**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: 001-39138

**JASPER THERAPEUTICS, INC.**
(Exact name of registrant as specified in its charter)

| **Delaware** | **84-2984849** |
|---|---|
| (State or other jurisdiction of incorporation or organization) | (I.R.S. Employer Identification No.) |
| **2200 Bridge Pkwy Suite #102 Redwood City, CA** | **94065** |
| (Address of principal executive offices) | (Zip Code) |

**(650) 549-1400**
(Registrant's telephone number, including area code)

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

| Title of each class | Trading Symbol(s) | Name of each exchange on which registered |
|---|---|---|
| Voting Common Stock, par value $0.0001 per share | JSPR | The Nasdaq Stock Market LLC |
| Redeemable Warrants, each ten warrants exercisable for one share of Voting Common Stock at an exercise price of $115.00 | JSPRW | The Nasdaq Stock Market LLC |

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 Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See 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 ☐
Non-accelerated filer ☒

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 Act). Yes ☐ No ☒

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant as of June 30, 2025 (the last business day of the registrant's most recently completed second fiscal quarter) was approximately $74.8 million based on the closing price of the registrant's common stock on June 30, 2025 of $5.55 per share, as reported by the Nasdaq Capital Market.

As of March 25, 2026, the number of shares of the registrant's common stock outstanding was 27,996,819 shares of voting common stock, $0.0001 par value per share, and no shares of non-voting common stock, $0.0001 par value per share.

DOCUMENTS INCORPORATED BY REFERENCE

None.

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**JASPER THERAPEUTICS, INC.**

As used in this Annual Report on Form 10-K, unless the context requires otherwise, references to the "Company", "Jasper", "we", "us", "our", and similar terms refer to Jasper Therapeutics, Inc., a Delaware corporation formerly known as Amplitude Healthcare Acquisition Corporation ("AMHC"), and its consolidated subsidiary.

Unless otherwise noted or the context requires otherwise, references to our "common stock" refer to our voting common stock, par value $0.0001 per share. In addition, except as otherwise indicated, all information in this Annual Report on Form 10-K gives effect to the 1-for-10 reverse stock split of the common stock that was effected on January 4, 2024.

**CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS**

Certain statements contained in this Annual Report on Form 10-K may constitute "forward-looking statements" for purposes of federal securities laws. Such statements can be identified by the fact that they do not relate strictly to historical or current facts. In addition, any statements that refer to projections, forecasts or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements. The words "*anticipate,*" "*believe,*" "*contemplate,*" "*continue,*" "*could,*" "*estimate,*" "*expect,*" "*intends,*" "*may,*" "*might,*" "*plan,*" "*possible,*" "*potential,*" "*predict,*" "*project,*" "*should,*" "*will,*" "*would*" and similar expressions (including the negative of any of the foregoing) may identify forward-looking statements, but the absence of these words does not mean that a statement is not forward-looking.

Forward-looking statements in this Annual Report on Form 10-K may include, for example, but are not limited to, statements about:

- our or our management team's expectations, hopes, beliefs, intentions or strategies regarding the future;
- our ability to research, discover and develop additional product candidates;
- the success, cost and timing of our product development activities and clinical trials;
- the potential attributes and benefits and safety and efficacy of our product candidates;
- our ability to obtain and maintain regulatory approval for our product candidates;
- our ability to obtain additional funding for our operations in future offerings;
- our projected financial information, anticipated growth rate and market opportunity;
- our ability to maintain the listing of our public securities on the Nasdaq Capital Market LLC ("Nasdaq");
- our public securities' potential liquidity and trading;
- our success in retaining or recruiting, or changes required in, officers, key employees or directors;
- our ability to grow and manage growth profitably;
- the implementation, market acceptance and success of our business model, developments and projections relating to our competitors and industry;

- our ability to obtain and maintain intellectual property protection and not infringe on the rights of others;
- our ability to identify, in-license or acquire additional technology;
- our ability to maintain our existing license agreements and manufacturing arrangements;
- our expectations regarding the anticipated benefits of our corporate reorganization, including the reduction in force, and our ability to implement and achieve the expected cost savings in connection therewith;
- our ability to continue as a going concern; and
- the volatility of the trading price of our common stock.

These forward-looking statements are based on current expectations and beliefs concerning future developments and their potential effects. There can be no assurance that future developments affecting us will be those that we have anticipated. These forward-looking statements involve a number of risks, uncertainties (some of which are beyond our control) or other assumptions that may cause actual results or performance to be materially different from those expressed or implied by these forward-looking statements. These risks and uncertainties include, but are not limited to, those factors described under the heading "Risk Factors" in this Annual Report on Form 10-K. Should one or more of these risks or uncertainties materialize, or should any of our assumptions prove incorrect, actual results may vary in material respects from those projected in these forward-looking statements. Some of these risks and uncertainties may in the future be amplified, and there may be additional risks that we consider immaterial or which are unknown. It is not possible to predict or identify all such risks. Readers are cautioned not to place undue reliance on forward-looking statements because of the risks and uncertainties related to them and to the risk factors. We do not undertake any obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required under applicable securities laws.

## PART I

### ITEM 1. BUSINESS

**Overview**

We are a clinical-stage biotechnology company focused on developing therapeutics targeting mast cell driven diseases such as Chronic Spontaneous Urticaria ("CSU"), Chronic Inducible Urticaria ("CIndU") and asthma and we continue to consider additional indications in mast cell driven diseases for potential future development. We have also historically explored development programs in diseases where targeting diseased hemopoietic stem cells can provide benefits, such as stem cell transplant conditioning regimens, but those programs have been discontinued and we are exclusively focused on mast cell driven diseases.

Our lead product candidate, briquilimab, is a monoclonal antibody designed to block stem cell factor ("SCF") from binding to and signaling through the CD117 ("KIT") receptor on mast and stem cells. The SCF/KIT pathway is a survival signal for mast cells and we believe that blocking this pathway may lead to depletion of these cells throughout the body, including in the lungs and in the skin, which could lead to significant clinical benefit for patients with mast-cell driven diseases such as asthma and chronic urticarias. To that end, we are focusing on advancing a portfolio of clinical programs in mast cell driven diseases. Development highlights include:

***CSU - BEACON Study***

We commenced the Phase 1b/2a BEACON study in CSU in late 2023. The BEACON study is a randomized, double-blind, and placebo-controlled Phase 1b/2a trial evaluating multiple ascending doses of briquilimab both as a single dose ("SD") (240mg & 360mg) as well as with repeat dosing (multiple dose levels from 10mg Q8W up to 240mg Q8W) as a therapy for adult patients with moderate to severe CSU. We reported positive preliminary data from the first 8 dosing cohorts (10mg, 40mg, 80mg Q8W, 120mg Q8W & Q12W, 180mg Q8W & Q12W and 240mg SD), in January 2025. We also reported preliminary data from 3 additional cohorts (360mg SD, 240mg Q8W and 240mg/180mg Q8W) in July 2025, and reported additional positive preliminary data from new patients enrolled in the 240mg/180mg Q8W cohort in January 2026. In general, data generated in the BEACON study has been positive with strong efficacy and a favorable safety profile observed in CSU patients. Highlights of the BEACON study data presented in those updates were as follows:

- Briquilimab demonstrated a rapid onset of clinical efficacy with clinical responses seen as early as 1 week post-dose and complete responses observed as early as week 2 post-dose.
- Briquilimab drove deep and meaningful clinical responses at dose levels of 180mg or higher, most notably with 100% of patients in the 240mg single dose cohorts achieving complete responses in the first 8 weeks.
- Briquilimab was well-tolerated and demonstrated a favorable safety profile:
    - KIT-related adverse events ("AEs") were generally transient, low-grade events;
    - The majority of AEs observed were resolved while on study prior to subsequent doses; and
    - No dose delays, missed doses or discontinuations were reported due to AEs possibly related to KIT blockade.

While the data generated to date in the BEACON study has generally been positive, in the July 2025 data update, results from the 240mg Q8W and the 240mg/180mg Q8W dose cohorts demonstrated an atypical absence of UAS7 reduction in 11 of the 13 patients enrolled, and as a result, we launched an investigation into those two cohorts. Factors examined included clinical site conduct, site dosing procedures, patient selection criteria, as well as potential product lot variability in one lot of drug product first introduced into the BEACON study in those two cohorts. We also provided new clinical drug supply from a different lot for ongoing dosing of existing patients and subsequently enrolled an additional 10 patients in aggregate across those two cohorts. Based on the work conducted during the investigation, we concluded the anomalous efficacy results in these two cohorts was not the result of any issues with the investigational product used, or from drug substance ("DS") or drug product ("DP") manufacturing or distribution processes, but rather appeared to be an issue resulting from patient selection process/criteria at certain clinical sites participating in the study. The conclusions reached as a result of the investigation were supported by expert panels comprised of key opinion leaders in clinical development and antibody manufacturing that reviewed the findings and provided feedback and recommendations on patient enrollment processes that are being integrated into the planned Phase 2b/3 CSU study to increase the likelihood that CSU patients enrolled in the study would be more likely to have mast cell driven disease. These recommendations were incorporated into enrollment of the additional patients in the 240mg Q8W and 240mg/180mg Q8W cohorts. Given the additional data reported in January 2026 for 6 patients dosed with briquilimab in the 240mg/180mgQ8W cohort showed deep and meaningful clinical responses with UAS7 reductions of as much as 29 points observed and 4 of 6 participants (67%) reporting a complete response at 12 weeks, we believe these recommendations have been effective and we are integrating them into our planned Phase 2b/3 CSU study.

***CIndU – SPOTLIGHT Study***

In early 2024, we commenced the Phase 1b/2a SPOTLIGHT study in CIndU. The SPOTLIGHT study is a Phase 1b/2a open label clinical trial evaluating single doses of subcutaneous briquilimab in adult participants with cold urticaria or symptomatic dermographism, the two most prevalent sub types of CIndU, who are refractory to antihistamines. The study enrolled 27 participants across three single dose cohorts of 40mg, 120mg, and 180mg. In October 2024, we presented positive preliminary data on the 40mg and 120mg cohorts from the study for a 6-week preliminary analysis period following dosing, and in June 2025, we reported positive preliminary data from the 180mg single dose cohort at the 8-week preliminary analysis period. Highlights of the data presented were as follows:

- Briquilimab treatment resulted in deep disease control at all three dose levels with 26 of 27 participants (96%) enrolled in the study achieving a clinical response within the 8-week preliminary analysis period following dosing, and 21 of 24 participants (88%) dosed at 120mg or 180mg achieving a complete response in that period; and

- Briquilimab was well-tolerated in the study, with KIT-related AEs being low-grade events, and no grade 3 or higher AEs possibly related to KIT blockade reported in any of the dose cohorts.

***Open Label Extension (OLE) Study***

In 2025, we commenced an Open Label Extension study (the "OLE") in which patients in the BEACON study in CSU and the SPOTLIGHT study in CIndU were eligible to roll over to once they either completed their initial safety follow up period or experienced a return of disease during the safety follow up period. All patients rolling over to the OLE study were treated with a 180mg Q8W dosing regimen. In January 2026, we reported preliminary data from the OLE study in both CSU and CIndU patients.

Highlights of the clinical efficacy observed in CSU and CIndU participants for the OLE study released in January 2026 were as follows:

- In CSU participants, briquilimab treatment resulted in deep and durable disease control in the OLE study with 27 of 36 participants (75%) achieving complete response or well controlled disease at the week 12 assessment; and

- In CIndU participants, briquilimab treatment resulted in deep and durable disease control as well, with 11 of 17 participants (65%) achieving complete response or partial response at the week 16 assessment, which was 8 weeks following administration of the second dose.

Across both CSU and CIndU participants in the OLE study, briquilimab continued to demonstrate a favorable safety profile:

- KIT-related AEs were generally transient, low-grade events;

- The majority of AEs observed were resolved while on study prior to subsequent doses;

- One patient discontinued therapy due to taste disturbance potentially related to briquilimab; and

- No other dose delays, missed doses or discontinuations were reported due to AEs possibly related to KIT blockade.

***Asthma – ETESIAN Study***

In late 2024, we commenced a Phase 1b study in asthma, the "ETESIAN" study, which is a single dose double-blind, placebo-controlled challenge study seeking to demonstrate proof-of-concept in asthma utilizing a potential therapeutic dose to inform future trials in the broader asthma population. The study was conducted utilizing a single 180mg dose of subcutaneous briquilimab and key assessments included measuring improvements in Forced Expiratory Volume in 1 second ("$FEV_1$") in both Early Asthmatic Response ("EAR"), and Late Asthmatic Response ("LAR") measured at 6 and 12 weeks, changes in airway hyperresponsiveness, mast cell depletion and recovery, and safety.

In December 2025, we reported preliminary results from the ETESIAN study in 14 participants (7 receiving a single dose of 180mg briquilimab and 7 receiving placebo) who completed at least the 6 week allergen challenge assessment following dosing with investigational product or placebo. Highlights of the clinical response observed in ETESIAN participants reported in December 2025 were as follows:

- Compared to baseline, briquilimab reduced the allergen induced LAR (measured by the mean maximum percentage fall in $FEV_1$ (%Max $FEV_1$) and fall in area under the $FEV_1$ time response curve ("AUC")) at both 6 and 12 weeks. Patients who received briquilimab showed an improvement in the LAR %Max $FEV_1$ of 10.4% at 6 weeks and 8.7% at 12 weeks compared to baseline, as well as demonstrating an improvement in the LAR AUC of 25.4% at 6 weeks and 23.3% at 12 weeks.

- Sputum eosinophils, a potential marker of inflammatory response, were also measured at 7 and 24 hours following allergen challenge at week 6 and week 12. Participants receiving briquilimab demonstrated notably lower eosinophil levels as compared to those receiving placebo, indicating a reduction in the inflammatory response to their allergen.

The positive proof of concept data generated in the ETESIAN study supports further development in the broader asthma population, however, advancing any future clinical studies in asthma would be based on an evaluation of the competitive landscape, the potential for strategic partnerships and capital availability.

Historically, we have also evaluated briquilimab as a one-time conditioning therapy for severe combined immunodeficiency ("SCID") patients undergoing a second stem cell transplant for which we conducted a Phase 1/2 clinical trial as well as via Investigator Sponsored Trials ("ISTs") in several other stem cell transplant indications. In July 2025, we re-focused resources on our mast cell disease development programs.

We intend to become a fully integrated discovery, development and commercial company in the field of mast cell therapeutics. We are developing our product candidates to be used individually or, in some cases, in combination with other therapeutics. Our goal is to advance our product candidates through regulatory approval and bring them to the commercial market based on the data from our clinical trials and communications with regulatory agencies and payor communities. We expect to continue to broaden our pipeline with additional mast cell indications.

We have an exclusive license agreement with Amgen Inc. ("Amgen") for the development and commercialization of the briquilimab monoclonal antibody in all indications and territories worldwide. We also have an exclusive license agreement with Stanford University for the right to use briquilimab in the clearance of diseased stem cells prior to the transplantation of hematopoietic stem cells ("HSCs").

**Briquilimab**

We believe briquilimab is a unique, humanized, monoclonal antibody that targets the underlying biology of mast cell survival to potentially serve as a therapeutic to prevent mast cell driven diseases. In addition, we believe briquilimab targets a key differentiation pathway for HSCs and may be developed to improve the efficacy and safety of hematopoietic stem cell transplantation. Briquilimab binds to human KIT, the receptor for SCF, which is expressed on the surface of various cells, including mast cells. The interaction of SCF and KIT is required for mast cells to survive. By blocking SCF from binding to KIT and disrupting these critical signals, briquilimab leads to the depletion of mast cells in the skin. Briquilimab is designed to bind to KIT with a greater affinity than SCF.

The monoclonal antibody isotype and other modifications of briquilimab were chosen carefully to retain high affinity binding to the KIT receptor and SCF signal blockade without recruiting other immune cells that could lead to receptor activation, mast cell degranulation or other off-target toxicities. For example, designing briquilimab as an IgG1 isotype instead of an IgG2 isotype results in more potent inhibition of KIT, potentially increasing the effect on mast cell depletion. Briquilimab was also designed to be aglycosylated in order to eliminate the recruitment of other immune effector cells that may bring unwanted effects to any cell that expresses KIT. This finding and other data demonstrate that not all anti-KIT antibodies behave equally or have the same mechanism of action.

We are focused on advancing Briquilimab in development as a chronic therapy in mast cell driven diseases such as CSU, CIndU, asthma and other mast cell driven indications currently under evaluation.

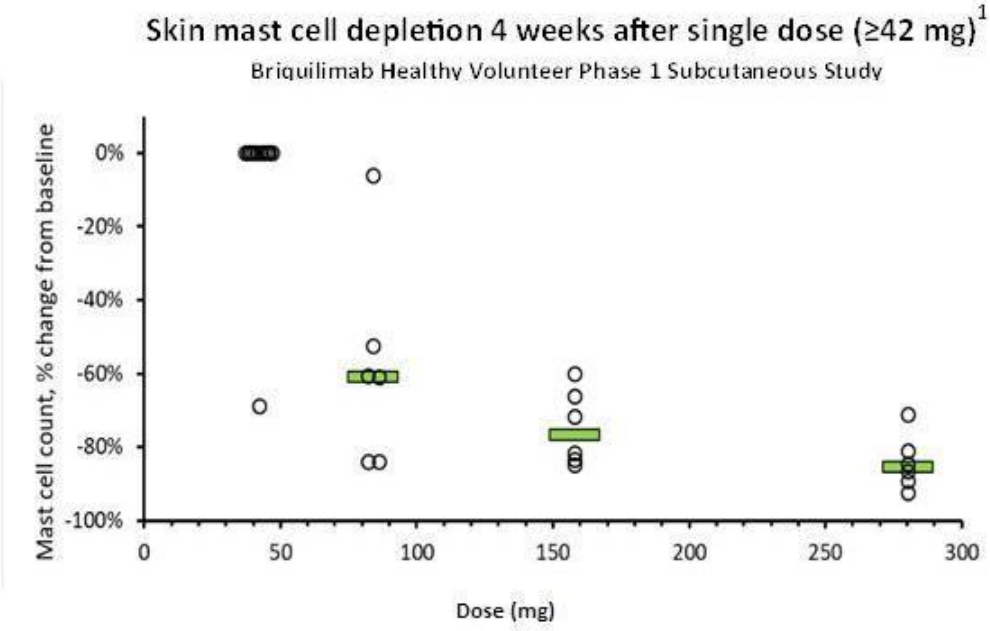
**Briquilimab as a Primary Therapeutic for Disorders of Mast Cells**

Mast cells are primary cells of the immune system derived from HSCs in the bone marrow. Mast cells store a number of different chemical mediators such as tryptase, histamine, interleukins and heparin in granules found throughout the cell. When a mast cell is triggered, such as by an allergen specific to membrane-bound Immunoglobulin E ("IgE") antibodies, the mast cell is activated and releases the content of the granules into the surrounding tissue. These chemical mediators attract other immune cells to help with any response as well as produce a local allergic reaction consisting of inflammation, swelling, contraction of smooth muscle and increased mucus secretion. Mast cells are usually long-lived and found at boundaries to the external environment such as the skin, mucosal surfaces of the gut and lungs and eye.

Dysfunctional regulation and activation of mast cells is thought to be a significant driver of multiple diseases, including urticarias, asthma, prurigo nodularis, allergic eye disease and others. Each of these diseases has been shown to have local concentrations of mast cells, cellular response consistent with mast cell degranulation and disease modification with use of antihistamines. Unfortunately, currently approved agents targeting mast cells in these diseases are ineffective in many patients, leading to continued high disease burden.

Briquilimab blocks signaling on the KIT receptor by inhibiting the binding of SCF, the ligand for the KIT receptor. The interaction of SCF/KIT on mast cells is critical for development, proliferation and survival. Without continued signaling through KIT, mast cells will undergo apoptosis and die. We have shown that a single subcutaneous dose of briquilimab leads to depletion of mast cells in the skin of healthy human volunteers for at least 29 days. We believe that depletion of mast cells in the skin of patients with chronic urticaria or other mast cell driven diseases has the potential to lead to improved disease control for those patients without adequate response to current therapies.

*Figure 1 – Healthy volunteers administered single doses of briquilimab 42 mg to 280 mg subcutaneously received punch skin biopsies to evaluate the decreases in mast cells at 4 weeks after briquilimab was administered compared to the baseline.*



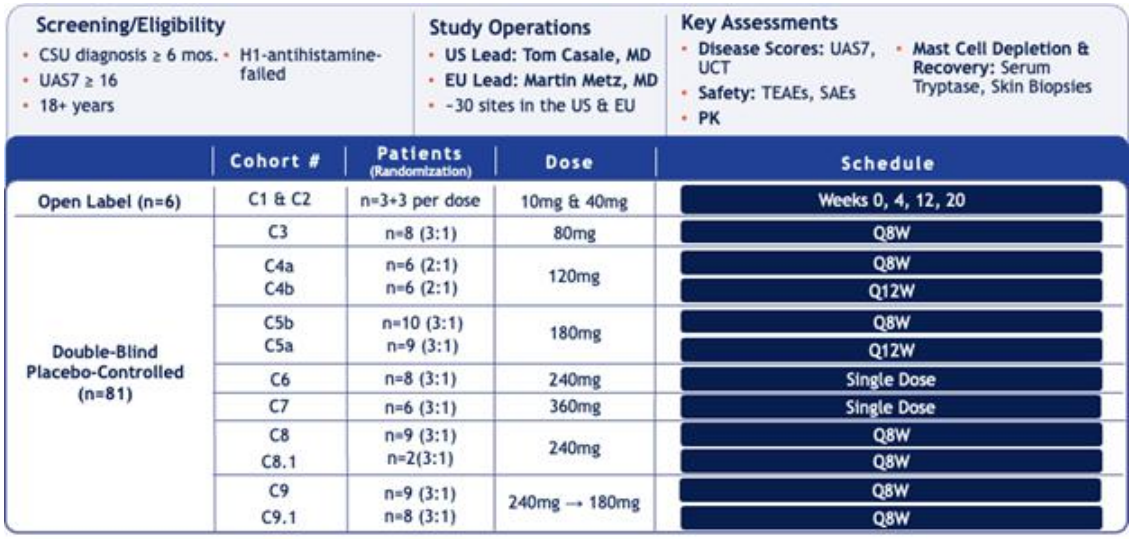

**(1) Jasper internal data (Phase 1a, healthy volunteer study).**

***Briquilimab in Chronic Urticaria***

Mast cells are immune cells that play a key role in the inflammatory response to pathogens or injury and are typically found in the skin, lungs, digestive track, conjunctiva of the eye and the mucosal linings of the mouth and nose. Typically, mast cells are triggered by a specific antigen or antibody interaction to release histamine, a variety of cytokines and other chemical mediators in order fight a potential infection and to recruit additional types of immune cells to aid in the body's response. However, with certain diseases, such as CSU, CIndU, allergic asthma, prurigo nodularis and eosinophilic esophagitis, the mast cell response is dysregulated and may lead to unwanted responses such as hives, itching, airway constriction or conjunctivitis. Current therapeutic approaches to controlling mast cell response include antihistamines to counteract the release of histamine by activated mast cells, anti-IgE antibody therapy to try to eliminate the antibodies responsible for a trigger of mast cell activation and inhibition of other signaling pathways such as Bruton's Tyrosine Kinase ("BTK") or IL4/IL13 that may suppress mast cell activation. We believe that new chronic therapies that target mast cells could be beneficial in treating many diseases that are a function of mast cell dysfunction.

In late 2023, we commenced a Phase 1b/2a clinical trial in patients with CSU. CSU is a disorder of mast cells in the skin in which patients experience swelling, redness and itching of the skin that lasts at least six weeks due to either an unknown cause, Type I autoimmunity with IgE against self or Type IIb autoimmunity with activating antibodies directed at mast cells. CSU is thought to affect over five million patients in the United States, France, Germany, Italy, Spain, and the United Kingdom. The U.S. Food and Drug Administration (the "FDA")-approved drug therapy for CSU includes second generation H1-antihistamines for first line use followed by consideration for use of omalizumab, a monoclonal antibody directed at circulating IgE; dupilumab, a monoclonal antibody directed at the IL-4 and IL-13 signaling pathways; and remibrutinib, a small molecule inhibitor of BTK. The biologic rationale for these therapies is based on modulating mast cell response. Antihistamines work to counteract the effects of histamine that is released from activated mast cells and the other agents are thought to remove or suppress signaling pathways that trigger mast cell activation. Based on human healthy volunteer clinical data showing that briquilimab can deplete mast cells from the skin and from data in a study of CSU patients showing that an anti-KIT antibody can control disease symptoms, we believe that briquilimab could be effective therapy for CSU patients. The Phase 1b/2a study is a monotherapy study being conducted in CSU patients who are refractory to antihistamine therapy and who have had an inadequate response to omalizumab. The study design has three parts. The first part is an open-label 3+3 dose escalation with two dose cohorts (10mg and 40mg). The second part consists of seven dose cohorts (80mg Q8W, 120mg Q8W, 120mg Q12W, 180mg Q8W, 180mg Q12W, 240mg Q8W and 240mg/180mg Q8W) in a double-blind placebo controlled format. The final part is a single dose cohort with two dose levels being explored (240mg single-dose and 360mg single-dose) in a double-blind placebo controlled format.

*Figure 2 – Study design for the Phase 1b/2a BEACON study in CSU.*




In January 2025, we presented positive preliminary data from the first 8 dosing cohorts in this study (10mg, 40mg, 80mg Q8W, 120mg Q8W, 120mg Q12W, 180mg Q8W, 180mg Q12W, and 240mg single-dose). Average patient duration on study as of the cutoff date for the data presented was approximately 28 weeks. Highlights of the data presented were as follows:

- Briquilimab demonstrated a rapid onset of clinical efficacy with clinical responses seen as early as 1 week post-dose and complete responses observed as early as week 2 post-dose.

- Briquilimab drove deep and meaningful clinical responses with 100% complete responses through 8 weeks demonstrated at the 240mg dose level.

- Briquilimab was well-tolerated and demonstrated a favorable safety profile:

    - KIT-related AEs were generally transient, low-grade events;

    - The majority of AEs observed were resolved while on study prior to subsequent doses; and

    - No dose delays, missed doses or discontinuations were reported due to AEs possibly related to KIT blockade.

In July 2025, we reported updated data from the Phase 1b/2a BEACON study in CSU with updates on the 240mg and 360mg single dose cohorts as well as the 240mg Q8W and the 240mg/180mg Q8W cohorts. Highlights of the data update presented were as follows:

- Briquilimab administration continued to demonstrate deep and rapid disease control in the 240mg and 360mg single-dose cohorts with 8 of 9 (89%) of participants enrolled across both cohorts achieving a complete response, and with 7 of 9 (78%) achieving a clinical response by week 2.

