorities, as applicable, allowing clinical trials to begin in a timely manner, if at all. Moreover, even if these trials begin, issues may arise that could cause regulatory authorities to suspend or terminate such clinical trials. Events that may prevent successful or timely initiation or completion of clinical trials include: inability to generate sufficient preclinical, toxicology or other *in vivo* or *in vitro* data to support the initiation or continuation of clinical trials; delays in reaching a consensus with regulatory authorities on study design or implementation of the clinical trials; delays or failure in obtaining regulatory authorization to commence a trial; delays in reaching agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites; delays in identifying, recruiting and training suitable clinical investigators; delays in obtaining required IRB approval or positive ethics committee opinions at each clinical trial site; delays in manufacturing, testing, releasing, validating or importing/exporting sufficient stable quantities of our product candidates for use in clinical trials or the inability to do any of the foregoing; failure by our CROs, other third parties or us to adhere to clinical trial protocols; failure to perform in accordance with the FDA's or any other regulatory authority's good clinical practice ("GCP") requirements or regulatory guidelines; changes to the clinical trial protocols; clinical sites deviating from trial protocol or dropping out of a trial; changes in regulatory requirements, guidance or clinical trial plans that require amending or submitting new clinical protocols; selection of clinical endpoints that require prolonged periods of observation or analyses of resulting data; transfer of manufacturing processes to new or larger-scale facilities and delays or failure by our CMOs or us to make any necessary changes to such manufacturing process; and third parties being unwilling or unable to satisfy their contractual obligations to us.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs or ethics committees of the institutions in which such clinical trials are being conducted, by the Data Safety Monitoring Board, if any, for such clinical trial or by the FDA or comparable foreign regulatory authorities. Such authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical trial protocols, inspection of the clinical trial operations or trial site by the FDA or comparable foreign regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from the product candidate, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates, if the results of these trials are not positive or are only moderately positive or if there are safety concerns, our business and results of operations would be adversely affected.

We may find it difficult to enroll participants in our clinical trials, particularly given the relatively small patient population and significant competition for patients who have the diseases for which JADE101 is being developed. If we encounter difficulties enrolling participants in our current clinical trial of JADE101 or future clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

We may experience difficulties in enrollment in our current or future clinical trials for a variety of reasons. The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of participants who remain in the trial until our conclusion. In particular, as a result of the inherent difficulties in diagnosing IgAN, an indication with relatively small patient populations, and the significant competition for recruiting participants with IgAN in clinical trials, there may be delays in enrolling the participants we need to complete clinical trials on a timely basis, or at all. In addition, because we are initially focused on developing product candidates for indications for which there is significant competition for recruiting patients, we may encounter similar challenges for patient enrollment when we commence clinical programs for additional product candidates in the future. Further, there are four recently approved products for the treatment of IgAN, with additional products likely to gain approval in the next year, and participants may decide, or physicians may recommend, to use such approved treatments instead of enrolling in clinical trials.

The enrollment of participants in future trials for any of our product candidates will depend on many factors, including:

- size and nature of the patient population;
- severity of the disease under investigation;
- availability and efficacy of approved drugs for the disease under investigation;
- participant eligibility and exclusion criteria for the trial in question;

- patients' and clinicians' perceived risks and benefits of the product candidate under study;
- if patients choose to enroll in clinical trials, rather than using approved products, or if our competitors have ongoing clinical trials for product candidates that are under development for the same indications as our product candidates, and patients instead enroll in such clinical trials;
- efforts to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment;
- proximity and availability of clinical trial sites for prospective participants;
- continued enrollment of prospective participants by clinical trial sites; and
- the risk that enrolled participants will drop out of our trials prior to completion.

Additionally, the number of participants required for clinical trials of our product candidates may be larger than we anticipate, especially if regulatory bodies require the completion of non-inferiority or superiority trials. Even if we are able to enroll a sufficient number of participants for our future clinical trials, we may have difficulty maintaining participants in our clinical trials. Our inability to enroll or maintain a sufficient number of participants would result in significant delays in completing clinical trials or receipt of regulatory approvals and increased development costs or may require us to abandon one or more clinical trials altogether, which could cause our value to decline, limit our ability to obtain additional financing and otherwise harm our prospects.

Preliminary, "topline" or interim data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures.

From time to time, we may publicly disclose preliminary or topline data from our preclinical studies and clinical trials, which are based on a preliminary analysis of then-available data. The results and related findings and conclusions are subject to change following a more comprehensive review of the data. We also make assumptions, estimations, calculations and conclusions as part of our analyses of these data without the opportunity to fully and carefully evaluate complete data. As a result, the preliminary or topline results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated or subsequently made subject to audit and verification procedures. Any preliminary or topline data should be viewed with caution until the final data are available.

From time to time, we may also disclose interim data from our preclinical studies and clinical trials. Interim data are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available or as patients from our clinical trials continue other treatments.

Further, others, including regulatory authorities, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular product candidate, the approvability or commercialization of the particular product candidate and of us as a company. In addition, the information we choose to publicly disclose regarding a particular preclinical study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure. As a result, you or others may have reached different conclusions based on such extensive information in comparison to our publicly disclosed conclusion regarding a particular preclinical study or clinical trial. If the preliminary, topline or interim data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

Our current and future clinical trials or those of our current or future collaborators may reveal significant adverse events or undesirable side effects not seen in our preclinical studies and may result in a safety profile that could halt clinical development, inhibit regulatory approval or limit commercial potential or market acceptance of any of our product candidates.

Results of our clinical trials could reveal a high or unacceptable severity and prevalence of side effects, adverse events or unexpected characteristics. We have not yet completed any clinical trials in humans. If significant adverse events or other side effects are observed in any of our current or future clinical trials, we may have difficulty recruiting patients to such trials, participants may drop out of our trials, or we may be required to abandon the trials or our development efforts of one or more product candidates altogether.

We, the FDA or other applicable regulatory authorities, or an IRB or ethics committee, may suspend any clinical trials of any product candidate at any time for various reasons, including a belief that participants in such trials are being exposed to unacceptable health risks or adverse side effects. Some potential products developed in the biotechnology industry that initially showed therapeutic promise in early-stage studies and trials have later been found to cause side effects that prevented their further development. Other potential products have shown side effects in preclinical studies, which side effects do not present themselves in clinical trials in humans. Even if the side effects do not preclude the product candidate from obtaining or maintaining regulatory approval, undesirable side effects may inhibit market acceptance of the approved product due to our tolerability versus other therapies. In addition, an extended half-life could prolong the duration of undesirable side effects, which could also inhibit market acceptance. Treatment-emergent adverse events could also affect patient recruitment or the ability of enrolled subjects to complete our clinical trials or could result in potential product liability claims. Potential side effects associated with our product candidates may not be appropriately recognized or managed by the treating medical staff, as toxicities resulting from our product candidates may not be normally encountered in the general patient population and by medical personnel. Any of these occurrences could harm our business, financial condition, results of operations and prospects significantly.

In addition, even if we successfully advance our product candidates or any future product candidate through clinical trials, such trials will only include a limited number of participants and limited duration of exposure to our product candidates. As a result, we cannot be assured that adverse effects of our product candidates will not be uncovered when a significantly larger number of patients are exposed to the product candidate after approval. Further, any clinical trials may not be sufficient to determine the effect and safety consequences of using our product candidates over a multi-year period.

If any of the foregoing events occur or if one or more of our product candidates prove to be unsafe, our entire pipeline could be affected, any of which would have a material adverse effect on our business, financial condition, results of operations and prospects.

We may expend our limited resources to pursue a particular program and fail to capitalize on programs that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we focus our research and development efforts on certain selected programs. For example, we are initially focused primarily on our lead product candidate, JADE101. As a result, we may forgo or delay pursuit of opportunities with other programs that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development product candidates for specific indications may not yield any commercially viable product candidates. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate. In addition, we select product candidates amongst a variety of potential product candidates from Paragon, and the product candidates we select may fail to be viable commercial products or the product candidates we do not select may have a greater likelihood of success.

Any approved products resulting from our current programs or any future program may not achieve adequate market acceptance among clinicians, patients, healthcare third-party payors and others in the medical community necessary for commercial success and we may not generate any future revenue from the sale or licensing of such products.

Even if regulatory approval is obtained for a product candidate resulting from one of our current or future programs, we may not gain market acceptance among physicians, healthcare professionals, patients, healthcare payors or the medical community. We may not generate or sustain revenue from sales of the product due to factors such as whether the product can be sold at a competitive cost and whether it will otherwise be accepted in the market. Market acceptance will depend on many factors, including factors that are not within our control. There are five recently approved products and multiple product candidates in later stages of development for the treatment of IgAN, including Tarpeyo, Filspari, Fabhalta, Vanrafia and Voyxact. Tarpeyo and Filspari both lead to modest benefits on kidney function. Vanrafia received accelerated approval in April 2025 for the treatment of IgAN based on interim results in IgAN patients. Vanrafia treatment led to a 36% decrease in urine protein creatinine ratio (“UPCR”) compared to placebo. Voyxact received accelerated approval in November 2025 for the treatment of IgAN based on interim results in IgAN patients and achieved a 51% reduction in UPCR when compared to placebo. Vanrafia’s and Voyxact’s long-term effects on kidney function stabilization have not yet been reported. Market participants with significant influence over acceptance of new treatments, such as clinicians and third-party payors, may not adopt a biologic that incorporates anti-APRIL antibodies and half-life extension for our targeted indication, and we may not be able to convince the medical community and third-party payors to accept and use, or to provide favorable reimbursement for, any programs developed by us or

our existing or future collaborators. An extended half-life may make it more difficult for patients to change treatments and there is a perception that half-life extension could exacerbate side effects, each of which may adversely affect our ability to gain market acceptance. Market acceptance of our product candidates may be negatively impacted by potential poor performance of our competitors, including the occurrence of serious adverse events in such competitors' clinical trials or failure by such competitors to obtain and maintain regulatory approval for their product candidates. Additionally, although we believe that the improved dosing and convenience we expect our product candidates to provide will improve market acceptance of such product candidates and that our candidates will have a competitive efficacy profile, our predictions may not be accurate and other competitive products may instead gain and hold the applicable market. Sales of medical products also depend on the willingness of clinicians to prescribe the treatment. We cannot predict whether clinicians, clinicians' organizations, hospitals, other healthcare providers, government agencies or private insurers will determine that our product is safe, therapeutically effective, cost effective or less burdensome as compared with competing treatments. If any current or future product candidate is approved but does not achieve an adequate level of acceptance by such parties, we may not generate or derive sufficient revenue from that product candidate and may not become or remain profitable.

Certain of our programs may compete with our other programs, which could negatively impact our business and reduce our future revenue.

We are developing JADE101 for the treatment of IgAN and intend to develop JADE201 and JADE301 for other autoimmune indications, and we may in the future develop programs for additional autoimmune indications. However, developing multiple product candidates for autoimmune indications may negatively impact our business if the product candidates compete with each other. For example, if multiple product candidates are conducting clinical trials at the same time, they could compete for the enrollment of patients. In addition, if multiple product candidates are approved for the same indication, they may compete for market share, which could limit our future revenue.

We plan to conduct clinical trials for product candidates at sites outside the United States, and the FDA may not accept data from trials conducted in such locations.

We are currently conducting our Phase 1 clinical trial of JADE101 in New Zealand, and we may choose to conduct one or more of our future clinical trials outside the United States in whole or in part. Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of this data is subject to conditions imposed by the FDA. In cases where data from foreign clinical trials are intended to serve as the sole basis for regulatory approval in the U.S., the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the U.S. population and U.S. medical practice; (ii) the trials were performed by clinical investigators of recognized competence and pursuant to GCP regulations; and (iii) the data may be considered valid without the need for an on-site inspection by the FDA, or if the FDA considers such inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. In addition, even where the foreign study data are not intended to serve as the sole basis for approval, if the study was not otherwise subject to an IND, the FDA will not accept the data as support for an application for regulatory approval unless the study is well-designed and well-conducted in accordance with GCP requirements and the FDA is able to validate the data from the study through an onsite inspection if deemed necessary. Many foreign regulatory authorities have similar requirements for clinical data gathered outside of their respective jurisdictions. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any comparable foreign regulatory authority will accept data from trials conducted outside of the United States or the relevant jurisdiction, as applicable. If the FDA or any comparable foreign regulatory authority does not accept such data, it would likely result in the need for additional trials, which would be costly and time-consuming and would delay or permanently halt our development of the applicable product candidates or delay or prevent regulatory approval for commercialization in the applicable jurisdiction. Even if the FDA or any comparable foreign regulatory authority accepted such data, it could require us to modify our planned clinical trials to receive clearance to initiate such trials in the United States or the relevant jurisdiction, as applicable, or to continue such trials once initiated.

Further, conducting international clinical trials presents additional risks that may delay completion of our clinical trials. These risks include the failure of enrolled participants in foreign countries to adhere to clinical protocol as a result of differences in healthcare services or cultural customs that could restrict or limit our ability to conduct our clinical trials, the administrative burdens of conducting clinical trials under multiple sets of foreign regulations, foreign exchange fluctuations, diminished protection of intellectual property in some countries, as well as political and economic risks relevant to foreign countries.

Risks Related to Our Reliance on Third Parties

We rely on collaborations and licensing arrangements with third parties, including Paragon. If we are unable to maintain these collaborations or licensing arrangements, or if these collaborations or licensing arrangements are not successful, our business could be negatively impacted.

We rely on our collaboration with a third party, Paragon, for a substantial portion of our discovery capabilities and for the rights necessary to develop and commercialize our product candidates. In the future, we could also rely on additional licensing arrangements with third parties. For example, we have entered into the Paragon License Agreements. However, Paragon could terminate each of the Paragon License Agreements under certain circumstances, including our failure to make any payments owed to Paragon under the agreement or any uncured material breach of the agreement by us, in which event we may lose intellectual property rights and may not be able to develop or commercialize the product candidates covered by that agreement, including JADE101 or JADE201, as applicable.

Fairmount beneficially owns more than 5% of the Company's capital, currently has two representatives appointed to the Board and beneficially owns more than 5% of Paragon.

Collaborations or licensing arrangements that we enter into may not be successful, and any success will depend heavily on the efforts and activities of such collaborators or licensors. If any of our collaborators or licensors experiences delays in performance of, or fails to perform, our obligations under our agreement with us, disagrees with our interpretation of the terms of such agreement or terminates their agreement with us, our pipeline and product candidates and development timeline could be adversely affected. If we fail to comply with any of the obligations under our collaborations or license agreements, including payment terms and diligence terms, our collaborators or licensors may have the right to terminate such agreements, in which event we may lose intellectual property rights and may not be able to develop, manufacture, market or sell the products covered by our agreements or may face other penalties under our agreements. Our collaborators and licensors may also fail to properly maintain or defend the intellectual property we have licensed from them, if required by our agreement with them, leading to the potential invalidation of our intellectual property, or they may even infringe upon our intellectual property rights, any of which could subject us to litigation or arbitration, which would be time-consuming and expensive and could harm our ability to commercialize our product candidates. In addition, collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates and products if the collaborators believe that the competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours.

As part of our strategy, we plan to evaluate additional opportunities to enhance our capabilities and expand our development pipeline or add development or commercialization capabilities. We may not realize the benefits of such collaborations, alliances or licensing arrangements. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business.

We may face significant competition in attracting appropriate collaborators, and more established companies may also be pursuing strategies to license or acquire third-party intellectual property rights that we consider attractive. These companies may have a competitive advantage over us due to their size, financial resources and greater clinical development and commercialization capabilities. In addition, companies may be unwilling to assign or license rights to us, whether they perceive us to be a competitor or for other reasons. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Collaborations are complex and time-consuming to negotiate, document and execute. In addition, consolidation among large pharmaceutical and biotechnology companies has reduced the number of potential future collaborators. We may not be able to negotiate additional collaborations on a timely basis, on acceptable terms or at all. If we fail to enter into collaborations and does not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our product candidates or bring them to market.

Risks associated with the in-licensing or acquisition of product candidates could cause substantial delays in the preclinical and clinical development of our product candidates.

We have relied and continues to rely on Paragon, and expect to rely on our future licensing partners, to (i) conduct research and development in accordance with the applicable protocol, legal, regulatory and scientific standards, (ii) accurately report the results of all preclinical trials conducted prior to our licensing or acquisition of the relevant product candidates and (iii) correctly collect and interpret the data from these trials. If the research and development processes or the results of the development programs prior to our licensing or acquisition of our product candidates prove to be unreliable, this could result in increased costs

and delays in the development of our product candidates, which could adversely affect any future revenue from such product candidates, if approved.

We may also acquire or in-license additional product candidates for preclinical or clinical development in the future as we continue to build our pipeline. The risks associated with acquiring or in-licensing product candidates could result in delays in the commencement or completion of our preclinical studies and clinical trials, if they are ever commenced or completed, and our ability to generate revenues from our product candidates may be delayed. Please see the section titled "*Risk Factors - Risks Related to Our Intellectual Property - If we are unable to obtain or maintain necessary rights to our programs through acquisitions and in-licenses, our business may be materially harmed*" below for additional information regarding such risks.

We currently rely, and plan to rely in the future, on third parties to conduct and support our preclinical studies and clinical trials. If these third parties do not properly and successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval of or commercialize our product candidates.

We have utilized and plan to continue to utilize and depend upon independent investigators and collaborators, such as medical institutions, CROs, contract testing labs and strategic partners, to conduct and support our preclinical studies and clinical trials under agreements with us, some of which are involved in multiple studies or trials. We will rely heavily on these third parties over the course of our preclinical studies and clinical trials, and we control only certain aspects of their activities. As a result, we will have less direct control over the conduct, timing and completion of these preclinical studies and clinical trials and the management of data developed through preclinical studies and clinical trials than would be the case if we were relying entirely upon our own staff. Nevertheless, we are responsible for ensuring that each of our studies and trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on these third parties does not relieve us of our regulatory responsibilities. We and our third-party contractors and CROs are required to comply with GCP, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for all of our product candidates in clinical development. If we or any of these third parties fail to comply with applicable GCP regulations, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP. In addition, our clinical trials must be conducted with products manufactured in accordance with cGMP. Our failure to comply with these requirements may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws, and foreign equivalents.

Any third parties conducting our clinical trials will not be our employees and, except for remedies available to us under our agreements with such third parties, we cannot control whether they devote sufficient time and resources to our programs. These third parties may encounter challenges hiring and retaining sufficient qualified personnel or they may be involved in mergers, acquisitions or similar transactions and may have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other product development activities, which could negatively affect their performance on our behalf and the timing thereof and could lead to products that compete directly or indirectly with our current or future product candidates. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to complete development of, obtain regulatory approval of or successfully commercialize our product candidates. In addition, principal investigators for our clinical trials may be asked to serve as scientific advisors or consultants to us from time to time and may receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, or the FDA or foreign authorities conclude that the financial relationship may have affected the interpretation of the study, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection by the FDA of any BLA or similar foreign application we submit. Any such delay or rejection could prevent us from commercializing our product candidates.

Our reliance on foreign CROs and CMOs may increase the risks associated with our development programs.

We plan to rely on foreign CROs and CMOs, including WuXi Biologics (Hong Kong) Limited ("WuXi Biologics (Hong Kong)"), for formulation and manufacturing of our clinical trial materials, and will likely continue to rely on foreign CROs and CMOs in the future. Foreign CMOs may be the target of legislation, trade restrictions and foreign regulatory requirements which could increase the cost or reduce the supply of material available to us, delay the procurement or supply of such material, restrict or even prohibit our ability to work with such CMOs, or have an adverse effect on our ability to secure significant commitments from governments to purchase potential therapies. For example, the U.S. BIOSECURE Act, which was enacted in December

2025, prohibits federal agencies from procuring or using any biotechnology equipment or services from "biotechnology companies of concern", or entering into, extending, or renewing any contracts with entities that use such biotechnology equipment or services from "biotechnology companies of concern". Congress has interpreted a "biotechnology company of concern" as an entity that is under the control of a foreign adversary and that poses a risk to national security based on its research or multiomic data collection (e.g., collection of genomic information). While the U.S. BIOSECURE Act has a grandfathering period of five years for existing contracts, and has carveouts for manufacture of drugs for supply under Medicaid and Medicare Part B, subject to the Secretary of Veteran Affairs' discretion, the impact of the U.S. BIOSECURE Act on the biotechnology industry is uncertain. If the foreign CROs and CMOs we rely on become subject to trade restrictions, sanctions, increased tariffs or other regulatory requirements by the U.S. government (including designation as a "biotechnology company of concern" under the U.S. BIOSECURE Act), or if the U.S. or Chinese government take retaliatory actions due to recent or increased tensions between the U.S. and China, it may have the potential to severely restrict the ability of U.S. biopharmaceutical companies like us to purchase services or products from, or otherwise collaborate with, certain "biotechnology companies of concern" without losing the ability to contract with, or otherwise receive funding from, the U.S. government.

The biopharmaceutical industry in China is strictly regulated by the Chinese government. Changes to Chinese regulations or government policies affecting biopharmaceutical companies are unpredictable and may have a material adverse effect on our collaborators in China which could have an adverse effect on our business, financial condition, results of operations and prospects. In addition, the United States government has imposed significant tariffs on imports from China and other countries and may impose more restrictions on goods, including biologically derived substances, manufactured in or imported from China or other countries or impose other restrictions on companies' ability to work with Chinese or other foreign counterparties. Evolving changes in China's public health, economic, political, and social conditions and the uncertainty around China's relationship with other governments, such as the United States and the UK, could also negatively impact our ability to manufacture our product candidates for our clinical trials or have an adverse effect on our ability to secure government funding, which could adversely affect our financial condition and cause us to delay our clinical development programs. In addition, while we have established relationships with CROs and CMOs outside of China, moving to those suppliers in the event of a geopolitical instability affecting our collaborators in China could introduce delays into the development program.

We rely on the use of third-party CMOs to manufacture our product candidates, and we expect to continue to rely on third-party CMOs to produce our products, if approved. Our business could be adversely affected if we are unable to use third-party manufacturing suites or if the third-party manufacturers encounter difficulties in production.

We do not currently own any facility that may be used as our clinical-scale manufacturing and processing facility and must rely on CMOs to manufacture our product candidates. We have not yet caused our product candidates to be manufactured on a commercial scale and may not be able to do so for any of our product candidates, if approved. We currently have a single CMO source for our supply of our product candidates and an agreement with a second CMO supplier to develop additional supply capabilities. If there should be any disruption in such supply arrangement, including any adverse events affecting our suppliers, or if we experience delays or difficulties in transferring, or are unable to successfully transfer, our manufacturing processes, it could have a negative effect on the clinical development of our product candidates and other operations while we work to identify and qualify an alternate supply source. We have limited control over the manufacturing process of, and may be dependent on, our CMO partners for compliance with cGMP requirements and any other regulatory requirements of the FDA or comparable foreign regulatory authorities for the manufacture of our product candidates. Beyond periodic audits, we have limited control over the ability of our CMOs to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or another applicable regulatory authority does not approve these facilities for the manufacture of our product candidates or withdraws any approval in the future, we may need to find alternative manufacturing facilities, arrangements or partners, which would require the incurrence of significant additional costs and delays and materially adversely affect our ability to develop, obtain regulatory approval for or market our product candidates, if approved. We, or our future CMOs, any current or future collaborators and their CMOs could be subject to periodic unannounced inspections by the FDA, competent authorities of member states of the EU or other comparable foreign regulatory authorities, to monitor and ensure compliance with cGMP. Despite our efforts to audit and verify regulatory compliance, one or more of our third-party manufacturing vendors may be found on regulatory inspection by the FDA, competent authorities of EU or other comparable foreign regulatory authorities to be noncompliant with cGMP and comparable foreign regulations. Our failure, or the failure of our CMOs, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension, variation or withdrawal of approvals, license revocation, seizures or recalls of product candidates or drugs, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates or products, if approved, and harm our business and results of operations.

Moreover, our CMOs may experience manufacturing difficulties due to resource constraints, supply chain issues, intellectual property disputes or as a result of labor disputes or unstable political environments. If any CMOs on which we will rely fail to manufacture quantities of our product candidates at quality levels necessary to meet regulatory requirements and at a

scale sufficient to meet anticipated demand at a commercially reasonable cost, our business, financial condition and prospects could be materially and adversely affected. In addition, our CMOs are responsible for transporting temperature-controlled materials that can be inadvertently degraded during transport due to several factors, rendering certain batches unsuitable for trial use for failure to meet, among others, our integrity and purity specifications. We and any of our CMOs may also face product seizure or detention or refusal to permit the import or export of products. Our business could be materially adversely affected by business disruptions to our third-party providers that could materially adversely affect our anticipated timelines, potential future revenue and financial condition and increase our costs and expenses. Each of these risks could delay or prevent the completion of our preclinical studies and clinical trials or the approval of any of our product candidates by the FDA or comparable foreign regulatory authorities, result in higher costs or adversely impact commercialization of our product candidates.

Risks Related to Our Business and Operations

In order to successfully implement our plans and strategies, we will need to grow the size of our organization, and we may experience difficulties in managing this growth.

We expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of preclinical and clinical drug development, technical operations, clinical operations and regulatory affairs. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial personnel and systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team working together in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel.

We are highly dependent on our key personnel and anticipate hiring new key personnel. If we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.

Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our managerial, scientific and medical personnel, including our Chief Executive Officer, Chief Scientific Officer and Head of Research & Development and other key members of our leadership team. Although we have entered into employment agreements with our executive officers, each of them may terminate their employment with us at any time. We do not maintain “key person” insurance for any of our executives or other employees. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key personnel may be difficult and may take an extended period of time. If we do not succeed in attracting and retaining qualified personnel, it could materially adversely affect our business, financial condition and results of operations. We could in the future have difficulty attracting and retaining experienced personnel and may be required to expend significant financial resources in our employee recruitment and retention efforts.

Our future growth may depend, in part, on our ability to operate in foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties.

Our future growth may depend, in part, on our ability to develop and commercialize our product candidates, if approved, in foreign markets for which we may rely on collaboration with third parties. Recent and ongoing changes in the United States trade policy with foreign countries, including the continued uncertainty surrounding U.S. tariffs and potential retaliatory measures by foreign governments, may disrupt the global supply chain for biopharmaceutical products. For example, in September 2025, President Trump announced plans to impose 100% tariffs on imported branded or patented pharmaceuticals, unless the importing company is building U.S. manufacturing capacity. It is not yet clear whether these tariffs would apply to the importation of active pharmaceutical ingredients and possibly bulk drug products that are intended for use in clinical trials and not for commercial sale, which could increase the costs of materials for our clinical trials. Any direct tariffs, if imposed on pharmaceutical products, may result in increased costs for raw materials and contract manufacturing services, reduced ability to source critical CMOs, and a delay in our development timelines.

We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the applicable foreign regulatory authority, and we may never receive such regulatory approval for any of our product candidates. To obtain separate regulatory approval in many other countries, we must comply with numerous and varying regulatory requirements of such countries regarding safety and efficacy and governing, among other things, clinical trials and commercial sales, pricing and distribution of our product candidates, if approved, and we cannot predict success in these jurisdictions. If we fail to comply with the regulatory requirements in international markets and receive applicable regulatory approvals, our target market will be

reduced and our ability to realize the full market potential of our product candidates will be harmed and our business will be adversely affected. Moreover, even if we obtain approval of our product candidates and ultimately commercialize our product candidates in foreign markets, we would be subject to the risks and uncertainties, including the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements and reduced protection of intellectual property rights in some foreign countries.

Our estimates of market opportunity and forecasts of market growth may prove to be inaccurate, and even if the markets in which we compete achieve the forecasted growth, our business may not grow at similar rates, or at all.

Our market opportunity estimates and growth forecasts are subject to significant uncertainty and are based on assumptions and estimates which may not prove to be accurate. Our estimates and forecasts relating to size and expected growth of our target market may prove to be inaccurate. Even if the markets in which we compete meet our size estimates and growth forecasts, our business may not grow at similar rates, or at all. Our growth is subject to many factors, including our success in implementing our business strategy, which is subject to many risks and uncertainties.

Our revenue will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval, the accepted price for the product, the ability to obtain coverage and reimbursement and whether we own the commercial rights for that territory. If the number of our addressable patients is not as significant as we estimate, the indication approved by regulatory authorities is narrower than we expect or the treatment population is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such products, even if approved.

Our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs, CMOs, suppliers and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk that our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs, CMOs, suppliers and vendors acting for or on our behalf may engage in misconduct or other improper activities. Misconduct by these parties could include intentional, reckless or negligent conduct or disclosure of unauthorized activities to us that violates regulations, including those laws requiring the reporting of true, complete and accurate information to the FDA, manufacturing standards, federal and state healthcare laws and regulations, and laws that require the true, complete and accurate reporting of financial information or data. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Misconduct by these parties could also involve the improper use of individually identifiable information, including, without limitation, information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter misconduct by these parties and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations.

Our internal information technology systems, or those of any of our CROs, manufacturers, other contractors or consultants, third party service providers, or existing or future collaborators, may fail or suffer security or data privacy breaches or other unauthorized or improper access to, use of, or destruction of our proprietary or confidential data, employee data or personal data, which could result in additional costs, loss of revenue, significant liabilities, harm to our brand and material disruption of our operations.

We rely on computer systems, hardware, software, technology infrastructure and online sites and networks for both internal and external operations that are critical to our business. We own and manage some of these information technology systems but also rely on third parties for a range of information technology systems and related products and services. In the ordinary course of our business, we and the third parties upon which we rely collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, "Process") proprietary, confidential, and sensitive data, including personal data, intellectual property, trade secrets, and other sensitive data (collectively, "Confidential Information").

Despite the implementation of security measures in an effort to protect systems that store our information, given their size and complexity and the increasing amounts of information maintained on our internal information technology systems and those of our third-party CROs, other contractors (including sites performing our clinical trials), third party service providers and supply chain companies, and consultants, we face numerous and evolving cybersecurity risks that threaten the confidentiality, integrity and availability of our information technology systems and Confidential Information. Our information technology systems are potentially vulnerable to breakdown or other damage or interruption from service interruptions, system malfunction, social

engineering/phishing, bugs, misconfigurations, exploited vulnerability in software or hardware, natural disasters, terrorism, war and telecommunication and electrical failures, as well as security breaches from inadvertent or intentional actions by diverse threat actors such as our employees, contractors, consultants, business partners and/or other third parties, opportunistic hackers and hacktivists or other malicious third parties, which may compromise our system infrastructure or lead to the loss, destruction, alteration or dissemination of, or damage to, our data.

Some actors now engage and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we, and the third parties upon which we rely, may be vulnerable to a heightened risk of these attacks, including retaliatory cyber-attacks, that could materially disrupt our systems and operations. In particular, malware (including ransomware) attacks are becoming increasingly prevalent and can lead to significant interruptions in our operations, loss of sensitive data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments.