- Results from the 240mg Q8W and the 240mg/180mg Q8W dose cohorts demonstrated an atypical absence of UAS7 reduction in 11 of the 13 patients enrolled, and as a result, we launched an investigation into those two cohorts. Factors examined included clinical site conduct, site dosing procedures, patient selection criteria, as well as potential product lot variability in one lot of drug product first introduced into the BEACON study in those two cohorts. We also provided new clinical drug supply from a different lot for ongoing dosing of existing patients and subsequently enrolled an additional 10 patients in aggregate across those two cohorts.

In December 2025, we reported the completion of the investigation into the confounded efficacy results reported in July 2025 from the 240mg Q8W and the 240mg/180mg Q8W cohorts of the BEACON study in CSU. Based on the work conducted, we concluded the anomalous efficacy results in these two cohorts was not the result of any issues with the investigational product used, or from DS or DP manufacturing or distribution processes, but rather appeared to be an issue resulting from patient selection process/criteria at certain clinical sites participating in the study. This conclusion reflects, among other factors:

- a comprehensive review of manufacturing and distribution records;

- robust testing of multiple lots across the manufacturing and clinical supply chain;

- independent, blinded testing of returned drug product samples from trial sites;

- review of stability samples from the lots used in the two cohorts compared against other lots;
- review of patient selection and enrollment processes;
- review of investigational product handling and administration at the site level;
- review of drug delivery methods (for example, injection site, needle and injection media); and
- review of additional patient- and site-level data.

The conclusions reached as a result of the investigation were supported by expert panels comprised of key opinion leaders in clinical development and antibody manufacturing that reviewed the findings and provided feedback and recommendations that are being integrated into the planned Phase 2b/3 CSU study to increase the likelihood that CSU patients enrolled in the study would be more likely to have mast cell driven disease.

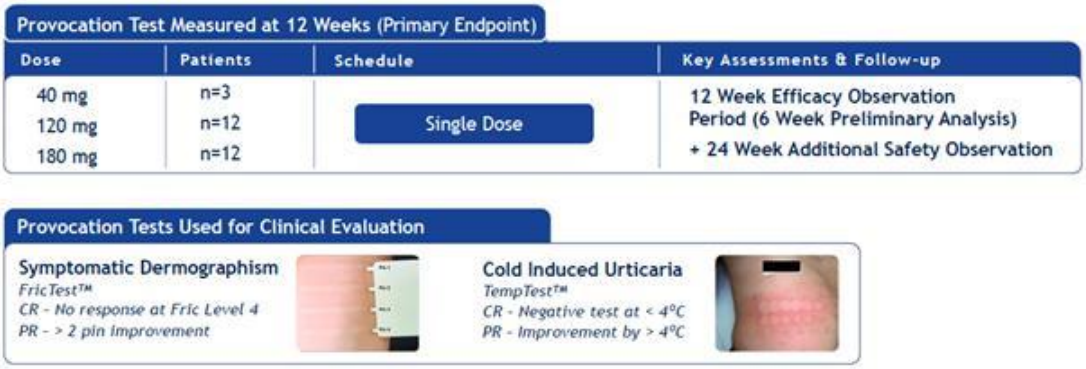
In January 2026, we reported updated data from the Phase 1b/2a BEACON study in CSU with updates on an additional 8 patients enrolled in the 240mg/180mg Q8W cohort (6 on briquilimab and 2 on placebo). Highlights of the data update were as follows:

- Briquilimab demonstrated a rapid onset of clinical efficacy with clinical responses achieved by 5 of 6 participants (83%) by week 3.
- Briquilimab drove deep and meaningful clinical responses with UAS7 reductions of as much as 29 points noted, and 4 of 6 participants (67%) reporting a complete response at 12 weeks.
- Briquilimab continued to be well-tolerated and demonstrated a favorable safety profile:
    - KIT-related AEs were generally transient, low-grade events;
    - The majority of AEs observed were resolved while on study prior to subsequent doses; and
    - No dose delays, missed doses or discontinuations were reported due to AEs possibly related to KIT blockade.

We are also conducting a Phase 1b/2a clinical trial in patients with CIndU. Similar to CSU, CIndU is a disorder of mast cells in the skin in which patients experience swelling, redness and itching of the skin that lasts at least six weeks, but CIndU is induced by specific physical or environmental stimuli, including cold, heat, exercise, pressure, sunlight and others. CIndU includes physical urticarias, such as symptomatic dermographism and cold urticaria, as well as non-physical urticarias caused by exposure to specific stimuli, such as cholinergic urticaria and aquagenic urticaria.

The FDA-approved drug therapy for CIndU consists solely of second generation H1-antihistamines. The biologic rationale for this therapy is based on modulating mast cell response. Antihistamines work to counteract the effects of histamine that is released from activated mast cells. CIndU is thought to affect over two million patients in the United States, France, Germany, Italy, Spain and the United Kingdom. Approximately 40% of these patients' CIndU is not controlled by first line antihistamines and these patients could be eligible for biologic therapy depending on disease severity. Based on preclinical and human healthy volunteer clinical data showing that briquilimab can deplete mast cells from the skin, we believe that briquilimab could be an effective therapeutic for CIndU patients. The Phase 1b/2a study is a monotherapy study being conducted in CIndU patients who are refractory to antihistamine therapy. The study design contains a single dose in three dosing cohorts (40mg, 120mg and 180mg) with a provocation test measured at various timepoints through 12 weeks post-dosing.

*Figure 3 – Study Design for the Phase 1b/2a SPOTLIGHT Study in CIndU*




In early 2024, we commenced the Phase 1b/2a SPOTLIGHT study in CIndU. In October 2024, we presented positive preliminary data on the 40mg and 120mg cohorts from the study showing the following for the 6-week preliminary analysis period following dosing, as follows:

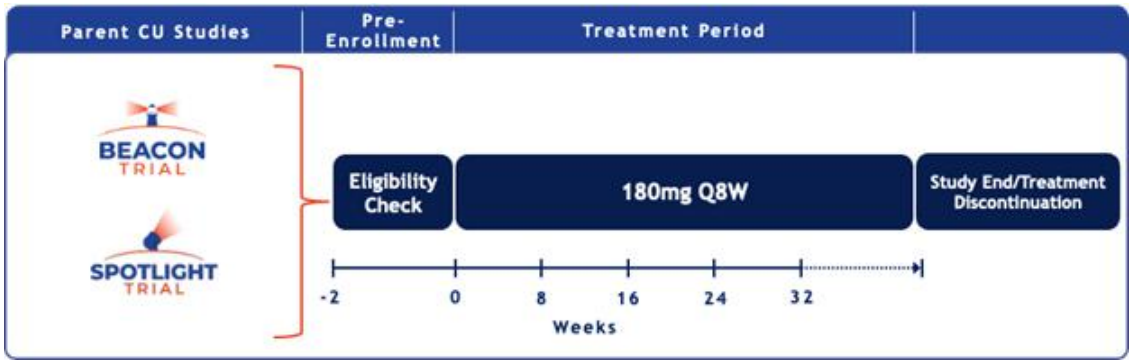
- Across the 40mg and 120mg dosing cohorts in the study, 14 of the 15 participants (93%) achieved a clinical response;
- In the 120mg dose cohort, 10 of 12 participants (83%) experienced a complete response, and 1 participant experienced a partial response; and
- Briquilimab has been well-tolerated in the study, with no serious adverse events ("SAEs") and no grade 3 or higher AEs reported.

In late 2024, we added a 180mg single dose cohort to the SPOTLIGHT study in CIndU. In June 2025, we reported positive preliminary data from the 180mg single dose cohort, the highlights of which were as follows:

- Briquilimab treatment resulted in deep disease control at 180mg, with 12 of 12 participants (100%) enrolled in the cohort achieving a clinical response within the preliminary analysis period;
- The efficacy observed was rapid and durable, with 8 of 12 participants (66%) achieving clinical response by week 2, and 7 of 12 participants (58%) maintaining clinical response through week 8; and
- Briquilimab continued to be well-tolerated in the study, with KIT-related AEs being low-grade events, and no grade 3 or higher AEs possibly related to KIT blockade reported in any of the dose cohorts.

In addition to the BEACON and SPOTLIGHT studies, we also commenced an Open Label Extension study (the "OLE") in which patients in the BEACON study in CSU and the SPOTLIGHT study in CIndU are eligible to roll over to once they have completed their initial safety follow up period or experienced return of disease during the safety follow up period. All patients rolling over to the OLE study are treated with a 180mg Q8W dosing regimen.

*Figure 4 – Study Design for the OLE Study in CSU and CIndU*




In January 2026, we reported preliminary data from the OLE study in both CSU and CIndU patients. Highlights of the clinical efficacy observed in CSU and CIndU participants for the OLE study released in January 2026 were as follows:

- In CSU participants, briquilimab treatment resulted in deep and durable disease control in the OLE study with 27 of 36 participants (75%) achieving complete response or well controlled disease at the week 12 assessment; and
- In CIndU participants, briquilimab treatment resulted in deep and durable disease control as well, with 11 of 17 participants (65%) achieving complete response or partial response at the week 16 assessment, which was 8 weeks following administration of the second dose.

Across both CSU and CIndU participants in the OLE study, briquilimab continued to demonstrate a favorable safety profile:

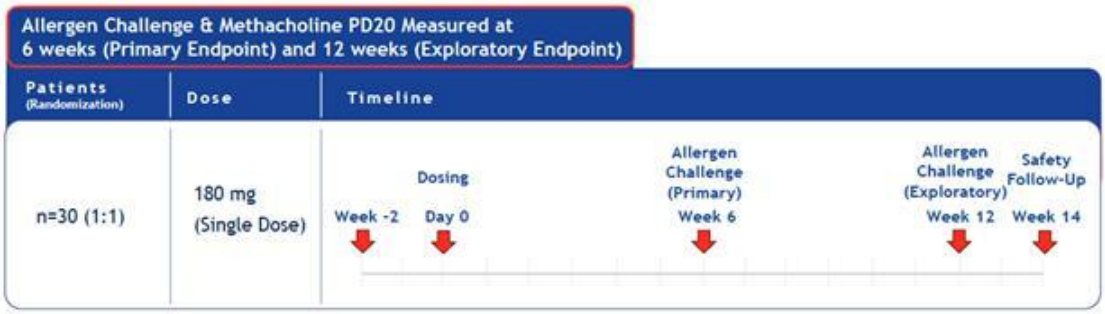
- KIT-related AEs were generally transient, low-grade events;
- The majority of AEs observed were resolved while on study prior to subsequent doses;
- One patient discontinued therapy due to taste disturbance potentially related to briquilimab; and
- No other dose delays, missed doses or discontinuations were reported due to AEs possibly related to KIT blockade.

***Briquilimab in Asthma***

Allergic asthma is a form of asthma triggered by specific allergens that leads to constriction of smooth muscles in the airways, cellular infiltration of various immune mediators and excess production of mucus. Patients with allergic asthma may have an increased number of mast cells in the bronchi and mast cells are believed to not only be a direct driver of inflammation the asthmatic response, but to also be recruiters of other cell types that contribute to that inflammation. Given these factors, we believe that asthma may be responsive to agents that modulate mast cell response, including antihistamines and anti-IgE monoclonal antibody therapy.

In late 2024, we commenced a Phase 1b clinical trial in patients with allergic asthma (the ETESIAN study). The Phase 1b study is a double-blind placebo controlled single-dose monotherapy allergen challenge study being conducted in allergic asthma patients. Patients enrolled in the study will either receive placebo, or a single 180mg dose of briquilimab. Endpoints evaluated will include both early and late asthmatic response, as measured by % decrease in $FEV_1$ relative to baseline, and change in airway hyperresponsiveness from baseline, and both will be measured at 6 weeks post-dose and 12 weeks post-dose.

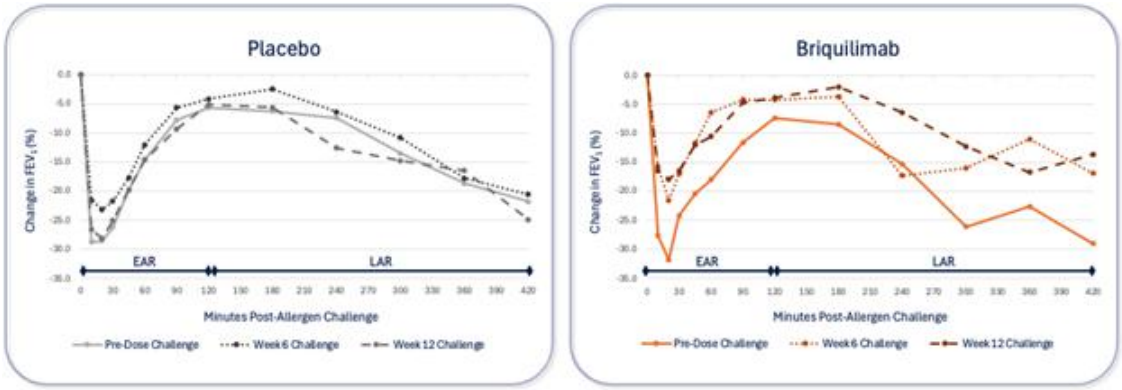
*Figure 5 – Study Design for the Phase 1b ETESIAN study in Asthma*




In December 2025, we reported preliminary results from the ETESIAN study in 14 participants (7 receiving a single dose of 180mg briquilimab and 7 receiving placebo) who completed at least 6 weeks of allergen challenge testing following dosing with investigational product. Highlights of the clinical response observed in ETESIAN participants reported in December 2025 were as follows:

- Compared to baseline, briquilimab reduced the allergen induced LAR (measured by the mean maximum percentage fall in $FEV_1$ (%Max $FEV_1$) and fall in area under the $FEV_1$ time response curve ("AUC")) at both 6 and 12 weeks with patients who received briquilimab showing an improvement in the LAR %Max $FEV_1$ of 10.4% at 6 weeks and 8.7% at 12 weeks compared to baseline and an improvement in the LAR AUC of 25.4% at 6 weeks and 23.3% at 12 weeks.

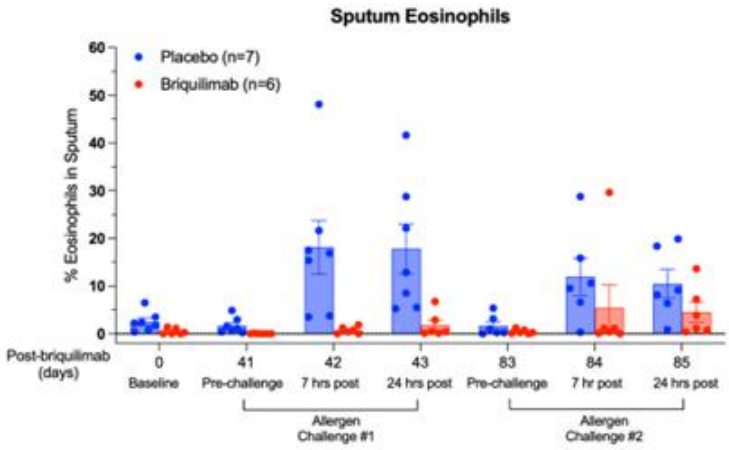
*Figure 6 – Change in $FEV_1$ observed in ETESIAN study*




- Patient airway hyperresponsiveness was also assessed pre- and post-allergen challenge by methacholine PD20. At baseline, prior to administration of briquilimab, patients randomized to both the placebo group and the briquilimab group had similar drops in the ratio of post- to pre-allergen challenge methacholine PD20 (dose of methacholine required to drive a 20% decrease in $FEV_1$) following allergen challenge of 0.50 and 0.46, respectively. At the week 6 challenge the shift in the methacholine PD20 response was 0.40 for placebo and 0.63 for briquilimab and at the week 12 challenge the shift was 0.60 for placebo and 1.58 for briquilimab indicating an increased resistance to methacholine following allergen in patients dosed with briquilimab.

- Sputum eosinophils, a potential marker of inflammatory response, were also measured at pre-challenge, 7 and 24 hours following allergen challenge at week 6 and week 12. Participants receiving briquilimab demonstrated notably lower eosinophil levels as compared to those receiving placebo, indicating a reduction in the inflammatory response to their allergen.

*Figure 7 –Reduced eosinophil levels observed in participants receiving briquilimab in the ETESIAN study*




The positive proof of concept data generated in the ETESIAN study supports further development in the broader asthma population, however, advancing any future clinical studies in asthma would be based on an evaluation of the competitive landscape, the potential for strategic partnerships and capital availability.

***Briquilimab in Other Mast Cell Disorders***

Mast cells may also be the key cellular target for a number of other inflammatory or autoimmune diseases outside of the chronic urticarias and asthma, such as atopic dermatitis, prurigo nodularis and food allergies.

Atopic dermatitis is a chronic disease that causes inflammation, redness, and irritation of the skin. It is a common condition that usually begins in childhood; however, anyone can get the disease at any age. Atopic dermatitis causes the skin to become extremely itchy. In most cases, there are periods of time when the disease is worse, called flares, followed by periods when the skin improves or clears up entirely, called remissions. Treatments include moisturizers, topical steroids, immunomodulators (tacrolimus and pimecrolimus) and biologic therapies (dupilumab). Mast cells may play an important role in the disease and agents that modulate mast cells may provide benefit to patients.

Prurigo Nodularis is also a disease that manifests in the skin. Patients develop severe itch and firm bumps on the skin, called nodules, that may lead to loss of sleep and bleeding due to scratching. Degranulation of mast cells in the skin is thought to trigger peripheral sensory neurons in the skin leading to itch. Various medications are used to treat Prurigo Nodularis including anti-itch creams and topical steroids. For cases that remain uncontrolled physicians may prescribe antihistamines or biologics such as dupilumab.

Food allergy is an immune-mediated disease characterized by an IgE-mediated response to specific dietary antigens, which leads to allergic hypersensitivity reactions. In IgE-mediated food allergies, allergic reactions from exposure to the food result from receptor-bound allergen-specific IgE antibodies binding to the food proteins, leading to the cross-linking of IgE receptors on mast cells and subsequently mast cell activation and degranulation; resulting in the release of chemical mediators of inflammation. Symptoms of food allergy can range from mild symptoms, such as hives and itching to potentially fatal systemic allergic reactions including anaphylaxis. Treatments include antihistamines and steroids for mild to moderate reactions, epinephrine for severe reactions and anaphylaxis, as well as preventative therapies such as oral immunotherapy or biologic therapies (omalizumab).

We have performed pre-clinical evaluation of briquilimab as a potential therapeutic in these and a number of other mast cell driven diseases and expect to continue to expand our portfolio of mast cell indications in clinical development in the future.

***Briquilimab in Non-Mast Cell Driven Disorders***

*Briquilimab as a Conditioning Agent for SCID Patients Undergoing Re-Transplantation*

We historically funded a program developing briquilimab as a conditioning agent for SCID patients undergoing a stem cell re-transplantation. Due to genetic errors at birth, SCID patients do not possess fully functional immune systems, which results in chronic infections, failure to thrive and significantly decreased lifespans. If available, these patients are typically given a transplant from a close relative with the goal of allowing healthy donor stem cells to establish in the patient's bone marrow, leading to production of normal immune cells. However, stem cell transplants are not universally successful. SCID patients with poor transplant outcomes are typically dependent on external therapies such as intravenous immunoglobin ("IVIG") and often have poor immunity, leading to chronic infections and decreased lifespans. SCID patients who fail transplant are not usually given a second transplant due to their fragile health and the significant toxicities of current conditioning agents.

We conducted a Phase 1/2 dose escalation open label clinical trial to evaluate briquilimab as the sole conditioning agent to achieve HSC engraftment in SCID patients undergoing stem cell re-transplantation. The primary endpoint in Phase 1 was to assess the safety and tolerability of briquilimab as a conditioning agent in SCID patients. The two primary efficacy endpoints defined in the Phase 2 study are the proportion of patients achieving adequate donor HSC engraftment and the proportion of patients achieving naïve CD4+ T cell production greater than or equal to 85 cells/uL, a level expected to provide immune reconstitution, during weeks 36 to 104 post-transplant. Secondary endpoints include durability of naïve T cell production, incidence and severity of GvHD, hematopoietic recovery and pharmacokinetic properties of briquilimab. Patients received a single intravenous infusion of briquilimab on study day 0 in one of four dose cohorts: 0.1 mg/kg, 0.3 mg/kg, 0.6mg/kg or 1.0 mg/kg. Patients were to potentially be followed for up to five years following transplant.

We believe briquilimab has enabled immune reconstitution for patients based on naïve CD4+ T-cell levels and has shown clinical benefit in T-B-SCID patients in a re-transplant setting. Patients have shown resolution of chronic infections, independence from or reduction of IVIG therapy and antibody response to vaccine challenge. Through December 31, 2024, in this open label clinical trial, eleven T-B-SCID re-transplant patients have been treated in the ongoing SCID Phase 1/2 study. Seven of the eleven transplanted patients with 1- 5 years of follow-up have shown engraftment of donor cells and production of functional immune cells. No briquilimab treatment-related "SAEs" have been reported through December 31, 2023 in this clinical trial. In July 2025, the SCID program was discontinued to focus resources exclusively on our mast cell disease development programs.

The FDA has granted rare pediatric disease designation to briquilimab as a conditioning treatment for patients with SCID. In addition, both the FDA and the European Medicines Agency ("EMA") have granted orphan drug designation to briquilimab for conditioning treatment prior to hematopoietic stem cell transplantation.

*Stem Cell Transplant Indications*

We have historically evaluated briquilimab in a number of stem cell transplant indications, including patients with Fanconi Anemia ("FA"), Sickle Cell Disease ("SCD"), Chronic Granulomatous Disease ("CGD"), GATA-2 MDS and others through ISTs run by partners including the National Institute of Health ("NIH"), the National Heart, Lung, and Blood Institute, the National Institute of Allergy and Infectious Diseases, the National Cancer Institute and Stanford University.

While promising data has been generated to date in FA, SCD, CGD and GATA-2 MDS, given our corporate focus on mast cell driven diseases, we have discontinued these ISTs and we have no plans to pursue additional clinical development in these indications.

**Our Strategy**

Our goal is to develop and commercialize briquilimab as a safe and efficacious therapeutic to address the significant unmet medical need for patients suffering from mast cell driven diseases such as CSU, CIndU and asthma. As part of our strategy, we aim to:

***Build a leading biotechnology company to enable cures via immune modulation.*** We are bringing together a team of biotech veterans, leading academic institutions and a strong syndicate of healthcare-focused investors to achieve our vision of developing and commercializing therapeutics with a focus on mast cell driven diseases.

***Advance the development of briquilimab as a chronic therapeutic in mast cell driven diseases.*** We are focused on developing briquilimab as a repeat dose therapy for disorders of mast cells, such as CSU, CIndU, asthma and additional potential mast cell driven indications.

***Commercialize our product candidates to expand the use of effective and safe mast cell therapies for patients and physicians in our target markets.*** If approved, we plan to bring our product candidates to the American, European and Japanese markets, focusing on the top physicians who administer the majority of mast cell therapies.

***Form and strengthen strategic collaborations with leading industry and academic organizations to further develop our pipeline, unlock the commercial potential of our portfolio and provide enabling technologies for collaborators.*** We intend to continue collaborations with our existing partners and enter new strategic partnerships to develop additional candidates, generate evidence, and commercialize new products in the field of mast cell therapies.

***Agreements with Amgen***

In November 2019, we entered into a worldwide exclusive license agreement with Amgen for briquilimab (formerly AMG-191 and JSP191) in all indications and territories worldwide, which also includes translational science and materials from Stanford University. We were assigned and accepted Amgen's rights and obligations, effective November 21, 2019, for the Investigator Sponsored Research Agreement ("ISRA"), entered into in June 2013, between Amgen and The Board of Trustees of the Leland Stanford Junior University ("Stanford") and Quality Agreement between Amgen and Stanford, effective as of October 7, 2015. Under the ISRA, we received an option to negotiate a definitive license with Stanford for rights to certain Stanford intellectual property related to the study of briquilimab in exchange for an option exercise fee of $1.0 million, payable over a two-year period (the "Option"). We exercised the Option to Stanford docket S06-265 "Antibody-based clearance of endogenous stem cell niches prior to transplantation of bone marrow or HSCs (KIT)" granted by Stanford under the ISRA on June 2, 2020. As a result, we have worldwide exclusive rights to develop and commercialize briquilimab in all indications, including stem cell transplants. The issued U.S. patents would be expected to expire in 2027, absent any applicable patent term extensions.

***License Agreement with Stanford***

In March 2021, we entered into an exclusive license agreement with respect to the use of briquilimab from the Stanford Office of Technology Licensing to license U.S. Patent Application Serial Number 60/856,435, filed Nov. 3, 2006, and U.S. Patent Application Serial Number 12/447,634 (publication number US 2010/0226927 Al) and know-how for the purpose of depleting endogenous blood stem cells in patients for whom hematopoietic cell transplantation is indicated.

**Intellectual Property**

Our success depends in part on our ability to obtain and maintain proprietary protection for our product candidates and other discoveries, inventions, trade secrets and know-how that are critical to our business operations. It also depends in part on our ability to operate without infringing the proprietary rights of others, and in part, on our ability to prevent others from infringing our proprietary rights. We have a series of in-licensed patents outlined below with an additional pending patent application in the United States.

***In-licensed Amgen Portfolio***

We have exclusively licensed a patent family from Amgen applicable to our clinical development programs that contains patents and applications directed to a humanized KIT antibody. As of March 25, 2026, this patent portfolio includes three issued U.S. patents and one European patent, as well as granted patents in Australia, Canada, Japan, and Mexico, and pending patent applications in Europe and Hong Kong. The issued U.S. and European patents would be expected to expire in 2027, absent any applicable patent term extensions.

***In-licensed Stanford Portfolio***

We have an exclusive license in the field of use of briquilimab for the purpose of depleting endogenous blood stem cells in patients for whom hematopoietic cell transplantation is indicated to a patent family from Stanford University applicable to targeted conditioning that contains patents and applications directed to immunodepletion of endogenous stem cell niche prior to hematopoietic stem cell transplantation. As of March 25, 2026, this patent portfolio includes two issued U.S. patents and one European patent, as well as pending European and Hong Kong patent applications. The issued U.S. and European patents would be expected to expire in 2027, absent any applicable patent term extensions.

***Jasper Portfolio***

As of March 25, 2026, we own two patent families directed to compositions and/or methods for hematopoietic stem cell transplantation, one patent family directed to other methods of treating certain hematopoietic malignancies, three patent families directed to treating mast cell-driven disease, and one patent family directed to therapeutic efficacy testing models. These patent families include one pending U.S. provisional applications, three pending U.S. utility applications, two pending Patent Cooperation Treaty applications, and applications pending certain other jurisdictions. Any patents that grant from these applications would be expected to expire in 2042 to 2046, absent any applicable patent term extensions.

***Additional Intellectual Property***

We also rely on trade secrets, including know-how, confidential information, unpatented technologies and other proprietary information, to strengthen or enhance our competitive position, and prevent competitors from reverse engineering or copying our technologies. We maintain, as trade secrets, information relating our product candidates currently in development, as well as information related to our business strategy and business methods. However, trade secrets and confidential know-how are difficult to protect. To avoid inadvertent and improper disclosure of trade secrets, and to avoid the risks of former employees using these trade secrets to gain future employment, it is our policy to require employees, consultants and independent contractors to assign to us all rights to intellectual property they develop in connection with their employment with or services for us. We also protect our existing and developing intellectual property expressly through confidentiality provisions in agreements with third parties. There can be no assurance, however, that these agreements will be self-executing or otherwise provide meaningful protection for our trade secrets or other intellectual property or proprietary information, or adequate remedies in the event of unauthorized use or disclosure of such trade secrets or other intellectual property or proprietary information. We also seek to preserve the integrity and confidentiality of our trade secrets and other confidential information by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in the measures we take to protect and preserve our trade secrets, such measures can be breached, and we may not have adequate remedies for any such breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors.

We intend to pursue additional intellectual property protection to the extent we believe it would advance our business objectives, which may include objectives within and outside the United States. Despite our efforts to protect our intellectual property rights these rights may not be respected in the future or may be circumvented or challenged (and potentially invalidated) in a legal proceeding in any jurisdiction where we have intellectual property rights. In addition, the laws of various foreign countries may not afford the same protections or assurances to the same extent as the laws in the United States. See the section titled “Risk Factors — Risks Related to Our Intellectual Property” for additional information regarding these and other risks related to intellectual property.

**Competition**

The industry we operate in is highly competitive and dynamic, subject to rapid technological change. We have competition in the market for both our product candidates and may face competition from large pharmaceutical and biotechnology companies, smaller pharmaceutical and biotechnology companies, specialty pharmaceutical companies, generic drug companies, academic institutions, government agencies, research institutions and others.

We believe that our intellectual property, proprietary scientific knowledge, development experience and partnerships will provide us with competitive advantages in the market we operate in.

We are aware of competing products and adjacent therapies, not limited to small molecules, biologics and cell therapies, that address the same domain of conditions we are targeting. The following list of competitors indicate companies that are directly competing with our product candidate.

Competitors for our briquilimab KIT targeted therapeutic program include the following:

- Celldex Therapeutics, Inc., which is developing an antibody to KIT that is being studied in mast cell diseases;
- Blueprint Medicines, which is developing a small molecule KIT inhibitor for mast cell diseases;
- Novartis, Inc., which is developing a small molecule inhibitor to Bruton's Tyrosine Kinase for mast cell diseases;
- Sanofi Aventis, Inc., which is developing an antibody to the Interleukin 4 receptor alpha for mast cell diseases;
- Evommune, Inc., which is developing a small-molecule antagonist of MRGPRX2 in mast cell driven diseases.

**Sales and Marketing**

We do not currently have sales and marketing infrastructure to support commercial launch of our product candidates, if approved. We may build such capabilities in North America prior to potential launch of briquilimab. Outside of North America, we may rely on licensing, co-sale and co-promotion agreements with strategic partners for the commercialization of our product candidates. If we build a commercial infrastructure to support marketing in North America, such commercial infrastructure could be expected to include a targeted sales force supported by sales management, internal sales support, an internal marketing group and distribution support. To develop the appropriate commercial infrastructure internally, we would have to invest financial and management resources, some of which would have to be deployed prior to any confirmation that briquilimab will be approved.

**Research and Development**

We invest significantly in our research and development efforts, to discover and validate therapeutics while improving our processes and approach to drug making. We strive to progress candidates that can address unmet or underserved clinical needs and favor programs with well-validated targets and defined regulatory approval paths. Our R&D team has played key roles in discovering and developing a number of promising candidates over the past 20 plus years. They have leveraged experience, insights and capabilities to optimize development, along with fostering collaboration with external partners to innovate and expand into potential additional indications. Our current development-stage portfolio consists of briquilimab in mast cell driven diseases.

**Manufacturing**

We do not currently own or operate any manufacturing facility. We rely on contract manufacturing organizations to produce our drug candidates in accordance with current good manufacturing practice ("cGMP") regulations for use in our clinical trials. The manufacture of pharmaceuticals is subject to extensive cGMP regulations, which impose various procedural and documentation requirements and govern all areas of record keeping, production processes and controls, personnel and quality control. Under our license agreement with Amgen, we have received a substantial amount of drug product to support initiation of our planned clinical trials of briquilimab. In November 2019, we entered into development and manufacturing agreements with Lonza Sales AG ("Lonza") relating to the manufacturing of briquilimab and product quality testing. The facility of Lonza in Slough, United Kingdom is responsible for production and testing of drug substance. The facility of Lonza in Stein, Switzerland is responsible for production and testing of drug product. Labelling, packaging and storage of finished drug product is provided by PCI Pharma Services, in San Diego, California. Our agreement with Lonza includes certain limitations that may impact our ability to enter into supply arrangements with any other supplier without Lonza's consent. In addition, Lonza has the right to increase the prices it charges us for certain supplies depending on a number of factors, some of which are outside of our control.

**Government Regulation**

Government authorities in the United States, at the federal, state and local level, and in other countries and jurisdictions, including the European Union, extensively regulate, among other things, the research, development, testing, manufacture, pricing, reimbursement, sales, quality control, approval, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, post-approval monitoring and reporting, and import and export of pharmaceutical products, including biological products. The processes for obtaining marketing approvals in the United States and in foreign countries and jurisdictions, along with subsequent compliance with applicable statutes and regulations and other regulatory authorities, require the expenditure of substantial time and financial resources.

***Licensure and Regulation of Biologics in the United States***

In the United States, our product candidates are regulated as biological products, or biologics, under the Public Health Service Act ("PHSA") and the Federal Food, Drug, and Cosmetic Act ("FDCA") and its implementing regulations and guidance. The failure to comply with the applicable U.S. requirements at any time during the product development process, including preclinical testing, clinical testing, the approval process, or post-approval process, may subject an applicant to delays in the conduct of the study, regulatory review, and approval, and/or administrative or judicial sanctions.

An applicant seeking approval to market and distribute a new biologic in the United States generally must satisfactorily complete each of the following steps:

- preclinical laboratory tests, animal studies, and formulation studies all performed in accordance with the FDA's good laboratory practice ("GLP") regulations;
- completion of the manufacture, under cGMP conditions, of the drug substance and drug product that the sponsor intends to use in human clinical trials along with required analytical and stability testing;
- submission to the FDA of an investigational new drug ("IND") application for human clinical testing, which must become effective before human clinical trials may begin;
- approval by an institutional review board ("IRB") representing each clinical site before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials to establish the safety, potency, and purity of the product candidate for each proposed indication, in accordance with good clinical practices ("GCPs");
- preparation and submission to the FDA of a biologics license application ("BLA") for a biologic product requesting marketing for one or more proposed indications, including submission of detailed information on the manufacture and composition of the product in clinical development and proposed labelling;
- review of the product by an FDA advisory committee, where appropriate or if applicable;

- satisfactory completion of one or more FDA inspections of the manufacturing facility or facilities, including those of third parties, at which the product, or components thereof, are produced to assess compliance with cGMP requirements and to assure that the facilities, methods, and controls are adequate to preserve the product's identity, strength, quality, and purity;

- satisfactory completion of any FDA audits of the preclinical studies and clinical trial sites to assure compliance with GLP, as applicable, and GCP and the integrity of clinical data in support of the BLA;

- payment of user fees under the Prescription Drug User Fee Act ("PDUFA");

- securing FDA approval of the BLA and licensure of the new biologic product; and

- compliance with any post-approval requirements, including the potential requirement to implement a Risk Evaluation and Mitigation Strategy ("REMS") and any post-approval studies or other post-marketing commitments required by the FDA.

*Preclinical Studies and Investigational New Drug Application*

Before testing any biologic product candidate in humans, the product candidate must undergo preclinical testing. Preclinical tests include laboratory evaluations of product chemistry, formulation and stability, as well as studies to evaluate the potential for efficacy and toxicity in animal studies. The conduct of the preclinical tests and formulation of the compounds for testing must comply with federal regulations and requirements. The results of the preclinical tests, together with manufacturing information and analytical data, are submitted to the FDA as part of an IND application.

An IND is an exemption from the FDCA that allows an unapproved product candidate to be shipped in interstate commerce for use in an investigational clinical trial and a request for FDA authorization to administer such investigational product to humans. The IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions about the product or conduct of the proposed clinical trial, including concerns that human research subjects will be exposed to unreasonable health risks. In that case, the IND sponsor and the FDA must resolve any outstanding FDA concerns before the clinical trials can begin or recommence.

As a result, submission of the IND may result in the FDA not allowing the trials to commence or allowing the trial to commence on the terms originally specified by the sponsor in the IND. If the FDA raises concerns or questions either during this initial 30-day period, or at any time during the IND review process, it may choose to impose a partial or complete clinical hold. Clinical holds are imposed by the FDA whenever there is concern for patient safety, may be a result of new data, findings, or developments in clinical, preclinical, and/or chemistry, manufacturing, and controls or where there is non-compliance with regulatory requirements. A clinical hold issued by the FDA would delay either a proposed clinical trial or cause suspension of an ongoing trial, until all outstanding concerns have been adequately addressed and the FDA has notified the company that investigations may proceed. This could cause significant delays or difficulties in completing our planned clinical trial or future clinical trials in a timely manner.

*Human Clinical Trials in Support of a BLA*

Clinical trials involve the administration of the investigational product candidate to healthy volunteers or patients with the disease or condition to be treated under the supervision of a qualified principal investigator in accordance with GCP requirements. Clinical trials are conducted under protocols detailing, among other things, the objectives of the trial, inclusion and exclusion criteria, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND.

A sponsor who wishes to conduct a clinical trial outside the United States may, but need not, obtain FDA authorization to conduct the clinical trial under an IND. When a foreign clinical trial is conducted under an IND, all FDA IND requirements must be met unless waived. When a foreign clinical trial is not conducted under an IND, the sponsor must ensure that the trial complies with certain regulatory requirements of the FDA in order to use the trial as support for an IND or application for marketing approval. Specifically, the FDA requires that such trials be conducted in accordance with GCP, including review and approval by an independent ethics committee and informed consent from participants. The GCP requirements encompass both ethical and data integrity standards for clinical trials. The FDA's regulations are intended to help ensure the protection of human subjects enrolled in non-IND foreign clinical trials, as well as the quality and integrity of the resulting data. They further help ensure that non-IND foreign trials are conducted in a manner comparable to that required for clinical trials in the United States.

Further, each clinical trial must be reviewed and approved by an IRB either centrally or individually at each institution at which the clinical trial will be conducted. The IRB will consider, among other things, clinical trial design, patient informed consent, ethical factors, the safety of human subjects, and the possible liability of the institution. An IRB must operate in compliance with FDA regulations. The FDA, IRB, or the clinical trial sponsor may suspend or discontinue a clinical trial at any time for various reasons, including a finding that the clinical trial is not being conducted in accordance with FDA requirements or that the participants are being exposed to an unacceptable health risk. Clinical testing also must satisfy extensive GCP rules and the requirements for informed consent.

Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board ("DSMB") or Independent Data Safety Monitoring Committee ("IDMC"). This group may recommend continuation of the trial as planned, changes in trial conduct, or cessation of the trial at designated check points based on certain available data from the trial to which only the DSMB or IDMC has access.

Clinical trials typically are conducted in three sequential phases, but the phases may overlap or be combined. Additional studies may be required after approval.

- Phase 1 clinical trials are initially conducted in a limited population to test the product candidate for safety, including adverse effects, dose tolerance, absorption, metabolism, distribution, excretion, and pharmacodynamics in healthy humans or, on occasion, in patients, such as cancer patients.

- Phase 2 clinical trials are generally conducted in a limited patient population to identify possible adverse effects and safety risks, evaluate the efficacy of the product candidate for specific targeted indications and determine dose tolerance and optimal dosage. Multiple Phase 2 clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more costly Phase 3 clinical trials.

- Phase 3 clinical trials proceed if the Phase 2 clinical trials demonstrate that a dose range of the product candidate is potentially effective and has an acceptable safety profile. Phase 3 clinical trials are undertaken within an expanded patient population to further evaluate dosage, provide substantial evidence of clinical efficacy, and further test for safety in an expanded and diverse patient population at multiple, geographically dispersed clinical trial sites. A well-controlled, statistically robust Phase 3 trial may be designed to deliver the data that regulatory authorities will use to decide whether or not to approve, and, if approved, how to appropriately label a biologic; such Phase 3 studies are referred to as "pivotal."

In some cases, the FDA may approve a BLA for a product but require the sponsor to conduct additional clinical trials to further assess the product's safety and effectiveness after licensure. Such post-approval studies are typically referred to as Phase 4 clinical trials. These studies are used to gain additional experience from the treatment of patients in the intended therapeutic indication and to document a clinical benefit in the case of biologics approved under accelerated approval regulations. The FDA may require a post-approval study to be underway prior to approval or within a specified time period following approval, and the submission of progress reports for the study. The FDA is authorized to initiate enforcement action for the failure to conduct with due diligence a required post-approval study, including a failure to meet any required conditions specified by the FDA or to submit timely reports. If the FDA approves a product while a company has ongoing clinical trials that were not necessary for approval, a company may be able to use the data from these clinical trials to meet all or part of any Phase 4 clinical trial requirement or to request a change in the product labeling. The failure to exercise due diligence with regard to conducting Phase 4 clinical trials could result in withdrawal of approval for products.

Information about applicable clinical trials must be submitted within specific timeframes to the NIH for public dissemination on its ClinicalTrials.gov website.

*Compliance with cGMP Requirements*

Before approving a BLA, the FDA typically will 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 comply with cGMP requirements and adequate to assure consistent production of the product within required specifications. The PHSA emphasizes the importance of manufacturing control for products like biologics whose attributes cannot be precisely defined.

Manufacturers and others involved in the manufacture and distribution of products must also register their establishments with the FDA and certain state agencies. Both domestic and foreign manufacturing establishments must register and provide additional information to the FDA upon their initial participation in the manufacturing process. Any product manufactured by or imported from a facility that has not registered, whether foreign or domestic, is deemed misbranded under the FDCA. Establishments may be subject to periodic unannounced inspections by government authorities to ensure compliance with cGMPs and other laws. Inspections must follow a "risk-based schedule" that may result in certain establishments being inspected more frequently. Manufacturers may also have to provide, on request, electronic or physical records regarding their establishments. Delaying, denying, limiting, or refusing inspection by the FDA may lead to a product being deemed to be adulterated.

*Review and Approval of a BLA*

The results of product candidate development, preclinical testing, and clinical trials, including negative or ambiguous results as well as positive findings, are submitted to the FDA as part of a BLA requesting a license to market the product. The BLA must contain extensive manufacturing information and detailed information on the composition of the product and proposed labeling as well as payment of a user fee. Under the Prescription Drug User Fee Act, as amended ("PDUFA"), each BLA must be accompanied by a significant user fee, which is adjusted on an annual basis. The sponsor of a licensed BLA is also subject to an annual program fee. Certain exceptions and waivers are available for some of these fees, such as an exception from the application fee for products with orphan designation and a waiver for certain small businesses.

The FDA has 60 days after submission of the application to conduct an initial review to determine whether it is sufficient to accept for filing based on the agency's threshold determination that it is sufficiently complete to permit substantive review. Once the submission has been accepted for filing, the FDA begins an in-depth review of the application. Under the goals and policies agreed to by the FDA under PDUFA, the FDA has ten months in which to complete its initial review of a standard application and respond to the applicant, and six months for a priority review of the application. The FDA does not always meet its PDUFA goal dates for standard and priority BLAs. Products are eligible for priority review (a status assigned by the FDA at filing) if the application is for a product intended to treat a serious or life-threatening condition and the product, if approved, would provide a significant improvement in safety or effectiveness compared to any existing licensed products for the same intended use. The FDA has substantial discretion in the approval process and may refuse to file any application or not approve an BLA if the FDA determines that the data are insufficient for approval. The review process may often be significantly extended by FDA requests for additional information or clarification. The review process and the PDUFA goal date may be extended by three months if the FDA requests or if the applicant otherwise provides additional information or clarification regarding information already provided in the submission within the last three months before the PDUFA goal date.

Under the PHSA, the FDA may approve a BLA if it determines that the product is safe, pure, and potent, and the facility where the product will be manufactured meets standards designed to ensure that it continues to be safe, pure, and potent. On the basis of the FDA's evaluation of the application and accompanying information, including the results of the inspection of the manufacturing facilities and any FDA audits of preclinical and clinical trial sites to assure compliance with GCPs, 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. If the application is not approved, the FDA will issue a complete response letter, or CRL, which will contain the conditions that must be met in order to secure final approval of the application, and when possible will outline recommended actions the sponsor might take to obtain approval of the application. Sponsors that receive a CRL may submit to the FDA information that represents a complete response to the issues identified by the FDA.

The FDA may also refer the application to an advisory committee for review, evaluation, and recommendation as to whether the application should be approved. In particular, the FDA may refer applications for novel biologic products or biologic products that present difficult questions of safety or efficacy to an advisory committee. Typically, an advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates, and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

If the FDA approves a new product, it may limit the approved indication(s) for use of the product. It may also require that contraindications, warnings, or precautions be included in the product labeling. In addition, the FDA may call for post-approval studies, including Phase 4 clinical trials, to further assess the product's efficacy and/or safety after approval. The agency may also require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution restrictions or other risk management mechanisms, including a Risk Evaluation and Mitigation Strategy ("REMS"), to help ensure that the benefits of the product outweigh the potential risks. REMS can include medication guides, communication plans for healthcare professionals, and elements to assure safe use. Additionally, post-approval, many types of changes to the approved product, such as adding new indications, changing manufacturing processes and adding labeling claims, are subject to further testing requirements and FDA review and approval.

*Expedited Review Programs*

The FDA is authorized to expedite the review of BLAs in several ways. Under the Fast Track program, the sponsor of a product candidate may request the FDA to designate the product for a specific indication as a Fast Track product concurrent with or after the filing of the IND. Candidate products are eligible for Fast Track designation if they are intended to treat a serious or life-threatening condition and demonstrate the potential to address unmet medical needs for the condition. Fast Track designation applies to the combination of the product candidate and the specific indication for which it is being studied. In addition to other benefits, such as the ability to have greater interactions with the FDA, the FDA may initiate review of sections of a Fast Track application before the application is complete, a process known as rolling review.

Any product candidate submitted to the FDA for marketing, including under a Fast Track program, may be eligible for other types of FDA programs intended to expedite development and review, such as breakthrough therapy designation, priority review and accelerated approval.

- Breakthrough therapy designation. To qualify for the breakthrough therapy program, product candidates must be intended to treat a serious or life-threatening disease or condition and preliminary clinical evidence must indicate that such product candidates may demonstrate substantial improvement on one or more clinically significant endpoints over existing therapies. The FDA will seek to ensure the sponsor of a breakthrough therapy product candidate receives intensive guidance on an efficient drug development program, intensive involvement of senior managers and experienced staff on a proactive, collaborative and cross-disciplinary review and rolling review.

- Priority review. A product candidate is eligible for priority review if it treats a serious condition and, if approved, it would be a significant improvement in the safety or effectiveness of the treatment, diagnosis or prevention compared to marketed products. The FDA aims to complete its review of priority review applications within six months as opposed to 10 months for standard review.

- Accelerated approval. Drug or biologic products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval. Accelerated approval means that a product candidate may be approved on the basis of adequate and well controlled clinical trials establishing that the product candidate has an effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit, or on the basis of an effect on a clinical endpoint other than survival or irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity and prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require that a sponsor of a drug or biologic product candidate receiving accelerated approval perform adequate and well controlled post-marketing clinical trials. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials.

- Regenerative advanced therapy. With passage of the 21st Century Cures Act (the "Cures Act") in December 2016, Congress authorized the FDA to accelerate review and approval of products designated as regenerative advanced therapies. A product is eligible for this designation if it is a regenerative medicine therapy that is intended to treat, modify, reverse or cure a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product candidate has the potential to address unmet medical needs for such disease or condition. The benefits of a regenerative advanced therapy designation include early interactions with the FDA to expedite development and review, benefits available to breakthrough therapies, potential eligibility for priority review and accelerated approval based on surrogate or intermediate endpoints.

None of these expedited programs change the standards for approval but they may help expedite the development or approval process of product candidates.

*Post-Approval Regulation*

If regulatory approval for marketing of a product or new indication for an existing product is obtained, the sponsor will be required to comply with all regular post-approval regulatory requirements as well as any post-approval requirements that the FDA have imposed as part of the approval process. The sponsor will be required to report certain safety and other postmarketing information and submissions, provide updated safety and efficacy information, implement product tracking and tracing requirements, and comply with requirements concerning advertising and promotional labeling requirements. Manufacturers and certain of their subcontractors are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with ongoing regulatory requirements, including cGMP regulations, which impose certain procedural and documentation requirements upon manufacturers. BLA holders using contract manufacturers, laboratories, or packagers are responsible for the selection and monitoring of qualified firms, and, in certain circumstances, qualified suppliers to these firms. These firms and, where applicable, their suppliers are subject to inspections by the FDA at any time, and the discovery of violative conditions, including failure to conform to cGMP, could result in enforcement actions that interrupt the operation of any such facilities or the ability to distribute products manufactured, processed or tested by them. Accordingly, the sponsor and its third-party manufacturers must continue to expend time, money, and effort in the areas of production and quality control to maintain compliance with cGMP regulations and other regulatory requirements.

A product may also be subject to official lot release, meaning that the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. If the product is subject to official lot release, the manufacturer must submit samples of each lot, 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, to the FDA. The FDA may in addition perform certain confirmatory tests on lots of some products before releasing the lots for distribution. Finally, the FDA will conduct laboratory research related to the safety, purity, potency, and effectiveness of pharmaceutical products.

Once an approval is granted, the FDA may withdraw the 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 trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- investigation or additional study obligations;
- adverse publicity or communications to prescribers or patients about specific information or issues;
- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning or untitled letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product license approvals;
- product recall, seizure or detention, or refusal to permit the import or export of products; or
- injunctions, consent decrees or the imposition of civil or criminal penalties.

Pharmaceutical products may be promoted only for the approved indications and in accordance with the provisions of the approved label. Although healthcare providers may prescribe products for uses not described in the drug's labeling, known as off-label uses, in their professional judgment, drug manufacturers are prohibited from soliciting, encouraging or promoting unapproved uses of a product. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

The FDA strictly regulates the marketing, labeling, advertising, and promotion of prescription drug products placed on the market. This regulation includes, among other things, standards and regulations for direct-to-consumer advertising, communications regarding unapproved uses, industry-sponsored scientific and educational activities, and promotional activities involving the Internet and social media. Promotional claims about a drug's safety or effectiveness are prohibited before the drug is approved. After approval, a drug product generally may not be promoted for uses that are not approved by the FDA, as reflected in the product's prescribing information.

If a company is found to have promoted off-label uses, it may become subject to adverse public relations and administrative and judicial enforcement by the FDA, the Department of Justice or the Office of the Inspector General of the Department of Health and Human Services, as well as state authorities. This could subject a company to a range of penalties that could have a significant commercial impact, including civil and criminal fines and agreements that materially restrict the manner in which a company promotes or distributes drug products. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed.

***Regulation and Procedures Governing Approval of Medicinal Products in the European Union***

In order to market any product outside of the United States, a company must also comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety, and efficacy, and governing, among other things, clinical trials, marketing authorization, commercial sales, and distribution of drug products. Whether or not it obtains FDA approval for a product, an applicant will need to obtain the necessary approvals by the comparable foreign regulatory authorities before it can commence clinical trials or marketing of the product in those countries or jurisdictions. Specifically, the process governing approval of medicinal products in the European Union generally follows the same lines as in the United States. It entails satisfactory completion of preclinical studies and adequate and well-controlled clinical trials to establish the safety and efficacy of the product for each proposed indication. It also requires the submission to the relevant competent authorities of a marketing authorization application ("MAA") and granting of a marketing authorization by these authorities before the product can be marketed and sold in the European Union.

*Clinical Trial Approval*

Pursuant to Clinical Trials Directive 2001/20/EC and the Directive 2005/28/EC on GCP, a system for the approval of clinical trials in the European Union was implemented through national legislation of the member states. Under this system, an applicant must obtain approval from the competent national authority of a European Union member state in which the clinical trial is to be conducted, or in multiple member states if the clinical trial is to be conducted in a number of member states. Furthermore, the applicant may only start a clinical trial at a specific site after the competent ethics committee has issued a favorable opinion. The clinical trial application must be accompanied by an investigational medicinal product dossier with supporting information prescribed by Directive 2001/20/EC and Directive 2005/28/EC and corresponding national laws of the member states and further detailed in applicable guidance documents.

In April 2014, the European Union adopted a new Clinical Trials Regulation (EU) No 536/2014, which became effective on January 31, 2022. It overhauled the current system of approvals for clinical trials in the European Union. Specifically, the new legislation, which is directly applicable in all member states, is aimed at simplifying and streamlining the approval of clinical trials in the European Union. For instance, the new Clinical Trials Regulation provides for a streamlined application procedure via a single-entry point, the Clinical Trials Information System ("CTIS"), and strictly defined deadlines for the assessment of clinical trial applications.

The conduct of all clinical trials commenced in the European Union prior to January 31, 2022 will continue to be bound by the previously applicable provisions. However, if a clinical trial continues for more than three years after January 31, 2022, the Clinical Trials Regulation will at that time begin to apply to the clinical trial. As of January 31, 2023, all new trial authorizations must be applied for under the Clinical Trials Regulation and utilize CTIS.

*Marketing Authorization*

To obtain a marketing authorization for a product under the European Union regulatory system, an applicant must submit an MAA, either under a centralized procedure administered by the EMA or one of the procedures administered by competent authorities in European Union Member States (decentralized procedure, national procedure, or mutual recognition procedure). A marketing authorization may be granted only to an applicant established in the European Union. Regulation (EC) No 1901/2006 provides that prior to obtaining a marketing authorization in the European Union, an applicant must demonstrate compliance with all measures included in an EMA approved Pediatric Investigation Plan ("PIP") covering all subsets of the pediatric population, unless the EMA has granted a product specific waiver, class waiver, or a deferral for one or more of the measures included in the PIP.