To the extent that any disruption or security breach were to result in loss, destruction, unavailability, alteration or dissemination of, or damage to, our data or applications, or for it to be believed or reported that any of these occurred, we could incur liability and reputational damage and the development and commercialization of our product candidates could be delayed. Further, our insurance policies may not be adequate to compensate us for the potential losses arising from any such disruption in, or failure or security breach of, our systems or third-party systems where information important to our business operations or commercial development is stored.

Our remote workforce may create additional risks for our information technology systems and data because our employees work remotely and utilize network connections, computers, and devices working at home, while in transit and in public locations. Additionally, business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies.

While we have implemented security measures (including a cybersecurity risk management program and processes) designed to protect against security incidents, there can be no assurance that these measures will be fully implemented, complied with or effective in protecting our information technology systems and Confidential Information. We may be unable in the future to detect vulnerabilities in our information technology systems because threat actors are becoming increasingly sophisticated in using techniques and tools – including artificial intelligence – that circumvent security controls, evade detection and remove forensic evidence. These techniques and tools change frequently, are often sophisticated in nature, and may not be detected until after a security incident has occurred. Further, we may experience delays in developing and deploying remedial measures designed to address any such identified vulnerabilities. Applicable data privacy and security obligations may require us to notify relevant stakeholders of security incidents. Such disclosures are costly, and the disclosure or the failure to comply with such requirements could lead to adverse consequences.

We rely on third-party service providers and technologies to operate critical business systems to Process Confidential Information in a variety of contexts. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. If our third-party service providers experience a security incident or other interruption, we could experience adverse consequences. Additionally, any integration of artificial intelligence in our or any third party's operations, products or services is expected to pose new or unknown cybersecurity risks and challenges. While we may be entitled to damages if our third-party service providers fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. In addition, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties' infrastructure in our supply chain or our third-party partners' supply chains have not been compromised.

If we (or a third party upon whom we rely) experience a security incident or are perceived to have experienced a security incident, we may experience adverse consequences, such as government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on Processing Confidential Information (including personal data); litigation (including class actions); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; interruptions in our operations (including availability of data); financial loss; and other similar harms. Security incidents and attendant consequences may cause stakeholders (including investors and potential customers) to stop supporting our platform, deter new customers from products, and negatively impact our ability to grow and operate our business.

Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims.

We are subject to stringent and changing laws, regulations and standards, and contractual obligations relating to privacy, data protection, and data security. The actual or perceived failure to comply with such obligations could lead to government enforcement actions (which could include civil or criminal penalties), fines and sanctions, private litigation and/or adverse publicity and could negatively affect our operating results and business.

We, and third parties we work with, are or may become subject to numerous domestic and foreign laws, regulations, and standards relating to privacy, data protection, and data security of personal information, such as information that we may collect in connection with clinical trials in the U.S. and abroad. The scope of the global data protection landscape is rapidly changing, subject to differing applications and interpretations, and may be inconsistent among countries, or conflict with other rules. Implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, and we cannot yet determine the impact future laws, regulations, standards, or perception of their requirements may have on our business. This evolution may create uncertainty in our business, affect our ability to operate in certain jurisdictions or to collect, store, transfer use and share personal information, necessitate the acceptance of more onerous obligations in our contracts, result in liability or impose additional costs on us. The cost of compliance with these laws, regulations and standards is high and is likely to increase in the future. Any failure or perceived failure by us to comply with federal, state or foreign laws or regulations, our internal policies and procedures or our contracts governing our processing of personal information could result in negative publicity, government investigations and enforcement actions, claims by third parties and damage to our reputation, any of which could have a material adverse effect on our business, results of operation, and financial condition.

In the U.S., we may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under HIPAA. Depending on the facts and circumstances, we could be subject to significant penalties if we violate HIPAA.

Additionally, in 2024, the National Security Division of the U.S. Department of Justice (DOJ) issued a new rule—referred to as the "Data Security Program" (DSP)—to implement Executive Order 14117 aimed at preventing access to "bulk U.S. sensitive personal data" and "government-related data" by "countries of concern" (including China, Russia, Iran, North Korea, Cuba, and Venezuela) and "covered persons" (as all such terms are defined in the DSP). Effective as of April 8, 2025, and fully enforceable as of July 9, 2025, the DSP imposes stringent obligations on companies within its scope and prohibits or restricts "covered data transactions" that grant countries of concern or covered persons access to bulk U.S. sensitive personal data or any amount of government-related data. The DSP is new, complex and has yet to be enforced, and as such, there is a risk that our interpretation of its applicability, scope, and requirements is incorrect, incomplete, or misapplied. Compliance with the DSP may require us to invest in compliance measures, such as implementing and complying with the Cybersecurity and Infrastructure Security Agency's guidelines and other recordkeeping, reporting, and auditing requirements. It may also require us to implement new processes, stop or restrict certain data transfers, alter the geographic scope of our operations, cease doing business with certain third parties or using certain tools or vendors, or change how data flows throughout our business, any of which could materially impact our business operations or hinder our ability to grow our business. Finally, non-compliance with the DSP could result in significant civil or criminal penalties, which could materially adversely affect our business, results of operations, and financial condition.

Moreover, we are and may become subject to the terms of contractual obligations related to privacy, data protection, and data security. Our obligations may also change or expand as our business grows. The actual or perceived failure by us or third parties related to us to comply with such laws, regulations and obligations could increase our compliance and operational costs, expose us to regulatory scrutiny, actions, fines and penalties, result in reputational harm, lead to a loss of customers, result in litigation and liability, and otherwise cause a material adverse effect on our business, financial condition, and results of operations.

Our business may be affected by the evolving regulatory framework for AI Technologies.

We use artificial intelligence ("AI"), machine learning, and automated decision-making technologies, (collectively, "AI Technologies") in our business. We expect that increased investment will be required in the future to continuously improve our use of AI Technologies. As with many technological innovations, there are significant risks involved in developing, maintaining and deploying these technologies, including that AI-generated content, analyses, or recommendations we utilize could be deficient, that our competitors may more quickly or effectively adopt AI capabilities, or that our use of AI or other emerging

technologies increases regulatory, cybersecurity and other significant risks. There can be no assurance that the usage of or our investments in such technologies will always be beneficial to our business, including our efficiency or profitability.

In particular, if the models underlying our AI Technologies are: incorrectly designed or implemented; trained or reliant on incomplete, inadequate, inaccurate, biased or otherwise poor quality data, or on data to which we do not have sufficient rights or in relation to which we and/or the providers of such data have not implemented sufficient legal compliance measures; used without sufficient oversight and governance to ensure their responsible use; and/or adversely impacted by unforeseen defects, technical challenges, cybersecurity threats or material performance issues, the performance of our products, services and business, as well as our reputation, could suffer or we could incur liability resulting from the violation of laws or contracts to which we are a party or civil claims.

We are in varying stages of development in relation to our business processes involving AI Technologies. The continuous development, maintenance and operation of our AI Technologies is expensive and complex, and may involve unforeseen difficulties including material performance problems, undetected defects or errors. For instance, the models underlying AI Technologies can experience decay (also known as "model drift") in which its performance and accuracy decreases over time without further human intervention to correct such decay.

We may not be successful in our ongoing development and maintenance of these technologies in the face of novel and evolving technical, reputational and market factors.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations may involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or commercialization efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

We may be subject to adverse legislative or regulatory tax changes that could negatively impact our financial condition.

The rules governing U.S. federal, state and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service ("IRS") and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect our stockholders or us. We assess the impact of various tax reform proposals and modifications to existing tax treaties in all jurisdictions where we have operations to determine the potential effect on our business and any assumptions we have made about our future taxable income. We cannot predict whether any specific proposals will be enacted, the terms of any such proposals or what effect, if any, such proposals would have on our business if they were to be enacted.

For example, the United States enacted the Inflation Reduction Act of 2022, which implements, among other changes, a 1% excise tax on certain stock buybacks. In addition, beginning in 2022, the Tax Cuts and JOBS Act (the "JOBS Act") eliminated the previously available option to deduct research and development expenditures and requires taxpayers to amortize them generally over five years for research activities conducted in the United States and over fifteen years for research activities conducted outside the United States. July 4, 2025, the U.S. Congress enacted the One Big Beautiful Bill Act, which includes a provision restoring the immediate deductibility of domestic research and development expenditures. The impact of this newly enacted law on our tax position will depend on how the provision is implemented and interpreted by the IRS and other regulatory authorities. In addition, we have no assurance as to whether, when and how this provision may be subject to further amendment or repeal. Such changes, among others, may adversely affect our effective tax rate, results of operation and financial condition.

We may acquire businesses, product candidates or products, or form strategic alliances, in the future, and may not realize the benefits of such acquisitions or alliances.

We may acquire additional businesses, product candidates or products, form strategic alliances, or create joint ventures with third parties that we believe will complement or augment our existing business. If we acquire businesses with promising markets or technologies, we may not be able to realize the benefit of acquiring such businesses if we are unable to successfully integrate them with our existing operations and company culture. We may encounter numerous difficulties in developing, manufacturing and marketing any new product candidates or products resulting from a strategic alliance or acquisition that delay or prevent us from realizing their expected benefits or enhancing our business. There is no assurance that, following any such acquisition, we

will achieve the synergies expected in order to justify the transaction, which could result in a material adverse effect on our business and prospects.

We maintain our cash at financial institutions, often in balances that exceed federally-insured limits. The failure of financial institutions could adversely affect our ability to pay our operational expenses or make other payments.

Our cash held in non-interest-bearing and interest-bearing accounts exceeds the FDIC insurance limits. If such banking institutions were to fail, we could lose all or a portion of those amounts held in excess of such insurance limitations. For example, the FDIC took control of Silicon Valley Bank in March 2023. The Federal Reserve subsequently announced that account holders would be made whole. However, the FDIC may not make all account holders whole in the event of future bank failures. In addition, even if account holders are ultimately made whole with respect to a future bank failure, account holders' access to their accounts and assets held in their accounts may be substantially delayed. Any material loss that we may experience in the future or inability for a material time period to access our cash and cash equivalents could have an adverse effect on our ability to pay our operational expenses or make other payments, which could adversely affect our business.

Risks Related to Our Intellectual Property

We do not currently own any issued patents or pending patent applications and we in-license rights to JADE101 and JADE201 and hold an exclusive option to in-license rights to JADE301. Therefore, our ability to obtain and protect our patent rights, and protect other proprietary rights, is uncertain, exposing us to the possible loss of competitive advantage.

We will rely upon a combination of patents, trademarks, trade secret protection, copyrights and confidentiality agreements and the Paragon Option Agreement and the Paragon License Agreements to protect the intellectual property related to our programs and technologies and to prevent third parties from competing unfairly with us. Our success depends in large part on our ability to obtain and maintain patent protection for our product candidates and their uses, as well as our ability to operate without infringing on or violating the proprietary rights of others. We do not currently own any patents but have licensed certain patent rights from Paragon under the Paragon License Agreements and expect to prosecute underlying intellectual property for JADE101 and JADE201 and in the future to prosecute underlying intellectual property for JADE301. However, we may not be able to obtain or protect our intellectual property rights throughout the world and the legal systems in certain countries may not favor enforcement or protection of at least certain patents, trade secrets or other intellectual property. Filing, prosecuting, maintaining and defending patents on product candidates and other related inventions worldwide would be expensive and our intellectual property rights in some foreign jurisdictions can be less extensive than those in the United States; the reverse may also occur. As such, we may not have patents in all countries or all major markets and may not be able to obtain patents in all jurisdictions even if we or our licensor files patent applications to obtain such rights. Our competitors may operate in countries where we do not have patent protection and may be able to freely use our technologies and discoveries in such countries, at least to the extent not forbidden by law.

Our intellectual property portfolio is at an early stage. We do not currently own any issued patents or pending patent applications, and we in-license our rights to JADE101 and JADE201 and hold an exclusive option to license JADE301. Our currently licensed or future optioned, in-licensed or owned patent applications may not result in patents being issued. Any issued patents may not afford sufficient protection of our product candidates or their intended uses against competitors, nor can there be any assurance that the patents issued will not be infringed, designed around, or invalidated by third parties, or effectively prevent others from commercializing competitive technologies, products or product candidates. Even if these patents are granted, they may be difficult to enforce. Further, any issued patents that we may license or own covering our product candidates could be narrowed or found invalid or unenforceable if challenged in court or before administrative bodies in the United States or abroad, including the USPTO. If we do not obtain patent coverage for the work we are conducting, or if we obtain such rights but they are invalidated or rendered unenforceable, we may be unable to exclude competitors from pursuing and marketing the same or similar product candidates. Other risks we face if we are not able to obtain and maintain patent coverage for our product candidates are the reduction in valuation of our product candidates, and ultimately of us as a company, by potential investors, and our inability to assert claims for infringement against third parties or counterclaim against such third parties or negotiate more advantageous settlement parameters. Further, if we encounter delays in our clinical trials or delays in obtaining regulatory approval, the period of time during which we could market our product candidates under patent protection would be reduced. Thus, the patents that we may own or license may not afford us any meaningful exclusivity period or competitive advantage.

In addition to seeking patents for some of our technology and product candidates, we may also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. Any disclosure, either intentional or unintentional, by our employees, the employees of third parties with whom we share our facilities or third-party consultants and vendors that we engage to perform research, clinical trials or manufacturing activities, or misappropriation by third parties (such as through a cybersecurity breach) of our trade secrets or proprietary information could

enable competitors to duplicate or surpass our technological achievements, thus eroding our competitive position in our market. In order to protect our proprietary technology and processes, we rely in part on confidentiality agreements with our collaborators, employees, consultants, outside scientific collaborators and sponsored researchers and other advisors. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. We may need to share our proprietary information, including trade secrets, with future business partners, collaborators, contractors and others located in countries at heightened risk of theft of trade secrets, including through direct intrusion by private parties or state actors and those affiliated with or controlled by state actors. In addition, while we undertake reasonable efforts to protect our trade secrets and other confidential information from disclosure, others may independently discover trade secrets and proprietary information, and in such cases, we may not be able to assert any trade secret rights against such party. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights and failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

Lastly, if our trademarks and trade names are not registered or adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

If we are unable to obtain or maintain necessary rights to our programs through acquisitions and in-licenses, our business may be materially harmed.

Because our development programs currently do and may in the future require the use of proprietary rights held by third parties, the growth of our business will depend in part on our ability to acquire, in-license, or use these third-party proprietary rights. We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify as necessary for our programs. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain intellectual property rights we obtain in the future, we may have to abandon development of the relevant program, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

While we have the right to control prosecution, defense, maintenance and enforcement of patents in-licensed under the Paragon License Agreements, there may be times when rights for patents and patent applications relating to our product candidates are controlled by our future licensors or collaboration partners. For example, Paragon currently has the right to file patent applications and control prosecution with respect to any other inventions that may fall within the Paragon Option Agreement, including those that may apply to JADE301. If we, Paragon or any of our future licensors or collaboration partners fail to prosecute, defend, maintain and enforce such patents and patent applications in a manner consistent with our best interests, including by payment of all applicable fees for patents covering our product candidates, we could lose our rights to the intellectual property or our exclusivity with respect to those rights, our ability to develop and commercialize those product candidates may be adversely affected and we may not be able to prevent competitors from making, using and selling competing products. In addition, even if we have the right to control prosecution of patents and patent applications we have licensed to and from third parties, including under the Paragon License Agreements, we may still be adversely affected or prejudiced by actions or inactions of Paragon, additional licensees, or licensors and their counsel prior to the date upon which we assumed control over patent prosecution. For example, prior to entering into the Paragon License Agreements, Paragon was responsible for the prosecution, defense, maintenance and enforcement of patents related to JADE101 and JADE201. Subsequent to entering into such license agreements, we control patent prosecution over JADE101 and JADE201.

Our future licensors may not be the sole and exclusive owners of all rights in the patents we may in-license. If other third parties have rights to our future in-licensed patents, they may be able to license such patents to our competitors, and our competitors could market competing products and technology. This could have a material adverse effect on our competitive position, business, financial condition, results of operations, and prospects.

It is possible that we may be unable to obtain licenses at a reasonable cost or on reasonable terms, if at all. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to redesign our product candidates, or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates, which could harm our business, financial condition, results of operations, and prospects significantly. We cannot provide any

assurances that third-party patents do not exist which might be enforced against our product candidates, manufacturing methods or future products or methods resulting in either an injunction prohibiting our manufacture or future sales, or, with respect to our future sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties, which could be significant.

Disputes may arise between us and our future licensors regarding intellectual property subject to a license agreement, including (but not limited to): the scope of rights granted under the license agreement and other interpretation-related issues; whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement; our right to sublicense patents and other rights to third parties; our right to transfer or assign the license; the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our future licensors and us and our partners; and the priority of invention of patented technology. If we or our future licensors breach the terms of our license agreements, such breach may have a material adverse effect on our business and the commercialization efforts for our programs.

We may be subject to intellectual property lawsuits or may need to file lawsuits to protect our intellectual property, which could result in substantial costs and liability and prevent us from commercializing our potential products.

Because the intellectual property landscape in the biotechnology industry is rapidly evolving and interdisciplinary, it is difficult to conclusively assess our freedom to operate and guarantee that we can operate without infringing on or violating third party rights. If certain of our product candidates are ultimately granted regulatory approval, patent rights held by third parties could be alleged to render one or more of our product candidates infringing. If a third party successfully brings a claim against us, and our rights are not held invalid or unenforceable, we may be required to pay substantial damages, be forced to abandon any affected product candidate and/or seek a license from the patent holder. In addition, any intellectual property claims (e.g., patent infringement or trade secret misappropriation) brought against us, whether or not successful, may cause us to incur significant legal expenses and divert the attention of our management and key personnel from other business concerns. We cannot be certain that future patents, if filed and issued, owned or licensed by us will not be challenged by others, whether in the course of litigation or in agencies like the USPTO. Some of our competitors may be able to sustain the costs of complex intellectual property litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise funds.

Competitors may infringe or otherwise violate our future patents, trademarks, copyrights or other intellectual property. To counter infringement or other violations, we may be required to file claims, which can be expensive and time-consuming. Any such claims could provoke these parties to assert counterclaims against us, including claims alleging that we infringe their patents or other intellectual property rights. In addition, in a patent infringement proceeding, a court or administrative body may decide that one or more of the patents we assert is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly or refuse to prevent the other party from using the technology at issue on the grounds that our patents do not cover the technology. Similarly, if we assert trademark infringement claims, a court or administrative body may determine that the marks we have asserted are invalid or unenforceable or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In such a case, we could ultimately be forced to cease use of such marks. In any intellectual property litigation, even if we are successful, any award of monetary damages or other remedy we receive may not be commercially valuable.

Further, we may be required to protect our future patents, if filed and issued, through procedures created to attack the validity of a patent at the USPTO. An adverse determination in any such submission or proceeding could reduce the scope or enforceability of, or invalidate, our patent rights, which could adversely affect our competitive position. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action.

In addition, if our product candidates are found to infringe the intellectual property rights of third parties, these third parties may assert infringement claims against our future licensees or customers and other parties with whom we have business relationships and we may be required to indemnify those parties for any damages they suffer as a result of these claims, which may require us to initiate or defend protracted and costly litigation on behalf of licensees or other parties regardless of the merits of such claims. If any of these claims succeed, we may be forced to pay damages on behalf of those parties or may be required to obtain licenses for the products they use.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or other legal proceedings relating to our intellectual property rights, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation or other proceedings.

Our success will depend in part on our and our current and future licensors' ability to obtain, maintain and enforce patent protection for our licensed intellectual property.

Our success will depend in part on our and our current and future licensors' (including Paragon's) ability to obtain, maintain and enforce patent protection for our licensed intellectual property. After entry into the Paragon License Agreements, we control the prosecution, maintenance, enforcement and defense of JADE101 and JADE201, and Paragon currently controls the prosecution, maintenance, enforcement and defense of JADE301. Prior to entering into the Paragon License Agreements, Paragon held such rights with respect to JADE101 and JADE201. We, Paragon and our future licensors may not successfully prosecute the patent applications that cover our product candidates. Even if patents are issued in respect of these patent applications, we and our future licensors (including Paragon) may fail to maintain these patents, may determine not to pursue litigation against other companies that are infringing these patents, or may pursue such litigation less aggressively than we would. Without protection for any in-licensed intellectual property, other companies might be able to offer substantially identical products for sale, which could adversely affect our competitive business position and harm our business prospects.

We may be subject to claims that we have wrongfully hired an employee from a competitor or that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.

As is common in the biotechnology industry, in addition to our employees, we engage the services of consultants to assist us in the development of our product candidates. Many of these consultants, and many of our employees, were previously employed at, or may have previously provided or may be currently providing consulting services to, other biotechnology or pharmaceutical companies including our competitors or potential competitors. We could in the future be subject to claims that we or our employees have inadvertently or otherwise used or disclosed alleged trade secrets or other confidential information of former employers or competitors. Although we take measures to ensure that our employees and consultants do not use the intellectual property, proprietary information, know-how or trade secrets of others in their work for us, we may become subject to claims that we caused an employee to breach the terms of his or her non-competition or non-solicitation agreement, or that we or these individuals have, inadvertently or otherwise, used or disclosed the alleged trade secrets or other proprietary information of a former employer or competitor.

While we may litigate to defend against these claims, even if we are successful, litigation could result in substantial costs and could be a distraction to management and other employees. If our defenses to these claims fail, in addition to requiring us to pay monetary damages, a court could prohibit us from using technologies or features that are essential to our product candidates, if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers. Moreover, any such litigation or the threat thereof may adversely affect our reputation, our ability to form strategic alliances or sublicense our rights to collaborators, engage with scientific advisors or hire employees or consultants, each of which would have an adverse effect on our business, results of operations and financial condition. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

Changes to patent laws in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products.

Changes in either the patent laws or interpretation of patent laws in the United States, including patent reform legislation such as the Leahy-Smith America Invents Act (the "Leahy-Smith Act") could increase the uncertainties and costs surrounding the prosecution of our owned and in-licensed patent applications and the maintenance, enforcement or defense of our owned and in-licensed issued patents. The Leahy-Smith Act included a number of significant changes to United States patent law, including provisions that affect the way patent applications are prosecuted, redefined prior art, provided more efficient and cost-effective avenues for competitors to challenge the validity of patents, and enabled third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent at USPTO-administered post-grant proceedings, including post-grant review, inter partes review, and derivation proceedings. Notably, after March 2013, under the Leahy-Smith Act, the United States transitioned to a first-to-file system in which, assuming that the other statutory requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. Additionally, there have been proposals for additional changes to the patent laws of the United States and other countries that, if adopted, could impact our ability to enforce our proprietary technology.

In addition, the patent positions of companies in the development and commercialization of biologics and pharmaceuticals are particularly uncertain. U.S. Supreme Court and U.S. Court of Appeals for the Federal Circuit rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations, including in the antibody arts. For example, the United States Supreme Court in *Amgen, Inc. v. Sanofi* ("*Amgen*") recently held that Amgen's patent claims to a class of antibodies functionally defined by their ability to bind a particular antigen were invalid for lack of enablement where the patent specification provided 26 exemplary antibodies, but the claimed class of antibodies covered a "vast number" of additional antibodies not disclosed in the specification. The Court stated that if patent claims are directed to an entire class of compositions of matter, then the patent specification must enable a person skilled in the art to make and use the entire class of compositions. This decision makes it unlikely that we will be granted U.S. patents with composition of matter claims as broad as Amgen's directed to antibodies functionally defined by their ability to bind a particular antigen. Even if we are granted claims directed to functionally defined antibodies, it is possible that a third party may challenge our patents, when issued, relying on the reasoning in *Amgen* or other precedential court decisions. This combination of events has created uncertainty with respect to the validity and enforceability of patents once obtained. Depending on future actions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our patent rights and our ability to protect, defend and enforce our patent rights in the future.

In addition, the U.S. Supreme Court's July 2024 decision to overturn established case law giving deference to regulatory agencies' interpretations of ambiguous statutory language has introduced uncertainty regarding the extent to which the FDA's regulations, policies and decisions may become subject to increasing legal challenges, delays, and/or changes. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. Geopolitical instability in the United States and in foreign countries could increase the uncertainties and costs surrounding the prosecution or maintenance of patent applications and the maintenance, enforcement or defense of issued patents. In addition, the Unified Patent Court ("UPC") entered into force on June 1, 2023. The UPC is a common patent court that hears patent infringement and revocation proceedings effective for EU Member States. Under the UPC, all European patents, including those issued prior to ratification of the European Patent Package, will be default automatically fall under the jurisdiction of the UPC. This could enable third parties to seek revocation of a European patent in a single proceeding at the UPC rather than through multiple proceedings in each of the jurisdictions in which the European patent is validated, thereby providing our competitors with a new forum to centrally revoke our European patents, and allow for the possibility of a competitor to obtain pan-European injunctions.

Although we do not currently own any European patents or applications, if we obtain or license such patents and applications in the future, any such revocation and loss of patent protection could have a material adverse impact on our business and our ability to commercialize or license our technology and products. Moreover, the controlling laws and regulations of the UPC will develop over time and may adversely affect our ability to enforce or defend the validity of any European patents we may obtain. We may decide to opt out from the UPC any future European patent applications that we may file and any patents we may obtain. If certain formalities and requirements are not met, however, such European patents and patent applications could be challenged for non-compliance and brought under the jurisdiction of the UPC. We cannot be certain that future European patents and patent applications will avoid falling under the jurisdiction of the UPC, if we decide to opt out of the UPC.

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

Periodic maintenance fees, renewal fees, annuities fees and various other governmental fees on patents and/or patent applications are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent and/or patent application. The USPTO and various foreign governmental patent agencies also require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we fail to maintain any future patents and patent applications, if filed and issued, covering our product candidates, our competitive position would be adversely affected.

We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent, which might adversely affect our ability to develop and market our products.

We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction. The scope of a patent claim is determined by an interpretation of

the law, the written disclosure in a patent, the patent's prosecution history and in some cases certain extrinsic evidence of the meaning of terms in a claim. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect. For example, we may incorrectly determine that our products are not covered by a third-party patent or may incorrectly predict whether a third-party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our products.

In addition, because some patent applications in the United States may be maintained in secrecy until the patents are issued, patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing, and publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our future issued patents or our pending applications, if filed, or that we were the first to invent the technology. Our competitors may have filed, and may in the future file, patent applications covering our products or technology similar to ours. Any such patent application may have priority over our future patent applications or patents, if filed and issued, which could require us to obtain rights to issued patents covering such technologies.

We may become subject to claims challenging the inventorship or ownership of our patents, if issued, and other intellectual property.

We may be subject to claims that former employees, collaborators or other third parties have an interest in our future patents, if filed and issued, or other intellectual property as an inventor or co-inventor. The failure to name the proper inventors on a patent application can result in the patents issuing thereon being invalid or unenforceable. Inventorship disputes may arise from conflicting views regarding the contributions of different individuals named as inventors, the effects of foreign laws where foreign nationals are involved in the development of the subject matter of the patent, conflicting obligations of third parties involved in developing our programs or as a result of questions regarding co-ownership of potential joint inventions. Litigation may be necessary to resolve these and other claims challenging inventorship and/or ownership. Alternatively, or additionally, we may enter into agreements to clarify the scope of our rights in such intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Our current or future licensors may have relied on third-party consultants or collaborators or on funds from third parties, such as the U.S. government, such that our licensors are not the sole and exclusive owners of the patents we in-licensed. If other third parties have ownership rights or other rights to our in-licensed patents, they may be able to license such patents to our competitors, and our competitors could market competing products and technology. This could have a material adverse effect on our competitive position, business, financial condition, results of operations, and prospects.

Patent terms may be inadequate to protect our competitive position of our product candidates for an adequate amount of time.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from our earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products, including generics or biosimilars. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

Our technology licensed from various third parties may be subject to retained rights.

Our future licensors may retain certain rights under the relevant agreements with us, including the right to use or license the licensed technology outside of the scope of our license, use the underlying technology for noncommercial academic and research use, to publish general scientific findings from research related to the technology, and to make customary scientific and scholarly disclosures of information relating to the technology. It is difficult to monitor whether our licensors limit their use of the technology to these uses, and we could incur substantial expenses to enforce our rights to our licensed technology in the event of misuse. In addition, while there are certain restrictions on Paragon's ability to develop products that could be competitive with ours as more fully described in Note 12 to the consolidated financial statements included elsewhere in this Annual Report on Form 10-K, these restrictions may not prevent the possible future license or development by Paragon of certain technology that

could lead to product candidates competitive with ours. This could have a material adverse effect on our competitive position, business, financial condition, results of operations, and prospects.

Risks Related to Government Regulation

The regulatory approval processes of the FDA and other comparable foreign regulatory authorities are lengthy, time-consuming and inherently unpredictable. If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals for our product candidates, we will not be able to commercialize, or will be delayed in commercializing, our product candidates, and our ability to generate revenue will be materially impaired.

The process of obtaining regulatory approvals, both in the United States and abroad, is unpredictable, expensive and typically takes many years following commencement of clinical trials, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. We cannot commercialize product candidates in the United States without first obtaining regulatory approval from the FDA. Similarly, we cannot commercialize product candidates outside of the United States without obtaining regulatory approval from comparable foreign regulatory authorities. Before obtaining regulatory approvals for the commercial sale of our product candidates, including JADE101, JADE201, and JADE301, we must demonstrate through lengthy, complex and expensive preclinical studies and clinical trials that our product candidates are safe, pure, and potent (or effective) for each targeted indication. Securing regulatory approval also requires the submission of information about the drug manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Further, our product candidates may not be effective, may be only moderately effective, may prove to have undesirable or unintended side effects, toxicities or other characteristics, or may fail to improve on the applicable standard of care, any of which may preclude our obtaining regulatory approval.

The FDA or comparable foreign regulatory authorities can delay, limit or deny approval of a product candidate for many reasons, including:

- such authorities may disagree with the design or execution of our clinical trials;
- negative or ambiguous results from our clinical trials or results may not meet the level of statistical significance or persuasiveness required by the FDA or comparable foreign regulatory authorities for approval;
- serious and unexpected drug-related side effects may be experienced by participants in our clinical trials or by individuals using drugs similar to our product candidates;
- the population studied in the clinical trial may not be sufficiently broad or representative to assure safety in the full population for which we seek approval;
- such authorities may not accept clinical data from trials that are conducted at clinical facilities or in countries where the standard of care is potentially different from that of their own country;
- we may be unable to demonstrate that a product candidate’s clinical and other benefits outweigh its safety risks;
- such authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- such authorities may not agree that the data collected from clinical trials of our product candidates are acceptable or sufficient to support the submission of a BLA or other submission or to obtain regulatory approval in the U.S. or elsewhere, and such authorities may impose requirements for additional preclinical studies or clinical trials;
- such authorities may disagree with us regarding the formulation, labeling and/or the product specifications of our product candidates;
- approval may be granted only for indications that are significantly more limited than those sought by us, and/or may include significant restrictions on distribution and use;
- such authorities may find deficiencies in the manufacturing processes or facilities of the third-party manufacturers with which we contract for clinical and commercial supplies; or
- such authorities may not accept a submission due to, among other reasons, the content or formatting of the submission.