The centralized procedure provides for the grant of a single marketing authorization by the European Commission that is valid for all European Union member states. Pursuant to Regulation (EC) No. 726/2004, the centralized procedure is compulsory for specific products, including for medicines produced by certain biotechnological processes, products designated as orphan medicinal products, advanced therapy products and products with a new active substance indicated for the treatment of certain diseases, including products for the treatment of cancer. For products with a new active substance indicated for the treatment of other diseases and products that are highly innovative or for which a centralized process is in the interest of patients, the centralized procedure may be optional. Manufacturers must demonstrate the quality, safety, and efficacy of their products to the EMA, which provides an opinion regarding the MAA. The European Commission grants or refuses marketing authorization in light of the opinion delivered by the EMA.

Under the centralized procedure, the CHMP established at the EMA is responsible for conducting an initial assessment of a product. Under the centralized procedure in the European Union, the maximum timeframe for the evaluation of an MAA is 210 days, excluding clock stops when additional information or written or oral explanation is to be provided by the applicant in response to questions of the CHMP. Accelerated evaluation may be granted by the CHMP in exceptional cases, when a medicinal product is of major interest from the point of view of public health and, in particular, from the viewpoint of therapeutic innovation. If the CHMP accepts such a request, the time limit of 210 days will be reduced to 150 days, but it is possible that the CHMP may revert to the standard time limit for the centralized procedure if it determines that it is no longer appropriate to conduct an accelerated assessment.

**Coverage, Pricing, and Reimbursement**

Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we may seek regulatory approval by the FDA or other government authorities. In the United States and markets in other countries, patients who are prescribed treatments for their conditions and providers performing the prescribed services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Patients are unlikely to use any product candidates we may develop unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of such product candidates. Even if any product candidates we may develop are approved, sales of such product candidates will depend, in part, on the extent to which third-party payors, including government health programs in the United States such as Medicare and Medicaid, commercial health insurers, and managed care organizations, provide coverage, and establish adequate reimbursement levels for, such product candidates. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Third-party payors are increasingly challenging the prices charged, examining the medical necessity, and reviewing the cost-effectiveness of medical products and services and imposing controls to manage costs. Third-party payors may limit coverage to specific products on an approved list, also known as a formulary, which might not include all of the approved products for a particular indication.

In order to secure coverage and reimbursement for any product that might be approved for sale, a company may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product, in addition to the costs required to obtain FDA or other comparable marketing approvals. Nonetheless, product candidates may not be considered medically necessary or cost-effective. A decision by a third-party payor not to cover any product candidates we may develop could reduce physician utilization of such product candidates once approved and have a material adverse effect on our sales, results of operations and financial condition. Additionally, a payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage and reimbursement for the product, and the level of coverage and reimbursement can differ significantly from payor to payor. Third-party reimbursement and coverage may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development. In addition, any 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 any companion diagnostics.

The containment of healthcare costs also has become a priority of federal, state and foreign governments and the prices of pharmaceuticals have been a focus in this effort. Governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement, and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit a company's revenue generated from the sale of any approved products. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which a company or its collaborators receive marketing approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

If we obtain approval in the future to market in the United States any product candidates we may develop, we may be required to provide discounts or rebates under government healthcare programs or to certain government and private purchasers in order to obtain coverage under federal healthcare programs such as Medicaid. Participation in such programs may require us to track and report certain drug prices. We may be subject to fines and other penalties if we fail to report such prices accurately.

Outside the United States, ensuring adequate coverage and payment for any product candidates we may develop will face challenges. Pricing of prescription pharmaceuticals is subject to governmental control in many countries. Pricing negotiations with governmental authorities can extend well beyond the receipt of regulatory marketing approval for a product and may require us to conduct a clinical trial that compares the cost-effectiveness of any product candidates we may develop to other available therapies. The conduct of such a clinical trial could be expensive and result in delays in our commercialization efforts.

In the European Union, pricing and reimbursement schemes vary widely from country to country. Some countries provide that products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost-effectiveness of a particular product candidate to currently available therapies (so called health technology assessments) in order to obtain reimbursement or pricing approval. For example, the European Union provides options for its member states to restrict the range of products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. European Union member states may approve a specific price for a product, or they may instead adopt a system of direct or indirect controls on the profitability of the company placing the product on the market. Other member states allow companies to fix their own prices for products but monitor and control prescription volumes and issue guidance to physicians to limit prescriptions. Recently, many countries in the European Union have increased the amount of discounts required on pharmaceuticals and these efforts could continue as countries attempt to manage healthcare expenditures, especially in light of the severe fiscal and debt crises experienced by many countries in the European Union. The downward pressure on healthcare costs in general, particularly prescription products, has become intense. As a result, increasingly high barriers are being erected to the entry of new products. 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 European Union member states, and parallel trade (arbitrage between low-priced and high-priced member states), can further reduce prices. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products, if approved in those countries.

*Healthcare Law and Regulation*

Healthcare providers and third-party payors play a primary role in the recommendation and prescription of drug products that are granted marketing approval. Arrangements with providers, consultants, third-party payors, and customers are subject to broadly applicable fraud and abuse, anti-kickback, false claims laws, patient privacy laws and regulations and other healthcare laws and regulations that may constrain our business and/or financial arrangements. Restrictions under applicable federal and state healthcare laws and regulations, include the following:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, paying, receiving, or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid;

- the federal civil and criminal false claims laws, including the civil False Claims Act, and civil monetary penalties laws, which prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false, fictitious, or fraudulent or knowingly making, using, or causing to made or used a false record or statement to avoid, decrease, or conceal an obligation to pay money to the federal government;

- the FCPA, which prohibits companies and their intermediaries from making, or offering or promising to make improper payments to non-U.S. officials for the purpose of obtaining or retaining business or otherwise seeking favorable treatment; and

- the federal transparency requirements known as the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies to report annually to the CMS within the U.S. Department of Health and Human Services, information related to payments and other transfers of value made by that entity to physicians and certain other licensed health care practitioners, as defined by such law, and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members.

Similar federal, state and foreign fraud and abuse laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services. Such laws are generally broad and are enforced by various state agencies and private actions. Also, many states have similar fraud and abuse statutes or regulations that may be broader in scope and may apply regardless of payor, in addition to items and services reimbursed under Medicaid and other state programs. Further, some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring pharmaceutical manufacturers to report information related to payments to physicians and other healthcare providers or marketing expenditures. In addition, certain state and local laws require the registration of pharmaceutical sales representatives in the jurisdiction. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), thus complicating compliance efforts.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies regularly scrutinize interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Failure to comply with these laws described above or any other governmental regulations that apply to us, may subject us to, without limitation, civil, criminal, and administrative penalties, damages, monetary fines, disgorgement, exclusion from government-funded healthcare programs, such as Medicare and Medicaid or similar programs in other countries or jurisdictions, integrity oversight and reporting obligations to resolve allegations of non-compliance, imprisonment, contractual damages, reputational harm, diminished profits and future earnings and curtailment or restructuring of our operations, any of which could adversely affect our business, financial condition and results of operations.

**Employees and Human Capital**

As of December 31, 2025, we employed 22 full-time employees. The 22 full-time employees were engaged in research and development, operations, finance, and business development. Five employees held Ph.D. degrees and one held an M.D. degree. Our employees are not represented by labor unions or covered under any collective bargaining agreements. We consider our relationship with our employees to be good.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and additional employees. The principal purposes of our equity incentive plans are to attract, retain and motivate selected employees and directors through the granting of stock-based compensation awards.

**Facilities**

We lease a total of approximately 25,900 square feet of space across two buildings for our headquarters in Redwood City, California under a single lease agreement that expires in August 2026. Thereafter, at our option, we may extend the term for an additional five years to August 2031. In February 2026, we sublet approximately 13,400 square feet of the space under a short-term sublease agreement that runs through June 2026. We believe that our existing facilities are adequate to meet our current needs, and that suitable additional alternative spaces will be available in the future on commercially reasonable terms.

**Indemnification and Insurance**

Our business exposes us to potential liability including, but not limited to, potential liability for (i) non-compliance with applicable laws and regulations, and (ii) employment-related claims. In certain circumstances, we may also be liable for the acts or omissions of others, such as suppliers of goods or services.

We attempt to manage our potential liability to third parties through contractual protection (such as indemnification and limitation of liability provisions) in our contracts and through insurance. The contractual indemnification provisions vary in scope and generally do not protect us against all potential liabilities. In addition, in the event that we seek to enforce such an indemnification provision, the indemnifying party may not have sufficient resources to fully satisfy its indemnification obligations or may otherwise not comply with its contractual obligations.

We currently maintain insurance coverage with limits we believe to be appropriate. The coverage provided by such insurance may not be adequate for all claims made, and such claims may be contested by applicable insurance carriers.

**Organization**

We were organized as a corporation under the laws of the State of Delaware on August 13, 2019 under the name “Amplitude Healthcare Acquisition Corporation”. On September 24, 2021, we consummated the previously announced business combination (the “Business Combination”) among us, Ample Merger Sub, Inc. (“Merger Sub”) and a private Delaware corporation that is now our wholly-owned subsidiary and named Jasper Tx Corp. (formerly known as Jasper Therapeutics) (“Old Jasper”). Pursuant to the terms of the Business Combination, a Business Combination or Reverse Recapitalization for accounting purposes between AMHC and Old Jasper was effected through the merger of Merger Sub with and into Old Jasper with Old Jasper surviving as AMHC’s wholly-owned subsidiary. In connection with the Business Combination, AMHC changed its name from Amplitude Healthcare Acquisition Corporation to Jasper Therapeutics, Inc.

**Website Access to SEC Filings**

We file annual, quarterly and special reports, proxy statements and other information with the Securities and Exchange Commission (the “SEC”). The SEC maintains an Internet website at http://www.sec.gov that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC, including Jasper. We maintain an Internet website at www.jaspertx.com. The information contained on our website or that can be accessed through our website does not constitute a part of this report. We make available, free of charge through our Internet website, our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), as soon as reasonably practicable after we electronically file or furnish this information to the SEC.

## ITEM 1A. RISK FACTORS

*Investing in our common stock involves a high degree of risk. Before making an investment decision, you should carefully consider the risks described below before deciding whether to invest in our common stock. Before you make a decision to buy our securities, in addition to the risks and uncertainties discussed above under "Cautionary Note Regarding Forward-Looking Statements", you should carefully consider the specific risks set forth herein. If any of these risks actually occur, it may materially harm our business, financial condition, liquidity and results of operations. As a result, the market price of our securities could decline, and you could lose all or part of your investment. Additionally, the risks and uncertainties described below are not the only risks and uncertainties that we face. Additional risks and uncertainties not presently known to us or that we currently believe to be immaterial may become material and adversely affect our business.*

***Risk Factor Summary***

Below is a summary of the principal factors that make an investment in our common stock speculative or risky. This summary does not address all of the risks that we face. Additional discussion of the risks summarized in this risk factor summary, and other risks that we face, can be found below and should be carefully considered, together with other information in this Annual Report on Form 10-K and our other filings with the SEC before making an investment decision regarding our common stock.

- Risks Related to Our Financial Position and Need for Additional Capital, including, among others, that:
    - We have incurred significant net losses and negative operating cash flows since our inception which raises substantial doubt about our ability to continue as a going concern. We expect to incur net losses for the foreseeable future and may never achieve or maintain profitability.
    - We will need substantial additional funding, which may not be available on acceptable terms, or at all. If we are unable to raise capital when needed, we would be forced to delay, reduce or eliminate our research and product development programs or future commercialization efforts.
    - As a result of our history of losses and negative cash flows from operations, our management has performed an analysis and concluded that substantial doubt exists about our ability to continue as a going concern, and we will need to raise additional financing to continue our products' development.
- Risks Related to Discovery, Development, Manufacturing and Commercialization, including, among others, that:
    - We are substantially dependent on the success of our most advanced product candidate, briquilimab. If we are unable to complete development of, obtain approval for and commercialize our product candidates, including briquilimab, in a timely manner or at all, our business will be harmed.
    - Delays in the commencement or completion of clinical trials could result in increased costs to us and delay our ability to establish strategic collaborations.
    - We may not be successful in our efforts to develop and commercialize briquilimab in additional indications or to identify additional product candidates. If these efforts are unsuccessful, we may never become a commercial stage company or generate any revenues.

- We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

- If any of our product candidates cause serious adverse events, undesirable side effects or unexpected characteristics, such events, side effects or characteristics could delay or prevent regulatory approval of the product candidate, limit our commercial potential or result in significant negative consequences following any potential marketing approval.

- Results of preclinical studies and early clinical trials may not be predictive of results of future clinical trials, and such results do not guarantee approval of a product candidate by regulatory authorities. In addition, our clinical trials to date have been limited in scope, and results received to date may not be replicated in expanded or additional future clinical trials.

- We have never obtained regulatory approval for a drug, may never receive regulatory approval for any of our product candidates, and may therefore never generate revenues from product sales.

- We face significant competition in an environment of rapid technological change, and there is a possibility that our competitors may achieve regulatory approval before us or develop therapies that are safer or more advanced or effective than ours, which may harm our financial condition and our ability to successfully market or commercialize our product candidates.

- Risks Related to Regulatory Review, including, among others, that:

  - If clinical trials of our product candidates fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of such product candidates.

- Risks Related to Our Relationships with Third Parties, including, among others, that:

  - We rely on third parties to conduct our preclinical and clinical trials and will rely on them to perform other tasks for us. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or comply with regulatory requirements, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

  - We currently rely on a single manufacturer for our clinical supply of our product candidates. In the event of a loss of this manufacturer, or a failure by such manufacturer to comply with FDA regulations, we may not be able to find an alternative source on commercially reasonable terms, or at all. In addition, third-party manufacturers and any third-party collaborators may be unable to successfully scale-up manufacturing of our current or future product candidates in sufficient quality and quantity, which would delay or prevent us from developing our product candidates and commercializing approved products, if any.

- Risks Related to Our Intellectual Property, including, among others, that:
    - We are highly dependent on intellectual property licensed from third parties, and termination of any of these licenses could result in the loss of significant rights, which would harm our business.
    - Our commercial success depends on our ability to obtain, maintain and protect our intellectual property and proprietary technology.
- Risks Related to Ownership of Our Common Stock and Warrants, including, among others, that:
    - We have incurred and will continue to incur significant increased expenses and administrative burdens as a public company, which could negatively impact our business, financial condition and results of operations.

**Risks Related to Our Financial Position and Need for Additional Capital**

***We have incurred significant net losses and negative operating cash flows since our inception which raises substantial doubt about our ability to continue as a going concern. We expect to incur net losses for the foreseeable future and may never achieve or maintain profitability.***

We are a clinical-stage biotechnology company dedicated to enabling cures through therapeutics targeting mast and hematopoietic stem cells and have a limited operating history. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate effect or an acceptable safety profile, gain regulatory approval and become commercially viable. We have no products approved for commercial sale and have not generated any revenue from product sales to date, and we continue to incur significant research and development and other expenses related to our ongoing operations. As a result, we are not profitable and have incurred losses and negative operating cash flows in each period since our inception, which raises substantial doubt about our ability to continue as a going concern beyond one year from the date of filing of this Annual Report on Form 10-K. See below risk factor, "As a result of our history of losses and negative cash flows from operations, our management has performed an analysis and concluded that substantial doubt exists about our ability to continue as a going concern, and we will need to raise additional financing to continue our products' development." for additional details. For the years ended December 31, 2025 and 2024, we reported net losses of $75.8 million and $71.3 million, respectively. For the years ended December 31, 2025 and 2024, we reported negative operating cash flows of $77.2 million and $62.6 million, respectively. As of December 31, 2025, we had an accumulated deficit of $316.7 million. We have devoted all of our efforts to organizing and staffing our company, business and scientific planning, raising capital, acquiring and developing technology, identifying potential product candidates, undertaking research and preclinical studies of potential product candidates, developing manufacturing capabilities and evaluating a clinical path for our pipeline programs. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future, and we expect these losses to increase as we continue our research and development of, and seek regulatory approvals for, our product candidates.

The net losses we incur may fluctuate significantly from quarter to quarter. We anticipate that our expenses will increase substantially if and as we:

- continue the clinical development of briquilimab in chronic diseases such as CSU and Chronic Inducible Urticaria ("CIndU");
- elect to continue development of briquilimab in allergic asthma;
- continue our current research programs and development of other potential product candidates from our current research programs;

- seek to identify additional product candidates and research programs;
- initiate preclinical testing and clinical trials for any other product candidates we identify and develop;
- maintain, expand, enforce, defend and protect our intellectual property portfolio, and provide reimbursement of third-party expenses related to our patent portfolio;
- seek marketing approvals for any product candidates that successfully complete clinical trials;
- ultimately establish a sales, marketing and distribution infrastructure to commercialize any product candidates for which we may obtain marketing approval;
- adapt our regulatory compliance efforts to incorporate requirements applicable to any approved product candidates;
- hire additional research and development and clinical personnel;
- hire commercial personnel and advance market access and reimbursement strategies;
- add operational, financial and management information systems and personnel, including personnel to support our product development;
- acquire or in-license product candidates, intellectual property and technologies;
- develop or in-license manufacturing and distribution technologies;
- should we decide to do so and receive approval for any of our product candidates, build and maintain, or purchase and validate, commercial-scale manufacturing facilities designed to comply with current Good Manufacturing Practices ("cGMP") requirements; and
- incur additional legal, accounting and other expenses in operating as a public company.

As a company, we have not completed clinical development of any product candidate and expect that it will be several years, if ever, before we have a product candidate ready for commercialization. To become and remain profitable, we must develop and, either directly or through collaborators, eventually commercialize a product or products with significant market potential. This will require us to be successful in a range of challenging activities, including identifying product candidates, completing preclinical testing and clinical trials of product candidates, obtaining marketing approval for these product candidates, manufacturing, marketing and selling those products for which we may obtain marketing approval and satisfying any post-marketing requirements.

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. Our product candidates and research programs are currently only in the early stages of development. Because of the numerous risks and uncertainties associated with developing product candidates, we are unable to predict the extent of any future losses or when we will become profitable, if at all. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

***We will need substantial additional funding, which may not be available on acceptable terms, or at all. If we are unable to raise capital when needed, we would be forced to delay, reduce or eliminate our research and product development programs or future commercialization efforts.***

We expect to spend substantial amounts of cash to conduct further research and development and preclinical testing and clinical trials of our product candidates, to seek regulatory approvals for our product candidates and to launch and commercialize any product candidates for which we receive regulatory approval. Furthermore, we expect to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in order to maintain our continuing operations. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and product development programs or future commercialization efforts. For example, advancing any future clinical studies in asthma would be based on an evaluation of the competitive landscape, the potential for strategic partnerships and capital availability. As of December 31, 2025, our cash and cash equivalents were $28.7 million and we had an accumulated deficit of $316.7 million. Although we raised net proceeds of $27.5 million in September 2025 in connection with the issuance and sale of 11,670,707 shares of common stock, pre-funded warrants to purchase up to an aggregate of 675,000 shares of common stock and common warrants to purchase up to an aggregate of 12,345,707 shares of common stock, we will need to raise additional financing to continue our products' development for the foreseeable future, and will continue to need to do so until we become profitable. Our future financing requirements will depend on many factors, including:

- the initiation, progress, timing, costs and results of preclinical studies and clinical trials for our product candidates;
- the costs of continuing to build our technology platform for use in developing our product candidates;
- the costs of developing, acquiring or in-licensing additional targeted therapies to use in combination with briquilimab and other product candidates we may develop;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property and proprietary rights and defending intellectual property-related claims in the United States and internationally;
- the number and characteristics of product candidates that we develop or may in-license;
- our ability to establish and maintain collaborations on favorable terms, if at all;
- the achievement of milestones or occurrence of other developments that trigger payments under any collaboration agreements we enter into;
- the outcome, timing and cost of meeting regulatory requirements established by the U.S. Food and Drug Administration (the "FDA"), the European Medicines Agency (the "EMA") and other comparable foreign regulatory authorities;
- the cost and timing of completion of commercial-scale outsourced manufacturing activities;
- the cost of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval in regions where we choose to commercialize our products on our own; and
- the costs of operating as a public company.

Conducting preclinical testing 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, even if we successfully develop product candidates and those are approved, we 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 several years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives.

We currently have an effective universal shelf registration statement on Form S-3, which we filed with the SEC on March 19, 2025, and which was declared effective on March 26, 2025 and will expire on March 26, 2028 (the "Shelf Registration Statement"). Pursuant to the Shelf Registration Statement, we may offer from time to time up to an aggregate of $300.0 million of securities, including any combination of common stock, preferred stock, debt securities, warrants, rights, units and depositary shares. On March 19, 2025, we entered into an Open Market Sale Agreement$^{SM}$ with Jefferies LLC (the "Agent"), pursuant to which we may offer and sell through or to the Agent, as sales agent or principal, shares of common stock from time to time (the "ATM Offering"). On March 26, 2025, we filed with the SEC a prospectus under the Shelf Registration Statement in connection with the ATM Offering (the "ATM Prospectus"), pursuant to which we may offer and sell shares of our common stock having an aggregate offering price of up to $100.0 million. As of December 31, 2025, we have issued and sold an aggregate of 1,231,447 shares of our common stock for net proceeds of approximately $6.5 million pursuant to the ATM Prospectus.

On September 22, 2025, we completed an underwritten public offering of our common stock (the "September Offering") pursuant to the Shelf Registration Statement. In the September Offering, we sold (i) an aggregate of 11,670,707 shares of common stock and accompanying warrants (the "Common Warrants") to purchase up to an aggregate of 11,670,707 shares of common stock and (ii) pre-funded warrants to purchase up to an aggregate of 675,000 shares of common stock (the "Pre-Funded Warrants") and accompanying Common Warrants to purchase up to an aggregate of 675,000 shares of common stock. Upon the closing of the September Offering, we received net proceeds of $27.5 million, after deducting underwriting discounts, commissions and other offering expenses.

As of March 25, 2026, $93.5 million remains allocated and available under the ATM Prospectus and approximately $170.0 million remains available and unallocated under the Shelf Registration Statement.

If we raise additional capital by issuing equity securities, the percentage ownership of our existing stockholders may be reduced, and accordingly these stockholders may experience substantial dilution. We may also issue equity securities that provide for rights, preferences and privileges senior to those of our common stock. Given our need for cash and that equity issuances are the most common type of fundraising for similarly situated companies, the risk of dilution is particularly significant for our stockholders.

Any additional fundraising efforts may divert our management from our day-to-day activities, which may adversely affect our ability to develop and commercialize product candidates. We cannot be certain that additional funding will be available on acceptable terms, or at all. We have no committed source of additional capital and, if we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of product candidates or other research and development initiatives. Our license agreements and any future collaboration agreements may also be terminated if we are unable to meet the payment or other obligations under the agreements. We could be required to seek collaborators for product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available or relinquish or license on unfavorable terms our rights to product candidates in markets where we otherwise would seek to pursue development or commercialization ourselves.

***As a result of our history of losses and negative cash flows from operations, our management has performed an analysis and concluded that substantial doubt exists about our ability to continue as a going concern, and we will need to raise additional financing to continue our products' development.***

Our history of operating losses and negative cash flows from operations combined with our anticipated use of cash to fund operations raises substantial doubt about our ability to continue as a going concern beyond one year from the date of filing of this Annual Report on Form 10-K. Our financial statements as of December 31, 2025 do not include any adjustments that might result from the outcome of this uncertainty. Based on our current operating plan, we will need to raise additional financing to continue our products' development for the foreseeable future, and until we become profitable. Our future viability as an ongoing business is dependent on our ability to generate cash from our operating activities or to raise additional capital to finance our operations. We expect to finance our future cash needs through equity or debt financings, collaborations or a combination of these approaches. The sale of equity or convertible debt securities may result in dilution to our stockholders, and, in the case of preferred equity securities or convertible debt, those securities could provide for rights, preferences or privileges senior to those of our common stock. Debt financings may subject us to covenant limitations or restrictions on our ability to take specific actions, such as incurring additional debt or making capital expenditures. Our ability to raise additional funds may be adversely impacted by negative global economic conditions and any disruptions to and volatility in the credit and financial markets in the United States and worldwide or other factors. There can be no assurance that we will be successful in acquiring additional funding at levels sufficient to fund our operations or on terms favorable or acceptable to us. If we are unable to obtain adequate financing when needed or on terms favorable or acceptable to us, we may be forced to delay, reduce the scope of or eliminate one or more of our research and development programs.

The perception that we might be unable to continue as a going concern may also make it more difficult to obtain financing for the continuation of our operations on terms that are favorable to us, or at all, and could result in the loss of confidence by investors and employees. Our consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty. If we are unable to continue as a going concern, we may have to liquidate our assets and may receive less than the value at which those assets are carried on our consolidated financial statements, and it is likely that our investors will lose all or a part of their investment.

***We may not realize the expected benefits from our corporate reorganization and workforce reduction and we may incur additional costs implementing it or other difficulties or unexpected consequences.***

On July 8, 2025, we implemented a corporate reorganization to extend our cash runway, including a workforce reduction of approximately 50% of our employees at that time. In connection with this corporate reorganization, we refined our operating plan to focus on our briquilimab clinical development programs in chronic urticaria and halted enrollment in our Phase 1b asthma study and halted our other clinical and preclinical programs. These changes to our business strategy and the reduction in workforce may yield unintended consequences and costs, such as the loss of institutional knowledge and expertise, attrition beyond our intended workforce reduction, a reduction in morale among our remaining employees, and the risk that the reorganization may not achieve the anticipated benefits, all of which may have an adverse effect on our development activities, ability to progress our product candidate development, and results of operations or financial condition. The total cost related to the workforce reduction is estimated to be approximately $2.3 million, all of which is cash-based expenditure related primarily to severance payments. We recognized substantially all the charges related to the workforce reduction in the year ended December 31, 2025. These estimates are subject to a number of assumptions and actual results may differ.

In December 2025, our board of directors approved a plan to cease operations of our vivarium and to terminate three of the four remaining research personnel associated with those operations. We determined that certain fixed assets and our right of use asset related to our vivarium space were abandoned. Accordingly, we recognized an impairment loss of $1.1 million.