Of the large number of drugs in development, only a small percentage successfully complete the FDA or applicable foreign regulatory approval processes and are commercialized. The lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market our product candidates, which would significantly harm our business, results of operations and prospects.

If we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, including failing to approve the most commercially promising indications, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals for our product candidates, we will not be able to commercialize, or will be delayed in commercializing, this could have a material adverse effect on our competitive position, business, financial condition, results of operations, and prospects.

In addition, FDA and foreign regulatory authorities may change their approval policies and new regulations may be enacted. The EU pharmaceutical legislation has been undergoing a complete review process, in the context of the Pharmaceutical Strategy for Europe initiative, launched by the European Commission in November 2020. The European Commission's proposal for revision of several legislative instruments related to medicinal products was published on April 26, 2023. The proposed changes were since discussed and negotiated by the European Parliament and the Council of the EU as part of the EU ordinary legislative process. A provisional agreement has been reached by the European Parliament and Council of the EU on the proposed revisions on December 11, 2025. The proposed revisions (affecting the duration of regulatory data protection and market protection, including for orphan medicinal products, revising the eligibility for expedited pathways, etc.) remain to be formally adopted by the two institutions, which is not anticipated before early 2026. The proposed changes are not expected to enter into application before 2028 and may have a significant impact on the biopharmaceutical industry in the long term.

We may not be able to meet requirements for the chemistry, manufacturing and control of our product candidates.

In order to receive approval of our products by the FDA and comparable foreign regulatory authorities, we must show that we and our contract manufacturing partners are able to characterize, control and manufacture our drug products safely and in accordance with regulatory requirements. This includes manufacturing the active ingredient, developing an acceptable formulation, manufacturing the drug product, performing tests to adequately characterize the formulated product, documenting a repeatable manufacturing process, and demonstrating that our drug products meet stability requirements. Meeting these chemistry, manufacturing and control requirements is a complex task that requires specialized expertise. If we are not able to meet the chemistry, manufacturing and control requirements, we may not be successful in getting our products approved.

Our product candidates for which we intend to seek approval as biologics may face competition from biosimilars sooner than anticipated.

The ACA includes a subtitle called the Biologics Price Competition and Innovation Act of 2009 ("BPCIA"), which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Under the BPCIA, an application for a highly similar or "biosimilar" product may not be submitted to the FDA until four years following the date that the reference product was first approved by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first approved. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product.

We believe that any of our product candidates approved as biologics under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for competition sooner than anticipated. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of litigation. Moreover, the extent to which a biosimilar, once approved, will be substituted for any reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

Even if we receive regulatory approval of our product candidates, we will be subject to extensive ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.

Any regulatory approvals that we may receive for our product candidates will require the submission of reports to regulatory authorities and surveillance to monitor the safety and efficacy of the product candidate, may contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, and may include burdensome post-approval study or risk management requirements. For example, the FDA may require a risk evaluation and mitigation strategy, or REMS, in order to approve our product candidates, which could entail requirements for a medication guide, physician training and communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Comparable foreign regulatory authorities may impose similar requirements.

In addition, if the FDA or comparable foreign regulatory authorities approve our product candidates, our product candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, distribution, import and export will be subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by comparable foreign regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as on-going compliance with cGMPs and GCPs for any clinical trials that we conduct following approval. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic, unannounced inspections by the FDA and other regulatory authorities for compliance with cGMPs. If we or a regulatory authority discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facilities where the product is manufactured, a regulatory authority may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing, delays or restrictions on our ability to conduct clinical trials or delays or refusal to grant a marketing authorization, including full or partial clinical holds on ongoing or planned trials, restrictions on the manufacturing process, warning or untitled letters, civil and criminal penalties, injunctions, product seizures, detentions or import bans, suspension, withdrawal or variation of any marketing authorization that has been granted, voluntary or mandatory publicity requirements and imposition of restrictions on operations, including costly new manufacturing requirements. Similar penalties may apply in case of failure by us or by any of our third-party partners, including suppliers, manufacturers and distributors, to comply with FDA and EU laws and the related national laws of individual EU member states and other applicable regulatory authorities governing the conduct of clinical trials, manufacturing approval, marketing authorization of medicinal products and marketing of such products, both before and after grant of a marketing authorization, statutory health insurance, bribery and anti-corruption or other applicable regulatory requirements, including administrative, civil or criminal penalties. The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and generate revenue and could require us to expend significant time and resources in response and could generate negative publicity.

The FDA's and other regulatory authorities' policies may change and additional government regulations may be promulgated that could prevent, limit or delay marketing authorization of any product candidates we develop. We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may be subject to enforcement action and we may not achieve or sustain profitability.

Disruptions at the FDA, the SEC and other government agencies and regulatory authorities caused by funding shortages, staffing limitations or policy changes could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA and comparable foreign regulatory authorities to review regulatory filings and our ability to commence human clinical trials can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC, and other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies or comparable foreign regulatory authorities may also slow the time necessary for the review and approval of applications for clinical trial or marketing authorization, which would adversely affect our business. For example, in recent years, including in 2018, 2019 and 2025, the U.S. government shut down and certain regulatory agencies, such as the FDA and the SEC, had to furlough critical employees and stop critical activities. . In addition, the current

U.S. Presidential administration has issued certain policies and Executive Orders directed towards reducing the employee headcount and costs associated with U.S. administrative agencies, including the FDA, and it remains unclear the degree to which these efforts may limit or otherwise adversely affect the FDA's ability to conduct routine activities.

If a prolonged government shutdown occurs, or if funding shortages, staffing limitations or similar factors hinder or prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, such events could significantly impact the ability of the FDA or other such regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses.

The FDA strictly regulates marketing, labeling, advertising and promotion of prescription drugs. These regulations include standards and restrictions for direct-to-consumer advertising, industry-sponsored scientific and educational activities, promotional activities involving the internet and off-label promotion. Any regulatory approval that the FDA grants is limited to those specific diseases and indications for which a product is deemed to be safe and effective by FDA. While physicians in the United States may choose, and are generally permitted, to prescribe drugs for uses that are not described in the product's labeling and for uses that differ from those tested in clinical trials and approved by the regulatory authorities, our ability to promote any products will be narrowly limited to those indications that are specifically approved by the FDA. If we are found to have promoted such off-label uses, we may become subject to significant liability. The U.S. federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the promotion any product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition. Similar risks may exist in foreign jurisdictions.

We may face difficulties from healthcare and regulatory legislative reform measures.

Existing regulatory policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. For example, the Trump administration has discussed several changes to the reach and oversight of the FDA, which could affect its relationship with the pharmaceutical industry, transparency in decision making and ultimately the cost and availability of prescription drugs. See "Business—Government Regulation—Healthcare Reform". If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any regulatory approval that we may have obtained and we may not achieve or sustain profitability.

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers will be subject to applicable healthcare regulatory laws, which could expose us to penalties.

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute our product candidates, if approved. Such laws include, without limitation, the federal Anti-Kickback Statute ("AKS"), the federal False Claims Act ("FCA"), the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") and similar foreign, federal and state fraud, abuse and transparency laws.

The AKS prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering or paying remuneration, to induce, or in return for, either the referral of an individual, or the purchase or recommendation of an item or service for which payment may be made under any federal healthcare program. The term remuneration has been interpreted broadly to include anything of value. The AKS has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand, and prescribers and purchasers on the other. The government often takes the position that to violate the AKS, only one purpose of the remuneration need be to induce referrals, even if there are other legitimate purposes for the remuneration. In addition, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from AKS prosecution, but they are drawn narrowly and practices that involve remuneration, such as consulting agreements, that may be alleged to be intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor. Our practices may not in all cases meet all of the criteria for protection under a statutory exception or regulatory safe harbor. Failure to meet all of the requirements of a particular applicable

statutory exception or regulatory safe harbor does not make the conduct per se illegal under the AKS. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances.

Civil and criminal false claims laws, including the FCA, and civil monetary penalty laws, which can be enforced through civil whistleblower or qui tam actions, prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment of federal government funds, including in federal healthcare programs, that are false or fraudulent. Pharmaceutical and other healthcare companies have been prosecuted under these laws for engaging in a variety of different types of conduct that caused the submission of false claims to federal healthcare programs. Under the AKS, for example, a claim resulting from a violation of the AKS is deemed to be a false or fraudulent claim for purposes of the FCA. In 2025, the Department of Justice continued to apply the Supreme Court's 2023 scienter framework in United States ex rel. Schutte v. SuperValu Inc. for FCA matters, focusing on a defendant's subjective understanding and beliefs at the time of claim submission, thus expanding the use of the FCA against recipients of federal funds that allegedly misrepresented compliance with federal civil rights laws.

HIPAA created additional federal criminal statutes that prohibit, among other things, executing a scheme to defraud any healthcare benefit program, including private third-party payors, and making false statements relating to healthcare matters. A person or entity does not need to have actual knowledge of the healthcare fraud statute implemented under HIPAA or specific intent to violate the statute in order to have committed a violation.

The FDCA addresses, among other things, the design, production, labeling, promotion, manufacturing, and testing of drugs, biologics and medical devices, and prohibits such acts as the introduction into interstate commerce of adulterated or misbranded drugs or devices. The PHSA also prohibits the introduction into interstate commerce of unlicensed or mislabeled biological products.

The U.S. federal Physician Payments Sunshine Act requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to annually report to the Centers for Medicaid & Medicare Services ("CMS") information related to payments or other transfers of value to various healthcare professionals including physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (including physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiologist assistants and certified nurse-midwives), and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Beginning on January 1, 2023, California Assembly Bill 1278 requires California physicians and surgeons to notify patients of the Open Payments database established under the federal Physician Payments Sunshine Act. In 2025, CMS continued incremental Open Payments program updates, published updates to data publication timelines, and expanded taxonomy lists for covered recipients, which may increase reporting and validation burdens for manufacturers and expand public transparency regarding transfers of value.
We are also subject to additional similar U.S. state and foreign law equivalents of each of the above federal laws, which, in some cases, differ from each other in significant ways, and may not have the same effect, thus complicating compliance efforts.

Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. If our operations are found to be in violation of any of these laws or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, exclusion from government-funded healthcare programs, integrity oversight and reporting obligations to resolve allegations of non-compliance, disgorgement, individual imprisonment, contractual damages, reputational harm, diminished profits and the curtailment or restructuring of our operations. Further, defending against any such actions can be costly and time-consuming and may require significant personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

Even if we are able to commercialize any product candidates, due to unfavorable pricing regulations and/or third-party coverage and reimbursement policies, we may not be able to offer such product candidates at competitive prices, which would seriously harm our business.

We intend to seek approval to market our product candidates in both the United States and in selected foreign jurisdictions. If we obtain approval in one or more foreign jurisdictions for our product candidates, we will be subject to rules and regulations in those jurisdictions. Our ability to successfully commercialize any product candidates that we may develop will depend in part on the extent to which reimbursement for these product candidates and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. Government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. These entities may create preferential access policies for a

competitor's product, including a branded or generic/biosimilar product, over our products in an attempt to reduce their costs, which may reduce our commercial opportunity. See "Business—Government Regulation—Coverage and Reimbursement".

We are subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws, and anti-money laundering laws and regulations. We can face criminal liability and other serious consequences for violations, which can harm our business.

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls, the U.S. Foreign Corrupt Practices Act of 1977, as amended, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. Governmental regulation of the import or export of our drug candidates, or our failure to obtain any required import or export authorization for our candidates, when applicable, could harm international operations. Furthermore, export control laws and economic sanctions prohibit the provision of certain items, technology, and services to countries, governments, and persons targeted by sanctions programs. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors, and other collaborators from authorizing, promising, offering, or providing, directly or indirectly, improper payments or anything else of value to or from recipients in the public or private sector. We may engage third parties to sell our products outside the United States, to conduct clinical trials, and/or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors, and other collaborators, even if we do not explicitly authorize or have actual knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences.

Governments outside the United States tend to impose strict price controls, which may adversely affect our revenue, if any.

In some countries, particularly EU member states, the pricing of prescription drugs is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after receipt of regulatory approval for a therapeutic. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various EU member states and parallel distribution, or arbitrage between low-priced and high-priced EU member states, can further reduce prices. To obtain coverage and reimbursement or pricing approvals in some countries, we or future collaborators may be required to conduct a clinical trial or other studies that compare the cost-effectiveness of our product candidates to other available therapies in order to obtain or maintain reimbursement or pricing approval. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If reimbursement of any product candidate approved for marketing is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business, financial condition, results of operations or prospects could be materially and adversely affected.

If we seek and are unable to obtain accelerated approval, the amount, size and duration of our clinical trials could be greater than planned, which could increase the expense, reduce the likelihood, and/or delay the timing of obtaining necessary regulatory approvals. Even if we receive accelerated approval, if confirmatory trials do not verify clinical benefit, or if we do not comply with rigorous post-approval requirements, such authorities may withdraw accelerated approval.

We may in the future seek accelerated approval for one or more of our product candidates. Under the accelerated approval program, the FDA may grant accelerated approval to a product candidate designed to treat a serious or life-threatening condition that provides meaningful therapeutic benefit over available therapies upon a determination that the product candidate has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. The FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease, such as irreversible morbidity or mortality. For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit.

The accelerated approval pathway may be used in cases in which the advantage of a new drug or biologic over available therapy may not be a direct therapeutic advantage, but is a clinically important improvement from a patient and public health perspective. If granted, accelerated approval is usually contingent on the sponsor's agreement to conduct, in a diligent manner, additional confirmatory studies to verify and describe the drug's predicted clinical benefit. If such post-approval studies fail to confirm the drug's clinical benefit or are not completed in a timely manner, the FDA may withdraw its approval of the drug on an expedited basis. In addition, the Food and Drug Omnibus Reform Act of 2022, among other things, provided FDA additional statutory authority to mitigate potential risks to patients from continued marketing of ineffective drugs previously granted accelerated approval. Under these provisions, the FDA may require a sponsor of a product seeking accelerated approval to have a confirmatory trial well underway prior to such approval being granted.

Prior to seeking accelerated approval for any of our product candidates, we intend to seek feedback from the FDA and will otherwise evaluate our ability to seek and receive accelerated approval. There can be no assurance that after our evaluation of the feedback and other factors we will decide to pursue or submit an BLA for accelerated approval or any other form of expedited development, review or approval. Furthermore, if we decide to submit an application for accelerated approval for our product candidates, there can be no assurance that such application will be accepted or that any expedited development, review or approval will be granted on a timely basis, or at all. The FDA or other comparable foreign regulatory authorities could also require us to conduct further studies prior to considering our application or granting approval of any type. A failure to obtain accelerated approval or any other form of expedited development, review or approval for our product candidate would result in a longer time period to commercialization of such product candidate, if any, could increase the cost of development of such product candidate and could harm our competitive position in the marketplace.

General Risk Factors

We may become exposed to costly and damaging liability claims, when testing a product candidate in the clinical stage or at the commercial stage, and our product liability insurance may not cover all damages from such claims.

We are exposed to potential product liability and professional indemnity risks that are inherent in the research, development, manufacturing, marketing and use of pharmaceutical products. While we currently have no products that have been approved for commercial sale, the future use of a product candidate in clinical trials, and the sale of any approved products in the future, may expose us to liability claims. These claims may be made by patients that use the product or product candidate, healthcare providers, pharmaceutical companies, or others selling such product. Any claims against us, regardless of their merit, could be difficult and costly to defend and could materially and adversely affect the market for our products or any prospects for commercialization of our products. Although we intend to obtain product liability insurance for our future clinical trials, it is possible that our liabilities could exceed our insurance coverage or that in the future we may not be able to maintain insurance coverage at a reasonable cost or obtain insurance coverage that will be adequate to satisfy any liability that may arise. If a successful product liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover such claims and our business operations could be impaired.

Litigation costs and the outcome of litigation could have a material adverse effect on our business.

From time to time, we may be subject to litigation claims through the ordinary course of our business operations regarding, but not limited to, securities litigation, employment matters, security of patient and employee personal information, contractual

relations with collaborators and licensors and intellectual property rights. Litigation to defend ourselves against claims by third parties, or to enforce any rights that we may have against third parties, could result in substantial costs and diversion of our resources, causing a material adverse effect on our business, financial condition, results of operations or cash flows.

Our business could be adversely affected by economic downturns, inflation, fluctuating interest rates, natural disasters, public health crises, political crises, geopolitical events, or other macroeconomic conditions, which could have a material and adverse effect on our results of operations and financial condition.

The global economy, including credit and financial markets, has experienced extreme volatility and disruptions, including, among other things, diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, supply chain shortages, increases in inflation rates, fluctuating interest rates, and uncertainty about economic stability. Adverse macroeconomic conditions, including inflation, slower growth or recession, new or increased tariffs imposed by the U.S. government and potential retaliatory measures by foreign governments and other barriers to trade, especially in light of recent comments and executive orders made by the Trump administration, changes to fiscal and monetary policy or government budget dynamics (particularly in the pharmaceutical and biotech areas), government shutdowns, tighter credit, higher interest rates, volatility in financial markets, high unemployment, labor availability constraints, currency fluctuations and other challenges in the global economy have in the past adversely affected, and may in the future adversely affect, we and our business partners and suppliers. For example, the COVID-19 pandemic resulted in widespread unemployment, economic slowdown and extreme volatility in the capital markets. In addition, the U.S. has imposed and taken action to pause, resume or adjust tariffs on imports from a number of countries. Since February 2025, the United States government has imposed various tariffs on imports from most countries, including tariffs on imports from China and South Korea. In September 2025, President Trump announced plans to impose 100% tariffs on imported branded or patented pharmaceuticals, unless the importing company is building U.S. manufacturing capacity. It is not yet clear whether these tariffs would apply to the importation of active pharmaceutical ingredients and possibly bulk drug products that are intended for use in clinical trials and not for commercial sale, which could increase the costs of materials for our clinical trials. There still remains substantial uncertainty about the duration of existing tariffs and whether additional tariffs may be imposed, modified or suspended. Historically, tariffs have led to increased trade and political tensions. In response to tariffs, other countries have implemented retaliatory tariffs on U.S. goods. Uncertainty and political tensions as a result of trade policies could reduce trade volume, investment, technological exchange and other economic activities between major international economies, resulting in a material adverse effect on global economic conditions and the stability of global financial markets. The Federal Reserve has raised interest rates multiple times in recent years in response to concerns about inflation, despite having since lowered rates and it may raise them again. High interest rates, coupled with reduced government spending and volatility in financial markets, may increase economic uncertainty and affect consumer spending. Similarly, the ongoing military conflict between Russia and Ukraine and in the Middle East and rising tensions with China and other countries have created extreme volatility in the global capital markets and may have further global economic consequences, including disruptions of the global supply chain. Any such volatility and disruptions may adversely affect our business or the third parties on whom we rely. If the equity and credit markets deteriorate, including as a result of political unrest or war, it may make any necessary debt or equity financing more costly, more dilutive, or more difficult to obtain in a timely manner or on favorable terms, if at all. Increased inflation rates can adversely affect us by increasing our costs, including labor and employee benefit costs.

We may in the future experience disruptions as a result of such macroeconomic conditions, including delays or difficulties in initiating or expanding clinical trials and manufacturing sufficient quantities of materials. Any one or a combination of these events could have a material and adverse effect on our results of operations and financial condition.

Risks Related to the Ownership of Our Common Stock

The market price of our common stock has been and is expected to continue to be volatile.

The market price of our common stock has been and is expected to continue to be subject to significant fluctuations. Some of the factors that may cause the market price of our common stock to fluctuate include:

- results of clinical trials and preclinical studies of our product candidates, or those of our competitors or our existing or future collaborators;
- failure to meet or exceed financial and development projections we may provide to the public;
- failure to meet or exceed the financial and development projections of the investment community;
- if we do not achieve the perceived benefits of our recent merger as rapidly or to the extent anticipated by financial or industry analysts;

- announcements of significant acquisitions, strategic collaborations, joint ventures or capital commitments by us or our competitors;
- actions taken by regulatory agencies with respect to our product candidates, clinical studies, manufacturing process or sales and marketing terms;
- disputes or other developments relating to proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our technologies;
- additions or departures of key personnel;
- significant lawsuits, including patent or stockholder litigation;
- if securities or industry analysts do not publish research or reports about our business, or if they issue adverse or misleading opinions regarding our business and stock;
- changes in the market valuations of similar companies;
- general market or macroeconomic conditions or market conditions in the pharmaceutical and biotechnology sectors;
- sales of securities by us or our securityholders in the future;
- if we fail to raise an adequate amount of capital to fund our operations or continued development of our product candidates;
- trading volume of our common stock;
- announcements by competitors of new commercial products, clinical progress or lack thereof, significant contracts, commercial relationships or capital commitments;
- adverse publicity relating to precision medicine product candidates, including with respect to other products in such markets;
- the introduction of technological innovations or new therapies that compete with our products and services; and
- period-to-period fluctuations in our financial results.

Moreover, the stock markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies. These broad market fluctuations may also adversely affect the trading price of our common stock. In addition, a recession, depression or other sustained adverse market event could materially and adversely affect our business and the value of our common stock. In the past, following periods of volatility in the market price of a company's securities, stockholders have often instituted class action securities litigation against such companies. Furthermore, market volatility may lead to increased shareholder activism if we experience a market valuation that activists believe is not reflective of our intrinsic value. Activist campaigns that contest or conflict with our strategic direction or seek changes in the composition of our board of directors could have an adverse effect on our operating results, financial condition and cash flows.

We are governed by Nevada law and our articles of incorporation and bylaws, provisions of which have anti-takeover implications.

We and our organizational documents are governed by Nevada law. Chapter 78 of the Nevada Revised Statutes contains provisions that may enable our board of directors to discourage, delay or prevent a change in our ownership or in our management. The combinations with interested stockholders provisions of the Nevada Revised Statutes, subject to certain exceptions, restrict our ability to engage in any combination with an interested stockholder for two years after the date a stockholder becomes an interested stockholder, unless either, prior to the stockholder becoming an interested stockholder, our board of directors approved the combination or transaction by which the stockholder first became an interested stockholder or the combination is approved by our board of directors and at least 60% of the outstanding voting power, excluding shares beneficially owned by the interested stockholder, its affiliates and associates. If the combination or acquisition was not so approved prior to the stockholder becoming an interested stockholder, the interested stockholder may effect a combination after the two-year period only if either the stockholder receives approval from at least a majority of the outstanding voting power, excluding shares beneficially owned by the interested stockholder, its affiliates or associates, or the consideration to be paid by the interested stockholder exceeds certain thresholds set forth in the statute. For purposes of the foregoing provisions, "interested stockholder" means either a person, other than us or our subsidiaries, who directly or indirectly beneficially owns 10% or more of the voting

power of our outstanding voting shares, or one of our affiliates or associates which at any time within two years immediately before the date in question directly or indirectly beneficially owned 10% or more of the voting power of our outstanding shares.

Because our articles of incorporation and bylaws limit the court in which you may bring an action against us, you may have difficulty obtaining a more favorable judicial forum or you may incur more expense enforcing any rights which you may claim as compared to another forum.

Our charter and our bylaws provide that, to the extent permitted by law, any person who acquires equity in our company shall be deemed to have notice and consented to the forum selection provision of our bylaws, which require actions to be brought only in state court in Clark County, Nevada, which may inhibit or deter stockholders' actions (i) brought in the name of our company or on our behalf; (ii) asserting a claim for breach of any fiduciary duty owed by any of our directors, officers, employees or agents to us or our stockholders; (iii) arising or asserting a claim arising pursuant to any provision of NRS Chapters 78 or 92A or any provision of our articles of incorporation or bylaws; (iv) to interpret, apply, enforce or determine the validity of any provision of our articles of incorporation or bylaws; or (v) asserting a claim governed by the internal affairs doctrine. This exclusive forum provision may limit our stockholders' ability to obtain what they believe to be a favorable judicial forum for disputes with us and our officers and directors. This provision does not apply to claims brought under the Securities Act of 1933, as amended (the "Securities Act") or the Securities Exchange Act of 1934, as amended, (the "Exchange Act").

Any person or entity purchasing or otherwise acquiring any interest in any of our securities shall be deemed to have notice of and consented to this provision. These exclusive-forum provisions may limit a stockholder's ability to bring a claim in a judicial forum of its choosing for disputes with us or our directors, officers, or other employees, which may discourage lawsuits against us and our directors, officers, and other employees. If a court were to find either exclusive-forum provision in our bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving the dispute in other jurisdictions, which could harm our results of operations.

We will incur additional costs and increased demands upon management as a result of complying with the laws and regulations affecting public companies.

We will incur significant legal, accounting and other expenses as a public company, including costs associated with public company reporting obligations under the Exchange Act. Our executive officers and other personnel need to devote substantial time to comply with public company reporting requirements and additional applicable laws and obligations. Any changes we make to comply with these obligations may not be sufficient to allow us to satisfy our obligations as a public company on a timely basis, or at all. These reporting requirements, rules and regulations, coupled with the increase in potential litigation exposure associated with being a public company, could also make it more difficult for us to attract and retain qualified persons to serve on the board of directors or on board committees or to serve as executive officers, or to obtain certain types of insurance, including directors' and officers' insurance, on acceptable terms.

Once we are no longer a smaller reporting company or otherwise no longer qualify for applicable exemptions, we will be subject to additional laws and regulations affecting public companies that will increase our costs and the demands on management and could harm our operating results and cash flows.

We are subject to the reporting requirements of the Exchange Act, which require, among other things, that we file with the SEC, annual, quarterly and current reports with respect to our business and financial condition as well as other disclosure and corporate governance requirements. However, as a "smaller reporting company," as such term is defined in Rule 12b-2 under the Exchange Act, in at least the near term, we may take advantage of exemptions from disclosure requirements and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. In addition, as a smaller reporting company with less than $100.0 million in annual revenue, we are not required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act. Once we are no longer a smaller reporting company or otherwise no longer qualify for these exemptions, we will be required to comply with these additional legal and regulatory requirements applicable to public companies and will incur significant legal, accounting and other expenses to do so. If we are not able to comply with the requirements in a timely manner or at all, our financial condition or the market price of our common stock may be harmed. For example, if we or our independent auditor identifies deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, we could face additional costs to remedy those deficiencies, the market price of our stock could decline or we could be subject to sanctions or investigations by the SEC or other regulatory authorities, which would require additional financial and management resources.

If we fail to maintain proper and effective internal controls, our ability to produce accurate financial statements on a timely basis could be impaired.

We are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act and the rules and regulations of Nasdaq. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. We must perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting in our Annual Report on Form 10-K filing for that year, as required by Section 404 of the Sarbanes-Oxley Act. As a private company, prior to our recent merger, we were not required to document and test our internal controls over financial reporting nor had our management been required to certify the effectiveness of our internal controls and our auditors had not been required to opine on the effectiveness of our internal controls over financial reporting. We are required to incur substantial professional fees and internal costs to expand our accounting and finance functions and expend significant management efforts. We may experience difficulty in meeting these reporting requirements in a timely manner.

We may discover weaknesses in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our financial statements. Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act, or if we are unable to maintain proper and effective internal controls, we may not be able to produce timely and accurate financial statements. If that were to happen, the market price of our common stock could decline and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities.

We do not anticipate that we will pay any cash dividends in the foreseeable future.

The current expectation is that we will retain our future earnings, if any, to fund the growth of our business as opposed to paying dividends. As a result, capital appreciation, if any, of our common stock will be the sole source of gain, if any, for our stockholders for the foreseeable future.

Future sales of shares by existing stockholders could cause our stock price to decline.

If existing securityholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market after legal restrictions on resale in connection with our recent merger lapse, the trading price of our common stock could decline. In addition, shares of common stock that are subject to outstanding options will become eligible for sale in the public market to the extent permitted by the provisions of various vesting agreements and Rules 144 and 701 under the Securities Act. If these shares are sold, the trading price of our common stock could decline.

Our executive officers, directors and principal stockholders have the ability to control or significantly influence all matters submitted to our stockholders for approval.

Our executive officers, directors and principal stockholders, in the aggregate, beneficially own a significant portion of our outstanding shares of common stock (on a fully-diluted basis), subject to beneficial ownership limitations. As a result, if these stockholders were to choose to act together, they would be able to control or significantly influence all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these stockholders, if they choose to act together, would control or significantly influence the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of voting power could delay or prevent an acquisition of us on terms that other stockholders may desire.

Conflicts of interest may arise between us and Paragon or us and Fairmount.

Paragon is a biotechnology company that performs research and development activities to discover and engineer novel antibody candidates for various therapeutic targets. Fairmount beneficially owns more than 5% of our capital, currently has two representatives appointed to our Board and beneficially owns more than 5% of Paragon. In addition, Paragon is the licensor of JADE101 and JADE201 and has granted us an exclusive option to an exclusive license with respect to JADE301. Specifically, we and Paragon have entered into the Paragon License Agreements and we, Paragon and Parade, an entity formed by Paragon to hold equity in us and share profits with certain employees of Paragon, have entered into the Paragon Option Agreement, pursuant to which we have the option to acquire exclusive rights to certain antibody candidates discovered and developed by Paragon with respect to our JADE301 program. Although we have the right to control the prosecution, defense, maintenance and enforcement of the patents underlying the licenses we have obtained and in the future may obtain from Paragon in connection with the Paragon Option Agreement after entry into the applicable license agreement and the trigger for transfer of prosecution control is met, we rely on Paragon to obtain, maintain and enforce such patents prior to our exercise of the option and entry into a license agreement. We also reimburse Paragon for certain development costs related to our selected targets and have granted and will grant Parade warrants to purchase our common stock as part of the Paragon Option Agreement. Fairmount, an investment firm, that has launched and funded several biotechnology companies, including us, beneficially own 9.99% of our common stock assuming no conversion of the Series A Preferred Stock, which is non-voting, into common stock, and 19.99% assuming conversion of the Series A Preferred Stock into common stock (in each case, subject to beneficial ownership limitations and based on the number of shares of common stock outstanding as of December 31, 2025, and assuming no exercise of outstanding options).

Two of our non-employee directors, Tomas Kiselak and Chris Cain, are affiliated with Fairmount. Our third non-employee director, Lawrence Klein, is an executive officer at Oruka Therapeutics, Inc., another entity affiliated with Fairmount and Paragon. The remaining members of our board of directors are not affiliated with Fairmount or Paragon. Our relationship with Paragon, Parade, Fairmount and our non-employee directors may create, or may create the appearance of, conflicts of interest when we are faced with decisions that could have different implications for Paragon or Parade than the decisions have for us. For example, such conflicts may arise in connection with the selection of additional targets, the exercise of options under the Paragon Option Agreement, the negotiation of the terms of any future license agreements, the allocation of resources and expenses, the enforcement or defense of intellectual property rights, the pursuit of strategic partnerships or transactions, or the resolution of any disputes that may arise between us and Paragon or Parade. Furthermore, because Paragon and Fairmount have interests in other biotechnology companies that may compete with us or pursue similar or complementary product candidates or technologies, they may have an incentive to favor or support such other companies over us. These potential conflicts of interest may make it more difficult for us to favorably advance our business interests and may adversely affect our competitive position, business, financial condition, results of operations and prospects.

If equity research analysts do not publish research or reports, or publish unfavorable research or reports, about us, our business or our market, then our stock price and trading volume could decline.

The trading market for our common stock is influenced by the research and reports that equity research analysts publish about us and our business. Equity research analysts may elect to not provide research coverage of our common stock, and such lack of research coverage may adversely affect the market price of our common stock. In addition, we do not have any control over the analysts or the content and opinions included in their reports. The price of our common stock could decline if one or more equity research analysts downgrade our stock or issue other unfavorable commentary or research. If one or more equity research analysts cease coverage of us or fail to publish reports on us regularly, demand for our common stock could decrease, which in turn could cause our stock price or trading volume to decline.

Our ability to use net operating loss ("NOL") carryforwards and other tax attributes may be limited, including as a result of our recent merger.

We do not expect to become profitable in the near future and may never achieve profitability. As of December 31, 2025, we had federal and state NOL carryforwards and federal and state research and development credits that may be used to offset future taxable income. Under current law, our U.S. federal NOLs incurred in tax years beginning after December 31, 2017 may be carried forward indefinitely, but the deductibility of such net operating loss carryforwards is limited to 80% of taxable income. It is uncertain if and to what extent various states will conform to federal law. In addition, under Sections 382 and 383 of the Internal Revenue Code (the "Code"), U.S. federal NOL carryforwards and other tax attributes may become subject to an annual limitation in the event of certain cumulative changes in ownership. An "ownership change" pursuant to Section 382 of the Code generally occurs if one or more stockholders or groups of stockholders who own at least 5% of a company's stock increase their ownership by more than 50 percentage points over their lowest ownership percentage within a rolling three-year period. Our ability to utilize our net operating loss carryforwards and other tax attributes to offset future taxable income or tax liabilities may be limited as a result of ownership changes, including, as discussed above, in connection with our recent merger or other transactions. Similar rules may apply under state tax laws. If we earn taxable income, such limitations could result in increased future income tax liability to us, and our future cash flows could be adversely affected.

The class structure of our capital stock may limit your ability to influence corporate matters and may limit your visibility with respect to certain transactions.

The class structure of our capital stock may limit your ability to influence corporate matters. Holders of our common stock are entitled to one vote per share, while holders of the Series A Preferred Stock are not entitled to any votes. Nonetheless, each share of the Series A Preferred Stock may be converted at any time into 1,000 shares of our common stock at the option of our holder by providing written notice to us, subject to the limitations provided for in our articles of incorporation. Consequently, if holders of the Series A Preferred Stock exercise their option to make this conversion, this will have the effect of increasing the relative voting power of those prior holders of the Series A Preferred Stock, and correspondingly decreasing the voting power of the holders of our common stock, which may limit your ability to influence corporate matters. Additionally, stockholders who hold, in the aggregate, more than 10% of our common stock and Series A Preferred Stock but 10% or less of our common stock, and are not otherwise an insider, may not be required to report changes in their ownership due to transactions in the Series A Preferred Stock pursuant to Section 16(a) of the Exchange Act, and may not be subject to the short-swing profit provisions of Section 16(b) of the Exchange Act.

We are an "emerging growth company" and we cannot be certain if the reduced disclosure requirements applicable to emerging growth companies will make our common stock less attractive to investors.

We are an "emerging growth company" as defined in the JOBS Act. As an emerging growth company, we are only required to provide two years of audited financial statements and management discussion and analysis of financial condition and results of operations disclosure. In addition, we are not required to obtain auditor attestation of reporting on internal control over financial reporting, have reduced disclosure obligations regarding executive compensation and are not required to hold non-binding advisory votes on executive compensation. We cannot predict whether investors will find our common stock to be less attractive as a result of our reliance on these exemptions. If some investors find our common stock to be less attractive as a result, there may be a less active trading market for our common stock and the price of the common stock may be more volatile.

We will remain an emerging growth company until the earliest of: (i) the end of the fiscal year in which we have total annual gross revenue of $1.235 billion; (ii) December 31, 2026; (iii) the date on which we issue more than $1.0 billion in non-convertible debt during the preceding three-year period; or (iv) the end of the fiscal year in which the market value of our common stock held by non-affiliates exceeds $700 million as of the last business day of our most recently completed second fiscal quarter.

Further, there is no guarantee that the exemptions available under the JOBS Act will result in significant savings. To the extent that we choose not to use exemptions from various reporting requirements under the JOBS Act, we will incur additional compliance costs, which may impact our financial condition.

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity.

Cybersecurity Risk Management and Strategy

We have developed and implemented a cybersecurity risk management program intended to protect the confidentiality, integrity, and availability of our critical systems and information.

Our cybersecurity program aligns with the National Institute of Standards and Technology (NIST) Cybersecurity Framework (CSF) and is consistently updated as NIST recommendations change year over year. This does not imply that we meet any particular technical standards, specifications, or requirements, only that we use NIST as a guide to help us identify, assess, and manage cybersecurity risks relevant to our business.

Our assessment and management of material risks from cybersecurity threats are integrated into the Company's overall risk management process. Cybersecurity risks are identified by monitoring and evaluating our threat environment, and then assessed by various methods, for example, by manual and automated tools designed to identify and combat cybersecurity threats. Other methods may include analyzing reports of threats, conducting scans and assessments of the threat environment and identifying vulnerabilities, and the use of detection and response services and conducting reviews of third-party service providers, among other things. Depending on the threat environment, we implement and maintain various technical, physical, organizational measures, processes, standards and policies designed to manage and mitigate material risks from cybersecurity threats to our information systems and data. For example, we implement physical security, access controls, asset management, systems monitoring, incident detection and response, the implementation of security standards, encryption of data, network security controls, and a recovery/business continuity plan, among other mitigation tactics. Our recovery/business continuity plan is designed to mitigate and remediate identified cybersecurity incidents and escalate certain incidents as appropriate to management and the Audit Committee.

In sum, key elements of our cybersecurity risk management program include but are not limited to the following:

- risk assessments designed to help identify material risks from cybersecurity threats to our critical systems and information;
- an internal team responsible for, inter alia, managing (1) our cybersecurity risk assessment processes, (2) our security controls, and (3) our response to cybersecurity incidents;
- a cybersecurity incident response plan that includes procedures for responding to cybersecurity incidents;
- the use of third-party information technology service providers who have implemented and maintain various information security processes designed to identify, assess, and manage material risks from cybersecurity threats to our information technology systems, including critical computer networks, third party hosted services, communications systems, hardware and software, and our data residing on these systems;
- cybersecurity awareness training of our employees, including incident response personnel and senior management; and
- a risk management evaluation process for key service providers based on our assessment of their criticality to our operations and respective risk profile, suppliers, and vendors with access to our information systems or data.

In the last fiscal year, we have not identified any risks from known cybersecurity threats, including as a result of any prior cybersecurity incidents that have materially affected us, including our operations, business strategy, results of operations, or financial condition. However, we face certain ongoing cybersecurity risks or threats that, if realized, are reasonably likely to materially affect us. For a description of the risks from cybersecurity threats that may materially affect the Company and how they may do so, see our "Risk Factors" under Part 1 Item 1A. Risk Factors, in this Annual Report on Form 10-K.

Cybersecurity Governance

The Board of Directors, as a whole and at the committee level, considers cybersecurity risk as part of its risk oversight function. The Audit Committee has been designated by our Board to oversee cybersecurity risks, including oversight of management's implementation of our cybersecurity risk management program. In addition, management is required to update the

Audit Committee, where it deems appropriate, regarding any cybersecurity incidents it considers to be significant or potentially significant.

The Audit Committee receives regular updates on cybersecurity and information technology matters and related risk exposures from our management team. The Board also receives updates from management and the Audit Committee on cybersecurity risks on a regular basis. Our Vice President of Information Technology, together with our senior management, is responsible for assessing and managing cybersecurity risks, managing our cybersecurity programs and evaluating material cybersecurity threats to our overall business. Our Chief Financial Officer has over six years of experience overseeing IT and cybersecurity. Our Vice President of Information Technology has over 25 years of experience leading IT organizations, including a decade overseeing cybersecurity programs.

Our management team takes steps to stay informed about and monitor efforts to prevent, detect, mitigate, and remediate cybersecurity risks and incidents through various means, including through briefings from internal security personnel; threat intelligence and other information obtained from governmental, public or private sources, including external consultants engaged by us; and alerts and reports produced by security tools deployed in our information technology environment.

Item 2. Properties.

We are a primarily remote company and do not maintain a physical headquarters. We believe this arrangement supports our current and near-term future anticipated needs. For administrative purposes, we lease office space in Vancouver, Canada and maintain a mailing address at 221 Crescent St., Building 23, Suite 105, Waltham, MA. As we expand, we believe that suitable additional alternative spaces will be available in the future on commercially reasonable terms, if required.

Item 3. Legal Proceedings.

From time to time, we may be involved in legal proceedings arising in the ordinary course of our business. We are not presently a party to or aware of any legal proceedings that, in the opinion of management, would have, individually or in the aggregate, a material adverse effect on our business, financial condition or results of operations. Regardless of outcome, litigation can have an adverse impact on us due to defense and settlement costs, diversion of management resources, negative publicity and reputational harm, and other factors.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information

Our common stock is listed on The Nasdaq Capital Market under the symbol "JBIO".

Holders

As of February 27, 2026, there were approximately 78 holders of record of our common stock. However, because many of our outstanding shares are held in accounts with brokers and other institutions, we believe we have more beneficial owners.

Dividends

We currently intend to retain all available funds and future earnings, if any, for the operation and expansion of our business and do not anticipate declaring or paying any dividends in the foreseeable future. Any future determination related to our dividend policy will be made at the discretion of our Board of Directors after considering our financial condition, results of operations, capital requirements, contractual requirements, business prospects, and other factors the Board of Directors deems relevant, and subject to the restrictions contained in any future financing instruments.

Securities Authorized for Issuance Under Equity Compensation Plans

Information about securities authorized for issuance under our equity compensation plans is incorporated herein by reference to Item 12 of Part III of this Annual Report on Form 10-K.

Performance Graph

As a "smaller reporting company," as defined by Rule 12b-2 of the Exchange Act and in Item 10(f)(1) of Regulation S-K, and pursuant to Instruction 6 to Item 201(e) of Regulation S-K, we are not required to provide the stock performance graph.

Recent Sales of Unregistered Securities

On December 31, 2025, in accordance with the Paragon Option Agreement and to settle the Company's 2025 obligations under the Paragon Option Obligation (as defined below), we issued to Paragon a warrant to purchase an aggregate of up to 804,519 shares of our common stock, with a per share exercise price equal to $15.43, which was the closing price of a share of the Company's common stock on December 31, 2025 (the "Issue Date"), effective as of the Issue Date and with an expiration date of the 10th anniversary of the Issue Date. We have relied on the exemption from registration requirements provided by Section 4(a)(2) under the Securities Act of 1933, as amended, relating to a transaction not involving any public offering to a single accredited investor.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

Item 6. [Reserved]

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with the consolidated financial statements and the related notes thereto and other financial information included elsewhere in this Annual Report on Form 10-K. This discussion contains forward-looking statements based upon current plans, estimates and beliefs related to future events and our future financial performance that involve risks, uncertainties and assumptions. Our actual results and the timing of events could differ materially from those discussed in these forward-looking statements as a result of various factors. Factors that could cause or contribute to these differences include, but are not limited to, those discussed below and elsewhere in this Annual Report on Form 10-K, particularly in the section titled "Risk Factors." Please also see the section titled "Cautionary Statement Concerning Forward-Looking Statements." As used in this Annual Report on Form 10-K, unless the context suggests otherwise, "we", "us", "our", "the Company", or "Jade" refer to Jade Biosciences, Inc. and its consolidated subsidiaries, taken as a whole.

Overview

We are a clinical-stage biopharmaceutical company developing novel biologic therapies for patients living with autoimmune diseases. Our goal is to improve meaningfully upon the existing treatment paradigm through the delivery of

improved dosing and convenience, a comparable safety profile, and potentially increased clinical activity. Our approach is to discover and efficiently develop biologics that address emerging targets supported by third-party clinical data and that overcome shortcomings of existing product candidates in development, such as potency, bioavailability, formulation, and pharmacokinetic properties.

Our lead product candidate, JADE101, is a monoclonal antibody ("mAb") targeting a cytokine called "A PRoliferation Inducing Ligand" ("APRIL") that modulates plasma cell survival and immunoglobulin production, which we plan to initially develop for the treatment of IgA nephropathy ("IgAN"). We initiated a Phase 1 clinical trial of JADE101 in healthy volunteers in New Zealand in August 2025, with the aim of generating interim data, including mechanistic biomarker data, in the second quarter of 2026. We plan to initiate an open-label Phase 2 clinical trial in IgAN patients in the middle of 2026, with interim data expected in 2027. Our second product candidate is JADE201, a mAb targeting B cell activating factor receptor ("BAFF-R") for the treatment of multiple autoimmune disorders. We plan to initiate a Phase 1 clinical trial evaluating JADE201 in patients with rheumatoid arthritis in the second quarter of 2026, with interim data expected in 2027. Our third product candidate is JADE301, targeting an undisclosed pathway. We expect to initiate a Phase 1 clinical trial for JADE301 in the first half of 2027.

Since our inception, we have devoted substantially all of our resources to raising capital, organizing and staffing the company, business and scientific planning, conducting discovery and research activities, establishing arrangements with third parties, and providing general and administrative support for these operations. We do not have any products approved for sale and have not generated any revenue from product sales. To date, we have funded our operations primarily with proceeds from the issuance of convertible notes ("Convertible Notes"), from which we received gross proceeds of $80.0 million in July 2024 and $15.0 million in September 2024, $205.0 million in gross proceeds from the Pre-Closing Financing (as defined and described in "*—Corporate Transactions—Pre-Closing Financing*" below), approximately $135.0 million in gross proceeds from a private placement in October 2025, (the "October 2025 PIPE") and $45.0 million in gross proceeds from a private placement in December 2025 (the "December 2025 PIPE") (as described in "*—Liquidity and Capital Resources—Sources of Liquidity"* below).

We have incurred operating losses since inception. Our ability to generate product revenue sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of JADE101, JADE201 and any future product candidates we may develop. We have generated net losses of $127.4 million for the year ended December 31, 2025. As of December 31, 2025, we had an accumulated deficit of $174.4 million. For the year ended December 31, 2025, we used net cash of $94.7 million for our operating activities. We expect to continue to incur significantly increased expenses for the foreseeable future if and as we continue our development of, seek regulatory approval for and potentially commercialize any of our product candidates.

We will not generate revenue from product sales unless and until we successfully initiate and complete clinical development and obtain regulatory approval for any product candidates. If we obtain regulatory approval for any of our product candidates and do not enter into a commercialization partnership, we expect to incur significant expenses related to developing our commercialization capability to support product sales, manufacturing, marketing, and distribution.

As a result of all the foregoing, we expect to need substantial additional funding to support our continued operations and growth strategy. Until such a time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through the sale of equity, debt financings or other capital sources, including collaborations with other companies or other strategic transactions. We may be unable to raise additional funds or enter into such other agreements on favorable terms, or at all. If we fail to raise capital or enter into such agreements as, and when needed, we may have to significantly delay, scale back or discontinue the development and commercialization of one or more of our programs.

Because of the numerous risks associated with product development, we are unable to accurately predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability. Even if we are able to generate product sales, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce or terminate our operations.

As of December 31, 2025, we had cash and cash equivalents, and investments of $336.2 million. We expect that our existing cash and cash equivalents, and investments, will be sufficient to fund our operating expenses and capital expenditure requirements for at least twelve months from the date our consolidated financial statements for the year ended December 31, 2025 were issued.

Corporate Transactions

The Merger

On April 28, 2025, we consummated the previously announced transaction (the "Closing") pursuant to that certain Agreement and Plan of Merger, dated as of October 30, 2024 (the "Merger Agreement"), by and among Jade Biosciences, Inc., a private Delaware corporation ("Pre-Merger Jade"), Aerovate Therapeutics, Inc., a Delaware corporation ("Aerovate"), Caribbean Merger Sub I, Inc., a Delaware corporation and wholly-owned subsidiary of Aerovate ("First Merger Sub"), and Caribbean Merger Sub II, LLC, a Delaware limited liability company and wholly-owned subsidiary of Aerovate ("Second Merger Sub"). As part of the Closing, First Merger Sub merged with and into Pre-Merger Jade, with Pre-Merger Jade continuing as a wholly owned subsidiary of Aerovate and the surviving corporation of the merger (the "First Merger" and such time, the "First Effective Time"), and Pre-Merger Jade merged with and into Second Merger Sub, with Second Merger Sub being the surviving entity of the merger (the "Second Merger" and, together with the First Merger, the "Merger"). In connection with the Merger, Second Merger Sub changed its name to "Jade Biosciences, LLC" and Aerovate changed its name to "Jade Biosciences, Inc." Subsequently, Jade Biosciences, LLC merged with and into Jade Biosciences, Inc. We are led by Pre-Merger Jade's management team and focus on developing differentiated biologic therapies for patients living with autoimmune diseases.

Following the Reverse Stock Split (as defined below), which occurred immediately prior to the Closing of the Merger, and as a result of and upon the First Effective Time, (i) each then-outstanding share of common stock, par value $0.0001 per share, of Pre-Merger Jade (the "Pre-Merger Jade common stock") (including shares of Pre-Merger Jade common stock issued in connection with the Pre-Closing Financing) immediately prior to the First Effective Time (excluding shares cancelled pursuant to the Merger Agreement and excluding dissenting shares) automatically converted into the right to receive a number of shares of common stock, par value $0.0001, of Aerovate (the "Company common stock" and prior to the effective time of the Merger, the "Aerovate common stock") equal to an exchange ratio determined in accordance with the Merger Agreement (the "Exchange Ratio"), (ii) each then-outstanding share of Series Seed Convertible Preferred Stock, par value $0.0001 per share, of Pre-Merger Jade immediately prior to the First Effective Time (excluding shares cancelled pursuant to the Merger Agreement and excluding dissenting shares) automatically converted into the right to receive a number of shares of Series A Non-Voting Convertible Preferred Stock, par value $0.0001 per share, of Aerovate, which are each convertible into 1,000 shares of Company common stock, equal to the Exchange Ratio divided by 1,000, (iii) each then-outstanding option to purchase Pre-Merger Jade common stock was assumed by Aerovate and was converted into an option to purchase shares of Company common stock, subject to adjustment as set forth in the Merger Agreement, and (iv) each then-outstanding pre-funded warrant to purchase shares of Pre-Merger Jade common stock (including any pre-funded warrants to purchase shares of Pre-Merger Jade common stock issued in the Pre-Closing Financing) was converted into a pre-funded warrant to purchase shares of Company common stock (subject to adjustment as set forth in the Merger Agreement and the form of pre-funded warrant).

The Exchange Ratio was calculated using a formula intended to allocate existing Aerovate and Pre-Merger Jade security holders a percentage of the Company. Based on Aerovate's and Pre-Merger Jade's values as of the date of the Merger Agreement and capitalization as of April 28, 2025, the Exchange Ratio (as adjusted for the Reverse Stock Split (as defined below)) was 0.6311 shares of Aerovate common stock for each share of Pre-Merger Jade common stock.

The Merger was accounted for as a reverse recapitalization in accordance with U.S. GAAP. Under this method of accounting, Pre-Merger Jade was deemed to be the accounting acquirer for financial reporting purposes. This determination was primarily based on the fact that, immediately following the Merger: (i) Pre-Merger Jade stockholders owned a substantial majority of the voting rights in the combined company; (ii) Pre-Merger Jade's largest stockholders retained the largest interest in the combined company; (iii) Pre-Merger Jade designated a majority of the initial members of the board of directors of the combined company; and (iv) Pre-Merger Jade's executive management team became the management team of the combined company. Accordingly, for accounting purposes: (i) the Merger was treated as the equivalent of Pre-Merger Jade issuing stock to acquire the net assets of Aerovate, and (ii) the reported historical operating results of the combined company prior to the Merger are those of Pre-Merger Jade. See Note 3 to our financial statements included elsewhere in this Annual Report on Form 10-K for additional information regarding the Merger.

Pre-Closing Financing

In connection with the Merger, Pre-Merger Jade entered into a subscription agreement with certain new and existing investors of Pre-Merger Jade, in order to provide Jade with additional capital for its development programs, pursuant to which Pre-Merger Jade issued and sold, and certain new and existing investors purchased, 43,947,116 shares of common stock of Pre-Merger Jade ("Pre-Merger Jade common stock") and 12,305,898 pre-funded warrants, exercisable for 12,305,898 shares of Pre-Merger Jade common stock ("Pre-Merger Jade pre-funded warrants"), at a purchase price of $5.9407 per share or a purchase price of $5.9406 per pre-funded warrant, for an aggregate amount of $334.2 million, which included $95.0 million of proceeds previously received from the issuance of Convertible Notes (as defined herein) and accrued interest of $8.3 million on such

Convertible Notes and the conversion of the Convertible Notes into shares of Pre-Merger Jade pre-funded warrants (the "Pre-Closing Financing").

Under the Merger Agreement, these shares of Pre-Merger Jade common stock and Pre-Merger Jade pre-funded warrants were converted into shares of Company common stock and pre-funded warrants to purchase Company common stock in accordance with the Exchange Ratio.

Reverse Stock Split

Immediately prior to the consummation of the Merger, Aerovate effected a 1-for-35 reverse stock split of Aerovate common stock, which became legally effective on April 28, 2025 (the "Reverse Stock Split"). The Company common stock commenced trading on a post-Reverse Stock Split, post-Merger basis at the open of trading on April 29, 2025. All references to common stock, options to purchase common stock, outstanding common stock warrants, common stock share data, per share data, and related information contained in the consolidated financial statements have been retrospectively adjusted to reflect the effect of the Reverse Stock Split for all periods presented, unless otherwise specifically indicated or the context otherwise requires.

Redomestication

On April 28, 2025, we changed our jurisdiction of incorporation from the State of Delaware to the State of Nevada (the "Redomestication") pursuant to a plan of conversion. The Redomestication became effective on April 28, 2025.

The common stock of the Nevada Corporation resulting from the Redomestication continues to be traded on The Nasdaq Capital Market ("Nasdaq") under the symbol "JBIO." The Redomestication did not cause any interruption in the trading of such common stock.

Components of Results of Operations

Operating Expenses

Our operating expenses consist of (i) research and development expenses and (ii) general and administrative expenses.

Research and Development

Research and development expenses consist primarily of costs incurred in connection with the research and development of our programs. These expenses include:

- external research and development expenses incurred under agreements with third parties that conduct research and development activities on our behalf, including services rendered under the Antibody Discovery and Option Agreement (the "Paragon Option Agreement") with Paragon Therapeutics, Inc. ("Paragon") and Parade Biosciences Holding, LLC ("Parade"), with respect to JADE101 for the selected target APRIL, JADE201 for the selected target BAFF-R and our JADE301 program, which has a currently undisclosed target;
- external expenses incurred under agreements with third parties, contract research organizations ("CROs"), as well as investigative sites and consultants that conduct our clinical trials, preclinical studies and other scientific development services, costs related to compliance with quality and regulatory requirements, costs of laboratory supplies and acquiring and developing preclinical and clinical trial materials, including expenses associated with our third-party manufacturers; and
- personnel-related expenses, including recruiting costs, salaries, bonuses, benefits and equity-based compensation expense.

We expense research and development costs as incurred. For the year ended December 31, 2025, we recognized $28.6 of expenses, in connection with services provided by Paragon under the Paragon Option Agreement and the JADE101 License Agreement as well as the Parade warrants in our consolidated statement of operations and comprehensive loss compared to $24.6 million for the period from June 18, 2024 to December 31, 2024. We track direct costs on a program specific basis. Indirect internal costs are applied broadly across multiple programs rather than to any single program, and as such, are not separately classified.

Research and development activities are central to our business model. We expect that our research and development expenses will increase significantly for the foreseeable future as we continue to identify and develop product candidates,

particularly as more of our product candidates move into clinical development and later stages of clinical development. The successful development of any of our product candidates or product candidates we may develop in the future is highly uncertain. Preclinical and clinical development timelines, the probability of success and total development costs can differ materially from expectations. We anticipate that we will make determinations as to which product candidates and indications to pursue and how much funding to direct to each product candidate on an ongoing basis in response to the results of ongoing and future preclinical studies and clinical trials, regulatory developments, and our ongoing assessments as to each product candidate's commercial potential. Therefore, we cannot reasonably estimate or know the nature, timing and estimated costs of the\ efforts that will be necessary to complete the development and commercialization of any of our product candidates. This is due to the numerous risks and uncertainties associated with developing product candidates, many of which are outside of our control. We may never succeed in obtaining regulatory approval for any of our product candidates.

Our future research and development expenses may vary significantly based on a wide variety of factors such as:

- the number and scope, rate of progress, expense and results of preclinical activities and clinical trials;
- per participant trial costs;
- the number of trials required for approval;
- the number of sites included in the trials;
- the countries in which the trials are conducted;
- the length of time required to enroll eligible participants;;
- the number participants; that participate in the trials;
- the number of doses that participants; receive;
- the drop-out or discontinuation rates of participants;;
- the potential additional safety monitoring requested by regulatory agencies;
- the duration of subject participation in the trials and follow-up;
- the cost and timing of manufacturing our product candidates;
- the phase of development of our candidates;
- the extent of changes in government regulation and regulatory guidance;
- the efficacy and safety profile of our product candidates;
- the timing, receipt, and terms of any approvals from applicable regulatory authorities; and
- the extent to which we establish collaboration, license, or other arrangements.

A change in the outcome of any of these variables with respect to development of any of our product candidates could significantly change the costs and timing associated with the development of that product candidate.

General and Administrative

General and administrative expenses consist primarily of personnel-related expenses, including recruiting costs, salaries, bonuses, benefits, and equity-based compensation, for individuals in our executive, finance, operations, human resources, legal, business development and other administrative functions. Other significant general and administrative expenses include legal fees relating to corporate matters and patent-related activities, insurance costs, information technology, and professional and consulting fees associated with accounting, audit, tax and investor and public relations.

We expect that our general and administrative expenses will increase substantially for the foreseeable future as we increase our headcount to support our expected growth. We also incurred and expect to continue to incur increased expenses associated with becoming a public company, including increased costs of accounting, audit, legal, regulatory and tax related services associated with maintaining compliance with SEC requirements, additional director and officer insurance costs, and investor and public relations costs. We also expect to incur additional intellectual property-related expenses as we file patent applications to protect innovations arising from our research and development activities.

Other Income (Expense)

Other income primarily relates to interest income. Change in fair value of convertible notes payable relates to the fair value adjustment related to our Convertible Notes.

Income Taxes

We have recorded a full valuation allowance against our net deferred tax assets at each balance sheet date, as we believe it is more likely than not that the benefit will not be realized due to our cumulative losses generated to date and expectation of future losses.

Results of Operations for the Year Ended December 31, 2025 and for the Period from June 18, 2024 (Inception) to December 31, 2024

The following table summarizes our consolidated statement of operations and comprehensive loss for the periods presented (in thousands):

	Year Ended December 31, 2025	Period from June 18, 2024 (Inception) to December 31, 2024	$ Change
Operating expenses			
Research and development[1]	$ 93,121	$ 31,234	$ 61,887
General and administrative[2]	20,421	4,304	16,117
Total operating expenses	113,542	35,538	78,004
Loss from operations	(113,542)	(35,538)	(78,004)
Other income (expense), net			
Interest income	$ 7,782	$ 1,159	$ 6,623
Change in fair value of convertible notes payable[3]	(21,584)	(12,600)	(8,984)
Other expense	(8)	—	(8)
Total other income (expense), net	(13,810)	(11,441)	(2,369)
Net loss before income tax expense	(127,352)	(46,979)	(80,373)
Income tax expense	(58)	—	(58)
Net Loss	$ (127,410)	$ (46,979)	$ (80,431)

(1) Includes related party amount of $28.6 million for the year ended December 31, 2025 and $24.6 million for the period from June 18, 2024 (inception) to December 31, 2024.
(2) Includes related party amount of $0.3 million for the year ended December 31, 2025 and $1.0 million for the period from June 18, 2024 (inception) to December 31, 2024.
(3) Includes related party amount of $4.6 million for the year ended December 31, 2025 and $2.7 million for the period from June 18, 2024 (inception) to December 31, 2024.

Research and Development Expenses

The following table summarizes our research and development expenses incurred for the periods presented (in thousands):

	Year Ended December 31, 2025	Period from June 18, 2024 (Inception) to December 31, 2024	$ Change
External research and development costs:			
JADE101[(1)]	$ 28,943	$ 22,992	$ 5,951
JADE201[(2)]	24,249	2,437	21,812
JADE301[(3)]	8,897	2,141	6,756
Other research and development costs:			
Personnel-related (including equity-based compensation)[(4)]	28,560	3,509	25,051
Other (including general allocated shared costs, licenses, insurance, and regulatory)	2,472	155	2,317
Total research and development expenses	$ 93,121	$ 31,234	$ 61,887

(1) Includes related party amount of $4.6 million for the year ended December 31, 2025 and $18.9 million for the period from June 18, 2024 (inception) to December 31, 2024.
(2) Includes related party amount of $5.7 million for the year ended December 31, 2025 and $2.4 million for the period from June 18, 2024 (inception) to December 31, 2024.
(3) Includes related party amount of $8.2 million for the year ended December 31, 2025 and $2.1 million for the period from June 18, 2024 (inception) to December 31, 2024.
(4) Includes related party amount of $10.1 million for the year ended December 31, 2025 and $1.1 million for the period from June 18, 2024 (inception) to December 31, 2024.

Research and development expenses were $93.1 million for the year ended December 31, 2025 and $31.2 million from June 18, 2024 (inception) to December 31, 2024. The increase in research and development expenses was primarily driven by:

- $20.5 million increase in research and development expenses on CMC related costs for our programs with a third-party contract research organization in preparation for clinical trial activities;
- $11.7 million increase in research and development expenses on toxicology studies, primarily related to our JADE101 and JADE201 programs;
- $4.1 million increase in research and development expenses related to clinical trial costs primarily related to our Phase 1 clinical trial for JADE101 as well as other early start-up activities for additional clinical trials;
- $5.9 million increase in research and development expenses related to milestone payments primarily driven by milestones paid under the Paragon Option Agreement; and
- $12.1 million increase in personnel-related costs related to salaries, bonus benefits, recruiting costs and other compensation-related costs, as well as an additional increase of $13.0 million related to stock-based compensation expense. We recognized $10.1 million of stock-based compensation expense related to the Parade warrants in 2025 compared to $1.1 million in 2024.