In addition, we may incur additional costs not currently contemplated due to events that may occur as a result of, or that are associated with, the corporate reorganization and workforce reduction. For example, we may be unsuccessful in distributing the duties and obligations of departed employees among our remaining employees. Reductions in our workforce could also make it difficult for us to pursue, or prevent us from pursuing, new opportunities and initiatives due to insufficient personnel, or require us to incur additional and unanticipated costs to hire new personnel to pursue such opportunities or initiatives. If we are unable to realize the anticipated benefits from the reductions in force, or if we experience significant adverse consequences from the reductions in force, our business, financial condition, and results of operations may be materially adversely affected. Furthermore, we may undertake further similar cost-saving initiatives in the future, which may include additional restructuring or workforce reductions. These types of cost-reduction activities can be complex and result in unintended consequences and costs, which could adversely impact our business.

***We have no history of commercializing pharmaceutical products, which may make it difficult to evaluate the prospects for our future viability.***

We are a clinical stage company. We were founded and commenced operations in March 2018. Our operations to date have been limited to organizing and staffing our company, business planning, raising capital, acquiring and developing our technology, identifying potential product candidates and undertaking preclinical studies and clinical trials. Although we have initiated clinical trials for briquilimab, we have not yet demonstrated an ability to successfully complete clinical trials of our product candidates; obtained marketing approvals; manufactured a commercial-scale medicine or therapy, or arranged for a third party to do so on our behalf; or conducted sales and marketing activities necessary for successful commercialization. Typically, it takes about 10 to 15 years to develop a new medicine from the time it is discovered to when it is available for treating patients. Consequently, any predictions we make 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 a clinical stage company, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. We will need to transition at some point from a company with a research and development focus to a company capable of supporting commercial activities. We may not be successful in such a transition.

***We have never generated revenue from product sales and may never be profitable.***

Our ability to generate revenue from product sales and achieve profitability depends on our ability, alone or with collaborators, to successfully complete the development of, and obtain the regulatory approvals necessary to commercialize, product candidates. We do not anticipate generating revenues from product sales for the next several years, if ever. Our ability to generate future revenue from product sales depends heavily on our, or our future collaborators', ability to successfully:

- identify product candidates and complete research and preclinical and clinical development of any product candidates we may identify;
- seek and obtain regulatory and marketing approvals for any product candidates for which we complete clinical trials;
- launch and commercialize any product candidates for which we obtain regulatory and marketing approval by establishing a sales force, marketing and distribution infrastructure or, alternatively, collaborating with a commercialization partner;

- qualify for coverage and adequate reimbursement by government and third-party payors for any product candidates for which we obtain regulatory and marketing approval;
- develop, maintain, and enhance a sustainable, scalable, reproducible, and transferable manufacturing process for the product candidates we may develop;
- establish and maintain supply and manufacturing relationships with third parties that can provide adequate, in both amount and quality, products and services to support clinical development and the market demand for any product candidates for which we obtain regulatory and marketing approval;
- obtain market acceptance of product candidates as viable treatment options;
- address competing technological and market developments;
- implement internal systems and infrastructure, as needed;
- negotiate favorable terms in any collaboration, licensing or other arrangements into which we may enter, and perform our obligations in such arrangements;
- maintain, protect, enforce, defend and expand our portfolio of intellectual property rights, including patents, trade secrets and know-how, in the United States and internationally;
- avoid and defend against third-party interference, infringement and other intellectual property claims in the United States and internationally; and
- attract, hire and retain qualified personnel.

Even if one or more of the product candidates we develop are approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate. Our expenses could increase beyond expectations if we are required by the FDA, the EMA or other regulatory authorities to perform clinical and other studies in addition to those that we currently anticipate.

Many of the factors listed above are beyond our control, and could cause us to experience significant delays or prevent us from completing the development of our product candidates, obtaining regulatory approvals or commercializing our product candidates. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. A failure to become or remain profitable could result in a decline in the value of our company and could also cause you to lose all or part of your investment.

***Our ability to utilize our net operating loss carryforwards and certain other tax attributes to offset taxable income or taxes may be limited.***

As of December 31, 2025, we had net operating loss carryforwards for federal income tax purposes of $210.4 million that can be carried forward indefinitely. As of December 31, 2025, we had net operating loss carryforwards for state income tax purposes of $64.9 million that begin to expire in 2038. Portions of these net operating loss carryforwards could expire unused and be unavailable to offset future income tax liabilities. Under the legislation enacted in 2017, informally titled the Tax Cuts and Jobs Act (the "Tax Act"), as modified by the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act"), U.S. federal net operating losses incurred in taxable years beginning after December 31, 2017 may be carried forward indefinitely, but the deductibility of such federal net operating losses in taxable years beginning after December 31, 2020 is limited. It is uncertain how various states will respond to the Tax Act and the CARES Act. For state income tax purposes, there may be periods during which the use of net operating loss carryforwards is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the "Code"), and corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a greater than 50% change, by value, in its equity ownership over a three-year period, 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 or taxes may be limited. Our existing net operating loss carryforwards may be subject to limitations arising out of previous ownership changes and we may be limited as to the amount that can be utilized each year as a result of such previous ownership changes, including the Business Combination and related transactions. In addition, future changes in our stock ownership, including future offerings, as well as other changes that may be outside of our control, could result in additional ownership changes. We have completed a Section 382 analysis covering taxable periods from its inception through the year ended December 31, 2021. We experienced an ownership change on November 21, 2019 for both federal and California tax purposes related to its Series A redeemable convertible preferred stock financing. Any net operating loss generated for taxable periods in 2018 and through November 21, 2019 in excess of $2.87 million will be permanently limited for California tax purposes. We reduced our California net operating loss deferred tax assets balance by the permanently limited amount of $0.6 million as of December 31, 2021. There would be no permanent loss of federal net operating loss based on the limits. We experienced an additional ownership change on September 24, 2021; however, we do not expect there are additional tax attributes that will expire unused before the expiration periods. There is a full valuation allowance for net deferred tax assets, including net operating loss carryforwards for the year ended December 31, 2025.

***Business disruptions caused by natural or man-made disasters, acts of war or other hostilities could seriously harm our future revenues and financial condition and increase our costs and expenses generally.***

Our corporate headquarters are located in the San Francisco Bay Area, a region known for seismic activity. Our suppliers may also experience a disruption in their business as a result of natural or man-made disasters. A significant natural or man-made disaster, such as an earthquake, prolonged or repeated power outage, hurricane, flood, fire, drought or other extreme weather events and changing weather patterns, which are increasing in frequency due to the impacts of climate change, could severely damage or destroy our headquarters or facilities or the facilities of our manufacturers or suppliers, which could have a material and adverse effect on our business, financial condition and results of operations. In addition, terrorist acts, acts of war or the outbreak of hostilities against the U.S. or other countries globally, could cause damage or disruption to us, our employees, facilities, partners and suppliers, which could have a material adverse effect on our business, financial condition and results of operations.

***Recent and future changes to tax laws could materially adversely affect our company.***

The tax regimes we are subject to or operate under, including with respect to income and non-income taxes, are unsettled and may be subject to significant change. Changes in tax laws, regulations, or rulings, or changes in interpretations of existing laws and regulations, could materially adversely affect our company. For example, the Tax Cuts and JOBS Act, the Coronavirus Aid, Relief, and Economic Security Act, and the Inflation Reduction Act, or the IRA, enacted many significant changes to the U.S. tax laws. Future guidance from the Internal Revenue Service and other tax authorities with respect to such legislation may affect us, and certain aspects thereof could be repealed or modified in future legislation. For example, the IRA includes provisions that impact the U.S. federal income taxation of certain corporations, including imposing a 15% minimum tax on the book income of certain large corporations and a 1% excise tax on certain corporate stock repurchases that would be imposed on the corporation repurchasing such stock. Additionally, new income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could adversely affect our business operations and financial performance. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us. For example, on July 4, 2025, new legislation was enacted in the United States which includes significant provisions, including, but not limited to, modifications of capitalization of research and development expenses and accelerated fixed asset depreciation. We have evaluated the impact of the new legislation and determined that it does not have a material impact on our consolidated financial statements. It is also uncertain if and to what extent various states will conform to federal tax laws. In addition, many countries in Europe, as well as a number of other countries and organizations (including the Organization for Economic Cooperation and Development and the European Commission), have proposed, recommended, or (in the case of countries) enacted or otherwise become subject to changes to existing tax laws or new tax laws that could significantly increase our tax obligations in the countries where we do business or require us to change the manner in which we operate our business. Future tax reform legislation could have a material impact on the value of our deferred tax assets, could result in significant one-time charges, and could increase our future tax expense.

**Risks Related to Discovery, Development, Manufacturing and Commercialization**

***We are substantially dependent on the success of our most advanced product candidate, briquilimab. If we are unable to complete development of, obtain approval for and commercialize our product candidates, including briquilimab, in a timely manner or at all, our business will be harmed.***

Our future success is dependent on our ability to timely advance and complete clinical trials, obtain marketing approval for and successfully commercialize our product candidates. We are not permitted to market or promote briquilimab or any other product candidate before we receive marketing approval from the FDA and comparable foreign regulatory authorities, and we may never receive such marketing approvals.

The success of our product candidates will depend on several factors, including the following:

- the acceptance of individual institutional review boards ("IRBs") and scientific review committees at each clinical trial site as to the adequacy of the preclinical data package to support clinical development of briquilimab and their overall general agreement with the use of briquilimab in the intended patient population in the intended manner;
- the initiation and successful patient enrollment and completion of additional clinical trials of briquilimab in CSU, CIndU, and asthma on a timely basis;
- the frequency and severity of adverse events in the clinical trials;
- the successful and timely completion of our ongoing Phase 1b/2a clinical trial of subcutaneous briquilimab for the treatment of CIndU, planned Phase 2b/3 trial of briquilimab in patients with CSU, and the Phase 1b clinical trial of briquilimab in allergic asthma;
- maintaining and establishing relationships with contract research organizations ("CROs") and clinical sites for the clinical development of briquilimab both in the United States and internationally;
- successful completion of toxicology studies, biodistribution studies and minimally efficacious dose studies in animals, where applicable;
- successful completion of clinical trials and other studies, under the FDA's current Good Clinical Practices ("GCPs") and the FDA's current Good Laboratory Practices;
- effective investigational new drug ("IND") applications or Clinical Trial Authorizations that allow commencement of our planned clinical trials or future clinical trials for our product candidates;
- the efficacy, safety and tolerability profiles that are satisfactory to the FDA, EMA or any comparable foreign regulatory authority for marketing approval;
- the timely receipt of marketing approvals for our product candidates from applicable regulatory authorities;

- the extent of any required post-marketing approval commitments to applicable regulatory authorities;
- the maintenance of existing or the establishment of new supply arrangements with third-party suppliers and manufacturers for clinical development of briquilimab;
- the maintenance of existing, or the establishment of new, scaled production arrangements with third-party manufacturers to obtain finished products that are appropriate for commercial sale of briquilimab, if it is approved;
- obtaining and maintaining patent protection, trade secret protection and regulatory exclusivity, both in the United States and internationally;
- a continued acceptable safety profile following any marketing approval;
- commercial acceptance by patients, the medical community and third-party payors;
- our ability to obtain coverage and adequate reimbursement from third-party payors for our products, and patients' willingness to pay out-of-pocket in the absence of such coverage and adequate reimbursement; and
- our ability to compete with other treatments.

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 and the manufacturing, marketing, distribution and sales efforts of any future collaborator. If we are not successful with respect to one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize briquilimab, which would materially harm our business. If we do not receive marketing approvals for briquilimab, we may not be able to continue our operations.

***Delays in the commencement or completion of clinical trials could result in increased costs to us and delay our ability to establish strategic collaborations.***

Delays in the commencement or completion of clinical trials could significantly impact our drug development costs. We do not know whether planned clinical trials will begin on time or be completed on schedule, if at all. The commencement of clinical trials can be delayed for a variety of reasons, including, but not limited to, delays related to:

- o obtaining regulatory approval to commence one or more clinical trials;
- o reaching agreement on acceptable terms with prospective CROs and clinical trial sites;
- o in quantities of a product candidate or other materials necessary to conduct clinical trials, as well as receiving the supplies and materials needed to conduct our clinical trials, including interruptions in global shipping that may affect the transport of clinical materials;

- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements, which may negatively impact the supply chain or cause other disruptions;
- obtaining institutional review board or ethics committee approval to conduct one or more clinical trials at a prospective site;
- recruiting and enrolling patients to participate in one or more clinical trials, especially as patients may be reluctant or unable to visit clinical sites, or may delay seeking treatment for chronic conditions;
- the failure of our collaborators to adequately resource our product candidates due to their focus on other programs or as a result of general market conditions;
- recruiting clinical site investigators, clinical site staff and potential closure of clinical facilities; and
- changes in regulations, which may require us to change the ways in which our clinical trials are conducted.

In addition, once a clinical trial has begun, it may be suspended or terminated by us, our collaborators, the institutional review boards or data safety monitoring boards charged with overseeing our clinical trials, the FDA, EMA or comparable foreign authorities due to a number of factors, including:

- failure to conduct the clinical trial in accordance with regulatory requirements or clinical protocols;
- inspection of the clinical trial operations or clinical trial site by the FDA, EMA or comparable foreign authorities resulting in the imposition of a clinical hold;
- unforeseen safety issues; or
- lack of adequate funding to continue the clinical trial.

If we experience delays in the completion or termination of any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to commence product sales and generate product revenues from any of our product candidates will be delayed. For example, in July 2025, we reported that results from the 240mg Q8W and the 240mg/180mg Q8W dose cohorts in our Phase 1b/2a BEACON study in CSU demonstrated an atypical absence of UAS7 reduction in 11 of the 13 patients enrolled, and as a result, we investigated the results of those two cohorts. The investigation has been completed, and based on the work completed, the additional data from subsequent dosing of the US patients and input from the KOL panel, we concluded that the unexpected lack of efficacy observed in the US patients was not the result of any issues with drug product, but rather appears to be the result of patient selection issues, specifically the fact that it appears that 9 of the 10 CSU patients enrolled in the study may not have had mast-cell driven disease. In addition, in July 2025, we halted enrollment in the ETESIAN study due to the fact that clinical material for the ETESIAN study was supplied from a drug product lot under investigation due to an atypical lack of efficacy noted in two of the cohorts in the BEACON study in which material from that drug product lot was also used. These and any other delays in completing our clinical trials have and will continue to increase our costs and slow down our product candidate development and approval process. Delays in completing our clinical trials could also allow our competitors to obtain marketing approval before we do or shorten the patent protection period during which we may have the exclusive right to commercialize our product candidates. Any of these occurrences may harm our business, financial condition and prospects significantly. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

***We may not be successful in our efforts to develop and commercialize briquilimab in additional indications or to identify additional product candidates. If these efforts are unsuccessful, we may never become a commercial stage company or generate any revenues.***

The success of our business depends primarily upon our ability to develop, and commercialize briquilimab in additional indications or to identify additional product candidates. We are currently planning a Phase 2b/3 study of briquilimab in patients with CSU. We may fail to identify additional indications for clinical development or product candidates for clinical development for a number of reasons. Our methodology may be unsuccessful in identifying attractive potential product candidates, potential product candidates identified may be shown to have harmful side effects in preclinical in vitro experiments or animal model studies, they may not show promising signals of efficacy in such experiments or studies or they may have other characteristics that may make the product candidates impractical to manufacture, unmarketable or unlikely to receive marketing approval. The historical failure rate for product candidates is high due to risks relating to safety, efficacy, clinical execution, changing standards of medical care, and other unpredictable variables. In addition, given capital constraints and changing market conditions, our ability to expand our portfolio may never materialize. For example, advancing any future clinical studies in asthma will be based on an evaluation of the competitive landscape, the potential for strategic partnerships and capital availability.

If any of these events occur, we may be forced to abandon our development efforts for a program or programs, which would have a material adverse effect on our business, financial condition, results of operations and prospects. Additional clinical development programs in new indications or with new product candidates require substantial technical, financial and human resources. We may focus our efforts and resources on potential programs or product candidates that ultimately prove to be unsuccessful, which would be costly and time-consuming.

***We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications 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 on research programs and product candidates that we identify for specific indications among many potential options. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. For example, on July 8, 2025, we implemented a corporate reorganization and refined our operating plan to focus on our briquilimab clinical development programs in chronic urticaria and halted enrollment in our Phase 1b asthma study and halted our other clinical and preclinical programs, including our severe combined immunodeficiency ("SCID") program and any remaining Investigator Sponsored Trials ("ISTs"). Our resource allocation decisions may cause us to fail to capitalize on viable commercial medicines or profitable market opportunities. Our projections of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with our product candidates, are based on estimates. If any of our estimates are inaccurate, the market opportunities for any of our product candidates could be significantly diminished and have an adverse material impact on our business. Additionally, the potentially addressable patient population for our product candidates may be limited, or may not be amenable to treatment with our product candidates. Our spending on current and future research and development programs and 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 (including briquilimab), 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. Any such event could have a material adverse effect on our business, financial condition, results of operations and prospects.

***If any of our product candidates cause serious adverse events, undesirable side effects or unexpected characteristics, such events, side effects or characteristics could delay or prevent regulatory approval of the product candidate, limit our commercial potential or result in significant negative consequences following any potential marketing approval.***

Undesirable side effects or adverse events caused by briquilimab or other therapeutics we may develop could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. Treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete the trials or result in potential product liability claims.

If any product candidates we develop are associated with serious adverse events, undesirable side effects or unexpected characteristics, we may need to abandon their development or limit development to certain uses or subpopulations in which the serious adverse events, undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective, any of which would have a material adverse effect on our business, financial condition, results of operations, and prospects. Many product candidates that initially showed promise in early stage testing have later been found to cause side effects that prevented further clinical development of the product candidates.

***Results of preclinical studies and early clinical trials may not be predictive of results of future clinical trials, and such results do not guarantee approval of a product candidate by regulatory authorities. In addition, our clinical trials to date have been limited in scope, and results received to date may not be replicated in expanded or additional future clinical trials.***

The outcome of preclinical studies and early clinical trials may not be predictive of the success of later clinical trials, and interim results of clinical trials do not necessarily predict success in the results of completed clinical trials. There can be no assurance that any of our current or future preclinical and clinical trials will ultimately be successful or support further preclinical or clinical development of any of our product candidates. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials after achieving positive results in earlier development, and we could face similar setbacks. The design of a clinical trial can determine whether its results will support approval of a product, and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. Many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain regulatory approval for their product candidates. In addition, preclinical and clinical data are often susceptible to varying interpretations and analyses, which may delay, limit or prevent regulatory approval. In addition, regulatory delays or rejections may be encountered as a result of many factors, including changes in regulatory policy during the period of product development. Any such adverse events may cause us to delay, limit or terminate planned clinical trials, any of which would have a material adverse effect on our business, financial condition, results of operations and prospects.

In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the dosing regimen and other clinical trial procedures and the rate of dropout among clinical trial participants. If we fail to receive positive results in clinical trials of our product candidates, the development timeline and regulatory approval and commercialization prospects for our most advanced product candidate, and, correspondingly, our business and financial prospects would be negatively impacted.

***If we experience delays or difficulties in the enrollment of patients in clinical trials, the cost of developing product candidates could increase and our receipt of necessary regulatory approvals could be delayed or prevented.***

Patient enrollment is a significant factor in the timing of clinical trials. The timing of our clinical trials depends, in part, on the speed at which we can recruit patients to participate in our trials. We or our collaborators may not be able to continue clinical trials for briquilimab or any other product candidates we identify or develop if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA, the EMA or other analogous regulatory authorities outside the United States, or as needed to provide appropriate statistical power for a given trial. Patients may be unwilling to participate in our clinical trials because of negative publicity from adverse events related to the biotechnology competitive clinical trials for similar patient populations, clinical trials in competing products or for other reasons. As a result, the timeline for recruiting patients, conducting trials and obtaining regulatory approval of product candidates may be delayed.

Patient enrollment is also affected by other factors, including:

- severity of the disease under investigation;
- size of the patient population and process for identifying patients;
- design of the trial protocol;
- availability and efficacy of approved medications for the disease under investigation;
- availability of genetic testing for potential patients;
- ability to obtain and maintain patient informed consent;
- risk that enrolled patients will drop out before completion of the trial;
- eligibility and exclusion criteria for the trial in question;
- perceived risks and benefits of the product candidate under trial;
- perceived risks and benefits of the companion therapeutics that may be administered in combination or in sequence with briquilimab;
- efforts to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians;
- ability to monitor patients adequately during and after treatment;
- proximity and availability of clinical trial sites for prospective patients, especially for those conditions that have small patient pools; and
- other factors outside of our control, such as overall economic conditions and volatility in the credit and financial markets, tariffs imposed by the U.S. and other countries, inflationary pressures, trade wars, the Russian invasion of Ukraine, conflicts in the Middle East, instability in Venezuela and other geopolitical conflicts.

In addition, our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us because some patients who have opted to enroll in our trials may instead opt to enroll in a trial being conducted by a competitor. We may conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial sites.

Enrollment delays in our clinical trials may result in increased development costs for briquilimab or any other product candidates we may develop, which would cause the value of our company to decline and limit our ability to obtain additional financing. If we or our collaborators have difficulty enrolling a sufficient number of patients to conduct our clinical trials as planned, we may need to delay, limit or terminate ongoing or planned clinical trials, any of which would have an adverse effect on our business, financial condition, results of operations and prospects.

***We have never obtained regulatory approval for a drug, may never receive regulatory approval for any of our product candidates, and may therefore never generate revenues from product sales.***

As a company, we have never obtained regulatory approval for, or commercialized, a drug. It is possible that the FDA may refuse to accept any or all future product candidates for substantive review or may conclude after review of our data that our application is insufficient to obtain regulatory approval for any current or future product candidates. If the FDA does not approve any future product candidates, it may require that we conduct additional costly clinical, preclinical or manufacturing validation studies before the FDA will reconsider one or more of our applications. Depending on the extent of these or any other FDA-required studies, approval of any product candidates or other application that we submit may be significantly delayed, possibly for several years, or may require us to expend more resources than we have available. Any failure or delay in obtaining regulatory approvals would prevent us from commercializing briquilimab or any other product candidate, generating revenues and achieving and obtaining or sustaining profitability. It is also possible that additional studies, if performed and completed, may not be considered sufficient by the FDA to approve any new drug application or other application we submit. If any of these outcomes occur, we may be forced to abandon the development of our product candidates, which would materially adversely affect our business and could potentially cause us to cease operations. We face similar risks for our applications in foreign jurisdictions.

***Our commercial success depends upon attaining significant market acceptance of our product candidates, if approved, among physicians, patients, healthcare payers and operators of major clinics, and we may not be successful in attaining such market acceptance.***

Even with the requisite approvals from the FDA in the U.S., the EMA in the European Union and other regulatory authorities internationally, the commercial success of our product candidates will depend, in part, upon the degree of market acceptance by physicians, patients, third-party payors and others in the medical community. Any product that we commercialize may not gain acceptance by physicians, patients, health care payors and others in the medical community. If these products do not achieve an adequate level of acceptance, we may not generate significant product revenue and may not become profitable. Efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources, including our management's time and financial resources, and may not be successful. Even if any product candidate we develop receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, healthcare payors and others in the medical community. The degree of market acceptance of any product candidate we develop, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and safety of such product candidate as demonstrated in clinical trials;
- the efficacy and safety of other products that are used in combination or in sequence with our product candidates;

- the potential and perceived advantages of our product candidates compared to alternative treatments;
- the limitation to our targeted patient population and limitations or warnings contained in approved labeling by the FDA or other regulatory authorities;
- the ability to offer our products for sale at competitive prices;
- convenience and ease of administration compared to alternative treatments;
- the clinical indications for which the product candidate is approved by the FDA, the EMA or other regulatory agencies;
- the willingness of the target patient population to try novel biologics and of physicians to prescribe these treatments;
- product labeling or product insert requirements of the FDA, the EMA or other regulatory authorities, including any limitations or warnings contained in a product's approved labeling;
- relative convenience and ease of administration;
- the strength of marketing and distribution support;
- availability of third-party coverage and sufficiency of reimbursement; and
- the prevalence and severity of any side effects.

Even if a product candidate is approved, such product may not achieve an adequate level of acceptance, we may not generate significant product revenues, and we may not become profitable.

***If we are unable to establish effective marketing and sales capabilities or enter into agreements with third parties to market and sell our product candidates, if approved, we may not be able to effectively market and sell our product candidates, if approved, or generate product revenues.***

We have limited marketing capabilities and limited experience in the sale, marketing or distribution of pharmaceutical products. In addition, we do not have a large sales, promotion and marketing budget. As a result of our limited marketing capabilities, to achieve commercial success for any approved product for which we retain sales and marketing responsibilities, we must either develop a sales and marketing organization or outsource these functions to third parties. In the future, we may choose to build a focused sales, marketing and commercial support infrastructure to sell, or participate in sales activities with our collaborators for, some of our product candidates if and when they are approved.

Factors that may inhibit our efforts to commercialize our product candidates on our own include:

- our inability to recruit and retain adequate numbers of effective sales, marketing, reimbursement, customer service, medical affairs and other support personnel;
- the inability of sales personnel to obtain access to physicians or educate adequate numbers of physicians on the benefits of prescribing any future products;
- the inability of reimbursement professionals to negotiate arrangements for formulary access, reimbursement and other acceptance by payors;
- restricted or closed distribution channels that make it difficult to distribute our product candidates to segments of the patient population;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent commercialization organization.

We may not be successful in entering into arrangements with third parties to commercialize our product candidates or may be unable to do so on terms that are favorable to us. We may have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we do not establish commercialization capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.

***We face significant competition in an environment of rapid technological change, and there is a possibility that our competitors may achieve regulatory approval before us or develop therapies that are safer or more advanced or effective than ours, which may harm our financial condition and our ability to successfully market or commercialize our product candidates.***

The development and commercialization of new drug and biologic products is highly competitive. Moreover, the biotechnology field generally is characterized by rapidly changing technologies, significant competition and a strong emphasis on intellectual property. We will face competition with respect to briquilimab and any other product candidates that we develop or commercialize in the future from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

There are a number of large pharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of products for the treatment of the disease indications for which we have product candidates and research programs. Some of these competitive products and therapies are based on scientific approaches that are the same as or similar to our approach, and others are based on entirely different approaches. Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future that are approved to treat the same diseases for which we may obtain approval for our product candidates. This may include other types of therapies, such as small molecule, antibody and/or protein therapies.

Many of our current or potential competitors, either alone or with their collaboration partners, may 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, biotechnology and gene therapy industries 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 and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize product candidates that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than our product candidates or that would render our product candidates obsolete or non-competitive. Our competitors also may obtain FDA or other regulatory approval for their product candidates more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. Additionally, technologies developed by our competitors may render our product candidates uneconomical or obsolete, and we may not be successful in marketing any product candidates against competitors.

Competitors of briquilimab include the following:

- Celldex Therapeutics, Inc., which is developing an antibody to KIT that is being studied in mast cell diseases;
- Blueprint Medicines which is developing a small molecule KIT inhibitor for mast cell diseases;
- Novartis, Inc., which is developing a small molecule inhibitor to Bruton's Tyrosine Kinase for mast cell diseases;
- Sanofi Aventis, Inc., which is developing an antibody to the Interleukin 4 receptor alpha for mast cell diseases;
- Evommune, Inc., which is developing a small-molecule antagonist of MRGPRX2 in mast cell driven diseases.

***If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.***

We face an inherent risk of product liability exposure related to the testing in human clinical trials of our product candidates and will face an even greater risk if we commercially sell any products that we may develop. For example, we may be sued if our product candidates cause, or are perceived to cause, injury or are found to be otherwise unsuitable during clinical trials, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we could incur substantial liabilities or be required to limit commercialization of our product candidates. Even a successful defense would require significant financial and management resources. Regardless of merit or eventual outcome, liability claims may result in:

- the inability to commercialize any products that we may develop;
- decreased demand for our product candidates or products that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;

- significant time and costs to defend the related litigation;
- substantial monetary awards to trial participants or patients; and
- loss of revenue.

Although we maintain product liability insurance coverage, it may not be adequate to cover all liabilities that we may incur. We anticipate that we will need to increase our insurance coverage as we continue clinical trials and if we successfully commercializes any product. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

***Our product candidates are complex and difficult to manufacture. We could experience delays in satisfying regulatory authorities or production problems that result in delays in our development or commercialization programs, limit the supply of our product candidates, or otherwise harm our business.***

Our product candidates require processing steps that are more complex than those required for most chemical and other biological pharmaceuticals. As a result, assays of the finished product candidate may not be sufficient to ensure that the product candidate will perform in the intended manner. Problems with the manufacturing process, even minor deviations from the normal process, could result in product defects or manufacturing failures that result in lot failures, product recalls, product liability claims, insufficient inventory or potentially delay progression of our clinical trials. If we successfully develop product candidates, we may encounter problems achieving adequate quantities and quality of clinical-grade materials that meet FDA, EMA or other comparable applicable foreign standards or specifications with consistent and acceptable production yields and costs. In addition, our product candidates will require complicated delivery modalities, such as electroporation, which will introduce additional complexities into the manufacturing process.

In addition, the FDA, the EMA and other regulatory authorities may require us to submit samples of any lot of approved product together with the protocols showing the results of applicable tests at any time. Under some circumstances, the FDA, the EMA or other regulatory authorities may require that we not distribute a lot until the agency authorizes its release. Slight deviations in the manufacturing process, including those affecting quality attributes and stability, may result in unacceptable changes in the product that could result in lot failures or product recalls. Lot failures or product recalls could cause us to delay clinical trials or product launches, which could be costly to us and otherwise harm our business, financial condition, results of operations and prospects.

Moreover, the clinical development of our product candidates depends on the availability of certain materials and agents used in our clinical trials. Specifically, our clinical trial protocols for briquilimab-based conditioning include the administration of fludarabine, and the FDA recently reported a shortage of fludarabine. Any failure or delays by us or by our clinical sites to obtain sufficient quantities of fludarabine or other components and agents necessary for the conduct of our clinical trials, may delay our ability to enroll and treat patients in, or complete, our current or future clinical trials of our product candidates on time, if at all.

Some of the raw materials that we anticipate will be required in our manufacturing process are derived from biologic sources. Such raw materials are difficult to procure and may be subject to contamination or recall. A material shortage, contamination, recall or restriction on the use of biologically derived substances in the manufacture of our product candidates could adversely impact or disrupt the commercial manufacturing or the production of clinical material, which could materially harm our development timelines and our business, financial condition, results of operations and prospects.

***If we or any contract research organizations, contract manufacturers or suppliers that we engage 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 and any contract research organizations, contract manufacturers and suppliers we engage are subject to numerous federal, state and local environmental, health and safety laws, regulations and permitting requirements, including those governing laboratory procedures; the generation, handling, use, storage, treatment and disposal of hazardous and regulated materials and wastes; the emission and discharge of hazardous materials into the ground, air and water; and employee health and safety. Our operations involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. Our operations also produce hazardous waste. We generally contract with third parties for the disposal of these materials and wastes. Although we believe that our and such third parties' procedures for handling, storing and disposing of these materials and waste comply with legally prescribed standards, we cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. Under certain environmental laws, we could be held responsible for costs relating to any contamination at our current or past facilities and at third-party facilities. We also could incur significant costs associated with civil or criminal fines and penalties.

Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair our product development and research efforts. In addition, we cannot entirely eliminate the risk of accidental injury or contamination from these materials or wastes. Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not carry specific biological or hazardous waste insurance coverage, and our property, casualty and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws, regulations and permitting requirements. These current or future laws, regulations and permitting requirements may impair our research, development or production efforts. Failure to comply with these laws, regulations and permitting requirements also may result in substantial fines, penalties or other sanctions or business disruption, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Any third-party contract research organizations, contract manufacturers and suppliers we engage will also be subject to these and other environmental, health and safety laws and regulations. Liabilities they incur pursuant to these laws and regulations could result in significant costs or an interruption in operations, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

**Risks Related to Regulatory Review**

***If clinical trials of our product candidates fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of such product candidates.***

Before obtaining marketing approval from regulatory authorities for the sale of briquilimab and any other product candidates we identify and develop, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of such product candidates in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of testing. The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses. Many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their product candidates.

We and our collaborators, if any, may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize any product candidates, including:

- delays in reaching a consensus with regulators on trial design;
- regulators, IRBs, independent ethics committees or scientific review boards may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- delays in reaching or failing to reach agreement on acceptable clinical trial contracts or clinical trial protocols with prospective CROs and clinical trial sites;
- clinical trials of product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development or research programs;
- difficulty in designing well-controlled clinical trials due to ethical considerations that may render it inappropriate to conduct a trial with a control arm that can be effectively compared to a treatment arm;
- difficulty in designing clinical trials and selecting endpoints for diseases that have not been well-studied and for which the natural history and course of the disease is poorly understood;
- the number of patients required for clinical trials of briquilimab and any other product candidates we may develop may be larger than we anticipate; enrollment of suitable participants in these clinical trials may be delayed or slower than we anticipate; or patients may drop out of these clinical trials 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;
- regulators, IRBs or independent ethics committees may require that we or our investigators suspend or terminate clinical research or clinical trials for various reasons, including noncompliance with regulatory requirements, a finding of undesirable side effects or other unexpected characteristics, or that the participants are being exposed to unacceptable health risks or after an inspection of our clinical trial operations or trial sites;
- the cost of clinical trials may be greater than we anticipate;
- the supply or quality of product candidates or other materials necessary to conduct clinical trials may be insufficient or inadequate, including as a result of delays in the testing, validation, manufacturing and delivery of product candidates to the clinical sites by us or by third parties with whom we have contracted to perform certain of those functions;
- delays in having patients complete participation in a trial or return for post-treatment follow-up;
- clinical trial sites dropping out of a trial;
- selection of clinical endpoints that require prolonged periods of clinical observation or analysis of the resulting data;

- occurrence of serious adverse events associated with product candidates that are viewed to outweigh their potential benefits;
- occurrence of serious adverse events in trials of the same class of agents conducted by other sponsors; and
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols.

If we or our collaborators, if any, are required to conduct additional clinical trials or other testing of product candidates beyond those that we currently contemplate, if we or our collaborators are unable to successfully complete clinical trials or other testing of product candidates, or if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we or our collaborators may:

- be delayed in obtaining marketing approval for any such product candidates or not obtain marketing approval at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings, including boxed warnings;
- be subject to changes in the way the product is administered;
- be required to perform additional clinical trials to support approval or be subject to additional post-marketing testing requirements;
- have regulatory authorities withdraw or suspend their approval of the product or impose restrictions on its distribution in the form of a Risk Evaluation and Mitigation Strategy ("REMS") or through modification to an existing REMS;
- be sued; or
- experience damage to our reputation.

Product development costs will also increase if we or our collaborators experience delays in clinical trials or other testing or in obtaining marketing approvals. We do not know whether any clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize product candidates, could allow our competitors to bring products to market before we do and could impair our ability to successfully commercialize product candidates, any of which may harm our business, financial condition, results of operations and prospects.

Further, disruptions at the FDA and other agencies may prolong the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, including the FDA, have furloughed critical employees and stopped critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

***Failure to obtain marketing approval in foreign jurisdictions would prevent any product candidates we develop from being marketed in such jurisdictions, which, in turn, would materially impair our ability to generate revenue.***

In order to market and sell any product candidates we develop in the European Union and many other foreign jurisdictions, we or our collaborators must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, it is required that the product be approved for reimbursement before the product can be approved for sale in that country. We or our collaborators may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. We may not be able to file for marketing approvals and may not receive necessary approvals to commercialize our product candidates in any jurisdiction, which would materially impair our ability to generate revenue.

Additionally, we could face heightened risks with respect to seeking marketing approval in the United Kingdom as a result of the recent withdrawal of the United Kingdom from the European Union on December 31, 2020, commonly referred to as Brexit. Pursuant to the formal withdrawal arrangements agreed between the United Kingdom and the European Union, the United Kingdom withdrew from the European Union, effective December 31, 2020. On December 24, 2020, the United Kingdom and European Union entered into a Trade and Cooperation Agreement. The agreement sets out certain procedures for approval and recognition of medical products in each jurisdiction.

Since the regulatory framework for pharmaceutical products in the United Kingdom covering the quality, safety, and efficacy of pharmaceutical products, clinical trials, marketing authorization, commercial sales, and distribution of pharmaceutical products is derived from European Union directives and regulations, Brexit could materially impact the future regulatory regime that applies to products and the approval of product candidates in the United Kingdom. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, would prevent us from commercializing any product candidates in the United Kingdom and/or the European Union and restrict our ability to generate revenue and achieve and sustain profitability. If any of these outcomes occur, we may be forced to restrict or delay efforts to seek regulatory approval in the United Kingdom and/or the European Union for any product candidates, which could significantly and materially harm our business.

***The regulatory approval processes of the FDA and comparable foreign regulatory authorities are lengthy, time-consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business, financial condition and results of operations will be substantially harmed. Even if we complete the necessary clinical trials, we cannot predict when, or if, we will obtain regulatory approval to commercialize our product candidates in the United States or any other jurisdiction, and any such approval may be for a more narrow indication than we seek.***

We cannot commercialize a product candidate until the appropriate regulatory authorities have reviewed and approved the product candidate. Even if our product candidates meet their safety and efficacy endpoints in clinical trials, the regulatory authorities may not complete their review processes in a timely manner, or we may not be able to obtain regulatory approval. The time required to obtain marketing approval from the FDA or comparable foreign regulatory authorities for a product candidate is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities, and its outcome is inherently uncertain. Additional delays may result if an FDA Advisory Committee or other regulatory authority recommends non-approval or restrictions on approval. In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action, or changes in regulatory authority policy during the period of product development, clinical trials and the review process.

Regulatory authorities also may approve a product candidate for more limited indications than requested or they may impose significant limitations in the form of narrow indications, warnings or a REMS. These regulatory authorities may require labeling that includes precautions or contra-indications with respect to conditions of use, or they may grant approval subject to the performance of costly post-marketing clinical trials. In addition, regulatory authorities may not approve the labeling claims that are necessary or desirable for the successful commercialization of our product candidates. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates and materially adversely affect our business, financial condition, results of operations and prospects.

Marketing approval by the FDA in the United States, if obtained, does not ensure approval by regulatory authorities in other countries or jurisdictions, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. In addition, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not guarantee regulatory approval in any other country. Approval processes vary among countries and can involve additional product candidate testing and validation and additional administrative review periods. Seeking foreign regulatory approval could result in difficulties and costs for us and require additional preclinical studies or clinical trials, which could be costly and time-consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our product candidates we may develop in those countries. The foreign regulatory approval process involves all of the risks associated with FDA approval. We do not have any product candidates approved for sale in any jurisdiction, including international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of our product candidates will be unrealized.

***Even if we obtain regulatory approval of any of our product candidates, the approved products may be subject to post-approval studies and will remain subject to ongoing regulatory requirements. If we fail to comply, or if concerns are identified in subsequent studies, our approval could be withdrawn, and our product sales could be suspended.***

If we are successful at obtaining regulatory approval for briquilimab or any of our other product candidates, regulatory agencies in the U.S. and other countries where a product will be sold may require extensive additional clinical trials or post-approval clinical trials that are expensive and time-consuming to conduct. These studies may be expensive and time-consuming to conduct and may reveal side effects or other harmful effects in patients that use our therapeutic products after they are on the market, which may result in the limitation or withdrawal of our drugs from the market. Alternatively, we may not be able to conduct such additional trials, which might force us to abandon our efforts to develop or commercialize certain product candidates. Even if post-approval studies are not requested or required, after our products are approved and are on the market, there might be safety issues that emerge over time that require a change in product labeling, additional post-market studies or clinical trials, imposition of distribution and use restrictions under a REMS or withdrawal of the product from the market, which would cause our revenue to decline.

Additionally, any products that we may successfully develop will be subject to ongoing regulatory requirements after they are approved. These requirements will govern the manufacturing, packaging, marketing, distribution, and use of our products. If we fail to comply with such regulatory requirements, approval for our products may be withdrawn, and product sales may be suspended. We may not be able to regain compliance, or we may only be able to regain compliance after a lengthy delay, significant expense, lost revenues and/or damage to our reputation.

We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. For example, certain policies of the current U.S. administration may impact our business and industry. Namely, recent U.S. administrations have taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. There remains substantial uncertainty as to how the current U.S. administration will seek or continue to modify or revise the requirements and policies of the FDA and other regulatory agencies with jurisdiction over our product candidates. State governments may also attempt to address or react to changes at the federal level with changes to their own regulatory frameworks in a manner that is adverse to our operations. This uncertainty could present new challenges or potential opportunities as we navigate the clinical development and approval process for our product candidates. If these executive actions impose constraints on FDA's ability to engage in oversight and implementation activities in the normal course, our business, financial condition and results of operations may be negatively affected.

The FDA's and other regulatory authorities' policies may change, and additional laws or government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. 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 marketing approval that we may have obtained, which would adversely affect our ability to generate revenue and achieve or sustain profitability. Changes in law or government regulations may also alter the competitive landscape, potentially to our disadvantage.

In addition, three decisions from the U.S. Supreme Court in June and July 2024 may lead to an increase in litigation against regulatory agencies that could create uncertainty and thus negatively impact our business. The first decision overturned established precedent that required courts to defer to regulatory agencies' interpretations of ambiguous statutory language. The second decision overturned a regulatory agency's ability to impose civil penalties in administrative proceedings. The third decision extended the statute of limitations within which entities may challenge agency actions. These cases may result in increased litigation by industry against regulatory agencies and impact how such agencies choose to pursue enforcement and compliance actions. However, the specific, lasting effects of these decisions, which may vary within different judicial districts and circuits, is unknown. We also cannot predict the extent to which FDA and other agency regulations, policies, and decisions may become subject to increasing legal challenges, delays and changes.

***Interim "top-line" and preliminary results from our clinical trials that we may announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.***

From time to time, we may publish interim top-line or preliminary results from our preclinical studies and clinical trials, which are based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. In particular, we have announced, and may in the future announce, interim results from our ongoing clinical trials of briquilimab. Interim results from clinical trials that we may complete 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. Preliminary or top-line results also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim and preliminary data should be viewed with caution until the final data are available. Differences between preliminary or interim data and final data could significantly harm our business prospects and may cause the trading price of our common stock to fluctuate significantly.

Further, others, including regulatory agencies, 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 program, the approvability or commercialization of the particular product candidate or product and us in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, investors or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product, product candidate or our business. If the interim, topline or preliminary 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.

***We may seek Fast Track or other accelerated review designations for some or all of our product candidates. We may not receive such designation, and even for those product candidates for which we do, it may not lead to a faster development or regulatory review or approval process, and will not increase the likelihood that product candidates will receive marketing approval.***

We may seek Fast Track or other accelerated review designations for some or all of our other product candidates. If a drug or biologic is intended for the treatment of a serious or life-threatening condition or disease, and nonclinical or clinical data demonstrate the potential to address an unmet medical need, the product may qualify for FDA Fast Track designation, for which sponsors must apply. If granted, a Fast Track or other accelerated review designation makes a product candidate eligible for more frequent interactions with the FDA to discuss the development plan and clinical trial design, as well as rolling review of the application, which means that we can submit completed sections of our marketing application for review prior to completion of the entire submission. Marketing applications of product candidates with a Fast Track or other accelerated review designation may qualify for priority review under the policies and procedures offered by the FDA, but a Fast Track or other accelerated review designation does not assure any such qualification or ultimate marketing approval by the FDA. The FDA has broad discretion with respect to whether or not to grant this designation. Thus, even if we believe a particular product candidate is eligible for this designation, the FDA may decide not to grant it. Moreover, even if we do receive a Fast Track or another accelerated review designation, we or our collaborators may not experience a faster development process, review or approval compared to conventional FDA procedures. In addition, the FDA may withdraw a Fast Track or other accelerated review designation if it believes that the designation is no longer supported by data from our clinical development program.

***We may seek priority review designation for our product candidates, but we might not receive such designation, and even if we do, such designation may not lead to a faster development or regulatory review or approval process.***

If the FDA determines that a product candidate offers a treatment for a serious condition and, if approved, the product would provide a significant improvement in safety or effectiveness, the FDA may designate the product candidate for priority review. A priority review designation means that the goal for the FDA to review an application is six months, rather than the standard review period of ten months. The FDA has broad discretion with respect to whether or not to grant priority review status to a product candidate, so even if we believe a particular product candidate is eligible for such designation or status, the FDA may decide not to grant it. Moreover, a priority review designation does not necessarily mean a faster development or regulatory review or approval process or necessarily confer any advantage with respect to approval compared to conventional FDA procedures. Receiving priority review from the FDA does not guarantee approval within the six-month review cycle or at all.

In addition, the FDA's Rare Pediatric Disease Priority Review Voucher Program, or PRV Voucher Program, awards Priority Review Vouchers, or PRVs, to sponsors of rare pediatric product applications that meet certain criteria. Under the program, a company that receives an approval for a product for a rare pediatric disease (as determined by the applicable regulations) may qualify for a PRV that can be redeemed to receive Priority Review of a subsequent marketing application for a different product. PRVs may also be sold by the company to third parties. Under the FDCA, a rare pediatric disease product application may be eligible for a rare pediatric disease priority review voucher if the drug receives marketing approval before September 30, 2029.The FDA has granted rare pediatric disease designation to briquilimab as a conditioning treatment for patients with SCID. In July 2025, we discontinued the SCID program and any remaining ISTs to focus our resources exclusively on our mast cell disease development portfolio. However, if our qualifying product candidate or another of our product candidates receives rare pediatric disease designation and is approved by the FDA after the current approval deadlines, we will not be eligible to receive a PRV for our product candidate and accordingly, we would be unable to use such PRV for Priority Review for another one of our programs or to sell such PRV, which sale has the potential to generate significant proceeds.

***A Breakthrough Therapy Designation by the FDA, even if granted for any of our product candidates, may not lead to a faster development or regulatory review or approval process, and it does not increase the likelihood that our product candidates will receive marketing approval.***

We may seek a Breakthrough Therapy Designation for our product candidates if the clinical data support such a designation for one or more product candidates. A breakthrough therapy is defined as a drug or biologic that is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug, or biologic, may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For product candidates that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs and biologics designated as breakthrough therapies by the FDA may also be eligible for accelerated approval.

Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and determine not to make such designation. In any event, the receipt of a Breakthrough Therapy Designation for a product candidate may not result in a faster development process, review or approval compared to drugs considered for approval under non-expedited FDA review procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that the product no longer meets the conditions for such qualification.

***We may not be able to obtain orphan drug exclusivity for one or more of our product candidates, and even if we do, that exclusivity may not prevent the FDA or EMA from approving other competing products.***

Under the Orphan Drug Act of 1983, the FDA may designate a product as an orphan drug if it is a drug or biologic intended to treat a rare disease or condition. A similar regulatory scheme governs approval of orphan products by the EMA in the European Union. Generally, if a product candidate with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the FDA or EMA from approving another marketing application for the same product for the same therapeutic indication for that time period. The applicable period is seven years in the United States and ten years in the European Union. The exclusivity period in the European Union can be reduced to six years if a product no longer meets the criteria for orphan drug designation, in particular if the product is sufficiently profitable so that market exclusivity is no longer justified.

In order for the FDA to grant orphan drug exclusivity to one of our products, the FDA must find that the product is indicated for the treatment of a condition or disease with a patient population of fewer than 200,000 individuals annually in the United States. The FDA may conclude that the condition or disease for which we may seek orphan drug exclusivity does not meet this standard. Even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different products can be approved for the same condition. In particular, the concept of what constitutes the "same drug" for purposes of orphan drug exclusivity remains in flux in the context of gene therapies, and the FDA has issued guidance suggesting that it would not consider two genetic medicine products to be different drugs solely based on minor differences in the transgenes or vectors within a given vector class. In addition, even after an orphan drug is approved, the FDA can subsequently approve the same product for the same condition if the FDA concludes that the later product is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. Orphan drug exclusivity may also be lost if the FDA or EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the product to meet the needs of the patients with the rare disease or condition.

The FDA has historically taken the position that the scope of orphan exclusivity aligns with the approved indication or use of a product, rather than the disease or condition for which the product received orphan designation. However, in Catalyst Pharms., Inc. v. Becerra, 14 F.4th 1299 (11th Cir. 2021), the court disagreed with this position, holding that orphan-drug exclusivity blocked the FDA's approval of the same drug for all uses or indications within the same orphan-designated disease. On January 24, 2023, the FDA published a notice in the Federal Register to clarify that the FDA intends to continue to apply its longstanding interpretation of the regulations to all matters outside of the scope of the Catalyst order and will continue tying the scope of orphan-drug exclusivity to the uses or indications for which a drug is approved. In February 2026, legislation amended the FDCA to clarify the scope of the orphan-drug exclusivity to the same approved use or indication within the rare for which the drug is approved. It is unclear how future litigation and administrative actions will impact the scope of orphan drug exclusivity and it is uncertain how any such actions might adversely affect our business.

***Disruptions at the FDA, the SEC and other government agencies, including from government shutdowns, or funding changes, or other disruptions to these agencies' operations, 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.***

Over the last several years, the U.S. government has shut down several times, and certain regulatory agencies, such as the FDA, have had to furlough critical employees and stop certain critical activities. For example, beginning on October 1, 2025, the U.S. government shut down and remained shut down until November 12, 2025, during which time certain regulatory agencies, such as the FDA and the SEC, furloughed certain employees and stopped certain activities. Additionally, on October 10, 2025, the U.S. government implemented substantial layoffs and workforce reductions in connection with the ongoing federal government shutdown, which resulted in the suspension or delay of various government-funded programs. The ability of the FDA to review and approve new products, to provide feedback on clinical trials and development programs, to meet with sponsors and to otherwise review regulatory submissions can be affected by a variety of factors, including government budget and funding levels, reductions in workforce, ability to hire and retain key personnel and accept the payment of user fees, substantial changes in leadership and shifting policy priorities as a result of changes in the presidential administration and its appointees tasked to oversee the agency, and statutory, regulatory, and policy changes. In the past, average review times at the agency have fluctuated, and this may continue in the future. In addition, government funding of other agencies on which our operations may rely is subject to the political process, which is inherently fluid and unpredictable. If we or our collaborators experience delays in obtaining approval or if we or they fail to obtain approval of our product candidates, the commercial prospects for our product candidates may be harmed and our ability to generate revenue will be materially impaired.

Disruptions at the FDA and other agencies, including as a result of reductions in force, significant organizational changes, substantial leadership departures, and policy changes, may also slow the time necessary for new product candidates to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. There is substantial uncertainty as to how the current U.S. administration will continue to modify or revise the requirements and policies of the FDA and other regulatory agencies with jurisdiction over our product candidates. For example, the current U.S. administration has implemented and 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. The impending uncertainty could present new challenges or potential opportunities as we navigate the clinical development and approval process for our product candidates. The current U.S. administration has also taken steps to reduce the number of federal employees by establishing voluntary termination programs, by position eliminations or by involuntary terminations. If funding for the FDA is reduced, if the FDA workforce is reduced, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Further, a prolonged or future shutdown of the U.S. federal government could materially impact the operations of the SEC. For example, the SEC announced that during the current U.S. federal government shutdown, it will not declare registration statements effective. In the event of an extended shutdown, the SEC may operate with limited staff or suspend certain functions altogether, which could delay the review or effectiveness of our filings, including registration statements or other financing-related disclosures. Such delays could adversely affect our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue to fund our operations.

**Risks Related to Our Relationships with Third Parties**

***We rely on third parties to conduct our preclinical and clinical trials and will rely on them to perform other tasks for us. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or comply with regulatory requirements, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.***

Although we have recruited a team that has experience with clinical trials, as a company, we have limited experience in conducting clinical trials. Moreover, we do not have the ability to independently conduct preclinical studies and clinical trials, and we have relied upon, and plan to continue to rely upon, medical institutions, clinical investigators, contract laboratories and other third parties, or our CROs, to conduct preclinical studies and future clinical trials for our product candidates. We expect to rely heavily on these parties for execution of preclinical and future clinical trials for our product candidates and control only certain aspects of their activities. Nevertheless, we will be responsible for ensuring that each of our preclinical and clinical trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards and our reliance on CROs will not relieve us of our regulatory responsibilities. For any violations of laws and regulations during the conduct of our preclinical studies and clinical trials, we could be subject to warning letters or enforcement action that may include civil and other penalties up to and including criminal prosecution.

We and our CROs will be required to comply with regulations, including GCPs for conducting, monitoring, recording and reporting the results of preclinical and clinical trials to ensure that the data and results are scientifically credible and accurate and that the trial patients are adequately informed of the potential risks of participating in clinical trials and their rights are protected. These regulations are enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area and comparable foreign regulatory authorities for any drugs in clinical development. The FDA enforces GCP regulations through periodic inspections of clinical trial sponsors, IRBs, and principal investigators and trial sites. If we or our CROs fail to comply with applicable GCPs, 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, the FDA will determine that any of our future clinical trials will comply with GCPs. In addition, our clinical trials must be conducted with product candidates produced in accordance with the requirements in the FDA's current cGMPs requirements. Our failure or the failure of our CROs to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process and could also subject us to enforcement action.