The above costs were primarily offset by:

- $7.3 million related to decreased project start-up costs surrounding project enablement and development.

General and Administrative Expenses

The following table summarizes our total general and administrative expenses for the periods presented (in thousands):

	Year Ended December 31, 2025	Period from June 18, 2024 (Inception) to December 31, 2024	$ Change
Professional, consulting and other fees[1]	$ 6,933	$ 2,253	$ 4,680
Personnel-related (including stock-based compensation)[2]	12,691	1,714	10,977
Other[3]	797	337	460
Total general and administrative expenses	$ 20,421	$ 4,304	$ 16,117

(1) Includes no related party amounts for the year ended December 31, 2025 and $0.1 million for the period from June 18, 2024 (inception) to December 31, 2024.
(2) Includes no related party amounts for the year ended December 31, 2025 and $0.6 million for the period from June 18, 2024 (inception) to December 31, 2024.
(3) Includes related party amount of $0.3 million for the year ended December 31, 2025 and for the period from June 18, 2024 (inception) to December 31, 2024, respectively.

General and administrative expenses were $20.4 million for the year ended December 31, 2025 and $4.3 million for the period from June 18, 2024 (inception) to December 31, 2024. The increase in general and administrative expenses was primarily driven by:

- $4.4 million of professional and consulting fees associated with accounting, audit, investor and public relations and legal fees due to an increase in our business activity and as we began preparing to become a public company;
- $11.0 million increase in personnel-related costs related to recruiting costs, salaries, benefits and other compensation-related costs, including a $5.7 million increase related to stock-based compensation; and
- Less than $0.5 million of other business expenses.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception, we have incurred significant operating losses. We expect to incur significant expenses and operating losses for the foreseeable future as we continue the preclinical and clinical development of our product candidates. We have not yet commercialized any products and we do not expect to generate revenue from sales of products for several years, if at all. To date, we have funded our operations primarily with proceeds from the sale of our Convertible Notes and the Pre-Closing Financing. In July 2024, we received $80.0 million in gross proceeds from the issuance of our Convertible Notes, in September 2024 we received $15.0 million in gross proceeds for the issuance of additional Convertible Notes, and in April 2025 we received $205 million in gross proceeds from the Pre-Closing Financing. Additionally, we raised an additional $135.0 million in gross proceeds from the October 2025 PIPE and $45.0 million in gross proceeds from the December 2025 PIPE. As of December 31, 2025, we had cash and cash equivalents, and investments of $336.2 million.

On October 6, 2025, we entered into a Securities Purchase Agreement (the “Purchase Agreement”) for the October 2025 PIPE with certain investors (the “Purchasers”). Pursuant to the Purchase Agreement, the Purchasers purchased, for an aggregate purchase price of approximately $135 million, (i) an aggregate of 13,368,164 shares (the “Common Shares”) of our common stock at a price per share of $9.14, and (ii) pre-funded warrants (the “Pre-Funded Warrants”) to purchase an aggregate of 1,402,092 shares of our common stock at a purchase price of $9.1399 per Pre-Funded Warrant, which represents the per share purchase price of the Common Shares less the $0.0001 per share exercise price for each Pre-Funded Warrant. Aggregate proceeds from the October 2025 PIPE were approximately $126.4 million, which was net of issuance costs of $8.6 million. The Pre-

Funded Warrants are exercisable at any time after the date of issuance. A holder of Pre-Funded Warrants may not exercise the warrant if the holder, together with its affiliates, would beneficially own more than 4.99% or 9.99%, as applicable, of the number of shares of our common stock outstanding immediately after giving effect to such exercise. A holder of Pre-Funded Warrants may increase or decrease this percentage to a percentage not in excess of 19.99% by providing at least 61 days' prior notice to us.

On December 13, 2025, we entered into a Securities Purchase Agreement for the December 2025 PIPE with an investor. The closing of the December 2025 PIPE occurred on December 16, 2025. The investor purchased an aggregate of 3,214,286 shares of our common stock at a purchase price of $14.00 per share, for aggregate proceeds of approximately $43.9 million, which was net of issuance costs of $1.1 million.

Cash Flows

The following table summarizes our cash flows for the periods presented (in thousands):

	Year Ended December 31, 2025	Period from June 18, 2024 (Inception) to December 31, 2024
Net cash used in operating activities	$ (94,689)	$ (22,614)
Net cash used in investing activities	(247,006)	—
Net cash provided by financing activities	360,768	92,000
Effect of exchange rates on cash and cash equivalents	(21)	—
Net increase in cash and cash equivalents	$ 19,052	$ 69,386

Net Cash Used in Operating Activities

For the period ended December 31, 2025, net cash used in operating activities was $94.7 million, which was primarily attributable to a net loss of $127.4 million, partially offset by non-cash charges of $41.0 million and changes in operating assets and liabilities of $8.2 million. Non-cash charges consisted of a $21.6 million increase in the fair value of convertible notes payable and $20.0 million increase in stock-based compensation expense. Net cash provided by changes in our operating activities consisted of a change of $6.6 million related to accrued expenses and other current liabilities, partially offset by a $3.2 million decrease in related party accrued expenses and other current liabilities and a $10.3 million increase in prepaid expenses as well as a $1.7 million increase in other assets. The increase in accrued expenses and other current liabilities was primarily due to an increase in our business activity and vendor invoicing and payments. The increase in prepaid expenses and other current assets was primarily due to prepaid research and development expenses with our contract research organization as well as prepaid contracts for our Directors and Officers liability insurance.

From June 18, 2024 (inception) to December 31, 2024, net cash used in operating activities was $22.6 million, which was primarily attributable to a net loss of $47.0 million, partially offset by non-cash charges of $13.9 million and changes in operating assets and liabilities of $10.5 million. Non-cash charges consisted of a $12.6 million increase in the fair value of convertible notes payable and $1.3 million increase in stock-based compensation expense. Net cash provided by changes in our operating activities consisted of a $1.3 million increase in accounts payable, $4.0 million increase in accrued expenses and other current liabilities, and $5.5 million increase in related party accrued expenses and other current liabilities, partially offset by a $0.3 million increase in prepaid expenses and other current assets. The increase in accounts payable, accrued expenses and other current liabilities and amounts due to related parties was primarily due to an increase in our business activity, as well as vendor invoicing and payments. The increase in prepaid expenses and other current assets was primarily due to prepaid research and development expenses with our contract research organization.

Net Cash Used in Investing Activities

For the period ended December 31, 2025, net cash used in investing activities was $247.0 million, which was driven by purchases of investments and leasehold improvements related to the lease of our Canadian office space partially offset by proceeds from the sale/maturity of marketable securities.

There was no cash flow impact of investing activities for the period of June 18, 2024 (inception) to December 31, 2024.

Net Cash Provided by Financing Activities

For the period ended December 31, 2025, net cash provided by financing activities was $360.8 million, which primarily related to the $205.0 million in gross proceeds from the Pre-Closing Financing partially offset by $14.5 million of payments of offering costs. Additionally, we received gross proceeds of approximately $135.0 million related to the October 2025 PIPE financing and an additional $45.0 million related to the December 2025 PIPE financing partially offset by deferred offering costs.

From June 18, 2024 (inception) to December 31, 2024, net cash provided by financing activities was $92.0 million, consisting of $95.0 million of net proceeds from the issuance of the convertible notes, partially offset by $3.0 million of payments in deferred offering costs.

Future Funding Requirements

As of December 31, 2025 we had cash and cash equivalents, and investments of $336.2 million. We expect that our existing cash and cash equivalents, and investments, will be sufficient to fund our operating plans for at least twelve months from the issuance of the consolidated financial statements for the period ended December 31, 2025.

To date, we have not generated any revenue from product sales. We do not expect to generate revenue from product sales unless and until we successfully complete preclinical and clinical development of, receive regulatory approval for, and commercialize a product candidate. We do not know when, or if, that will occur. We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we advance the preclinical activities and studies and initiate and conduct clinical trials. In addition, if we obtain regulatory approval for any programs, we expect to incur significant expenses related to product sales, marketing, and distribution to the extent that such sales, marketing and distribution are not the responsibility of potential collaborators. Additionally, we expect to incur additional costs associated with operating as a public company.

Our funding requirements and timing and amount of our operating expenditures will depend on many factors, including, but not limited to:

- the rate of progress in the development of our existing and future research and development and discovery-related development of our JADE101, JADE201 and JADE301 programs, including potential expansion into additional indications;
- the scope, progress, results and costs of additional research programs and product candidates and discovery-related activities and preclinical studies for those programs;
- our ability to successfully file investigational new drug applications or comparable foreign applications and obtain authorization to commence our planned clinical trials or future clinical trials;
- the costs of enrollment and successful completion of clinical trials;
- the costs necessary to pursue positive results from our future clinical trials that support a finding of safety and effectiveness, an acceptable risk-benefit profile in the intended populations and a competitive efficacy, safety and half-life profile;
- the costs of hiring research and development, clinical, manufacturing and commercial personnel;
- the costs of adding operational, financial and management information systems and personnel;
- the costs necessary to obtain regulatory approvals, if any, for any approved products in the United States and other jurisdictions, and the costs of post-marketing studies that could be required by regulatory authorities in jurisdictions where approval is obtained;
- the costs of developing, maintaining and enhancing sustainable, scalable, reproducible and transferable clinical and commercial-scale cGMP capabilities through a third-party or our own manufacturing facility for our programs;

- the costs and timing of future commercialization activities, including establishing sales, marketing and distribution infrastructure to commercialize any product candidates, for any of our product candidates for which we receive regulatory approval;
- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- the costs and timing of preparing, maintaining, expanding, enforcing, defending and protecting our intellectual property rights and protection or regulatory exclusivity for any products we may develop and defending any intellectual property-related claims;
- the timing and payment of milestone, royalty or other payments we must make pursuant to our existing and potential future collaborations and licensing arrangements with third parties;
- the costs we incur in maintaining business operations;
- the costs associated with being a public company, including costs of audit, legal, regulatory and tax- related services associated with maintaining compliance with an exchange listing and SEC requirements, director and officer insurance premiums and investor and public relations costs;
- the effect of competing technological and market developments; and
- the extent to which we acquire or invests in businesses, products and technologies, including entering into licensing or collaboration arrangements for programs.

Identifying potential programs and product candidates and conducting preclinical studies and clinical trials is a time consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, our programs, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of products that we do not expect to be commercially available for many years, if ever. Accordingly, we will need to obtain substantial additional funds to achieve our business objectives.

Until such a time we can generate significant revenue from product sales, if ever, we expect to finance our operations through the sale of equity, debt financings or other capital sources, including collaborations with other companies or other strategic transactions. Adequate additional funds may not be available to us on acceptable terms, or at all. We do not currently have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, ownership interests will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our existing stockholders. Additional debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring debt, making capital expenditures or declaring dividends and may require the issuance of warrants, which could potentially dilute ownership interests.

If we raise additional funds through strategic collaborations or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs, or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit or terminate our product development programs or any future commercialization efforts or grant rights to develop and market product candidates to third parties that we would otherwise prefer to develop and market ourself.

Contractual Obligations and Other Commitments

We enter into contracts in the normal course of business with CROs, contract manufacturing organizations (“CMOs”), and with other vendors for preclinical research studies, clinical trials, manufacturing, and other services and products for operating purposes. These contracts generally provide for termination on notice or may have a potential termination fee if the contract is cancelled within a specified time, and therefore, are cancellable contracts. We do not expect any such contract terminations and did not have any non-cancellable obligations under these agreements for the periods presented. See Notes 12, 13, and 14 to the consolidated financial statements included elsewhere in this Annual Report on Form 10-K in for further information on our contractual lease obligations for our office in Vancouver, Canada, and other commitments, including the potential development and sales milestone payments and royalty payments we may be required to make under the Paragon Option Agreement, JADE101 License Agreement, JADE201 License Agreement and Parade warrant.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenues recognized and expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in Note 2 to our financial statements included elsewhere in this Annual Report on Form 10-K, we believe the following accounting policies used in the preparation of our consolidated financial statements require the most significant judgments and estimates.

Research and Development Contract Costs Accruals

We record the costs associated with research studies and manufacturing development as incurred. These costs are a significant component of our research and development expenses, with a substantial portion of our ongoing research and development activities conducted by third-party service providers, including CROs and CMOs, and our related party, Paragon.

We accrue for expenses resulting from obligations under the Paragon Option Agreement between Paragon, Parade, and us and agreements with CROs, CMOs, and other outside service providers for which payment flows do not match the periods over which materials or services are provided to us. Accruals are recorded based on estimates of services received and efforts expended pursuant to agreements established with Paragon, CROs, CMOs, and other outside service providers. These estimates are typically based on contracted amounts applied to the proportion of work performed and determined through analysis with internal personnel and external service providers as to the progress or stage of completion of the services. We make significant judgments and estimates in determining the accrual balance in each reporting period. In the event advance payments are made to Paragon, a CRO, CMO, or outside service provider, the payments will be recorded as a prepaid asset which will be expensed as the contracted services are performed. Changes in these estimates that result in material changes to our accruals could materially affect our results of operations. For the periods presented, we have not experienced any material deviations between accrued and actual research and development expenses.

Stock-Based Compensation

We measure stock-based awards granted to employees, directors, and non-employees in the form of stock options to purchase shares of our common stock, based on their fair value on the date of the grant using the Black-Scholes model. We measure restricted common stock awards using the difference, if any, between the purchase price per share of the award and the fair value of our common stock at the date of grant. Compensation expense for those awards is recognized using the straight-line method over the requisite service period, which is generally the vesting period of the respective award for employees. Compensation expense for awards to non-employees with service-based vesting conditions is recognized in the same manner as if we had paid cash in exchange for the goods or services, which is generally over the vesting period of the award. We account for forfeitures as they occur. We classify our stock-based compensation expenses in the same manner in which the award recipient's payroll costs are classified or in which the award recipient's service payments are classified.

The Black-Scholes model uses inputs that are determined by our board of directors on the date of grant and assumptions we make for the volatility of stock-based awards, the expected term of stock-based awards, the risk-free interest rate for a period that approximates the expected term of our stock-based awards and our expected dividend yield. We have historically been a private company and lack company-specific historical and implied volatility information of our stock. Therefore, we estimate our expected stock volatility based on the historical volatility of a representative group of public companies in the biotechnology industry for a term equal to the remaining time of the expected term. The expected term of our stock options has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" stock options. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve for time periods approximately equal to the remaining contractual term of the options on the date of measurement. We have estimated a 0% dividend yield based on the expected dividend yield and the fact that we have never paid, and do not expect to pay, any cash dividends in the foreseeable future.

Determination of Fair Value of Common Stock

A public trading market for our common stock was established in connection with the completion of the Merger and the Nasdaq listing of our common stock. As such, it is no longer necessary for our board of directors to estimate the fair value of our share awards in connection with our accounting for granted share-based awards or other such awards we may grant, as the fair value of our common stock and share-based awards is determined based on the quoted market price of our common stock.

Prior to the Merger, our pre-Merger common stock valuations were prepared by a third-party valuation firm using a hybrid method, including an option pricing method ("OPM"). The OPM treats common stock and preferred stock as call options on the total equity value of a company, with exercise prices based on the value thresholds at which the allocation among the various holders of a company's securities changes. Under this method, the common stock has value only if the funds available for distribution to stockholders exceed the value of the preferred stock liquidation preferences at the time of the liquidity event, such as a strategic sale or a merger. The hybrid method is a probability-weighted expected return method ("PWERM"), where the equity value in one or more of the scenarios is calculated using an OPM. The PWERM is a scenario-based methodology that estimates the fair value of common stock based upon an analysis of future values for a company, assuming various outcomes. The common stock value is based on the probability-weighted present value of expected future investment returns considering each of the possible outcomes available as well as the rights of each class of stock. The future value of the common stock under each outcome is discounted back to the valuation date at an appropriate risk-adjusted discount rate and probability weighted to arrive at an indication of value for the common stock. A discount for lack of marketability of the common stock is then applied to arrive at an indication of value for the common stock. Jade's independent third-party valuations were used, in part, by Jade's board of directors to determine the price per share of common stock and by management to determine the estimated fair value of the common stock.

The assumptions underlying these valuations represented management's best estimate, which involved inherent uncertainties and the application of management's judgment. As a result, if our pre-Merger common stock valuations had used significantly different assumptions or estimates, the fair value of our pre-Merger incentive shares and our share-based compensation expense could have been materially different.

Convertible Notes

Immediately prior to the effective time of the Merger, shares of Pre-Merger Jade common stock and Pre-Merger Jade pre-funded warrants were issued pursuant to the conversion of the Convertible Notes based on the aggregate principal amount of $95.0 million plus unpaid accrued interest divided by the conversion price in connection with the Pre-Closing Financing. As of December 31, 2025, there are no Convertible Notes outstanding. At the effective time of the Merger, the Pre-Merger Jade shares and warrants issued upon conversion of the Convertible Notes (including accrued interest) automatically converted into 9,433,831 shares of Jade Common Stock and 4,289,744 Jade pre-funded warrants.

Prior to the Closing, we accounted for our Convertible Notes under Accounting Standard Codification ("ASC") No. 815, Derivatives and Hedging ("ASC 815"). Under ASC 815, the election can be made at the inception of a financial instrument to account for the instrument under ASC No. 825, Fair Value Measurements and Disclosures (Including the Fair Value Option) ("ASC 825" and the "Fair Value Option"). We performed an analysis of all of the terms and features of the Convertible Notes and have elected to address simplification and cost-benefit considerations to use the Fair Value Option to account for the Convertible Notes as we have identified embedded derivatives, such as automatic conversion upon closing of the Next Equity Financing and automatic conversion upon the event of a Corporate Transaction, both of which required bifurcation and separate accounting. The Convertible Notes were remeasured at fair value at each balance sheet date until conversion. Changes to the fair value of the Convertible Notes were recorded in other expense in the consolidated statement of operations and comprehensive loss. There were no changes in fair value caused by instrument-specific credit risk. The analysis of the fair value of the Convertible Notes contained inherent assumptions related to the market interest rate, instrument-specific credit risk, the probability of alternate financing, change of control, initial public offering, maturity extension, and payment at original maturity. Due to the use of significant unobservable inputs, the overall fair value measurement of the Convertible Notes were classified as Level 3 while the Convertible Notes were outstanding.

Recently Issued Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact Jade's financial position, results of operations or cash flows is disclosed in Note 2 to our financial statements and Note 2 to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

Off-Balance Sheet Arrangements

For the periods presented, we did not have any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

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

We are a smaller reporting company, as defined by Rule 12b-2 under the Exchange Act and in Item 10(f)(1) of Regulation S-K, and are not required to provide the information under this item.

Item 8. Financial Statements and Supplementary Data.

The financial statements required to be filed pursuant to this Item 8 are appended to this Annual Report on Form 10-K beginning on page F-1. An index of those financial statements is found in Item 15, Exhibits and Financial Statement Schedules, of this Annual Report on Form 10-K.

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

None.

Item 9A. Controls and Procedures.

Management's Evaluation of Disclosure Controls and Procedures

Limitations on Effectiveness of Controls and Procedures

In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated, as of the end of the period covered by this Annual Report on Form 10-K, the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of December 31, 2025.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act). Management conducted an assessment of the effectiveness of the Company's internal control over financial reporting based on criteria established in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this assessment, our management concluded that, as of December 31, 2025, our internal control over financial reporting was effective.

Attestation Report of the Independent Registered Public Accounting Firm

This Annual Report on Form 10-K does not include an attestation report of our independent registered public accounting firm on internal control over financial reporting due to an exemption established by the JOBS Act for "emerging growth companies."

Changes in Internal Control Over Financial Reporting

There has been no change in our internal control over financial reporting identified in management's evaluation pursuant to Rules 13a-15(f) and 15d-15(f) of the Exchange Act during the quarter ended December 31, 2025 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

During the quarter ended December 31, 2025, none of our directors or officers adopted or terminated any Rule 10b5-1 trading arrangements or non-Rule 10b5-1 trading arrangements (in each case, as defined in Item 408 of Regulation S-K), except as set forth below.

On October 25, 2025, Tom Frohlich, our Chief Executive Officer, Andrew King, our Chief Scientific Officer & Head or Research and Development, Brad Dahms, our Chief Financial Officer, and Elizabeth Balta, our Chief Legal Officer and Corporate Secretary, each adopted a Rule 10b5-1 trading arrangement intended to satisfy the affirmative defense of Rule 10b5-1(c) authorizing the pre-arranged sale of common shares in order to satisfy tax withholding obligations of the Company that arise in connection with the vesting of any restricted stock units and/or performance stock units granted to them under the Jade Biosciences, Inc. 2025 Stock Incentive Plan and the Jade Biosciences, Inc. Amended and Restated 2024 Equity Incentive Plan, including under a successor plan and the related issuance of common shares. The number of common shares to be sold to satisfy the Company's tax withholding obligations under each arrangement is dependent on future events which cannot be known at this time, including the future trading price of our common shares. The expiration date relating to each arrangement is dependent on future events which cannot be known at this time, including the final vesting date of the applicable restricted stock units and performance stock units and the officer's termination of service.

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

Not Applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required under this item is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the Securities and Exchange Commission not later than 120 days after the close of our fiscal year ended December 31, 2025.

We have adopted a Code of Business Conduct and Ethics that applies to all officers, directors and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or person performing similar functions. A current copy of the Code of Business Conduct and Ethics is available on the Governance section of our website at www.jadebiosciences.com. If we make any substantive amendments to the Code of Business Conduct and Ethics or grant any waiver from a provision of the Code of Business Conduct and Ethics to any executive officer or director that are required to be disclosed pursuant to SEC rules, we will promptly disclose the nature of the amendment or waiver on our website or in a current report on Form 8-K.

We have adopted an insider trading policy and procedures governing the purchase, sale, and/or other dispositions of our securities by our directors, officers, employees and other covered persons that are designed to promote compliance with insider trading laws, rules and regulations, and the Nasdaq Stock Market LLC listing rules, as applicable. A copy of our Insider Trading Compliance Policy and Procedures is filed as Exhibit 19.1 to this Annual Report on Form 10-K. It is our policy to comply with U.S. insider trading laws and regulations, including with respect to transactions in our own securities.

Item 11. Executive Compensation.

The information required under this item is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the Securities and Exchange Commission not later than 120 days after the close of our fiscal year ended December 31, 2025.

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

The information required under this item is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the Securities and Exchange Commission not later than 120 days after the close of our fiscal year ended December 31, 2025.

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

The information required under this item is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the Securities and Exchange Commission not later than 120 days after the close of our fiscal year ended December 31, 2025.

Item 14. Principal Accounting Fees and Services.

The information required under this item is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the Securities and Exchange Commission not later than 120 days after the close of our fiscal year ended December 31, 2025.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a)(1) Financial Statements.

For a list of the financial statements included herein, see Index to the Consolidated Financial Statements on page F-1 of this Annual Report on Form 10-K, incorporated into this Item by reference.

(a)(2) Financial Statement Schedules.

Financial statement schedules have been omitted because they are either not required or not applicable or the information is included in the consolidated 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.

		Incorporated by Reference			
Exhibit Number	**Description**	**Form**	**Date**	**Number**	**Filed Herewith**
2.1†	Agreement and Plan of Merger, dated as of October 30, 2024, by and among Aerovate Therapeutics, Inc., Caribbean Merger Sub I, Inc., Caribbean Merger Sub II, LLC and Jade Biosciences, Inc.	8-K	10-31-2024	2.1	
2.2	Plan of Conversion.	8-K	5-1-2025	2.2	
3.1	Articles of Incorporation of the Company.	8-K	5-1-2025	3.4	
3.2	Bylaws of the Company.	8-K	5-1-2025	3.5	
3.3	Certificate of Designation of Series A Non-Voting Convertible Preferred Stock, effective April 28, 2025.	8-K	5-1-2025	3.7	
4.1	Form of Pre-Funded Warrant, dated April 28, 2025.	8-K	5-1-2025	4.1	
4.2	Form of Pre-Funded Warrant (October 2025 PIPE).	8-K	10-7-2025	4.1	
4.3	Parade Warrant, dated December 31, 2025.				X
4.4	Description of Registered Securities				X
10.1	Form of Registration Rights Agreement, dated as of April 28, 2025, by and among pre-Merger Jade Biosciences, Inc., Jade Biosciences, Inc. (fka Aerovate Therapeutics, Inc.) and the several investors signatory thereto.	8-K	10-31-2025	10.5	
10.2†††	Securities Purchase Agreement, dated October 6, 2025, by and among Jade Biosciences, Inc. and each purchaser identified on Annex A thereto.	8-K	10-7-2025	10.1	
10.3†	Form of Registration Rights Agreement, dated as of October 6, 2025, by and among Jade Biosciences, Inc. and the several investors signatory thereto.	8-K	10-7-2025	10.2	
10.4†	Securities Purchase Agreement, dated December 13, 2025, by and among Jade Biosciences, Inc. and the purchaser party thereto.	8-K	12-15-2025	10.1	
10.5†	Registration Rights Agreement, dated December 13, 2025, by and between Jade Biosciences, Inc. and the purchaser party thereto.	8-K	12-15-2025	10.2	
10.6#	Form of Indemnification Agreement for directors and officers.	S-4	3-14-2025	10.6	
10.7#	Jade Biosciences, Inc. Amended and Restated 2024 Equity Incentive Plan and the Form of Stock Option Agreement thereunder.	S-4	12-3-2024	10.7	
10.8#	First Amendment to the Jade Biosciences, Inc. 2024 Equity Incentive Plan.	8-K	5-1-2025	10.7	
10.9#	Jade Biosciences, Inc. 2025 Stock Incentive Plan.	8-K	5-1-2025	10.10	
10.10#	Jade Biosciences, Inc. 2025 Employee Stock Purchase Plan.	8-K	5-1-2025	10.11	
10.11#	Form of Restricted Stock Purchase Agreement.	S-4	12-3-2024	10.10	
10.12#	Form of Grant Notice for Stock Option and Standard Terms and Conditions for Stock Options under the Jade Biosciences, Inc. 2025 Stock Incentive Plan (Directors)	S-8	6-30-2025	99.2	

10.13#	Form of Grant Notice for Stock Option and Standard Terms and Conditions for Stock Options under the Jade Biosciences, Inc. 2025 Stock Incentive Plan (Employees).	S-8	6-30-2025	99.3	
10.14#	Form of Grant Notice for Restricted Stock Units and Standard Terms and Conditions for Restricted Stock Units under the Jade Biosciences, Inc. 2025 Stock Incentive Plan.				X
10.15#	Amended and Restated Employment Agreement, between Jade Biosciences, Inc. and Tom Frohlich, dated as of April 28, 2025.	8-K	5-1-2025	10.13	
10.16#	Amended and Restated Employment Agreement, between Jade Biosciences, Inc. and Andrew King, dated as of April 28, 2025.	8-K	5-1-2025	10.14	
10.17#	Amended and Restated Employment Agreement, between Jade Biosciences, Inc. and Elizabeth Balta, dated as of April 28, 2025.				X
10.18#	Employment Agreement, between Jade Biosciences, Inc. and Bradford Dahms, dated June 25, 2025.	10-Q	8-13-2025	10.7	
10.19#	Separation Agreement and Release, by and between Aerovate Therapeutics, Inc. and Timothy Noyes, dated as of April 18, 2025.	8-K	5-1-2025	10.8	
10.20#	Separation Agreement and Release, by and between Aerovate Therapeutics, Inc. and George Eldridge, dated as of April 18, 2025.	8-K	5-1-2025	10.9	
10.21#†	Separation Agreement and General Release, by and between Jade Biosciences, Inc. and Hetal Kocinsky, M.D., dated September 10, 2025.	10-Q	11-14-2025	10.3	
10.22†††	Antibody Discovery and Option Agreement, dated July 24, 2024, by and between Paragon Therapeutics, Inc., Parade Biosciences Holding, LLC and Jade Biosciences, Inc.	S-4	12-3-2024	10.16	
10.23†††	Amendment No. 1 to Antibody Discovery and Option Agreement, dated as of September 27, 2024.	S-4	12-3-2024	10.17	
10.24†††	Amended and Restated Biologics Master Services Agreement, effective February 3, 2025, by and between WuXi Biologics (Hong Kong) Limited and Jade Biosciences, Inc.	S-4/A	2-24-2025	10.18	
10.25†††	APRIL License Agreement, dated October 30, 2024, by and between Paragon Therapeutics, Inc. and Jade Biosciences, Inc.	S-4	12-3-2024	10.19	
10.26††	Amendment No. 1 to the APRIL License Agreement, dated as of May 27, 2025, by and between Paragon Therapeutics, Inc. and Jade Biosciences, Inc.	10-Q	8-13-2025	10.13	
10.27†††	BAFF-R License Agreement, dated October 3, 2025, by and between Paragon Therapeutics, Inc. and Jade Biosciences, Inc.				X
10.28†††	Amended and Restated Cell Line License Agreement, effective February 3, 2025, by and between WuXi Biologics Ireland Limited and Jade Biosciences, Inc.	S-4/A	2-24-2025	10.20	
10.29†††	Master Services Agreement, dated as of June 24, 2025, by and between Patheon Biologics LLC, part of Thermo Fisher Scientific, and Jade Biosciences, Inc.	10-Q	8-13-2025	10.14	
16.1	Letter from KPMG LLP, dated May 1, 2025.	8-K	5-1-2025	16.1	
19.1	Jade Biosciences, Inc. Insider Trading Compliance Policy and Procedures				X
21.1	List of Subsidiaries of Jade Biosciences, Inc.				X
23.1	Consent of PricewaterhouseCoopers LLP, independent registered public accounting firm.				X
24.1	Power of Attorney (included on signature page).				X
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
32.1*	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				X

32.2*	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	X
97.1#	Incentive Compensation Clawback Policy	X
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.	
101.SCH	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents	
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)	

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* Furnished herewith. The certifications on Exhibits 32.1 and 32.2 hereto are deemed not "filed" for purposes of Section 18 of the Exchange Act or otherwise subject to the liability of that Section. Such certifications will not be deemed incorporated by reference into any filing under the Securities Act or the Exchange Act.

\# Indicates management contract or compensatory plan, contract or arrangement.

† Exhibits and/or schedules have been omitted pursuant to Item 601(a)(5) of Regulation S-K. The registrant hereby undertakes to furnish supplementally copies of any of the omitted exhibits and schedules upon request by the SEC; provided, however, that the registrant may request confidential treatment pursuant to Rule 24b-2 under the Exchange Act for any exhibits or schedules so furnished.

†† Pursuant to Item 601(b)(10) of Regulation S-K, certain confidential portions of this exhibit (indicated by "[***]") have been omitted as the identified confidential portions are (i) not material and (ii) treated by the Registrant as private or confidential.

Item 16. Form 10-K Summary

None.

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**.**

Jade Biosciences, Inc.

Date: March 6, 2026

By: /s/ Bradford Dahms
Name: Bradford Dahms
Title: Chief Financial Officer & Treasurer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints Tom Frohlich and Bradford Dahms, jointly and severally, as his or her true and lawful attorneys-in-fact, each with full power of substitution, for him or her in any and all capacities, to sign any and all amendments to this Report on Form 10-K and to file the same, with all exhibits thereto and other documents in connection therewith, with the SEC, hereby ratifying and confirming all that each of said attorneys-in-fact, or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

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

Signature	Title	Date
/s/ Tom Frohlich Tom Frohlich	Chief Executive Officer & Director *(Principal Executive Officer)*	March 6, 2026
s/ Bradford Dahms Bradford Dahms	Chief Financial Officer and Treasurer *(Principal Financial Officer and Principal Accounting Officer)*	March 6, 2026
/s/ Eric Dobmeier Eric Dobmeier, J.D.	Chair of the Board	March 6, 2026
/s/ Chris Cain Chris Cain, Ph.D.	Director	March 6, 2026
/s/ Tomas Kiselak Tomas Kiselak	Director	March 6, 2026
/s/ Lawrence Klein Lawrence Klein, Ph.D.	Director	March 6, 2026
/s/ Erin Lavelle Erin Lavelle	Director	March 6, 2026

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of Jade Biosciences, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Jade Biosciences, Inc. and its subsidiaries (the "Company") as of December 31, 2025 and December 31, 2024, and the related consolidated statements of operations and comprehensive loss, of convertible preferred stock and stockholders' equity (deficit) and of cash flows for the year ended December 31, 2025 and for the period from June 18, 2024 (inception) to December 31, 2024, including the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2025 and December 31, 2024, and the results of its operations and its cash flows for the year ended December 31, 2025 and for the period from June 18, 2024 (inception) to December 31, 2024 in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

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

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

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

/s/ PricewaterhouseCoopers LLP
Boston, Massachusetts
March 6, 2026

We have served as the Company’s auditor since 2024.

JADE BIOSCIENCES, INC.
CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share amounts)

	December 31, 2025	December 31, 2024
ASSETS		
Current assets		
Cash and cash equivalents	$ 88,438	$ 69,386
Investments	247,720	—
Prepaid expenses and other current assets	12,658	268
Total current assets	348,816	69,654
Property and equipment, net	170	—
Operating lease right-of-use asset	726	—
Other assets	69	3,145
Total assets	$ 349,781	$ 72,799
LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities		
Accounts payable	$ 2,151	$ 1,290
Accrued expenses and other current liabilities	9,419	4,125
Related party accrued expenses and other current liabilities	4,969	5,504
Warrant liability, related party	—	1,077
Total current liabilities	16,539	11,996
Long-term liabilities		
Convertible notes payable[(1)]	—	107,600
Long-term lease liability	724	—
Total liabilities	17,263	119,596
Commitments and contingencies (Note 14)		
Series Seed convertible preferred stock, $0.0001 par value; no shares and 20,000,000 shares authorized as of December 31, 2025 and December 31, 2024, respectively; no shares and 20,000,000 issued and outstanding as of December 31, 2025 and December 31, 2024, respectively; liquidation preference of $2 as of December 31, 2024 and none as of December 31, 2025, respectively	—	2
Stockholders' equity (deficit):		
Series A non-voting convertible preferred stock, $0.0001 par value; 12,622 and no shares authorized as of December 31, 2025 and December 31, 2024, respectively; 12,622 shares and no shares issued and outstanding as of December 31, 2025 and December 31, 2024, respectively	2	—
Common stock, $0.0001 par value; 300,000,000 and 40,000,000 shares authorized as of December 31, 2025 and December 31, 2024, respectively; 49,316,287 and 3,672,794 shares issued and outstanding as of December 31, 2025 and December 31, 2024, respectively	5	1
Additional paid-in capital	506,771	179
Accumulated other comprehensive income	129	—
Accumulated deficit	(174,389)	(46,979)
Total stockholders' equity (deficit)	332,518	(46,799)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 349,781	$ 72,799

(1) Includes related party amount of $22.7 million as of December 31, 2024.

The accompanying notes are an integral part of these consolidated financial statements.

JADE BIOSCIENCES, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(In thousands, except share and per share amounts)

	Year Ended December 31, 2025	Period from June 18, 2024 (Inception) to December 31, 2024
Operating expenses		
Research and development[1]	$ 93,121	$ 31,234
General and administrative[2]	20,421	4,304
Total operating expenses	113,542	35,538
Loss from operations	(113,542)	(35,538)
Other income / (expense)		
Interest income	7,782	1,159
Change in fair value of convertible notes payable[3]	(21,584)	(12,600)
Other expense	(8)	—
Total other expense, net	(13,810)	(11,441)
Net loss before income tax expense	(127,352)	(46,979)
Income tax expense	(58)	—
Net loss	$ (127,410)	$ (46,979)
Other comprehensive income (loss):		
Currency translation adjustment	(28)	—
Unrealized gain on investments	157	—
Comprehensive loss	$ (127,281)	$ (46,979)
Net loss per share attributable to common stockholders, basic and diluted	$ (3.19)	$ (14.89)
Net loss per share attributable to Series A non-voting convertible preferred stockholders, basic and diluted	$ (3,193.30)	$ —
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	31,359,958	3,155,500
Weighted-average shares used in computing net loss per share attributable to Series A non-voting convertible preferred stockholders, basic and diluted	8,541	—

(1) Includes related party amount of $28.6 million for the year ended December 31, 2025 and $24.6 million for the period from June 18, 2024 (inception) to December 31, 2024 (see Note 13).
(2) Includes related party amount of $0.3 million for the year ended December 31, 2025 and $1.0 million for the period from June 18, 2024 (inception) to December 31, 2024 (see Note 13).
(3) Includes related party amount of $4.6 million for the year ended December 31, 2025 and $2.7 million for the period from June 18, 2024 (inception) to December 31, 2024 (see Note 13).

The accompanying notes are an integral part of these consolidated financial statements.

JADE BIOSCIENCES, INC.
CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)
(In thousands, except share amounts)

	Convertible Preferred Stock		Series A Convertible Preferred Stock		Common Stock		Additional Paid-in	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount			Shares	Amount	Capital	Income	Deficit	Equity (Deficit)
Balances At June 18, 2024 (inception)	20,000,000	$ 2	—	$ —	3,672,794	$ 1	$ —	$ —	$ —	$ 1
Stock-based compensation expense	—	—	—	—	—	—	179	—	—	179
Net loss	—	—	—	—	—	—	—	—	(46,979)	(46,979)
Balances At December 31, 2024	20,000,000	$ 2	—	$ 0	3,672,794	$ 1	$ 179	$ 0	$ (46,979)	$ (46,799)
Exchange of Series Seed convertible preferred stock for Series A non-voting convertible preferred stock upon the closing of the reverse recapitalization	(20,000,000)	$ (2)	12,622	$ 2	—	—	—	—	—	2
Conversion of convertible notes (including accrued interest and discount) into common stock and pre-funded warrants upon the closing of the reverse recapitalization	—	—	—	—	9,433,831	1	129,183	—	—	129,184
Issuance of common stock and pre-funded warrants in the Pre-Closing Financing	—	—	—	—	18,301,109	1	204,999	—	—	205,000
Issuance of common stock and pre-funded warrants in the October 2025 Financing	—	—	—	—	13,368,164	1	134,999	—	—	135,000
Issuance of common stock in the December 2025 Financing	—	—	—	—	3,214,286	1	44,999	—		45,000
Issuance costs of Pre-Closing Financing and reverse recapitalization	—	—	—	—	—	—	(18,887)	—	—	(18,887)
Issuance costs of October 2025 Financing	—	—	—	—	—	—	(8,657)	—	—	(8,657)
Issuance costs of December 2025 Financing	—	—	—	—	—	—	(1,066)	—	—	(1,066)
Issuance of common stock to former stockholders of Aerovate in connection with the closing of the reverse recapitalization	—	—	—	—	828,143	—	(448)	—	—	(448)
Issuance of common stock in connection with exercise of pre-funded warrants	—	—	—	—	390,853	—	—	—	—	—
Exercise of stock options	—	—	—	—	57,817		88	—	—	88
Issuance of stock under employee stock purchase plan	—	—	—	—	49,290		296	—	—	296
Currency translation adjustment	—	—	—	—	—	—	—	(28)	—	(28)
Stock-based compensation	—	—	—	—	—	—	9,943	—	—	9,943
Unrealized gain on investments	—	—	—	—	—	—	—	157	—	157
Issuance of Parade warrants	—	—	—	—	—	—	11,143	—	—	11,143
Net loss	—	—	—	—	—	—	—	—	(127,410)	(127,410)
Balances at December 31, 2025	—	$ —	12,622	$ 2	49,316,287	$ 5	$ 506,771	$ 129	$ (174,389)	$ 332,518

The accompanying notes are an integral part of these consolidated financial statements.

JADE BIOSCIENCES, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	Year Ended December 31, 2025	Period from June 18, 2024 (Inception) to December 31, 2024
Cash flows from operating activities:		
Net loss	$ (127,410)	$ (46,979)
Adjustments to reconcile net loss to net cash used in operating activities:		
Change in fair value of convertible notes payable	21,584	12,600
Stock-based compensation expense	20,009	1,256
Non-cash lease expense	83	—
Accretion/amortization on investments	(784)	—
Depreciation expense	26	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(11,969)	(265)
Other assets	(38)	—
Accounts payable	361	1,290
Accrued expenses and other current liabilities	3,944	3,980
Operating lease liabilities	40	—
Related party accrued expenses and other current liabilities	(535)	5,504
Net cash used in operating activities	(94,689)	(22,614)
Cash flows from investing activities:		
Purchases of investments	(261,194)	—
Proceeds from sales/maturities of investments	14,415	—
Payment of security deposit	(31)	—
Purchases of property and equipment	(196)	—
Net cash used in investing activities	(247,006)	—
Cash flows from financing activities:		
Proceeds from issuance of convertible notes payable[(1)]	—	95,000
Payment of deferred offering costs	—	(3,000)
Proceeds from the Pre-Closing Financing, net of $15,889 offering costs	189,111	—
Proceeds from the December 2025 PIPE Financing, net of $257 offering costs	44,743	—
Proceeds from the October 2025 PIPE Financing, net of $8,626 offering costs	126,374	—
Proceeds from stock option exercises	88	—
Proceeds from ESPP issuances	296	—
Cash acquired in connection with the reverse recapitalization	156	—
Net cash provided by financing activities	360,768	92,000
Effect of exchange rates on cash and cash equivalents	(21)	—
Net increase in cash and cash equivalents	19,052	69,386
Cash and cash equivalents at beginning of period	69,386	—
Cash and cash equivalents at end of period	$ 88,438	$ 69,386
Supplemental disclosure of non-cash operating and financing activities:		
Unpaid offering costs	$ 840	$ 145
Deferred offering costs reclassified from other assets to equity	$ 2,998	—
Operating lease liability arising from obtaining right-of-use asset	$ 773	—
Assets acquired in connection with the reverse recapitalization	$ 416	—
Other liabilities assumed in connection with the reverse recapitalization	$ (1,020)	—
Reclassification of warrant liability	$ 11,143	—
Convertible note principal and non-cash accrued interest converted to common stock	$ 129,184	—
Non-cash exchange of Pre-Merger Jade Series Seed Convertible Preferred Stock for Company Series A Non-Voting Convertible Preferred Stock	$ 2	—

(1) Includes no related party amount for the year ended December 31, 2025 and $20.0 million for the period from June 18, 2024 (inception) to December 31, 2024.

The accompanying notes are an integral part of these consolidated financial statements.

1. Nature of the Business and Basis of Presentation

Background and Basis of Presentation

Jade Biosciences, Inc. together with its subsidiaries ("Jade" or the "Company"), formerly known as Aerovate Therapeutics, Inc., is the resulting company of the Merger and Redomestication discussed below. Prior to the Merger and Redomestication, the private corporation Jade Biosciences, Inc. ("Pre-Merger Jade") was established and incorporated under the laws of the state of Delaware on June 18, 2024 (referred to in these notes as the inception of the Company). Jade is focused on developing therapies to address critical unmet needs in autoimmune diseases. Its lead product candidate, JADE101, is a monoclonal antibody ("mAb") targeting a cytokine called "A PRoliferation Inducing Ligand" ("APRIL") that modulates plasma cell survival and immunoglobulin production, which the Company plans to initially develop for the treatment of IgA nephropathy ("IgAN"). Jade's second product candidate is JADE201, a mAb targeting B cell activating factor receptor ("BAFF-R") for the treatment of multiple autoimmune disorders, and is currently in pre-clinical development. Jade's pipeline also includes JADE301 which is designed to target an undisclosed pathway, and for which the Company's is conducting preclinical research. Jade was launched based on assets licensed from Paragon Therapeutics Inc. ("Paragon"), an antibody discovery engine founded by healthcare investor Fairmount Funds Management LLC ("Fairmount").

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") and pursuant to the rules and regulations of the U.S. Securities and Exchange Commission ("SEC"). The accompanying consolidated financial statements include accounts of the Company and its wholly owned subsidiaries, Jade Biosciences Canada ULC, Jade Biosciences MA Security Corporation, and Aerovate MA Securities Corporation. All intercompany amounts are eliminated in consolidation.

Reverse Recapitalization and Pre-Closing Financing

On April 28, 2025 (the "Closing Date"), the Company consummated the previously announced transaction (the "Closing") pursuant to that certain Agreement and Plan of Merger and Reorganization, dated as of October 30, 2024, (the "Merger Agreement") by and among Pre-Merger Jade, Aerovate Therapeutics, Inc., a Delaware corporation ("Aerovate"), Caribbean Merger Sub I, Inc., a Delaware corporation and wholly-owned subsidiary of Aerovate ("First Merger Sub"), and Caribbean Merger Sub II, LLC, a Delaware limited liability company and wholly-owned subsidiary of Aerovate ("Second Merger Sub"). As part of the Closing, First Merger Sub merged with and into Pre-Merger Jade, with Pre-Merger Jade continuing as a wholly owned subsidiary of Aerovate and the surviving corporation of the merger (the "First Merger" and such time, the "First Effective Time"), and Pre-Merger Jade merged with and into Second Merger Sub, with Second Merger Sub being the surviving entity of the merger (the "Second Merger" and, together with the First Merger, the "Merger"). In connection with the Merger, Second Merger Sub changed its name to "Jade Biosciences, LLC" and Aerovate changed its name to "Jade Biosciences, Inc." Subsequently, Jade Biosciences, LLC merged with and into Jade Biosciences, Inc. The combined company following the Merger is the "Company." The Company is led by Pre-Merger Jade's management team and focuses on developing differentiated biologic therapies for patients living with autoimmune diseases.

In accordance with an exchange ratio determined in accordance with the terms of the Merger Agreement (the "Exchange Ratio"), as a result of and upon the First Effective Time, (i) each then-outstanding share of common stock, par value $0.0001 per share, of Pre-Merger Jade (the "Pre-Merger Jade common stock") (including shares of Pre-Merger Jade common stock issued in connection with the Pre-Closing Financing (as defined below)) immediately prior to the First Effective Time (excluding shares cancelled pursuant to the Merger Agreement and excluding dissenting shares) automatically converted into the right to receive a number of shares of common stock, par value $0.0001, of Aerovate (the "Company common stock" and prior to the effective time of the Merger, the "Aerovate common stock") equal to the Exchange Ratio, (ii) each then-outstanding share of Series Seed Convertible Preferred Stock, par value $0.0001 per share, of Pre-Merger Jade (the "Pre-Merger Jade Series Seed Convertible Preferred Stock") immediately prior to the First Effective Time (excluding shares cancelled pursuant to the Merger Agreement and excluding dissenting shares) automatically converted into the right to receive a number of shares of Series A Non-Voting Convertible Preferred Stock, par value $0.0001 per share, of Aerovate (the "Series A Preferred Stock"), which are each convertible into 1,000 shares of Company common stock, equal to the Exchange Ratio divided by 1,000, (iii) each then-outstanding option to purchase Pre-Merger Jade common stock was assumed by Aerovate and was converted into an option to purchase shares of Company common stock, subject to adjustment as set forth in the Merger Agreement, and (iv) each then-outstanding pre-funded warrant to purchase shares of Pre-Merger Jade common stock (including any pre-funded warrants to purchase shares of Pre-Merger Jade common stock issued in the Jade Pre-Closing Financing) was converted into a pre-funded warrant to purchase shares of Company common stock (subject to adjustment as set forth in the Merger Agreement and the form of pre-funded warrant).

The Exchange Ratio was calculated as 0.6311 shares of Aerovate common stock for each share of Pre-Merger Jade common stock (and 0.0006311 shares of Series A Preferred Stock for each share of Pre-Merger Jade Series Seed Convertible Preferred Stock) on the Closing Date, which gives effect to a 1-for-35 reverse stock split of shares of Aerovate common stock immediately prior to the Merger. The par value per share and the number of authorized shares were not adjusted as a result of the Exchange Ratio. The shares of Company common stock underlying outstanding stock options, restricted stock awards, and other equity instruments were proportionately reduced and the respective exercise prices, if applicable, were proportionately increased in accordance with the terms of the agreements governing such securities. All references to common stock, options to purchase common stock, common stock share data, per share data, and related information contained in the consolidated financial statements have been retrospectively adjusted to reflect the effect of the Exchange Ratio for all periods presented, unless otherwise specifically indicated or the context otherwise requires.

Immediately prior to the completion of the Merger, and in order to provide Jade with additional capital for its development programs, Pre-Merger Jade entered into a subscription agreement with certain investors (the "Subscription Agreement"), pursuant to which Pre-Merger Jade issued and sold, and certain new and existing investors purchased, 43,947,116 shares of Pre-Merger Jade common stock and 12,305,898 pre-funded warrants, exercisable for 12,305,898 shares of pre-exchange Pre-Merger Jade common stock (before giving effect to the Exchange Ratio), at a purchase price of $5.9407 per share or $5.9406 per Pre-Merger Jade pre-funded warrant, for an aggregate amount of $334.2 million, which included $95.0 million of proceeds previously received from the issuance of Convertible Notes (as defined herein) and accrued interest of $8.3 million on such Convertible Notes and the related conversion of the Convertible Notes into shares of Pre-Merger Jade common stock and Pre-Merger Jade pre-funded warrants (the "Pre-Closing Financing"). At the Closing, based on the Exchange Ratio, the Pre-Merger Jade common stock and Pre-Merger Jade pre-funded warrants subscribed for were converted into the right to receive 27,734,940 shares of Aerovate common stock and 7,766,247 Aerovate pre-funded warrants.

The Merger was accounted for as a reverse recapitalization in accordance with U.S. GAAP. Under this method of accounting, Pre-Merger Jade was deemed to be the accounting acquirer for financial reporting purposes. This determination was primarily based on the fact that, immediately following the Merger: (i) Pre-Merger Jade stockholders owned a substantial majority of the voting rights in the combined company; (ii) Pre-Merger Jade's largest stockholders retained the largest interest in the combined company; (iii) Pre-Merger Jade designated a majority of the initial members of the board of directors of the combined company; and (iv) Pre-Merger Jade's executive management team became the management team of the combined company. Accordingly, for accounting purposes: (i) the Merger was treated as the equivalent of Pre-Merger Jade issuing stock to acquire the net assets of Aerovate, and (ii) the reported historical operating results of the combined company prior to the Merger are those of Pre-Merger Jade. Additional information regarding the Merger is included in Note 3.

Private Placement Financings

On October 6, 2025, the Company entered into a Securities Purchase Agreement for a private placement (the "October 2025 Private Placement") with certain investors. The closing of the October 2025 Private Placement occurred on October 8, 2025. The investors purchased an aggregate of 13,368,164 shares of the Company's common stock at a purchase price of $9.14 per share and pre-funded warrants to purchase an aggregate of 1,402,092 shares of the Company's common stock at a purchase price of $9.1399 per pre-funded warrant, for aggregate net proceeds of approximately $126.4 million, net of issuance costs of $8.6 million.

On December 13, 2025, the Company entered into a Securities Purchase Agreement for a private placement (the "December 2025 PIPE") with an investor. The closing of the December 2025 PIPE occurred on December 16, 2025. The investor purchased an aggregate of 3,214,286 shares of the Company's common stock at a purchase price of $14.00 per share, for aggregate net proceeds of approximately $43.9 million, net of issuance costs of $1.1 million.

Redomestication

On April 28, 2025, Jade changed its jurisdiction of incorporation from the State of Delaware to the State of Nevada (the "Redomestication") pursuant to a plan of conversion. The Redomestication became effective on April 28, 2025.

The common stock of the Nevada corporation resulting from the conversion continues to be traded on The Nasdaq Capital Market ("Nasdaq") under the symbol "JBIO." The Redomestication did not cause any interruption in the trading of such common stock.

Going Concern

Since its inception, the Company has devoted substantially all of its resources to advancing the development of its portfolio of programs, organizing and staffing the Company, business planning, raising capital, and providing general and administrative support for these operations. Current and future programs will require significant research and development efforts, including preclinical and clinical trials, and, if the Company is successful in obtaining regulatory approval for one or more product

candidates, significant commercialization efforts. Until such time as the Company can generate significant revenue from product sales, if ever, the Company expects to finance its operating activities principally through equity offerings.

The Company has not generated any revenue from product sales or other sources and has incurred significant operating losses and negative cash flows from operations since inception. The Company has incurred a net loss of $127.4 million for the year ended December 31, 2025, respectively. For the year ended December 31, 2025, the Company used net cash of $94.7 million for its operating activities. As of December 31, 2025, the Company had cash and cash equivalents of $88.4 million, and investments of $247.7 million.

The Company expects that its research and development and general and administrative costs will continue to increase significantly, including in connection with conducting future pre-clinical activities and clinical trials and manufacturing for its product candidates and providing general and administrative support for its operations, including the costs associated with operating as a public company. The Company expects that its existing cash and cash equivalents, and investments of $336.2 million as of December 31, 2025, will be sufficient to fund its forecasted operating expenses and capital expenditure requirements for at least twelve months from the date these consolidated financial statements were issued.

2. Summary of Significant Accounting Policies

Principles of Consolidation

In November 2024, the Company formed Jade Biosciences Canada ULC and Jade Biosciences MA Security Corporation, both of which are wholly owned subsidiaries. Upon the reverse merger with Aerovate, the Company acquired the Aerovate Securities Corporation. This was dissolved on December 29, 2025. All intercompany balances and transactions have been eliminated in consolidation.

Use of Estimates

The preparation of the Company's consolidated financial statements in conformity with U.S. GAAP requires management to make estimates, assumptions, and judgments that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of expenses during the reporting periods. Significant estimates and assumptions reflected within these consolidated financial statements include but are not limited to research and development expenses and related prepaid or accrued costs, the valuation of stock-based compensation awards and related expenses, and the valuation of outstanding convertible notes. The Company bases its estimates on known trends and other market-specific or other relevant factors that it believes to be reasonable under the circumstances. On an ongoing basis, management evaluates its estimates, as there are changes in circumstances, facts, and experience. Actual results may differ materially from those estimates or assumptions.

Segment Information

The Company operates and manages its business as a single segment for the purposes of assessing performance and making operating decisions. The Company's chief executive officer, who is the chief operating decision maker (the "CODM"), reviews the Company's financial information for purposes of evaluating financial performance and allocating resources (see Note 17).

Concentrations of Credit Risk

Financial instruments that potentially expose the Company to concentrations of credit risk primarily consist of cash, cash equivalents, and investments. The Company's investment portfolio is comprised of money market funds, U.S. treasury securities, U.S. government-sponsored agency securities, commercial paper, and corporate debt securities. The Company maintains its deposits with accredited financial institutions in amounts that, at times, may exceed federally insured limits. However, the Company has not experienced any losses on its deposits and does not believe it is subject to unusual credit risk beyond the normal credit risk associated with commercial banking relationships.

The Company is dependent on third-party organizations to research, develop, manufacture, and process its potential product candidates for its development programs. The Company expects to continue to be dependent on a small number of manufacturers to supply it with its requirements for all products. The Company's research and development programs could be adversely affected by a significant interruption in the supply of the necessary materials. A significant amount of the Company's research and development activities are performed under its agreements with Paragon (see Note 12).

Cash and Cash Equivalents

The Company considers all highly liquid investments purchased with original maturities of 90 days or less from the date of purchase to be cash equivalents. Cash and cash equivalents may include cash held in banks and amounts held in interest-bearing money market funds, U.S. treasury securities, U.S. government-sponsored agency securities, commercial paper, and corporate debt securities.

Investments

The Company's investments are comprised of U.S. treasury securities, U.S. government-sponsored agency securities, commercial paper and corporate debt securities. Investments are classified at the time of purchase, based on management's intent, as held-to-maturity, available-for-sale, or trading. All of the Company's marketable security investments are classified as available-for-sale securities and are reported at fair value. The cost of securities sold is determined on a specific identification basis, and realized gains and losses are included as a component of other income (expense), net within the consolidated statements of operations and comprehensive loss. Any premium or discount arising at purchase is amortized and/or accreted to interest income and/or expense over the life of the underlying marketable security. Unrealized gains and losses are included as a component of other comprehensive income (loss) within the consolidated statements of operations and comprehensive loss.

The Company assesses its available-for-sale securities for impairment under the available-for-sale security impairment model in the Financial Accounting Standards Board's ("FASB") Accounting Standards Update ("ASU") 2016-13, *Financial Instruments-Credit Losses (Topic 326): Measurement of Credit Losses on Financial Statements* as of each reporting date in order to determine if a portion of any decline in fair value below carrying value is the result of a credit loss. The Company records credit losses for its available-for-sale securities in the consolidated statements of operations and comprehensive loss as credit loss expense, which is limited to the difference between the fair value and the amortized cost of the security. To date, the Company has not recorded any credit losses on its available-for-sale securities. Declines in fair value below carrying value attributable to non-credit related factors are recorded as other comprehensive income, which is a separate component of stockholders' equity (deficit).

Comprehensive Loss

Comprehensive loss includes net loss as well as other changes in stockholders' equity (deficit) that result from transactions and events other than those with stockholders. The Company's unrealized gains and losses on investments and unrealized foreign exchange fluctuations represent the only components of other comprehensive income (loss) that are excluded from the reported net loss and that are presented in the consolidated statements of operations and comprehensive loss.

Deferred Offering Costs

The Company capitalizes certain legal, professional, accounting, and other third-party fees that are directly associated with in-process equity financings as deferred offering costs until such financings are consummated. After the consummation of an equity financing, these costs are recorded as a reduction of the proceeds from the offering, either as a reduction of the carrying value of the preferred stock or in stockholders' deficit as a reduction of additional paid-in capital generated as a result of the offering. Should the in-process equity financing be abandoned, the deferred offering costs would be expensed immediately as a charge to operating expenses in the consolidated statement of operations and comprehensive loss. As of December 31, 2025, there were no deferred offering costs recorded as Other assets in the consolidated balance sheet. As of December 31, 2024, deferred offering costs of $3.1 million were recorded as Other assets in the consolidated balance sheet.

Fair Value Measurements

Certain assets and liabilities are carried at fair value under U.S. GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

- Level 1 - Quoted prices in active markets that are identical assets or liabilities.
- Level 2 - Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.

- Level 3 - Unobservable inputs that are supported by little or no market activity that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies, and similar techniques.

To the extent that the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

Items measured at fair value on a recurring basis as of December 31, 2025 include cash equivalents and investments. The carrying values of the Company's prepaid expenses and other current assets, accounts payable, and accrued expenses and other current liabilities approximate their fair values due to their relatively short maturity periods.

Foreign Currency and Currency Translation

Assets and liabilities in foreign currency amounts are translated into United States dollars at the exchange rate in effect on the consolidated balance sheet date as a result of our Canadian foreign subsidiary with a functional currency of the Canadian Dollar. Income and expenses are translated at the average exchange rate in effect during the period. Unrealized translation gains and losses are recorded as a translation adjustment, which is included in the Company's consolidated statements of convertible preferred stock and stockholders' equity (deficit) as a component of accumulated other comprehensive income. Adjustments that arise from exchange rate changes on transactions denominated in a currency other than the functional currency are included in other expense, net in total expense, net in the Company's consolidated statements of operations and comprehensive loss.

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation. Depreciation expense is recognized using the straight-line method over the estimated useful life of each asset as follows:

	Estimated Useful Life
Leasehold improvements	Shorter of useful life or remaining term of related lease

Leases

The Company evaluates arrangements entered into to determine whether or not it includes a lease. At the lease commencement date, when control of the underlying asset is transferred from the lessor to the Company, the Company classifies a lease as either an operating or finance lease and recognizes a right-of-use ("ROU") asset and a current and non-current lease liability, as applicable, in the balance sheet if the lease has a term greater than one year. Lease terms may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise its option.

At the lease commencement date, operating lease liabilities and their corresponding ROU assets are recorded at the present value of future minimum lease payments over the expected remaining lease term. The Company determines the present value of lease payments using the implicit rate, if it is readily determinable, or the incremental borrowing rate for the lease term. As the Company's leases do not provide an implicit rate, the Company uses its incremental borrowing rate to discount lease payments. The incremental borrowing rate represents an estimated rate of interest that the Company would have to pay to borrow equivalent funds on a collateralized basis at the lease commencement date. For operating leases, lease expense for lease payments is recognized on a straight-line basis over the lease term. For finance leases, lease expense includes amortization expense of the ROU asset recognized on a straight-line basis over the lease term and interest expense recognized on the finance lease liability. In addition, certain adjustments to the ROU asset may be required for items such as lease prepayments, incentives received or initial direct costs. As of December 31, 2025, the Company has one operating lease and no finance leases.

The Company accounts for lease and non-lease components related to operating leases as a single lease component. The Company has elected that costs associated with leases having an initial term of 12 months or less are recognized in the consolidated statement of operations and comprehensive loss on a straight-line basis over the lease term and are not recorded on its consolidated balance sheets. Variable lease expense is recognized as incurred and consists primarily of real estate taxes, utilities, and other office space related expenses.

Classification of Convertible Preferred Stock

Prior to the reverse recapitalization, Pre-Merger Jade had classified the Pre-Merger Jade Series Seed Convertible Preferred Stock outside of stockholders' equity (deficit) on the Company's consolidated balance sheet because the holders of such stock had certain liquidation rights in the event of a deemed liquidation event that, in certain situations, was not solely within the

control of Pre-Merger Jade and would require the redemption of the then-outstanding convertible preferred stock.