Although we intend to design our planned clinical trials for our product candidates, for the foreseeable future, CROs will conduct all of our planned clinical trials. As a result, many important aspects of our development programs, including their conduct and timing, will be outside of our direct control. Our reliance on third parties to conduct future preclinical studies and clinical trials will also result in less day-to-day control over 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.

If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs. If CROs 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, regulatory requirements or for other reasons, any preclinical studies or clinical trials with which such CROs are associated with may be extended, delayed or terminated. In such cases, we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates in the subject indication could be harmed, our costs could increase and our ability to generate revenue could be delayed.

***We currently rely on a single manufacturer for our clinical supply of our product candidates. In the event of a loss of this manufacturer, or a failure by such manufacturer to comply with FDA regulations, we may not be able to find an alternative source on commercially reasonable terms, or at all. In addition, third-party manufacturers and any third-party collaborators may be unable to successfully scale-up manufacturing of our current or future product candidates in sufficient quality and quantity, which would delay or prevent us from developing our product candidates and commercializing approved products, if any.***

We do not have any manufacturing facilities at the present time. We currently rely on third-party manufacturers, including Lonza Sales AG ("Lonza") as a single source supplier, for the manufacture and supply of our materials for preclinical studies and clinical trials, and expect to continue to do so for future clinical testing and for commercial supply of briquilimab and any other product candidates that we may develop and for which we or our collaborators obtain marketing approval. Our agreement with Lonza includes certain limitations on our ability to enter into supply arrangements with any other supplier without Lonza's consent. In addition, Lonza has the right to increase the prices it charges us for certain supplies depending on a number of factors, some of which are outside of our control. We may be unable to maintain or establish any agreements with third-party manufacturers or suppliers or to do so on acceptable terms. Even if we are able to establish agreements with third-party manufacturers or suppliers, reliance on third-party manufacturers entails additional risks, including:

- the possible breach of the manufacturing or supply agreement by the third party;
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us; and
- reliance on the third party for regulatory compliance, quality assurance, safety and pharmacovigilance and related reporting.

In addition, pursuant to our Exclusive License Agreement with Amgen Inc., Lonza Biologics, Inc. has been engaged to manufacture briquilimab for us. The agreement provides that in the event we wish to change the manufacturer of briquilimab to a different party, we must obtain Amgen Inc.'s prior consent. As a result, our ability to obtain any alternative supplier of briquilimab may be further limited.

Third-party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside the United States. Our failure, or the failure of our third-party manufacturers or suppliers, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocations, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products and harm our business, financial condition, results of operations and prospects.

Our product candidates may compete with other product candidates and products for access to manufacturing facilities and other supplies. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us. Also, prior to the approval of our product candidates, we would need to identify a contract manufacturer that could produce our products at a commercial scale and that could successfully complete FDA pre-approval inspection and inspections by other health authorities. Agreements with such manufacturers or suppliers may not be available to us at the time we would need to have that capability and capacity.

Any performance failure on the part of our existing or future manufacturers or suppliers, or any decision by a manufacturer or supplier to remove our products from the market or restrict access to our products, could delay clinical development or marketing approval. We do not currently have arrangements in place for redundant or guaranteed supply for many of the materials we currently use in our clinical trials or preclinical studies, and we may have difficulty or be unable to establish alternative sources of these materials.

***We may enter into collaborations with third parties for the research, development and commercialization of certain product candidates we may develop. If any such collaborations are not successful, we may not be able to capitalize on the market potential of those product candidates.***

We may seek third-party collaborators for the research, development and commercialization of certain product candidates we may develop. If we enter into any such arrangements with any third parties, we will likely have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization our product candidates. Our ability to generate revenues from these arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements. We cannot predict the success of any collaboration that we enter into.

Collaborations involving our current or future product candidates or research programs pose numerous risks to us, including the following:

- Collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborator's strategic focus or available funding or external factors such as an acquisition that diverts resources or creates competing priorities.

- Collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing.

- Collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours.

- Collaborators with marketing and distribution rights to one or more products may not commit sufficient resources to the marketing and distribution of such products.

- Collaborators may not properly obtain, maintain, enforce or defend our intellectual property or proprietary rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our proprietary information or expose us to potential litigation.

- Disputes may arise between the collaborators and us that result in the delay or termination of the research, development or commercialization of our products or product candidates or that result in costly litigation or arbitration that diverts management attention and resources.

- We may lose certain valuable rights under circumstances identified in our collaborations, including if we undergo a change of control; and

- Collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all. If a present or future collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program under such collaboration could be delayed, diminished or terminated.

If our collaborations do not result in the successful development and commercialization of product candidates, or if one of our collaborators terminates our agreement with us, we may not receive any future research funding or milestone or royalty payments under the collaboration. If we do not receive the funding we expect under these agreements, our development of product candidates could be delayed, and we may need additional resources to develop product candidates. In addition, if one of our collaborators terminates its agreement with us, we may find it more difficult to find a suitable replacement collaborator or attract new collaborators, and our development programs may be delayed or the perception of us in the business and financial communities could be adversely affected. All of the risks relating to product development, regulatory approval and commercialization described in this Annual Report on Form 10-K apply to the activities of our collaborators.

These relationships, or those like them, 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.

***If we are not able to establish collaborations on commercially reasonable terms, we may have to alter our development and commercialization plans.***

Our product development and research programs and the potential commercialization of briquilimab or any other product candidates we may develop will require substantial additional cash to fund expenses. For some of the product candidates we may develop, we may decide to collaborate with other pharmaceutical and biotechnology companies for the development and potential commercialization of those product candidates.

We would face significant competition in seeking appropriate collaborators. 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. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA, the EMA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge, and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us.

We may also be restricted under existing collaboration agreements from entering into future agreements on certain terms with potential collaborators. Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the product candidate for which we are seeking to collaborate, reduce or delay our development program or one or more of our other development programs, delay our potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to develop product candidates or bring them to market and generate product revenue.

**Risks Related to Our Intellectual Property**

***We are highly dependent on intellectual property licensed from third parties, and termination of any of these licenses could result in the loss of significant rights, which would harm our business.***

We are dependent on the patents, know-how and proprietary technology licensed from third parties for the development and, if approved, commercialization of briquilimab. Any termination of these licenses, or a finding that such intellectual property lacks legal effect, could result in the loss of significant rights and could harm our ability to commercialize our current or future product candidates.

For example, we rely on our worldwide exclusive license agreement with Amgen Inc., whereby we license a patent portfolio from Amgen Inc. applicable to our targeted conditioning program that contains patent families directed to humanized KIT antibody. We also rely on our license agreement with Stanford, whereby we license a patent portfolio applicable to our targeted conditioning program that contains patent families directed to immunodepletion of endogenous stem cell niche for engraftment.

Each of our license agreements with third parties impose certain obligations on us, including obligations to use diligent efforts to meet development thresholds and payment obligations. Non-compliance with such obligations may result in termination of the respective license agreement or in legal and financial consequences. If any of our licensors terminates its respective license agreement, we may not be able to develop or commercialize briquilimab or any other product candidates covered by these agreements. Termination of our license agreements or reduction or elimination of our rights under them may result in us having to negotiate a new or reinstated agreement, which may not be available to us on equally favorable terms, or at all, which may mean we are unable to develop, commercialize or sell the affected product candidate or may cause us to lose our rights under the agreement.

In addition, our licensors may make decisions in prosecuting, maintaining, enforcing and defending any licensed intellectual property rights that may not be in our best interest. Moreover, if our licensors take any action with respect to any licensed intellectual property rights, for example, any licensed patents or patent applications, that results in a successful challenge to the licensed intellectual property by a third party, such patents may be invalidated or held to be unenforceable, and we may lose our rights under such patents, which could materially harm our business.

Further, the agreements under which we currently license intellectual property from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. Accordingly, disputes may arise between us and our licensors regarding intellectual property subject to a license agreement. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement. If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, or are insufficient to provide us with the necessary rights to use the intellectual property, we may be unable to successfully develop and commercialize the affected product candidates.

***Our commercial success depends on our ability to obtain, maintain and protect our intellectual property and proprietary technology.***

Our commercial success depends in large part on our ability to obtain, maintain and protect intellectual property rights through patents, trademarks and trade secrets in the United States and other countries with respect to our proprietary product candidates. If we do not adequately protect our intellectual property rights, competitors may be able to erode, negate or preempt any competitive advantage we may have, which could harm our business and ability to achieve profitability.

To protect our proprietary position, we own and have in-licensed certain intellectual property rights, including certain issued patents and patent applications, and have filed and may file provisional and non-provisional patent applications in the United States or abroad related to our product candidates that are important to our business. Provisional patent applications are not eligible to become issued patents until, among other things, we file a non-provisional patent application within 12 months of the filing of one or more of our related provisional patent applications. If we do not timely file non-provisional patent applications, we may lose our priority date with respect to our provisional patent applications and any patent protection on the inventions disclosed in our provisional patent applications. While we intend to timely file non-provisional patent applications relating to our provisional patent applications, we cannot predict whether any such patent applications will result in the issuance of patents that provide us with any competitive advantage. Moreover, the patent application and approval process is expensive and time-consuming. We may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner.

The patent application, prosecution, and enforcement processes are subject to numerous risks and uncertainties, and there can be no assurance that we, our licensors, or any of our future collaborators will be successful in protecting our product candidates by obtaining, defending, and/or asserting patent rights. These risks and uncertainties include the following:

- the U.S. Patent and Trademark Office (the "USPTO") and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. There are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case;

- patent applications may not result in any patents being issued;

- patents that may be issued or in-licensed may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable or otherwise may not provide any competitive advantage;

- our competitors, many of whom have substantially greater resources and many of whom have made significant investments in competing technologies, may seek or may have already obtained patents that will limit, interfere with or eliminate our ability to make, use, and sell our potential product candidates;

- there may be significant pressure on the U.S. government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns; and

- countries other than the United States may have patent laws less favorable to patentees than those upheld by U.S. courts, allowing foreign competitors a better opportunity to create, develop and market competing product candidates.

In some instances, agreements through which we license intellectual property rights may not give us control over patent prosecution or maintenance, so that we may not be able to control which claims or arguments are presented, how claims are amended, and may not be able to secure, maintain or successfully enforce necessary or desirable patent protection from those patent rights. We cannot be certain that patent prosecution and maintenance activities by our licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents.

Moreover, some of our in-licensed patents and patent applications may be, and some of our future owned and licensed patents may be, co-owned with third parties. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us.

***The patent protection we obtain for our product candidates may not be sufficient enough to provide us with any competitive advantage or our patents may be challenged.***

Our owned and licensed patents and pending patent applications, if issued, may not provide us with any meaningful protection or may not prevent competitors from designing around our patent claims to circumvent our patents by developing similar or alternative technologies or therapeutics in a non-infringing manner. For example, a third party may develop a competitive product that provides benefits similar to one or more of our product candidates but falls outside the scope of our patent protection or license rights. If the patent protection provided by the patents and patent applications we hold or pursue with respect to our product candidates is not sufficiently broad to impede such competition, our ability to successfully commercialize our product candidates could be negatively affected, which would harm our business. Currently, a significant portion of our patents and patent applications are in-licensed, though similar risks would apply to any patents or patent applications that we now own or may own or in-license in the future.

It is possible that defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, for example with respect to proper priority claims, inventorship, claim scope or requests for patent term adjustments. If we or our partners, collaborators, licensees or licensors, whether current or future, fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If our partners, collaborators, licensees or licensors, are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised. If there are material defects in the form, preparation, prosecution or enforcement of our patents or patent applications, such patents may be invalid and/or unenforceable, and such applications may never result in valid, enforceable patents. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

In addition, the determination of patent rights with respect to clinical compositions of matter and treatment methods commonly involves complex legal and factual questions, which are dependent upon the current legal and intellectual property context, extant legal precedent and interpretations of the law by individuals. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are characterized by uncertainty.

Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. In addition, the laws of foreign countries may not protect our rights to the same extent or in the same manner as the laws of the United States. For example, patent laws in various jurisdictions, including significant commercial markets such as Europe, restrict the patentability of methods of treatment of the human body more than U.S. law does. If these changes were to occur, they could have a material adverse effect on our ability to generate revenue.

Pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. Assuming the other requirements for patentability are met, currently, the first party to file a patent application is generally entitled to the patent. However, prior to March 16, 2013, in the United States, the first party to invent was entitled to the patent. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. Similarly, we cannot be certain that parties from whom we do or may license or purchase patent rights were the first to make relevant claimed inventions, or were the first to file for patent protection for them. If third parties have filed prior patent applications on inventions claimed in our patents or applications that were filed on or before March 15, 2013, an interference proceeding in the United States can be initiated by such third parties to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. If third parties have filed such prior applications after March 15, 2013, a derivation proceeding in the United States can be initiated by such third parties to determine whether our invention was derived from theirs.

Moreover, because the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, our owned and licensed patents or pending patent applications may be challenged in the courts or patent offices in the United States and abroad. There is no assurance that all of the potentially relevant prior art relating to our patents and patent applications has been found. If such prior art exists, it may be used to invalidate a patent, or may prevent a patent from issuing from a pending patent application. For example, such patent filings may be subject to a third-party submission of prior art to the USPTO, or to other patent offices around the world. Alternately or additionally, we may become involved in post-grant review procedures, oppositions, derivation proceedings, ex parte reexaminations, inter parties review, supplemental examinations, or interference proceedings or challenges in district court, in the United States or in various foreign patent offices, including both national and regional, challenging patents or patent applications in which we have rights, including patents on which we rely to protect our business. For example, the two European patents we have licensed from Stanford are currently being opposed. An adverse determination in these oppositions or any other challenges to our patents or patent applications may result in loss of the patent or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, or in denial of the patent application or loss or reduction in the scope of one or more claims of the patent application, any of which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. In addition, given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized.

Issued patents that we have or may obtain or license may not provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner. Our competitors may also seek approval to market their own products similar to or otherwise competitive with our products. Alternatively, our competitors may seek to market generic versions of any approved products or pursue similar strategies in the United States or other jurisdictions, in which they claim that patents owned or licensed by us are invalid, unenforceable or not infringed. In these circumstances, we may need to defend or assert our patents, or both, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or other agency with jurisdiction may find our patents invalid or unenforceable, or that our competitors are competing in a non-infringing manner. Thus, even if we have valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

Other parties have developed or may develop technologies that may be related to or competitive with our approach, and may have filed or may file patent applications and may have been issued or may be issued patents with claims that overlap or conflict with our patent applications, either by claiming the same materials, formulations or methods, or by claiming subject matter that could dominate our patent position. In addition, certain parts or all of the patent portfolios licensed to us are, or may be, licensed to third parties and such third parties may have or may obtain certain enforcement rights. If the scope of the patent protection we or our licensors obtain is not sufficiently broad, we may not be able to prevent others from developing and commercializing technology and products similar or identical to ours. The degree of patent protection we require to successfully compete in the marketplace may be unavailable or severely limited in some cases and may not adequately protect our rights or permit us to gain or keep any competitive advantage. We cannot provide any assurances that any of our licensed patents have, or that any of our pending owned or licensed patent applications that mature into issued patents will include, claims with a scope sufficient to protect our product candidates or otherwise provide any competitive advantage, nor can we provide any assurance that our licenses will remain in force.

In addition, 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. Noncompliance 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.

***Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, 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 on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies 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. Noncompliance 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. In such an event, our competitors might be able to enter the market earlier than would otherwise have been the case, which would have a material adverse effect on our business, financial condition, results of operations, and prospects.

***If we are unable to protect the confidentiality of our trade secrets, our business and competitive position may be harmed.***

In addition to the protection afforded by patents, we rely upon trade secret protection, know-how and continuing technological innovation to develop and maintain our competitive position. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with our contractors, collaborators, scientific advisors, employees and consultants and invention assignment agreements with our consultants and employees. However, we may not obtain these agreements in all circumstances, and individuals with whom we have these agreements may not comply with their terms. The assignment of intellectual property rights under these agreements may not be self-executing or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. In addition, we may not be able to prevent the unauthorized disclosure or use of our technical know-how or other trade secrets by the parties to these agreements despite the existence of confidentiality agreements and other contractual restrictions. Monitoring unauthorized uses and disclosures is difficult and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. If any of the contractors, collaborators, scientific advisors, employees and consultants who are parties to these agreements breaches or violates the terms of any of these agreements, we may not have adequate remedies for any such breach or violation. As a result, we could lose our trade secrets. Enforcing a claim against a third party that illegally obtained and is using our trade secrets, like patent litigation, is expensive and time-consuming and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing or unwilling to protect trade secrets. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Moreover, our trade secrets could otherwise become known or be independently discovered by our competitors or other third parties. Competitors and other third parties could attempt to replicate some or all of the competitive advantages we derive from our development efforts, willfully infringe our intellectual property rights, design around our protected technology or develop their own competitive technologies that fall outside of our intellectual property rights. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If our trade secrets are not adequately protected or sufficient to provide an advantage over our competitors, our competitive position could be adversely affected, as could our business. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating our trade secrets.

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

Our current or future trademarks or trade names may be challenged, infringed, circumvented or declared generic or descriptive or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. Our company name and logo, as well as our product candidate names "briquilimab", "JSP191", and "JSP502", are not registered trademarks. If we seek to register any of our trademarks, during trademark registration proceedings, we may receive rejections of our applications by the USPTO or in other foreign jurisdictions. Although we would be given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected. We may license our trademarks and trade names to third parties, such as distributors. Although these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and tradenames by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names.

Moreover, any name we have proposed to use with our product candidate in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. Similar requirements exist in Europe. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA (or an equivalent administrative body in a foreign jurisdiction) objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. Furthermore, in many countries, owning and maintaining a trademark registration may not provide an adequate defense against a subsequent infringement claim asserted by the owner of a senior trademark. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. If we assert trademark infringement claims, a court 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 this case, we could ultimately be forced to cease use of such trademarks.

***We may not be successful in acquiring or in-licensing necessary rights to key technologies underlying briquilimab or any future product candidates we may develop.***

We currently have rights to intellectual property, through licenses from third parties, to develop briquilimab, and we expect to seek to expand our intellectual property footprint related to our product candidate pipeline in part by in-licensing the rights to key technologies. The future growth of our business will depend in part on our ability to in-license or otherwise acquire the rights to develop additional product candidates and technologies. Although we have succeeded in licensing technologies from third-party licensors, including Amgen Inc. and Stanford, in the past, we can give no assurance that we will be able to in-license or acquire the rights to other technologies relevant to our product candidates from third parties on acceptable terms or at all.

In order to market our product candidates, we may find it necessary or prudent to obtain licenses from such third-party intellectual property holders. However, it may be unclear who owns the rights to intellectual property we wish to obtain, or we may be unable to secure such licenses or otherwise acquire or in-license intellectual property rights from third parties that we identify as necessary for product candidates we may develop and technology we employ. We currently conduct our preclinical research and clinical trials under 35 U.S.C. § 271(e)(1), which provides a safe harbor from patent infringement for uses of patented technology reasonably related to the development and submission of information under a federal law which regulates the manufacture, use, or sale of drugs.

The licensing or acquisition of third-party intellectual property rights is a highly competitive area, and other companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. Such companies may have a competitive advantage over us, e.g., 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 the existing intellectual property rights we have, we may have to abandon development of the relevant program or product candidate, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Even if we were able to obtain such a license, it could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, we may be unable to commercialize our product candidates or such commercialization efforts may be significantly delayed, which could in turn significantly harm our business.

***Third-party claims of intellectual property infringement, misappropriation or other violations may prevent or delay our product discovery and development efforts and have a material adverse effect on our business.***

Our commercial success depends in part on us avoiding infringement, misappropriation and other violations of the patents and proprietary rights of third parties. There is a substantial amount of litigation involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, as well as administrative proceedings for challenging patents, including interference and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. Recently, under U.S. patent reform, new procedures including *inter partes* review and post grant review have been implemented. This reform will bring uncertainty to the possibility of challenge to our patents in the future. Numerous U.S.-and foreign-issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing our product candidates, and third parties may allege they have patent rights encompassing our product candidates, technologies or methods. Third parties may assert that we are employing their proprietary technology without authorization and may file patent infringement claims or lawsuits against us, and if we are found to infringe such third-party patents, we may be required to pay damages, cease commercialization of the infringing technology or obtain a license from such third parties, which may not be available on commercially reasonable terms or at all.

There may be third-party patents with patent rights to materials, formulations, methods of manufacture or methods of treatment related to the use or manufacture of our product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Further, we or our licensors may fail to identify even those relevant third-party patents that have issued or may incorrectly interpret the relevance, scope or expiration of such patents. The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or scope of a patent or a pending application may be incorrect. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of our product candidates, materials used in or formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize the product candidate unless we obtained a license under the applicable patents, or until such patents expire or they are finally determined to be held invalid or unenforceable. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of our materials, formulations or methods, including without limitation, combination therapy or patient selection methods, the holders of any such patent may be able to block our ability to develop and commercialize the product candidate unless we obtained a license or until such patent expires or is finally determined to be held invalid or unenforceable.

Parties making claims against us may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would involve a substantial diversion of employee resources from our business. We may not have sufficient resources to bring these actions to a successful conclusion, which may result in significant cost and may impede our inability to pursue any affected products or product candidates. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of shares of our common stock.

In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure.

***Some intellectual property that we have in-licensed may have been discovered through government-funded programs and thus may be subject to federal regulations such as "march-in" rights, certain reporting requirements and a preference for U.S.-based companies. Compliance with such regulations may limit our exclusive rights and limit our ability to contract with non-U.S. manufacturers.***

Any of the intellectual property rights that we have licensed or may license in the future and that have been generated through the use of U.S. government funding are subject to certain federal regulations. As a result, the U.S. government may have certain rights to intellectual property embodied in our current or future product candidates pursuant to the Bayh-Dole Act of 1980 ("Bayh-Dole Act"). These U.S. government rights in certain inventions developed under a government-funded program include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U.S. government would have the right to require us to grant exclusive, partially exclusive, or non-exclusive licenses to any such intellectual property rights to a third party if it determines that:

- adequate steps have not been taken to commercialize the invention;
- government action is necessary to meet public health or safety needs; or
- government action is necessary to meet requirements for public use under federal regulations (also referred to as "march-in rights").

The U.S. government also has the right to take title to such intellectual property rights if we, or the applicable licensor, fail to disclose the invention to the government and fail to file an application to register the intellectual property within specified time limits. Intellectual property generated under a government-funded program is also subject to certain reporting requirements, compliance with which may require us or the applicable licensor to expend substantial resources. We cannot be certain that our current or future licensors will comply with the disclosure or reporting requirements of the Bayh-Dole Act at all times, or be able to rectify any lapse in compliance with these requirements.

In addition, the U.S. government requires that any products embodying the subject invention or produced through the use of the subject invention be manufactured substantially in the United States. The manufacturing preference requirement can be waived if the owner of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. This preference for U.S. manufacturers may limit our ability to contract with non-U.S. product manufacturers for products covered by such intellectual property. To the extent any of our current or future intellectual property is generated through the use of U.S. government funding, the provisions of the Bayh-Dole Act may similarly apply.

***We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time-consuming and unsuccessful.***

Competitors may infringe our patents, trademarks, copyrights or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming and divert the time and attention of our management and scientific personnel. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents, in addition to counterclaims asserting that our patents are invalid or unenforceable, or both. In any patent infringement proceeding, there is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patent claims do not cover the invention. An adverse outcome in a litigation or proceeding involving our patents could limit our ability to assert our patents against those parties or other competitors, and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Any of these occurrences could adversely affect our competitive business position, business prospects and financial condition. Similarly, if we assert trademark infringement claims, a court 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 this case, we could ultimately be forced to cease use of such trademarks.

Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of shares of our common stock. Moreover, there can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings. Any of the foregoing may have a material adverse effect on our business, financial condition, results of operations and prospects.

***We may not be able to protect our intellectual property rights throughout the world.***

Filing, prosecuting, maintaining, defending and enforcing patents on our product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own drugs and may export otherwise infringing drugs to territories where we have patent protection, but enforcement rights are not as strong as those in the United States. These drugs may compete with our product candidates and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of some countries do not favor the enforcement of patents and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful.

Many countries have compulsory licensing laws under which a patent owner may be compelled under specified circumstances to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In those countries, we may have limited remedies if patents are infringed or if we are compelled to grant a license to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license, which could adversely affect our business, financial condition, results of operations, and prospects.

***If we do not obtain patent term extension and data exclusivity for briquilimab or any other product candidates we may develop, our business may be materially harmed.***

Depending upon the timing, duration and conditions of any FDA marketing approval of our product candidates, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments, and similar legislation in the European Union. The Hatch-Waxman Amendments permit a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. However, we may not receive an extension if we fail to exercise due diligence during the testing phase or regulatory review process, fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. Only one patent per approved product can be extended; the extension cannot extend the total patent term beyond 14 years from approval; and only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for the applicable product candidate will be shortened, and our competitors may obtain approval to market competing products sooner. As a result, our revenue from applicable products could be reduced. Further, if this occurs, our competitors may take advantage of our investment in development and trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case, and our competitive position, business, financial condition, results of operations, and prospects could be materially harmed.

***Third parties may assert that our employees or consultants have wrongfully used or disclosed confidential information or misappropriated trade secrets.***

We employ individuals who were previously employed at universities or other biopharmaceutical companies, including our competitors or potential competitors, and we may in the future be subject to claims that former employees, consultants, or other third parties have an interest in our patents or other intellectual property as an inventor, co-inventor, or owner of trade secrets. Although it is our policy to require our employees and consultants who may be involved in the conception or development of intellectual property to execute agreements assigning that intellectual property to us, we may be unsuccessful in executing such an agreement with each party who conceives or develops intellectual property that we regard as our own or such party may breach the assignment agreement, or we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of a former employer or other third parties. We may also be subject to claims that patents and applications that we may file to protect inventions of our employees or consultants are rightfully owned by their former employers or other third parties. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. 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. Any of the foregoing would harm our business, financial condition, results of operations, and prospects.

***Changes in U.S. patent law or the patent law of other countries or jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products.***

The U.S. has enacted and implemented wide-ranging patent reform legislation. The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on actions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce patents that we have licensed or that we might obtain in the future. Similarly, changes in patent law and regulations in other countries or jurisdictions or changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we have licensed or that we may obtain in the future. For example, the complexity and uncertainty of European patent laws have also increased in recent years. In Europe, in June 2023, a new unitary patent system was introduced, which will significantly impact European patents, including those granted before the introduction of the system. Under the unitary patent system, after a European patent is granted, the patent proprietor can request unitary effect, thereby getting a European patent with unitary Effect (a "Unitary Patent"). Each Unitary Patent is subject to the jurisdiction of the Unitary Patent Court ("UPC"). As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation. Patents granted before the implementation of the UPC will have the option of opting out of the jurisdiction of the UPC and remaining as national patents in the UPC countries. Patents that remain under the jurisdiction of the UPC may be potentially vulnerable to a single UPC-based revocation challenge that, if successful, could invalidate the patent in all countries who are signatories to the UPC. We cannot predict with certainty the long-term effects of the new unitary patent system.