Upon the closing of the Merger, the Company converted the Pre-Merger Jade Series Seed Convertible Preferred Stock to Series A Preferred Stock and has classified the Series A Preferred Stock within stockholders' equity (deficit) on its consolidated balance sheet because the Series A Preferred Stock is not redeemable or puttable to the Company by the holder under any circumstances.

Convertible Notes Payable

The Company performed an analysis of all of the terms and features of the Convertible Notes and has elected the fair value option ("FVO") to account for the Convertible Notes to address simplification as the Company has identified embedded derivatives, such as automatic conversion upon the closing of a $25.0 million or greater financing event, including an initial public offering (a "Next Equity Financing"), and automatic conversion upon certain events (e.g., a sale of substantially all Company assets, a merger, etc.), both of which would require bifurcation and separate accounting. The Convertible Notes were remeasured at fair value at each balance sheet date until repayment or conversion. Changes to the fair value of the Convertible Notes were recorded in other income (expense), net in the Company's consolidated statement of operations and comprehensive loss. The Company has also elected the option of combining interest expense and the change in fair value as a single line item within the Company's consolidated statement of operations and comprehensive loss. Changes in fair value resulting from changes in instrument-specific credit risk, if any, will be recognized separately in other comprehensive loss.

Research and Development Contract Costs Accruals

The Company records the costs associated with research studies and manufacturing development as incurred. These costs are a significant component of the Company's research and development expenses, with a substantial portion of the Company's ongoing research and development activities conducted by third-party service providers, including contract research organizations ("CROs") and contract manufacturing organizations ("CMOs"), and the Company's related party Paragon (see Note 10).

The Company accrues for expenses resulting from obligations under its antibody discovery and option agreement (as amended, the "Paragon Option Agreement") by and among the Company, Paragon and Parade Biosciences Holding LLC ("Parade"), an entity formed by Paragon as a vehicle to hold equity in the Company, and agreements with CROs, CMOs, and other outside service providers for which payment flows do not match the periods over which materials or services are provided to the Company. Accruals are recorded based on estimates of services received and efforts expended pursuant to agreements established with Paragon, CROs, CMOs, and other outside service providers. These estimates are typically based on contracted amounts applied to the proportion of work performed and determined through analysis with internal personnel and external service providers as to the progress or stage of completion of the services. The Company makes significant judgments and estimates in determining the accrual balance in each reporting period. In the event advance payments are made to Paragon, a CRO, CMO, or outside service provider, the payments will be recorded as a prepaid asset which will be expensed as the contracted services are performed. Changes in these estimates that result in material changes to the Company's accruals could materially affect the Company's results of operations. During the year ended December 31, 2025 and the period from June 18, 2024 (Inception) to December 31, 2024, the Company did not experience any material deviations between accrued and actual research and development expenses.

Research and Development Costs

Research and development costs are expensed as incurred. Research and development costs include amounts reimbursed to Paragon under the Paragon Option Agreement (see Note 10), salaries and bonuses, stock-based compensation, employee benefits, and external costs of vendors and consultants engaged to conduct research and development activities.

Nonrefundable advance payments for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses on the accompanying consolidated balance sheets. The prepaid amounts are expensed as the related goods are delivered or the services are performed, or when it is no longer expected that the goods will be delivered, or the services rendered. The Company had $9.8 million of prepaid research and development, which is included in prepaid expenses and other current assets on the Consolidated Balance Sheet as of December 31, 2025. If nonrefundable advance payments represent a one-time cost for obtaining goods or services, with anticipated benefits to be utilized within a year of period-end, the payment is expensed immediately.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and bonuses, stock-based compensation, employee benefits, finance and administration costs, and professional fees.

Commitments and Contingencies

The Company may be subject to contingent liabilities, such as legal proceedings and claims, that arise in the ordinary course of business activities. The Company accrues for loss contingencies when losses become probable and are reasonably estimable. If the reasonable estimate of the loss is a range and no amount within the range is a better estimate, the minimum amount of the range is recorded as a liability on the consolidated balance sheets. The Company does not accrue for contingent losses that, in its judgment, are considered to be reasonably possible, but not probable; however, it discloses the range of reasonably possible losses. As of December 31, 2025, no liabilities were recorded for loss contingencies (see Note 14).

Stock-Based Compensation

The Company classifies stock-based compensation expense in its consolidated statement of operations and comprehensive loss in the same manner in which the award recipient's payroll costs are classified or in which the award recipient's service payments are classified.

The Company grants stock options and restricted stock awards that are subject to service-based vesting conditions. Compensation expense for awards to employees and directors with service-based vesting conditions is recognized using the straight-line method over the requisite service period, which is generally the vesting period of the respective award. Compensation expense for awards to non-employees with service-based vesting conditions is recognized in the same manner as if the Company had paid cash in exchange for the goods or services, which is generally over the vesting period of the award. Forfeitures are accounted for as they occur. As of each reporting date, the Company estimates the probability that specified performance criteria will be met and does not recognize compensation expense until it is probable that the performance-based vesting condition will be achieved. The Company has issued stock options and restricted common stock awards ("RSAs") with service-based vesting conditions.

The Company measures all stock-based awards granted to employees, directors, and non-employees in the form of stock options to purchase shares of its common stock, based on the fair value of the awards on the date of grant using the Black-Scholes option-pricing model. The Company measures RSAs using the difference, if any, between the purchase price per share of the award and the fair value of the Company's common stock at the date of grant.

Prior to the Closing, the Company's common stock valuations were prepared using a hybrid method, including an option pricing method ("OPM"). The OPM treats common stock and preferred stock as call options on the total equity value of a company, with exercise prices based on the value thresholds at which the allocation among the various holders of a company's securities changes. Under this method, the common stock has value only if the funds available for distribution to stockholders exceed the value of the preferred stock liquidation preferences at the time of the liquidity event, such as a strategic sale or a merger. The hybrid method is a probability-weighted expected return method ("PWERM"), where the equity value in one or more of the scenarios is calculated using an OPM. The PWERM is a scenario-based methodology that estimates the fair value of common stock based upon an analysis of future values for the company, assuming various outcomes. The common stock value is based on the probability-weighted present value of expected future investment returns considering each of the possible outcomes available as well as the rights of each class of stock. The future value of the common stock under each outcome is discounted back to the valuation date at an appropriate risk- adjusted discount rate and probability weighted to arrive at an indication of value for the common stock. A discount for lack of marketability of the common stock is then applied to arrive at an indication of value for the common stock.

The assumptions underlying these valuations represented management's best estimate, which involved inherent uncertainties and the application of management's judgment. As a result, if the Company had used significantly different assumptions or estimates, the fair value of incentive shares and stock-based compensation expense could have been materially different.

Net Loss per Share Attributable to Common Stockholders

Basic and diluted net loss attributable to stockholders per share is presented in conformity with the two-class method required for participating securities (Pre-Merger Jade Series Seed Convertible Preferred Stock). Basic earnings per share is computed by dividing net income available to each class of shares by the weighted-average number of shares of common stock and participating securities outstanding during the period. Pre-funded warrants were included as the exercise price is negligible

and these warrants are fully vested and exercisable. Series A Preferred Stock shares the same characteristics as common stock and has no substantive preference attributed to them and, accordingly, has been considered a class of common stock in the computation of net loss per share regardless of their legal form.

Net loss is allocated to common stock based on its proportional ownership on an as-converted basis. Net loss is not allocated to participating securities as they do not have an obligation to fund losses. The weighted-average number of shares outstanding of common stock reflects changes in ownership over the periods presented.

Diluted net loss per share is computed by dividing the net loss attributable to stockholders adjusted for income (expenses), net of tax, related to any diluted securities, by the weighted-average number of shares of common stock and potentially dilutive securities outstanding for the period. For purposes of this calculation, stock options to purchase common stock, and unvested shares of restricted stock awards ("RSAs") are considered potentially dilutive securities.

The Company generated a net loss for the periods presented. Accordingly, basic and diluted net loss per share is the same because the inclusion of the potentially dilutive securities would be anti-dilutive.

Income Taxes

The Company accounts for income taxes using the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the consolidated financial statements or in the Company's tax returns. Deferred tax assets and liabilities are determined based on the differences between the financial statement basis and tax basis of assets and liabilities using enacted tax rates in effect for the years in which the differences are expected to reverse. Changes in deferred tax assets and liabilities are recorded in the provision for income taxes. The Company assesses the likelihood that its deferred tax assets will be recovered from future taxable income and, to the extent it believes, based upon the weight of available evidence, that it is more likely than not that all or a portion of the deferred tax assets will not be realized, a valuation allowance is established through a charge to income tax expense. The potential for recovery of deferred tax assets is evaluated by estimating the future taxable profits expected and considering prudent and feasible tax planning strategies.

The Company accounts for uncertainty in income taxes recognized in the consolidated financial statements by applying a two-step process to determine the amount of tax benefit to be recognized. First, the tax position must be evaluated to determine the likelihood that it will be sustained upon external examination by the taxing authorities. If the tax position is deemed more likely than not to be sustained, the tax position is then assessed to determine the amount of benefit to recognize in the consolidated financial statements. The amount of the benefit that may be recognized is the largest amount that has a greater than 50% likelihood of being realized upon ultimate settlement. The provision for income taxes includes the effects of any resulting tax reserves, or unrecognized tax benefits, that are considered appropriate as well as the related net interest and penalties. The Company had accrued no amounts for interest or penalties related to uncertain tax positions as of both December 31, 2025 and December 31, 2024. The Company did not have any uncertain tax positions as of both December 31, 2025 and December 31, 2024.

Recently Issued Accounting Pronouncements

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*. This ASU expands disclosures in an entity's income tax rate reconciliation table and disclosures regarding taxes paid both in the U.S. and foreign jurisdictions. This update is effective beginning with the Company's 2025 fiscal year annual reporting period. The Company adopted this standard on January 1, 2025, using a retrospective approach.

In November 2024, the FASB issued ASU 2024-03, *Income Statement-Reporting Comprehensive Income-Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses* ("ASU 2024-03"). The amendments in ASU 2024-03 require public entities to disclose specified information about certain costs and expenses. ASU 2024-03 is effective for the Company's annual reporting period beginning after December 15, 2026 and interim reporting periods beginning after December 27, 2027, with early adoption permitted. The Company is currently evaluating the impact of this standard on its consolidated financial statements.

In May 2025 the FASB issued ASU 2025-03, *Business Combinations (Topic 805) and Consolidation (Topic 810): Determining the Accounting Acquirer in the Acquisition of a Variable Interest Entity* ("ASU 2025-03"), which revises current guidance for determining the accounting acquirer for a transaction effected primarily by exchanging equity interests in which the legal acquiree is a variable interest entity that meets the definition of a business. The amendments require that an entity consider the same factors that are currently required for determining which entity is the accounting acquirer in other acquisition transactions. ASU 2025-03 is effective for the Company's annual reporting periods beginning after December 15, 2026, and

interim reporting periods within those annual reporting periods, with early adoption permitted. ASU 2025-03 is required to be applied prospectively. As of the date of these consolidated financial statements, the Company has not early adopted ASU 2025-03, therefore it did not apply the amendment to the Merger which closed on April 28, 2025.

In September 2025, the FASB issued ASU 2025-07, *Derivatives and Hedging (Topic 815) and Revenue from Contracts with Customers (Topic 606): Derivatives Scope Refinements and Scope Clarification for Share-Based Noncash Consideration from a Customer in a Revenue Contract ("ASU 2025-07")*. This update introduces a scope exception from derivative accounting for certain non-exchange-traded contracts and clarifies that Topic 606 applies initially to share-based noncash consideration received from a customer. ASU 2025-07 is effective for the Company's annual reporting period beginning after December 15, 2026 and interim reporting periods within those annual reporting periods, with early adoption permitted. The Company does not expect the adoption of this standard to have a significant impact upon the financial statements.

3. Reverse Recapitalization and Pre-Closing Financing

As described within the Reverse Recapitalization and Pre-Closing Financing section in Note 1, on April 28, 2025, the reverse Merger between Pre-Merger Jade and Aerovate was consummated. The Merger was accounted for as a reverse recapitalization in accordance with U.S. GAAP. At the effective time of the Merger, substantially all of the assets of Aerovate consisted of cash and cash equivalents and other non-operating assets and liabilities. No goodwill or intangible assets were recognized as a result of the Merger.

As part of the recapitalization, the Company acquired the assets and assumed the liabilities listed below (in thousands):

	Amount
Cash and cash equivalents	$ 156
Prepaids and other current assets	416
Other current liabilities	(1,020)
Net liabilities assumed	$ (448)

4. Investments

The following is a summary of the Company's investment portfolio (in thousands):

	As of December 31, 2025			
	Amortized Cost	Unrealized gains	Unrealized losses	Fair value
Investments:				
Current marketable securities:				
U.S treasury securities	$ 54,881	$ 46	$ —	$ 54,927
U.S. government-sponsored agency securities	61,310	25	(20)	61,315
Commercial paper	8,904	3	—	8,907
Corporate debt securities	122,468	104	(1)	122,571
Total	$ 247,563	$ 178	$ (21)	$ 247,720

As of December 31, 2025, all of the Company's investments are available to the Company for use in current operations. As a result, the Company has classified all of these securities as current assets even though the stated maturity of some individual securities may be one year or more beyond the balance sheet date. The following table shows the fair value of the Company's investments, by contractual maturity, as of December 31, 2025 (in thousands):

	As of December 31, 2025		
	Due within one year	Due after one year through five years	Total
Contractual Maturities:			
U.S. treasury securities	$ 49,893	$ 5,034	$ 54,927
U.S. government-sponsored agency securities	10,045	51,270	61,315
Commercial paper	8,907	—	8,907
Corporate debt securities	60,659	61,912	122,571
Total	$ 129,504	$ 118,216	$ 247,720

Accrued interest receivable on available-for-sale debt securities totaled $1.7 million as of December 31, 2025 and none as of December 31, 2024, and is excluded from the estimate of credit losses. This is included within prepaid expenses and other current assets on the Consolidated Balance Sheet as of December 31, 2025.

5. Fair Value Measurements

The following table presents information about the Company's assets and liabilities that are measured at fair value on a recurring basis as of December 31, 2025 and December 31, 2024 and indicates the fair value hierarchy of the valuation inputs the Company utilized to determine the fair value (in thousands):

	December 31, 2025			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$ 87,989	$ —	$ —	$ 87,989
Current investments:			—	
U.S. treasury securities	—	54,927	—	54,927
U.S. government-sponsored agency securities	14,024	47,290	—	61,314
Commercial paper	—	8,907	—	8,907
Corporate debt securities	109,075	13,497	—	122,572
Total	$ 211,088	$ 124,621	$ —	$ 335,709

	December 31, 2024			
	Level 1	Level 2	Level 3	Total
Assets				
Money market fund	$ 65,000	$ —	$ —	$ 65,000
Total assets	$ 65,000	$ —	$ —	$ 65,000
Liabilities				
Convertible notes payable, noncurrent	$ —	$ —	$ 107,600	$ 107,600
Total liabilities	$ —	$ —	$ 107,600	$ 107,600

As of December 31, 2025, cash equivalents consist of money market funds, which were valued by the Company based on quoted market prices, which represent a Level 1 measurement within the fair value hierarchy.

Additionally, the Company has current investments including corporate debt securities, and certain U.S. government-sponsored agency securities, which represent a Level 1 measurement within the fair value hierarchy. Furthermore, the Company has commercial paper, U.S. treasury securities, corporate debt securities and certain U.S. government-sponsored agency securities which were valued by the Company based on observable inputs, which represent a Level 2 measurement within the fair value hierarchy.

As of December 31, 2024, the Company had money market funds, which were valued by the Company based on quoted market prices, which represent a Level 1 measurement within the fair value hierarchy. Additionally, the Company had Convertible Notes payable, which were revalued at each remeasurement-date, prior to the conversion of the Convertible Notes into Pre-Merger Jade common stock and Pre-Merger Jade pre-funded warrants upon the Closing, using inputs that are generally unobservable and reflect management's estimates of assumptions that market participants would use in pricing the liability, which represent a Level 3 measurement within the fair value hierarchy.

For the year ended December 31, 2025 the only transfer of liabilities out of Level 3 was the conversion of the Convertible Notes payable. For the period from June 18, 2024 (inception) to December 31, 2024, there were no transfers of assets or liabilities into or out of Level 3 of the fair value hierarchy.

The following table presents the changes in the fair value of the Level 3 Convertible Notes payable (in thousands):

	Amounts
Balance as of June 18, 2024	$ —
Convertible Notes payable issuance	95,000
Change in fair value of Convertible Notes payable	12,600
Balance as of December 31, 2024	107,600
Change in fair value of Convertible Notes payable	21,584
Conversion of convertible notes into common stock and pre-funded warrants upon the Closing	(129,184)
Balance as of December 31, 2025	$ —

The Convertible Notes payable in the table above consists of the fair value of an aggregate principal amount of $95.0 million, and a fair value adjustment of $34.2 million, which includes accrued interest of $8.3 million, in Convertible Notes which the Company issued and sold to certain investors. Each holder of Convertible Notes was expected to contribute the principal amount and all accrued interest under the applicable Convertible Note in exchange for the Company's common stock or non-voting preferred stock in connection with a financing event under the Convertible Notes (see Note 7). As of December 31, 2024 the fair value of Convertible Notes was $107.6 million. The Convertible Notes were remeasured immediately prior to the Closing with a fair value of $129.2 million. The Company's valuation of the Convertible Notes payable utilized a scenario-based valuation analysis, which incorporated assumptions and estimates to value the Convertible Notes and a probability assessment of the achievement of the Next Equity Financing (as defined in the Convertible Notes). The Company assessed these assumptions and estimates on a quarterly basis as additional information impacting the assumptions was obtained. Immediately prior to the effective time of the Merger, shares of Pre-Merger Jade common stock and pre-funded warrants were issued pursuant to the conversion of the Convertible Notes (including accrued interest), which automatically converted into 9,433,831 shares of Jade Common Stock and 4,289,744 Jade pre-funded warrants at the effective time of the Merger.

The Convertible Notes were issued on July 24, 2024 and September 30, 2024. The following table presents the significant assumptions related to the change in fair value for the year ended December 31, 2024:

Time from Convertible Notes issuance to Next Equity Financing (in years)	0.58 - 0.77
Probability of Next Equity Financing	90.0%
Time from Convertible Notes issuance to Next Equity Financing / prior to trade sale (in years)	0.75 - 0.93
Probability of Next Equity Financing / prior to trade sale	10.0%
Interest rate	12.0%
Discount rate	67.0%

6. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following (in thousands):

	December 31, 2025	December 31, 2024
Accrued research and development contract costs	$ 3,323	$ 2,791
Accrued employee compensation and benefits	4,729	804
Accrued professional and consulting	1,367	530
	$ 9,419	$ 4,125

7. Convertible Notes Payable

In July 2024, the Company entered into the Purchase Agreement with a series of investors, pursuant to which the Company issued the convertible notes (the "Convertible Notes") with an initial principal amount of $80.0 million (of which $20.0 million is from Fairmount, a related party). In September 2024, the Company received an additional $15.0 million in gross proceeds from issuing additional Convertible Notes to additional investors. Under the terms of the Convertible Notes, the principal amount and all accrued interest of the Convertible Notes would automatically convert into the Company's common stock, pre-funded warrants or preferred stock in connection with the closing of a Next Equity Financing or certain other events (e.g., a sale of substantially all Company assets, a merger, etc.). On April 28, 2025, this automatic conversion took place. The Convertible Notes accrued interest at a rate of 12.0% per annum, compounded annually. All unpaid interest and principal were scheduled to mature

on December 31, 2026 (the “Maturity Date”). Prepayment was not permitted without prior written consent of the majority of the holders of the Convertible Notes. The principal payment along with the accrued interest on each Convertible Note was due in full on the Maturity Date.

In connection with the automatic conversion described above, the Convertible Notes were convertible into a number of shares of common stock equal to the quotient obtained by dividing the initial purchase price plus accrued and unpaid interest by the conversion price of the Convertible Notes, which is the product resulting from multiplying the price per share in the Next Equity Financing by 80% (“conversion price”).

There was less than $0.1 million of debt issuance cost incurred in connection with the Convertible Notes which was recognized in the financial statements for the period from June 18, 2024 (inception) to December 31, 2024. The Convertible Notes were recorded at the fair value of $95.0 million on the respective issuance dates and were remeasured to the fair value of $107.6 million as of December 31, 2024. The Convertible Notes were remeasured immediately prior to the Closing with a fair value of $129.2 million. For the twelve months ended December 31, 2025, the change in fair value was $21.6 million, which includes accrued interest of $3.6 million, and was recorded within other expense, net in the Company's consolidated statement of operations and comprehensive loss.

Immediately prior to the effective time of the Merger, the Convertible Notes converted into shares of Pre-Merger Jade common stock and Pre-Merger Jade pre-funded warrants based on the aggregate principal amount of $95.0 million plus unpaid accrued interest divided by the conversion price in connection with the Pre-Closing Financing. As of December 31,2025, there were no Convertible Notes outstanding. At the effective time of the Merger, the Pre-Merger Jade shares and warrants issued upon conversion of the Convertible Notes (including accrued interest) automatically converted into 9,433,831 shares of Pre-Merger Jade common stock and 4,289,744 Pre-Merger Jade pre-funded warrants.

8. Convertible Preferred Stock and Pre-Funded Warrants

Pre-Funded Warrants

In April 2025, pursuant to the Subscription Agreement and immediately prior to the Closing, certain new and current investors purchased Pre-Merger Jade pre-funded warrants, which, at the effective time of the Merger, were exercisable for 7,766,247 shares of Pre-Merger Jade Common Stock, at a price of $0.0001 per share. At the Closing, the Pre-Merger Jade common stock and Pre-Merger Jade pre-funded warrants were converted into shares of the Company common stock and Company pre-funded warrants, respectively.

The pre-funded warrants were recorded as a component of stockholders’ equity (deficit) within additional paid-in-capital and have no expiration date. As of December 31, 2025, 390,853 of the pre-funded warrants have been exercised and 7,375,394 pre-funded warrants remain outstanding related to the April 2025 financing.

In October 2025, in connection with the October 2025 Private Placement, the Company issued and sold 1,402,092 pre-funded warrants, at a purchase price of $9.1399 per warrant, exercisable for 1,402,092 shares of the Company’s common stock at an exercise price of $0.0001 per share. As of December 31, 2025, none of the pre-funded warrants have been exercised and 1,402,092 pre-funded warrants remain outstanding related to the October 2025 financing.

Convertible Preferred Stock

In June 2024, Pre-Merger Jade issued 20,000,000 shares of Series Seed Convertible Preferred Stock to a related party, Fairmount Healthcare Fund II L.P., an affiliate fund of Fairmount, at a purchase price of $0.0001 per share for gross proceeds of less than $0.1 million.

Upon the issuance of the Series Seed Convertible Preferred Stock, the Company assessed the embedded conversion and liquidation features of the securities as described below and determined that such features did not require the Company to separately account for these features as embedded derivatives.

In April 2025, upon the Closing, the Pre-Merger Jade Series Seed Convertible Preferred Stock was converted to 12,622 shares of Series A Preferred Stock.

As of December 31, 2025, Series A Preferred Stock consisted of the following (in thousands, except share amounts):

	December 31, 2025			
	Preferred Stock Authorized	Preferred Stock Issued and Outstanding	Carrying Value	Common Stock Issuable Upon Conversion
Series A Preferred Stock	12,622	12,622	$ 2	12,622,000

Pursuant to the Certificate of Designation of Preferences, Rights and Limitations of the Series A Preferred Stock (the "Series A Certificate of Designation") filed in connection with the Redomestication, holders of Series A Preferred Stock are entitled to receive dividends on shares of Series A Preferred Stock equal to, on an as-if-converted-to-Company common stock basis, and in the same form as, dividends actually paid on shares of Company common stock. Except as provided in the Series A Certificate of Designation or as otherwise required by law, the Series A Preferred Stock does not have voting rights. The Series A Preferred Stock shall rank on parity with the Company common stock as to the distribution of assets upon any liquidation, dissolution, or winding-up of the Company. Each share of Series A Preferred Stock is convertible at the option of the holder, at any time, and without the payment of additional consideration by the holder. As of December 31, 2025, each outstanding share of Series A Preferred Stock was convertible into common stock at a ratio of approximately 1:1,000.

9. Common Stock

As of December 31, 2025, the Company has the authority to issue a total of 300,000,000 shares of common stock at a par value of $0.0001 per share. As of December 31, 2025, 49,316,287 shares of common stock, including 339,473 RSAs were issued and outstanding. Each share of common stock entitles the holder to one vote, together with the holders of Series A Preferred Stock, on all matters submitted to the stockholders for a vote. The holders of common stock are entitled to receive dividends, if any, as declared by the Company's board of directors (the "Board of Directors"), subject to the preferential dividend rights of the holders of Series A Preferred Stock.

In October 2025, in connection with the October 2025 Private Placement, the Company issued and sold an aggregate of 13,368,164 shares of the Company's common stock at a purchase price of $9.14 per share.

In December 2025, in connection with the December 2025 Private Placement, the Company issued and sold an aggregate of 3,214,286 shares of the Company's common stock at a purchase price of $14.00 per share.

As of December 31, 2025, there were 31,940,083 shares of common stock reserved for issuance for the potential conversion of shares of Series A Preferred Stock into common stock, shares issuable under the exercise of pre-funded warrants, Parade warrants and exercise of outstanding stock options for common stock under the 2025 and 2024 Plans.

10. Stock-Based Compensation

2024 Equity Incentive Plan

The Jade Biosciences, Inc. 2024 Equity Incentive Plan ("2024 Plan") was adopted by the board of directors of Pre-Merger Jade on June 18, 2024. The 2024 Plan provided for Pre-Merger Jade to grant stock options, restricted stock awards and other stock-based awards to employees, officers, directors, consultants, and advisors. Stock options granted under the 2024 Plan generally vest over four years, subject to the participant's continued service, and expire after ten years, although stock options have been granted with vesting terms of less than four years. As of December 31, 2025, there are no shares remaining for future grant under the 2024 Plan.

2025 Equity Incentive Plan

The Jade Biosciences, Inc. 2025 Stock Incentive Plan ("2025 Stock Plan") was approved by the board of directors of Aerovate on February 19, 2025, and by Aerovate stockholders on April 16, 2025. The 2025 Stock Plan allows for the grant of stock options, stock appreciation rights, restricted stock awards, restricted stock units, other stock-based awards and incentive bonuses. The 2025 Stock Plan is administered by the Compensation Committee of the Board of Directors (the "Compensation Committee") or another committee designated by the Board of Directors to administer the 2025 Stock Plan. Current employees, officers, non-employee directors, and other individual service providers of the Company and its subsidiaries are eligible to participate in the 2025 Stock Plan. The initial share pool under the 2025 Stock Plan is 8,018,700 shares of Company common stock, and as of December 31, 2025, there are 6,167,494 shares remaining in the pool. The shares that may be issued under the 2025 Stock Plan will be automatically increased on January 1 of each year beginning in 2026 and ending with a final increase on January 1, 2035 in an amount equal to 5% of the diluted stock (including Company common stock, preferred stock and unexercised pre-funded warrants) on the preceding December 31, unless a lower, or no, increase is determined by the Compensation Committee. As of January 1, 2026, the Company's share pool increased by 3,535,788 shares.

2025 Employee Stock Purchase Plan

The Jade Biosciences, Inc. 2025 Employee Stock Purchase Plan (the "ESPP") was approved by the board of directors of Aerovate on February 19, 2025, and by Aerovate stockholders on April 16, 2025. The ESPP became effective on April 28, 2025 at which time 526,241 shares were reserved for issuance under the ESPP. The shares that may be issued under the ESPP will be automatically increased on January 1 of each year beginning in 2026 and ending with a final increase on January 1, 2035 in an

amount equal to the lesser of 1% of the diluted stock (including Company common stock, preferred stock and unexercised pre-funded warrants) on the preceding December 31, or 2,000,000, unless a lower, or no, increase is determined by the Compensation Committee. As of December 31, 2025, 49,290 shares have been issued under the ESPP. As of January 1, 2026, the Company's share pool increased by 707,157 shares.

Stock Option Valuation

The following table summarizes the weighted-average assumptions used in calculating the fair value of the awards for the activity during the twelve months ended December 31, 2025 and the period from June 18, 2024 (Inception) to December 31, 2024:

	Year Ended December 31, 2025	Period from June 18, 2024 (Inception) to December 31, 2024
Expected volatility	95.6%	95.4%
Expected term (in years)	6.1	6.1
Risk-free interest rate	4.3%	4.0%
Expected dividend yield	—%	—%

Stock Options

The following table summarizes the stock option activity for the twelve months ended December 31, 2025:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in thousands)
Balance as of December 31, 2024	2,392,751	$ 1.81	9.8	$ 10,993
Granted	7,911,195	7.04		
Exercised	(57,817)	1.53		
Forfeited	(510,051)	4.77		
Outstanding as of December 31, 2025	9,736,078	$ 5.91	9.1	$ 92,693
Vested and exercisable, December 31, 2025	951,636	$ 3.15	8.9	$ 11,684

The weighted average grant-date fair value of stock options granted for the twelve months ended December 31, 2025, was $7.04 per option. The aggregate intrinsic value of stock options is calculated as the difference between the exercise price of the stock options and the fair value of the Company’s common stock for those stock options that had an exercise price lower than the fair value of the Company’s common stock. The aggregate intrinsic value of options exercised for the period from January 1, 2025 through December 31, 2025 is $0.6 million.

Restricted Stock Awards

The Company’s RSAs have service-based vesting conditions only and vest over a four-year period or vest upon grant, during which time all unvested shares are subject to forfeiture by the Company in the event the holder’s service with the Company voluntarily or involuntarily terminates.

The following table summarizes the RSA activity for the twelve months ended December 31, 2025:

	Number of RSAs	Weighted Average Grant Date Fair Value
Unvested balance as of December 31, 2024	517,293	$ —
Granted	—	—
Vested	(177,820)	—
Forfeited	—	—
Unvested balance as of December 31, 2025	339,473	—

Parade Warrant Obligation

In July 2024, the Company entered into the Paragon Option Agreement (as defined below) with Paragon and Parade Biosciences Holding, LLC ("Parade"). Under the terms of the Paragon Option Agreement, Parade will be entitled to grants of warrants to purchase a number of shares equal to 1.00% of the then outstanding shares of the Company's stock, on a fully diluted basis, on December 31, 2025 and December 31, 2026, at the fair market value determined by the Board of Directors (the "Parade Warrant Obligation"). The grant dates for the issuance of warrants are expected to be December 31, 2025 and December 31, 2026, as all terms of the award, including number of shares and exercise price, will be known by all parties. Parade's research and discovery related activities has a service inception period for the grant preceding the grant date, with the full award being vested as of the grant date with no post-grant date service requirement. On December 31, 2025 Jade issued a warrant to purchase 804,519 shares of common stock to Parade, with an exercise price of $15.43. For the year ended December 31, 2025, the Company recognized $10.1 million, as stock-based compensation expense related to the Parade Warrant Obligation. For the period June 18, 2024 (inception) to December 31, 2024 , $1.1 million was recognized as stock-based compensation expense related to the Parade Warrant Obligation. The warrants expected to be granted to Parade are liability-classified and after the initial recognition, the liability is adjusted to fair value at the end of each reporting period, with changes in fair value recorded in the consolidated statements of operations and comprehensive loss within research and development. The liability was reclassified to equity upon grant as of December 31, 2025.

The following table summarizes the assumptions used in calculating the fair value of the warrant obligation as of December 31, 2025 and December 31, 2024:

	As of December 31, 2025	Period from June 18, 2024 (Inception) to December 31, 2024
Expected volatility	96.5%	93.3%
Expected term (in years)	10.0	10.0
Risk-free interest rate	4.2%	4.6%
Expected dividend yield	—%	—%

Stock-Based Compensation Expense

The following table summarizes the classification of the Company's stock-based compensation expense in the consolidated statement of operations and comprehensive loss for the year ended December 31, 2025 and the period from June 18, 2024 (Inception) to December 31, 2024 (in thousands):

	Year Ended December 31, 2025	Period from June 18, 2024 (Inception) to December 31, 2024
Research and development	$ 14,177	$ 1,161
General and administrative	5,832	95
	$ 20,009	$ 1,256

As of December 31, 2025, total unrecognized compensation cost related to the unvested stock options was $35.5 million, which is expected to be recognized over a weighted average period of approximately 2.9 years. As of December 31, 2025, total unrecognized compensation cost related to the unvested RSAs was less than less than $0.1 million, which is expected to be recognized over a weighted average period of 2.6 years. As of December 31, 2025, there was no unrecognized compensation cost related to the 2025 Parade Warrant Obligation.

The following table summarizes the stock-based compensation based on type of award for the year ended December 31, 2025 and the period from June 18 2024 (Inception) to December 31, 2024 (in thousands):

	Year Ended December 31, 2025	Period from June 18, 2024 (Inception) to December 31, 2024
Parade Warrant Obligation	$ 10,066	$ 1,077
Stock options	9,774	179
ESPP	169	—
Restricted stock awards	—	—
	$ 20,009	$ 1,256

11. Income Taxes

The components of (loss) income before (benefit) provision from income taxes were as follows:

	Year Ended December 31, 2025	Period from June 18, 2024 (Inception) to December 31, 2024
U.S.	$ (127,588)	$ (46,979)
Non-U.S.	236	—
Total	$ (127,352)	$ (46,979)

The components of our (benefit) provision from income taxes were as follows:

	Year Ended December 31, 2025	Period from June 18, 2024 (Inception) to December 31, 2024
Current:		
Federal	$ —	$ —
State	—	—
Foreign	$ 102	—
	$ 102	—
Deferred:		
Federal	—	—
State	—	—
Foreign	(44)	—
	(44)	—
Total (benefit) provision from income taxes	$ 58	—

A reconciliation of the Company's statutory income tax rate to the Company's effective income tax rate after the adoption of ASU 2023-09 is as follows:

	Year Ended December 31, 2025		Year Ended December 31, 2024	
	$'s	%'s	$'s	%'s
Federal statutory income tax rate	$ (26,744)	21.0%	$ (9,866)	21.0%
Nontaxable or nondeductible items:				
Non-taxable Fair market adjustments related to convertible notes	4,533	(3.6)%	2,646	(5.6)%
Non-taxable - Stock Compensation Expense	3,521	(2.8)%	—	—
Non-taxable - Other	63	—	39	(0.1)%
Tax credits:				
Research and development tax credits	(1,066)	0.8%	(253)	0.5%
Changes in valuation allowance	19,743	(15.5)%	7,434	(15.8)%
Foreign tax effects	8	—	—	—
Effective income tax rate	$ 58	(0.1)%	$ —	0.0%

In the year December 31, 2025 and the period from June 18, 2024 (Inception) to December 31, 2024, no federal, state or foreign income taxes were paid or refunds received.

Net deferred tax assets consisted of the following (in thousands):

	Year Ended December 31, 2025	Year Ended December 31, 2024
Deferred tax assets		
Net operating loss carryforwards	$ 11,560	$ 449
Research and development credits	1,542	255
Capitalized start-up expenses	375	396
Accruals and reserves	952	171
Capitalized research and development expenses	34,195	6,055
Share-based compensation	923	230
Deferred rent	412	—
Property and equipment	8	—
Other	2	—
Total deferred tax assets	49,969	7,556
Valuation allowance	(49,571)	(7,556)
Net deferred tax assets	$ 398	$ —
Deferred tax liabilities		
Right-of-use asset	(351)	—
Other	(8)	—
Total deferred tax liabilities	(359)	—
Net deferred tax assets	39	—

As of December 31, 2025, and December 31, 2024, the Company had a federal net operating loss carryforwards of $54.5 million and $2.1 million, respectively. As of December 31, 2025, and December 31, 2024, the Company had state net operating loss carryforwards of $1.9 million and $0.1 million, respectively. The federal net operating loss carryforwards may be carried forward indefinitely. The state net operating loss carryforwards begin to expire in 2045.

As of December 31, 2025, and December 31, 2024, the Company had federal research and development credits of $1.3 million and $0.3 million, respectively. As of December 31, 2025, and December 31, 2024, the Company had state research and development credits of $0.3 million and $0.1 million, respectively. The federal research and development credits begin to expire in 2044. The state research and development credits may be carried forward indefinitely.

Future realization of the tax benefits of existing temporary differences and net operating loss carryforwards ultimately depends on the existence of sufficient taxable income within the carryforward period. As of December 31, 2025, and December 31, 2024, the Company performed an evaluation to determine whether a valuation allowance was needed. The Company considered all available evidence, both positive and negative, which included the results of operations for the current year. The Company determined that it is more likely than not that all of the domestic deferred tax assets will not be realized. Accordingly, the Company maintained a full valuation allowance on its domestic net deferred tax assets as of December 31, 2025 and December 31, 2024, respectively.

For the year ending December 31, 2025 and December 31, 2024, the valuation allowance increased primarily due to the increases in net operating loss carryforwards and research and development tax credit carryforwards. The changes in the valuation allowance were as follows (in thousands):

	Year Ended December 31, 2025	Period from June 18, 2024 (Inception) to December 31, 2024
Valuation allowance as of the beginning of the year	$ 7,556	$ —
Increases recorded to deferred tax assets as a result of the reverse merger	21,801	—
Increases recorded to income tax provision	20,214	7,556
Valuation allowance as of the end of the year	$ 49,571	$ 7,556

On July 4, 2025, the One Big Beautiful Bill Act (“OBBBA”), was signed into law in the United States, OBBBA contains a broad range of tax reform provisions, which includes a new Internal Revenue Code ("IRC") Section 174A. Under Section 174A, commencing with tax years beginning after December 31, 2024, domestic research or experimental expenditures may be deducted in the current period rather than capitalized and amortized over multiple years, as previously required under IRC Section 174. OBBBA does not have a material impact on our effective tax rate, financial condition, or results of operations in 2025.

Under IRC Section 382, if a corporation undergoes an ownership change, the corporation’s ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income may be limited. The Company has not completed a study to assess whether an ownership change has occurred or whether there have been multiple ownership changes since the Company became a loss corporation as defined in Section 382. Future changes in the Company’s capital ownership, which may be outside of the Company’s control, may trigger an ownership change. In addition, future equity offerings or acquisitions that have equity as a component of the purchase price could result in an ownership change. If an ownership change has occurred or does occur in the future, utilization of the net operating loss carryforwards or other tax attributes may be limited, which could potentially result in increased future tax liability for the Company.

The calculation of the Company’s tax liabilities involves dealing with uncertainties in the application of complex tax laws and regulations for both federal taxes and the many states in which the Company operates or does business in, as well as Canada. ASC 740 states that a tax benefit from an uncertain tax position may be recognized when it is more likely than not that the position will be sustained upon examination, including resolutions of any related appeals or litigation processes, on the basis of the technical merits.

The Company records uncertain tax positions as liabilities in accordance with ASC 740 and adjusts these liabilities when the Company’s judgment changes as a result of the evaluation of new information not previously available. Because of the complexity of some of these uncertainties, the ultimate resolution may result in a payment that is materially different from the Company’s current estimate of the unrecognized tax benefit liabilities. These differences will be reflected as increases or decreases to income tax expense in the period in which new information is available. For the period ended December 31, 2025, and December 31, 2024, the Company has not recorded any uncertain tax positions in the Company’s consolidated financial statements.

The Company recognizes interest and penalties related to unrecognized tax benefits on the income tax expense line in the accompanying consolidated statement of operations and comprehensive loss. For the period ended December 31, 2025, and December 31, 2024, no accrued interest or penalties are included on the related tax liability line in the consolidated balance sheets.

The Company files tax returns as prescribed by the tax laws of the jurisdictions in which it operates. In the normal course of business, the Company is subject to examination by federal, state and foreign jurisdictions, where applicable. There are currently no pending tax examinations. Generally, the tax years 2022 through 2025 remain open to examination by the major taxing jurisdictions to which the Company is subject. To the extent the Company has tax attribute carryforwards, the tax years in which the attribute was generated may still be adjusted upon examination by the Internal Revenue Service, or state or foreign tax authorities, to the extent utilized in a future period.

12. Significant Agreements

Paragon Option Agreement

In July 2024, the Company entered into an Antibody Discovery and Option Agreement with Paragon and Parade (the "Paragon Option Agreement") for the selected target, APRIL, for the Company's initial research program, JADE101. The Paragon Option Agreement was amended in September 2024 to add two additional targets for JADE201 and JADE301. Under the Paragon Option Agreement, Jade has the exclusive option (an "Option"), on a Research Program-by-Research Program (as defined below) basis, to enter into a separate agreement with Paragon consistent with a set of terms that are pre-negotiated and attached to the Paragon Option Agreement as an exhibit (a "License Agreement"). If the Company exercises an Option and finalizes the related license agreement, it will be required to make non-refundable milestone payments to Paragon of up to $12.0 million under such license agreement upon the achievement of certain clinical development milestones, up to $10.0 million under such license agreement upon the achievement of certain regulatory milestones, as well as tiered royalty payments in the low-to-mid single-digits beginning on the first commercial sale of each developed product. From time to time, the Company can choose to add additional targets to the Paragon Option Agreement by mutual agreement with Paragon.

Under the terms of the Paragon Option Agreement, Paragon agreed to perform certain research activities to discover, generate, identify, and characterize one or more antibody candidates directed to certain mutually agreed therapeutic targets of interest to Jade (each, a "Research Program"). The Option with respect to each Research Program is exercisable at Jade's sole discretion at any time during the period beginning on the initiation of activities under the associated Research Program and ending a specified number of days following the delivery of the data package from Paragon related to the results of the Research Program (an "Option Period"). The Paragon Option Agreement requires Jade, Paragon, and Parade to develop a research plan for each target that includes design, modeling, synthesis, evaluation, and other mutually agreed activities (each, a "Research Plan"), which activities may include performing preclinical studies. Paragon will perform the activities set forth in each Research Plan on the timelines set forth in such Research Plan and in compliance with a mutually agreed budget. Each Research Program will be overseen and coordinated by a joint development committee consisting of two employees from Jade and two employees from Paragon, with Jade and Paragon each having one vote with respect to decisions of the committee. When Paragon and Parade have produced an antibody against a selected target, and upon the completion of each Research Program, Paragon and Parade will deliver to Jade a data package that includes sequence information for all then-existing antibodies and information directed to such target. Jade, Paragon and Parade have developed a Research Plan for JADE101, JADE201, and JADE301 consistent with the foregoing, and Paragon and Parade have delivered the respective antibodies in accordance with the Research Plans.

Any License Agreement entered into with respect to a given Research Program is expected to be consistent with pre-negotiated terms attached to the Paragon Option Agreement and shall contain the same milestone payment obligations as the Paragon Option Agreement, provided that any milestone set in the Paragon Option Agreement that has not yet been achieved and is duplicated in such License Agreement shall no longer be achievable and payable under the terms of the Paragon Option Agreement and shall only be achievable under the terms of the License Agreement. For the avoidance of doubt, if a milestone is achieved and paid by Jade pursuant to the Paragon Option Agreement for a certain Research Program, then there shall be no milestone payment due for the achievement of such milestone under a subsequently executed License Agreement for such Research Program. Further, under a License Agreement, Jade would also be required to make royalty payments to Paragon in the low to mid-single-digit percentage range based on net sales of products, subject to certain reductions. The royalty term will terminate on a product-by-product and country-by-country basis upon the later of the expiration of the last-to-expire valid claim within the relevant patent rights or the twelfth anniversary of the first commercial sale of such product in such country.

Unless terminated earlier, the Paragon Option Agreement shall continue in force on a Research Program-by-Research Program basis until the later of: (i) the end of the Option Period for such Research Program, as applicable, if such Option is not exercised by the Company; (ii) if the Company exercises its Option with respect to a Research Program, but the parties are unable to finalize and execute a License Agreement within 30 days, the expiration of such 30-day period (subject to any mutually agreed extension of such period); and (iii) the expiration of the applicable Research Term (as defined under the Paragon Option Agreement). The Company may terminate the Paragon Option Agreement or any Research Program at any time for any or no reason upon 30 days' prior written notice to Paragon, provided that the Company must pay certain unpaid fees due to Paragon upon such termination, as well as any non-cancellable obligations reasonably incurred by Paragon in connection with its activities under any terminated Research Program. Paragon may terminate the Paragon Option Agreement or a Research Program immediately upon written notice to the Company if, as a result of any action or failure to act by the Company or its affiliates, such Research Program or all material activities under the applicable Research Plan are suspended, discontinued or otherwise delayed for a certain consecutive number of months. Each party has the right to terminate the Paragon Option Agreement or any Research Program upon (i) 30 days' prior written notice of the other party's material breach that remains uncured for the 30-day period and (ii) the other party's bankruptcy.

Under the Paragon Option Agreement, the Company is responsible for any additional development costs incurred by Paragon relating to APRIL, which totaled $4.6 million for the year ended December 31, 2025, and $18.9 million for the period of June 18, 2024 (Inception) to December 31, 2024, respectively. These costs were recognized as research and development expense in the Company's consolidated statement of operations and comprehensive loss. As of December 31, 2025, there were no amounts relating to APRIL remaining in related party accrued expenses and other current liabilities in the Company's consolidated balance sheet.

Additionally, the Company is responsible for any additional development costs incurred by Paragon relating to JADE201, which totaled $5.7 million for the year ended December 31, 2025, and $2.4 million for the period of June 18, 2024 (Inception) to December 31, 2024, respectively. These costs were recognized as research and development expense in the Company's consolidated statement of operations and comprehensive loss. As of December 31, 2025, there were no amounts relating to JADE201 remaining in related party accrued expenses and other current liabilities in the Company's consolidated balance sheet.

Additionally, the Company is responsible for any additional development costs incurred by Paragon relating to JADE301, which totaled $8.2 million for the year ended December 31, 2025, and $2.1 million for the period of June 18, 2024 (Inception) to December 31, 2024. These costs were recognized as research and development expense in the Company's consolidated statement of operations and comprehensive loss. As of December 31, 2025, a total of $4.9 million related to JADE301 remains in related party accrued expenses and other current liabilities in the Company's consolidated balance sheet.

Additionally, the Company incurred general and administrative expenses of $0.3 million for the year ended December 31, 2025, and $1.0 million for the period of June 18, 2024 (Inception) to December 31, 2024, respectively.

Additionally, as part of the Paragon Option Agreement, on each of December 31, 2025 and December 31, 2026, Jade will grant Parade warrants to purchase a number of shares equal to 1.00% of Jade's outstanding capital stock as of the date of the grant on a fully-diluted basis, with an exercise price equal to the fair market value of the underlying shares of Jade common stock on each respective grant date. On December 31, 2025, Jade granted a warrant to purchase 804,519 shares of common stock to Parade which fulfilled the obligation for the 2025 warrant. Parade is an entity formed by Paragon as a vehicle to hold equity in Jade in order to share profits with certain employees of Paragon and will not perform any substantive role under the Paragon Option Agreement other than to receive such warrants.

In December 2025, Jade completed its selection of the JADE301 development candidate, and Jade recorded a $1.5 million milestone fee and recorded the accrual as research and development expense in the 2025 financial statements. This milestone fee was paid in January 2026.

JADE-001 License Agreement

In October 2024, Jade entered into a License Agreement with Paragon (the "JADE101 License Agreement"), pursuant to which Paragon granted Jade a royalty-bearing, worldwide, exclusive and sublicensable license to use, make, sell, import, export and otherwise exploit certain monospecific antibodies and products targeting APRIL in the field of prophylaxis, palliation, treatment and diagnosis of human disease and disorders in all therapeutic areas (the "field"). Among other rights, Paragon specifically granted Jade a royalty-bearing, worldwide, exclusive and sublicensable license in the field to Paragon's patents covering the antibodies generated under the APRIL Research Plan performed by Paragon under the Option Agreement, and their method of use and method of manufacture. Under the terms of the JADE101 License Agreement, Jade is obligated to pay Paragon up to $22.0 million based on specific development and regulatory milestones, including a $1.5 million fee for nomination of a development candidate, which was paid in December 2024, and a further milestone payment of $2.5 million upon the first dosing of a human participant in a Phase 1 trial, which was paid in September 2025. On a product-by-product basis, we are obligated to pay sublicensing fees of up to approximately $20.1 million, mainly upon the achievement of commercial milestones. Jade will pay Paragon a low to mid-single-digit percentage royalty based on annual net sales of the monospecific products in the field and a mid single-digit percentage royalty based on annual net sales of the multispecific products in the field and in the territory, subject to a 30% reduction if there is no valid patent covering the product in the country of sale. On a country-by-country basis, the royalty term for a product ends on the later of (i) the twelfth anniversary of the date of first sale of the product or (ii) the expiration of the last-to-expire valid patent covering the product in the country at issue.

Paragon will not conduct any new campaigns that generate APRIL monospecific antibodies in the field for at least five years. Jade and Paragon may pursue the development and commercialization of multispecific antibodies and products directed to APRIL in the field, and Jade has a right of first negotiation for any such multispecific antibodies and products proposed by Paragon for a period of five years from the execution of the JADE101 License Agreement. The JADE101 License Agreement may be terminated on 60 days' notice by us; on material breach without cure; and to the extent permitted by law, on a party's

insolvency or bankruptcy.

In December 2024, Jade completed its selection of the JADE101 development candidate, and Jade paid Paragon the related $1.5 million milestone payment and recorded the payment as research and development expense. In December 2024, Jade recorded a $0.1 million nonrefundable sublicensee fee under the JADE101 License Agreement as research and development expense. In August 2025, Jade recorded a $0.3 million nonrefundable sublicense fee related to a clinical development milestone under the JADE101 License Agreement as research and development expense. Additionally, the Company was also obligated to pay Paragon $2.5 million following the first in human clinical trial dosing, which occurred in August 2025, was expensed in research and development costs, and was paid in September 2025.

JADE201 License Agreement

In October 2025, Jade and Paragon entered into a License Agreement (the "JADE201 License Agreement"), pursuant to which Paragon granted the Company a royalty-bearing, worldwide, exclusive and sublicensable license to use, make, sell, import, export and otherwise exploit certain antibodies and products targeting BAFF-R in the field. Among other rights, Paragon specifically granted Jade a royalty-bearing, worldwide, exclusive and sublicensable license in the field to Paragon's patents covering the antibodies generated under the BAFF-R Research Plan performed by Paragon under the Option Agreement, and their method of use and method of manufacture. Under the terms of the JADE201 License Agreement, Jade is obligated to pay Paragon up to $22.0 million based on specific development, regulatory and clinical milestones for Jade's first monospecific product to reach such milestones, including a $1.5 million fee for nomination of a development candidate, which was paid in April 2025, and a further milestone payment of $2.5 million upon the first dosing of a human participant in a Phase 1 trial. Jade will pay Paragon a low to mid-single-digit percentage royalty based on annual net sales of monospecific products in the field, subject to a 30% reduction if there is no valid patent covering the product in the country of sale. On a country-by-country basis, the royalty term for a monospecific product ends on the later of (i) the twelfth anniversary of the date of first sale of the monospecific product or (ii) the expiration of the last-to-expire valid patent covering the monospecific product in the country at issue.

Paragon will not conduct any new campaigns that generate anti-BAFF-R monospecific antibodies in the field for at least 5 years. Paragon may pursue the development and commercialization of multispecific antibodies and products directed at the BAFF-R target in the field, subject to certain rights held by Jade, and Jade has a right of first negotiation for any such multispecific antibodies and products proposed by Paragon for a period of five years from the execution of the JADE201 License Agreement. Jade is obligated to pay Paragon up to $24.0 million based on specific development, regulatory and clinical milestones for each Jade multispecific product to reach such milestones and will pay Paragon a mid-single-digit percentage royalty based on annual net sales of all Jade multispecific products in the field, subject to a 30% reduction if there is no valid patent covering the product in the country of sale. On a country-by-country basis, the royalty term for a multispecific product ends on the later of (i) the twelfth anniversary of the date of first sale of the multispecific product or (ii) the expiration of the last-to-expire valid patent covering the multispecific product in the country at issue. The JADE201 License Agreement may be terminated on 60 days' notice by Jade; on material breach without cure; and to the extent permitted by law, on a party's insolvency or bankruptcy.

In March 2025, Jade completed its selection of its development candidate for the JADE201 program, and Jade paid Paragon the related $1.5 million monospecific milestone payment and recorded the payment as research and development expense. In January 2026, Jade paid Paragon a $1.0 million non-refundable, non-creditable fee (the "Reservation Fee") to obtain exclusive rights to develop a bispecific antibody directed to a specific target combination for a period of five years. The Reservation Fee will be recorded as research and development expense in the three months ending March 31, 2026.

Cell Line License Agreement

On February 3, 2025, the Company entered into an amended and restated cell line license agreement (the "Cell Line License Agreement") with WuXi Biologics Ireland Limited ("WuXi Biologics Ireland"). Under the Cell Line License Agreement, the Company received a non-exclusive, worldwide, sublicensable license to certain of WuXi Biologics Ireland's patent rights, know-how, cell line, biological materials and media and feeds to develop, manufacture, have manufactured, make, have made, import, sell, keep, commercialize and otherwise deal in, use and exploit certain therapeutic products produced through the use of the cell lines licensed by WuXi Biologics Ireland under the Cell Line License Agreement (the "WuXi Biologics Ireland Licensed Products"). JADE101 is, and Jade anticipates that any future product candidates under the JADE101 and JADE201 programs will be, manufactured using a cell line licensed under the Cell Line License Agreement. A cell line has not yet been selected for the JADE301 program.

In consideration for the license, the Company incurred a non-refundable license fee of $0.2 million in November 2024, which was recorded as research and development expense. Additionally, in June 2025 the Company incurred a non-refundable

license fee of $0.1 million, which was recorded as research and development expense. Additionally, if the Company manufactures all of its commercial supplies of bulk drug product for a particular product with a manufacturer other than WuXi Biologics Ireland or its affiliates, it is required to make royalty payments to WuXi Biologics Ireland in an amount equal to a fraction of a single digit percentage of global net sales of the WuXi Biologics Ireland Licensed Products manufactured by a third-party manufacturer (the "Royalty"). If the Company manufactures part of its commercial supplies of the WuXi Biologics Ireland Licensed Products with WuXi Biologics Ireland or its affiliates, then the Royalty will be reduced accordingly on a pro rata basis. The Company has the option, at any time, to pay WuXi Biologics Ireland a non-refundable lump-sum royalty buyout payment on a drug product-by-drug product basis to extinguish future Royalty obligations with respect to such drug product.

The Cell Line License Agreement will continue indefinitely unless terminated (i) by the Company upon six months' prior written notice and its payment of all undisputed amounts due to WuXi Biologics Ireland through the effective date of termination, (ii) by either party for a material breach by the other party that remains uncured for 60 days after written notice, (iii) by WuXi Biologics Ireland if the Company fails to make a payment and such failure continues for 30 days after receiving notice of such failure, or (iv) by either party upon the other party's bankruptcy.

13. Leases

In February 2025, the Company entered into a noncancelable operating lease agreement for office space located in Vancouver, Canada. The lease commencement date is March 1, 2025, with an initial term of 67 months. The rent commencement date is October 1, 2025. The total lease payment is expected to be approximately $1.2 million of principal payments plus $0.4 million of interest payments over the initial lease term. Payments for rent are made in Canadian dollars and therefore subject to foreign exchange impact. Lease liabilities are based on the net present value of the remaining lease payments over the remaining lease term. In determining the present value of lease payments, the Company used its incremental borrowing rate when measuring operating lease liabilities as discount rates were not implicit or readily determinable.

As of December 31, 2025, the Company had $0.7 million of operating lease ROU asset and long-term lease liability of $0.7 million on its consolidated balance sheets. As of December 31, 2025, the operating lease arrangement had a remaining lease term of 4.8 years and an internal borrowing rate of return of 14.24%. For the twelve months ended December 31, 2025, the Company recorded operating lease expense of $0.2 million, respectively, in general and administrative expenses in its consolidated statements of operations and comprehensive loss.

As of December 31, 2025, the total remaining operating lease payments included in the measurement of lease liabilities was as follows (in thousands):

Period ended December 31,	
2026	226
2027	231
2028	236
2029	240
2030	183
Total maturities	$ 1,116
Less: Imputed interest	(265)
Total present value of operating lease liability	$ 851

14. Commitments and Contingencies

401(k) Plan

The Company maintains a defined-contribution plan under Section 401(k) of the Internal Revenue Code of 1986 (the "401(k) Plan"). The 401(k) Plan covers all employees who meet defined minimum age and service requirements and allows participants to defer a portion of their annual compensation on a pre-tax basis. Matching contributions to the 401(k) Plan may be made at the discretion of management. For the twelve months ended December 31, 2025 and for the period of June 18, 2024 (Inception) to December 31, 2024, the Company has not recorded any expense related to 401(k) Plan match contributions

Indemnification Agreements

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, business partners and other parties with respect to certain matters including, but not limited to, losses arising out of breach

of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with each of its directors and executive officers that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or executive officers. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. To date, the Company has not incurred any material costs as a result of such indemnifications. The Company is not aware of any indemnification arrangements that could have a material effect on its financial position, results of operations or cash flows, and it has not accrued any liabilities related to such obligations in its consolidated financial statements as of December 31, 2025.

Legal Proceedings

From time to time, the Company may become involved in legal proceedings or other litigation relating to claims arising in the ordinary course of business. The Company accrues a liability for such matters when it is probable that future expenditures will be made and that such expenditures can be reasonably estimated. Significant judgment is required to determine both probability and estimated exposure amount. Legal fees and other costs associated with such proceedings are expensed as incurred. As of December 31, 2025, the Company was not a party to any material legal proceedings or claims.

15. Net Loss per Share

Basic and diluted net loss per share attributable to common stockholders and Series A Preferred stockholders was calculated as follows (in thousands, except share and per share amounts):

	Twelve Months Ended December 31, 2025		
	Loss Allocation	Weighted Average Shares Outstanding	Loss Per Share - Basic and Diluted
Common Stock	$ (100,136)	31,359,958	$ (3.19)
Series A Preferred Stock [1]	(27,274)	8,541	$ (3,193.30)
Net loss	$ (127,410)		

	Period from June 18, 2024 (Inception) to December 31, 2024		
	Loss Allocation	Weighted Average Shares Outstanding	Loss Per Share - Basic and Diluted
Common Stock	$ (46,979)	3,155,500	$ (14.89)
Net loss	$ (46,979)		

[1] The weighted average number of shares of as-converted Series A Preferred Stock used in the loss allocation was 8,541,463 for the twelve months ended December 31, 2025.

For the computation of basic net loss per share attributable to common stockholders, the amount of weighted-average common shares outstanding excludes all shares of unvested restricted common stock as such shares are not considered outstanding for accounting purposes until vested. The amount of weighted-average shares outstanding includes the pre-funded warrants as the exercise price is negligible and these warrants are fully vested and exercisable.

The Company's potentially dilutive securities have been excluded from the computation of diluted net loss per share as the effect would be to reduce the net loss per share. Therefore, the weighted-average number of common shares outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders is the same. The potentially dilutive securities are as follows:

	Twelve Months Ended December 31, 2025	Period from June 18, 2024 (Inception) to December 31, 2024
Convertible preferred stock (as converted to common stock)	—	12,622,000
Unvested restricted stock awards	339,473	517,293
Outstanding and issued common stock options	9,736,078	2,392,751
Outstanding and issued warrant to Parade	804,519	—
Total	10,880,070	15,532,044

16. Related Party Transactions

Paragon and Parade each beneficially own less than 5% of the Company's share capital through their respective holdings of Company's common stock.

Fairmount beneficially owns more than 5% of the Company's capital, currently has two representatives appointed to the board of directors and beneficially owns more than 5% of Paragon.

The following is a summary of related party accounts payable and other current liabilities (in thousands):

	December 31, 2025	December 31, 2024
Reimbursable fees under the terms of the Paragon Option Agreement	$ 4,942	$ 5,430
Paragon reimbursable legal fees	27	74
	$ 4,969	$ 5,504

17. Segment Reporting

The Company has one reportable segment relating to the research and development of its programs, JADE101, JADE201, and JADE301. The Company's chief operating decision maker ("CODM"), its Chief Executive Officer, manages the Company's operations on a consolidated basis and uses consolidated net loss for the allocation of resources and the assessment of performance. Although the Company's financial reporting package that is reviewed and approved by the CODM disaggregates significant expenses such as program-level external research and development costs, personnel costs, including stock-based compensation expense, and professional and consulting fees, all decisions made by the CODM are based upon reviewing operating metrics and performance indicators at the Company-wide consolidated level and consolidated net loss. The CODM uses consolidated net loss to evaluate loss generated from the Company's business activities in deciding how to allocate company resources and in monitoring budget versus actual results. Assets are also managed on a Company-wide consolidated basis.

The table below is a summary of the significant expenses categories regularly provided to the CODM (in thousands):

	Twelve Months Ended December 31, 2025	Period from June 18, 2024 (Inception) to December 31, 2024
Operating Expenses		
JADE101 external research and development costs	$ 28,943	$ 22,992
JADE201 external research and development costs	24,249	2,437
JADE301 external research and development costs	8,897	2,141
Research and development personnel-related costs (including stock-based compensation)	28,560	3,509
Other research and development costs	2,472	155
General and administrative personnel-related costs (including stock-based compensation)	12,691	1,714
Professional and consulting fees	6,933	2,253
Other general and administrative costs	797	337
Total operating expenses	$ 113,542	$ 35,538