**Risks Related to Other Legal Compliance Matters**

***If any of our product candidates are approved, an unfavorable reimbursement determination in any of the major markets could have a negative impact on us. Further, an unfavorable change in such regimes (e.g., price controls) could have a negative impact on us.***

The regulations that govern marketing approvals, pricing, and reimbursement for new medicines vary widely from country to country. Some countries require approval of the sale price of a medicine before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a medicine in a particular country, but then be subject to price regulations that delay our commercial launch of the medicine, possibly for lengthy time periods, and negatively impact the revenues we are able to generate from the sale of the medicine in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if any product candidates we may develop obtain marketing approval.

Our ability to commercialize any medicines successfully also will depend in part on the extent to which reimbursement for these medicines and related treatments will be available from government health administration authorities, private health insurers, and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. For example, in May 2019, the Centers for Medicare & Medicaid Services ("CMS") issued a final rule to allow Medicare Advantage Plans the option of using step therapy, a type of prior authorization for Medicare Party B drugs, beginning January 1, 2020. This final rule codified CMS's policy change that was effective January 1, 2019.

Congress has indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. Individual states in the U.S. have also increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. See the discussion below under the heading "The prices of prescription pharmaceuticals in the United States and foreign jurisdictions are subject to considerable legislative and executive actions and could impact the prices we obtain for our products, if and when licensed" for additional detail.

At the state level, legislatures have become increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing. Some of these measures include price or patient reimbursement constraints, discounts, restrictions on certain product access, marketing cost disclosure and transparency measures, and, in some cases, measures designed to encourage importation from other countries and bulk purchasing. In addition, regional health care 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 health care programs. Also, increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any medicine that we commercialize and, if reimbursement is available, the level of reimbursement. Reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval.

There may be significant delays in obtaining reimbursement for newly approved medicines, and coverage may be more limited than the purposes for which the medicine is approved by the FDA or similar regulatory authorities outside the U.S. Moreover, eligibility for reimbursement does not imply that any medicine will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new medicines, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the medicine and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost medicines and may be incorporated into existing payments for other services. Net prices for medicines may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of medicines from countries where they may be sold at lower prices than in the U.S. Any such reductions could negatively impact our net product sales, if any of our product candidates are ever approved.

***Any product candidate for which we obtain marketing approval could be subject to restrictions or withdrawal from the market, and we may be subject to substantial penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our medicines, when and if any of them are approved.***

The FDA and other regulatory agencies closely regulate the post approval marketing and promotion of medicines to ensure that they are marketed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA and other regulatory agencies impose stringent restrictions on manufacturers' communications regarding off label use, and if we do not market our medicines for their approved indications, we may be subject to enforcement action for off label marketing by the FDA and other federal and state enforcement agencies, including the Department of Justice. Violation of the Federal Food, Drug, and Cosmetic Act and other statutes, including the False Claims Act, relating to the promotion and advertising of prescription products may also lead to investigations or allegations of violations of federal and state healthcare fraud and abuse laws and state consumer protection laws.

In addition, later discovery of previously unknown problems with our medicines, third-party manufacturers, or manufacturing processes, or failure to comply with regulatory requirements, may yield various results, including:

- restrictions on such medicines, manufacturers, or manufacturing processes;
- restrictions on the labeling or marketing of a medicine;

- restrictions on the distribution or use of a medicine;
- requirements to conduct post marketing clinical trials;
- receipt of warning or untitled letters;
- withdrawal of the medicines from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of medicines;
- fines, restitution, or disgorgement of profits or revenue;
- suspension or withdrawal of marketing approvals;
- suspension of any ongoing clinical trials;
- refusal to permit the import or export of our medicines;
- product seizure; and
- injunctions or the imposition of civil or criminal penalties.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize any product candidates we develop and adversely affect our business, financial condition, results of operations, and prospects.

Additionally, if any of our product candidates receives marketing approval, the FDA could require it to adopt a Risk Evaluation and Mitigation Strategy, to ensure that the benefits outweigh its risks, which may include, among other things, a medication guide outlining the risks of the product for distribution to patients and a communication plan to healthcare practitioners. Furthermore, if we or others later identify undesirable side effects caused by any of our product candidates, several potentially significant negative consequences could result, including:

- regulatory authorities may suspend or withdraw approvals of such product candidate;
- regulatory authorities may require additional warnings on the label;
- we may be required to change the way such product candidate is administered or conduct additional clinical trials;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

***Our relationships with healthcare providers, including physicians, and third-party payors will be subject to applicable anti-kickback, fraud and abuse, anti-bribery and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.***

Healthcare providers and third-party payors play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our current and future arrangements with healthcare providers, third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we research as well as market, sell and distribute our products for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations, including certain laws and regulations applicable only if we have marketed products, include, but are not limited to, the following:

- the federal healthcare program Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, receiving, offering, or providing any remuneration (including any kickback, bribe or certain rebates), directly or indirectly, in cash or in kind, to induce, or in return for, either the referral of an individual, for the purchase, lease, order or recommendation of any item, good, facility or service for which payment may be made, in whole or in part, under federal healthcare programs, such as Medicare and Medicaid. 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;

- federal false claims, including the False Claims Act that can be enforced through whistleblower actions, false statements and civil monetary penalties laws, which prohibit, among other things, any person or entity from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment of government funds or knowingly making, or causing to be made, a false record or statement material to a false or fraudulent claim to get a false claim paid or to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;

- the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which, prohibits, among other things, executing, or attempting to execute, a scheme to defraud any healthcare benefit program or making false, fictitious, or fraudulent statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the federal Anti-Kickback Statute, 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;

- the federal false statements statute, which prohibits knowingly and willfully falsifying, concealing, or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items, or services;

- the federal Food, Drug, and Cosmetic Act, which among other things, strictly regulates drug marketing, prohibits manufacturers from marketing such products for off-label use and regulates the distribution of samples;

- federal laws that require pharmaceutical manufacturers to report certain calculated product prices to the government or provide certain discounts or rebates to government authorities or private entities, often as a condition of reimbursement under government healthcare programs;

- the federal Physician Payments Sunshine Act, which 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 certain exceptions) to report annually to the CMS within the U.S. Department of Health and Human Services, information related to payments or other transfers of value made during the previous year to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Beginning in 2022, such obligations include payments and other transfers of value provided in the previous year to certain other healthcare professionals, including physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiologist assistants and certified nurse midwives; and

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may be broader in scope and apply to healthcare items or services that are reimbursed by non-governmental third-party payors, including private insurers.

Some state laws also require pharmaceutical companies to comply with specific compliance standards, restrict financial interactions between pharmaceutical companies and healthcare providers or require pharmaceutical companies to report information related to payments to health care providers or marketing expenditures. Certain state laws also require the reporting of information related to drug pricing. Further, certain state and local laws require the registration of pharmaceutical sales representatives.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. Given the breadth of the laws and regulations and evolving government interpretations of the laws and regulations, governmental authorities may possibly conclude that our business practices, including certain of our advisory board arrangements with physicians, some of whom are compensated in the form of stock or stock options, may not comply with healthcare laws and regulations. If our operations are found to be in violation of any of the laws described above or any other government regulations that apply to us, we may be subject to significant penalties, including administrative, civil and criminal penalties, damages, fines, disgorgement, exclusion from participation in government health care programs, such as Medicare and Medicaid, imprisonment, integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings, and the curtailment or restructuring of our operations, any of which could adversely affect our business, financial condition, results of operations, and prospects.

The European Union has strict laws governing the provision of benefits or advantages to healthcare professionals in order to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products. Such laws and associated codes of practice set out the rules and requirements that the provision of hospitality, sponsorship, gifts and promotional items must meet before they can be accepted by healthcare professionals. The provision of benefits or advantages to healthcare professionals is also governed by the national anti-bribery laws of European Union Member States. Infringement of these laws could result in substantial fines and imprisonment.

Payments made to healthcare professionals in certain European Union Member States may be publicly disclosed. Moreover, agreements with healthcare professionals often must be the subject of prior notification and approval by the healthcare professionals' employer, his or her competent professional organization, and/or the regulatory authorities of the individual European Union Member States. These requirements are provided in the national laws, industry codes, or professional codes of conduct applicable in the European Union Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

***Healthcare and other reform legislation may increase the difficulty and cost for us and any collaborators we may have to obtain marketing approval of and commercialize briquilimab and any other product candidates we may develop and affect the prices we, or they, may obtain.***

In the United States and some foreign jurisdictions, there have been, and continue to be, ongoing efforts to implement legislative and regulatory changes regarding the healthcare system. Such changes could prevent or delay marketing approval of briquilimab and any other product candidates that we may develop, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidates for which we obtain marketing approval. Although we cannot predict what healthcare or other reform efforts will be successful, such efforts may result in more rigorous coverage criteria, in additional downward pressure on the price that we, or our future collaborators, may receive for any approved products or in other consequences that may adversely affect our ability to achieve or maintain profitability.

Within the United States, the federal government and individual states have aggressively pursued healthcare reform, as evidenced by the passing of the ACA and the ongoing efforts to modify or repeal that legislation. The ACA substantially changed the way healthcare is financed by both governmental and private insurers and contains a number of provisions that affect coverage and reimbursement of drug products and/or that could potentially reduce the demand for pharmaceutical products such as increasing drug rebates under state Medicaid programs for brand name prescription drugs and extending those rebates to Medicaid managed care and assessing a fee on manufacturers and importers of brand name prescription drugs reimbursed under certain government programs, including Medicare and Medicaid. Other aspects of healthcare reform, such as expanded government enforcement authority and heightened standards that could increase compliance-related costs, could also affect our business. There are, and may continue to be, judicial challenges, including review by the United States Supreme Court. We cannot predict the ultimate content, timing or effect of any changes to the ACA or other federal and state reform efforts. There is no assurance that federal or state healthcare reform will not adversely affect our future business and financial results, and we cannot predict how future federal or state legislative, judicial or administrative changes relating to healthcare reform will affect our business.

Federal and state governments have shown significant interest in implementing cost-containment programs to limit the growth of government-paid healthcare costs, including price controls, waivers from Medicaid drug rebate law requirements, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs. The private sector has also sought to control healthcare costs by limiting coverage or reimbursement or requiring discounts and rebates on products. We are unable to predict what additional legislation, regulations or policies, if any, relating to the healthcare industry or third party coverage and reimbursement may be enacted in the future or what effect such legislation, regulations or policies would have on our business. Any cost containment measures could significantly decrease the available coverage and the price we might establish for our potential products, which would have an adverse effect on our net revenues and operating results.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for biotechnology products. We cannot be sure whether additional legislative changes will be enacted, or whether FDA regulations, guidance or interpretations for biological products will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval and decision-making processes may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

***The prices of prescription pharmaceuticals in the United States and foreign jurisdictions are subject to considerable legislative and executive actions and could impact the prices we obtain for our products, if and when licensed.***

The prices of prescription pharmaceuticals have also been the subject of considerable discussion in the United States. To date, there have been several recent U.S. congressional inquiries and proposed and enacted state and federal legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of drugs under Medicare and reform government program reimbursement methodologies for products. At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In January 2024, the FDA authorized Florida's Agency for Health Care Administration's drug importation program, which is the first step toward Florida facilitating importation of certain prescription drugs from Canada. Authorization of other state programs may follow as other states have submitted importation program proposals. The Trump Administration has publicly supported such state-directed importation programs, and the FDA has taken steps to facilitate such states in initiating such programs. In addition, regional health care organizations 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 health care programs. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

In the European Union, similar political, economic and regulatory developments may affect our ability to profitably commercialize our product candidates, if approved. In markets outside of the United States and the European Union, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. In some countries, particularly the countries of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidates to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed, possibly materially.

In addition, on August 16, 2022, former President Biden signed into law the Inflation Reduction Act of 2022, which, among other things, includes policies that are designed to have a direct impact on drug prices and reduce drug spending by the federal government, took effect in 2023. Under the Inflation Reduction Act of 2022, Congress authorized Medicare beginning in 2026 to negotiate lower prices for certain costly single-source drug and biologic products that do not have competing generics or biosimilars. This provision is limited in terms of the number of pharmaceuticals whose prices can be negotiated in any given year and it only applies to drug products that have been approved for at least 9 years and biologics that have been licensed for 13 years. Drugs and biologics that have been approved for a single rare disease or condition are categorically excluded from price negotiation. Further, the new legislation provides that if pharmaceutical companies raise prices in Medicare faster than the rate of inflation, they must pay rebates back to the government for the difference. The new law also caps Medicare out-of-pocket drug costs at $2,000 a year. Various industry stakeholders, including pharmaceutical companies, have lawsuits pending against the federal government asserting that the price negotiation provisions of the IRA are unconstitutional. HHS has generally won the substantive disputes in these cases, but certain of these cases continue to be appealed. Under the Trump Administration, CMS has continued to negotiate drug prices pursuant to the IRA framework. The Trump Administration has also issued public statements about its commitment to lowering the cost of prescription drugs and has sought additional voluntary agreements to reduce drug pricing from certain pharmaceutical manufacturers. The effects of the IRA on our business is not yet known.

***Our employees, principal investigators, consultants and commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.***

We are exposed to the risk of fraud or other misconduct by our employees, consultants and commercial partners, and, if we commence clinical trials, our principal investigators. Misconduct by these parties could include intentional failures to comply with FDA regulations or the regulations applicable in the European Union and other jurisdictions, provide accurate information to the FDA, the EMA and other regulatory authorities, comply with healthcare fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Such misconduct also could involve the improper use of information obtained in the course of clinical trials or interactions with the FDA, the EMA or other regulatory authorities, which could result in regulatory sanctions and cause serious harm to our reputation. We have adopted a code of conduct applicable to all of our employees, but it is not always possible to identify and deter employee misconduct, 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 government investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, financial condition, results of operations and prospects, including the imposition of significant fines or other sanctions.

***Laws and regulations governing any international operations we may have in the future may preclude us from developing, manufacturing and selling certain product candidates outside of the United States and require us to develop and implement costly compliance programs.***

We may be subject to numerous laws and regulations in each jurisdiction outside of the United States in which we may operate. The creation, implementation and maintenance of international business practices compliance programs is costly and such programs are difficult to enforce, particularly where reliance on third parties is required.

The Foreign Corrupt Practices Act (the "FCPA") prohibits any U.S. individual or business from paying, offering, authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring us to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations. The anti-bribery provisions of the FCPA are enforced primarily by the Department of Justice. The SEC is involved with enforcement of the books and records provisions of the FCPA.

Similarly, the U.K. Bribery Act 2010 has extra-territorial effect for companies and individuals having a connection with the United Kingdom. The U.K. Bribery Act prohibits inducements both to public officials and private individuals and organizations. Compliance with the FCPA and the U.K. Bribery Act is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

Various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. Our expansion outside of the United States has required, and will continue to require, us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing or selling certain product candidates outside of the United States, which could limit our growth potential and increase our development costs. The failure to comply with laws governing international business practices may result in substantial penalties, including suspension or debarment from government contracting. Violation of the FCPA can result in significant civil and criminal penalties. Indictment alone under the FCPA can lead to suspension of the right to do business with the U.S. government until the pending claims are resolved. Conviction of a violation of the FCPA can result in long-term disqualification as a government contractor. The termination of a government contract or relationship as a result of our failure to satisfy any of our obligations under laws governing international business practices would have a negative impact on our operations and harm our reputation and ability to procure government contracts. The SEC also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions.

***Compliance with global privacy and data security requirements could result in additional costs and liabilities to us or inhibit our ability to collect and process data globally, and the failure to comply with such requirements could subject us to significant fines and penalties, which may have a material adverse effect on our business, financial condition and results of operations.***

The regulatory framework for the collection, use, safeguarding, sharing, transfer, and other processing of information worldwide is rapidly evolving and is likely to remain uncertain for the foreseeable future. Globally, virtually every jurisdiction in which we operate has established its own data security and privacy frameworks with which we must comply. For example, the collection, use, disclosure, transfer, or other processing of personal data regarding individuals in the European Union, including personal health data, is subject to the EU General Data Protection Regulation (the "GDPR"), which took effect across all member states of the European Economic Area (the "EEA") in May 2018. The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches, and taking certain measures when engaging third-party processors. The GDPR increases our obligations with respect to clinical trials conducted in the EEA by expanding the definition of personal data to include coded data and requiring changes to informed consent practices and more detailed notices for clinical trial subjects and investigators. In addition, the GDPR imposes strict rules on the transfer of personal data to countries outside the European Union, including the United States, and, as a result, increases the scrutiny that clinical trial sites located in the EEA should apply to transfers of personal data from such sites to countries that are considered to lack an adequate level of data protection, such as the United States. The GDPR also permits data protection authorities to require destruction of improperly gathered or used personal data and/or impose substantial fines for violations of the GDPR, which can be up to four percent of global revenues or 20 million Euros, whichever is greater, and it also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. In addition, the GDPR provides that European Union member states may make their own additional laws and regulations limiting the processing of personal data, including genetic, biometric or health data. In addition to the GDPR, other European Union and member state laws and regulations may impose further obligations or our restrictions on process health information in the EEA, such as the European Health Data Space Regulation.

The European Data Protection Board continues to release guidelines for industries and impose fines related to the GDPR, some of which have been very significant, including proposed amendments to the GDPR in November 2025. Meanwhile, there continues to be persistent uncertainty relating to the transfer of personal data from Europe to the U.S., or other non-adequate countries, following the Schrems II decision. On July 10, 2023, the European Commission adopted its adequacy decision on the EU-U.S. Data Privacy Framework ("DPF"). The decision, which took effect on the day of its adoption, concludes that the United States ensures an adequate level of protection for personal data transferred from the EEA to companies certified to DPF. However, it remains too soon to tell how the future of DPF will evolve and what impact it will have on our international activities. At least one challenge to the DPF is pending before the Court of Justice of the European Union.

Further, Brexit has led and could also lead to legislative and regulatory changes and may increase our compliance costs. Data processing in the United Kingdom is governed by a United Kingdom version of the GDPR (combining the GDPR and the Data Protection Act 2018) as well as other laws including the Data Use and Access Act and the Privacy and Electronic Communications Regulations, exposing us to two parallel regimes, each of which authorizes similar fines and other potentially divergent enforcement actions for certain violations. The European Commission adopted an Adequacy Decision for the United Kingdom, allowing for the relatively free exchange of personal data between the European Union and the United Kingdom (as the UK correspondingly allows transfers back to the European Union), which was extended through December 27, 2025. Other jurisdictions outside the European Union are similarly introducing or enhancing privacy and data security laws, rules and regulations.

In the EEA, the NIS 2 Directive ("NIS 2") is replacing the cybersecurity legal framework under the current NIS framework. NIS-2 applies to certain in-scope healthcare organizations, including to certain providers engaged in research and development of medicinal products. The new regime imposes direct obligations on management in respect of an in-scope organization's compliance with NIS 2, requires covered organizations to put in place certain cyber risk management measures, strengthens incident reporting requirements and provides supervisory authorities with greater oversight. The majority of obligations will come into force when national legislation implementing NIS 2 becomes effective in the relevant EU Member State. EU Member States had until October 17, 2024 to transpose NIS 2 into national legislation, although many countries have still not completed the transposition. As such, the cybersecurity regulatory landscape in the EU is currently fragmented and uncertain. To the extent that we are subject to NIS 2 in the future, we may require additional investment of our resources in compliance programs. Under NIS 2, companies may be subject to administrative fines of up to the higher amount of €10 million or 2% of worldwide turnover.

Similar actions are either in place or under way in the United States. There are a broad variety of data protection and breach notification laws that are applicable to our activities, and a wide range of enforcement agencies at both the state and federal levels that can review companies for privacy and data security concerns based on general consumer protection laws. All 50 U.S. states and territories and international jurisdictions have varying breach notification laws that may require us to notify patients, employees or regulators in the event of unauthorized access to or disclosure of personal or confidential data experienced by us or our service providers. These laws are not consistent, and compliance in the event of a widespread data breach is difficult and may be costly. We also may be contractually required to notify patients or other counterparties of a security breach. In addition to government regulation, privacy advocates and industry groups have and may in the future propose self-regulatory standards from time to time. These and other industry standards may legally or contractually apply to us, or we may elect to comply with such standards.

The Federal Trade Commission ("FTC") and state Attorneys General all are aggressive in reviewing privacy and data security protections for consumers. New laws also are being considered at both the state and federal levels and several states have passed comprehensive privacy laws. For example, the California Consumer Privacy Act (as amended, "CCPA") creates similar risks and obligations as those created by the GDPR, though the CCPA does exempt certain information collected as a part of clinical trial data. The CCPA may increase our compliance costs and potential liability, and we cannot yet predict the impact of the CCPA on our business. States have adopted statewide and comprehensive privacy laws and many other states have privacy legislation that is pending. Some state laws minimize what data can be collected from consumers and how businesses may use and disclose it. These state privacy laws also require businesses to make disclosures to consumers about data collection, use and sharing practices. . In addition, some of these laws (including the CCPA), along with other standalone health privacy laws, subject health-related information to additional safeguards and disclosures and some specifically regulate consumer health data, such as the Washington My Health My Data Act, which became effective in 2023 and 2024, Nevada's Consumer Health Data Privacy Law, which became effective in 2024, and Connecticut's amendments to its privacy law to address health data, which became effective in 2023. Additionally, a broad range of legislative measures also have been introduced at the federal level, including continued actions by the FTC, to enforce the FTC Act and violations of the Health Breach Notification Rule. Additionally, in 2024, the FTC finalized updates to the Health Breach Notification Rule that, among other things, clarified its applicability to health apps and other similar technologies and expanded the information the breach notification requirements for entities subject to the rule which may add additional complexity to compliance obligations going forward. We may also be subject to data privacy and security regulations under HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH") and its implementing regulations, mandates, among other things, the adoption of uniform standards for the electronic exchange of information in common healthcare transactions, as well as standards relating to the privacy and security of individually identifiable health information, which require the adoption of administrative, physical and technical safeguards to protect such information. 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 civil, criminal, and administrative penalties if we knowingly obtain, use, or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA. Requirements for compliance under HIPAA are also subject to change, as the U.S. Department of Health and Human Services Office of Civil Rights issued a proposed rule that would amend certain security compliance requirements for covered entities and business associates.

The U.S. Department of Justice issued a final rule entitled, "Access to U.S. Sensitive Personal Data and Government-Related Data by Countries of Concern or Covered Persons," codified at 28 CFR part 202 ("Bulk Transfer Rule"). The Bulk Transfer Rule prohibits and restricts bulk transfers of sensitive personal data (including genetic and health data) to countries of concern, such as China, Russia and Iran to prevent access by foreign adversaries. It restricts our ability to engage in certain cross-border transactions involving genomic or biological samples and related data, which may increase compliance costs, lead to increased regulatory scrutiny or liability, and may require additional contractual negotiations, which may adversely impact our business, financial condition, and operating results.

Accordingly, failure to comply with federal and state laws (both those currently in effect and future legislation) regarding privacy and security of personal data could expose us to fines and penalties under such laws. There also is the threat of consumer class actions related to these laws and the overall protection of personal data. This is particularly true with respect to data security incidents, and sensitive personal data, including health and biometric data. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could harm our reputation and business.

Our employees and personnel may use generative artificial intelligence technologies to perform their work, and the disclosure and use of personal data in generative artificial intelligence technologies is subject to various privacy laws and other privacy obligations. Governments have passed and are likely to pass additional laws regulating generative artificial intelligence. Our use of this technology could result in additional compliance costs, regulatory investigations and actions, and lawsuits. If we are unable to use generative artificial intelligence, it could make our business less efficient and result in competitive disadvantages.

Given the breadth and depth of changes in data protection obligations, preparing for and complying with these requirements is rigorous and time intensive and requires significant resources and a review of our technologies, systems and practices, as well as those of any third-party collaborators, service providers, CROs, contractors or consultants that process or transfer personal data collected in the European Union. The GDPR, new state privacy laws and other changes in laws or regulations associated with the enhanced protection of certain types of sensitive data, such as healthcare data or other personal data from our clinical trials, and access to certain data such as the European Health Data Space Regulation, could require us to change our business practices and put in place additional compliance mechanisms, may interrupt or delay our development, regulatory and commercialization activities and increase our cost of doing business, and could lead to government enforcement actions, private litigation and significant fines and penalties against us and could have a material adverse effect on our business, financial condition and results of operations. Similarly, failure to comply with federal and state laws regarding privacy and security of personal data could expose us to fines and penalties under such laws. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could harm our reputation and business.

***We and our partners may be subject to stringent privacy laws, information security laws, regulations, policies and contractual obligations related to data privacy and security, and changes in such laws, regulations, policies or how they are interpreted or changes in contractual obligations could adversely affect our business.***

There are numerous U.S. federal and state data privacy and protection laws and regulations that apply to the collection, transmission, processing, storage and use of personally-identifying information, which among other things, impose certain requirements relating to the privacy, security and transmission of personal information. The legislative and regulatory landscape for privacy and data protection continues to evolve in jurisdictions worldwide, and there has been an increasing focus on privacy and data protection issues with the potential to affect our business. Failure to comply with any of these laws and regulations could result in enforcement action against us, including fines, imprisonment of company officials and public censure, claims for damages by affected individuals, damage to our reputation and loss of goodwill, any of which could have a material adverse effect on our business, financial condition, results of operations or prospects.

If we are unable to properly protect the privacy and security of health-related information or other sensitive or confidential information in our possession, we could be found to have breached our contracts. Further, if we fail to comply with applicable privacy laws, including applicable HIPAA privacy and security standards, we could face significant administrative, civil and criminal penalties. Enforcement activity can also result in financial liability and reputational harm, and responses to such enforcement activity can consume significant internal resources. In addition, state attorneys general are authorized to bring civil actions seeking either injunctions or damages in response to violations that threaten the privacy of state residents.

**Risks Related to Employee Matters, Managing Growth and Information Technology**

***If we lose key management personnel, or if we fail to recruit additional highly skilled personnel, our ability to continue developing and to identify and develop new or next-generation product candidates will be impaired, which could result in delays in the development process, loss of market opportunities, make us less competitive and have a material adverse effect on our business, financial condition and results of operations.***

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 management, particularly our Chief Executive Officer, the members of our executive team, and key scientific and medical personnel employees. The loss of the services of any of our executive officers, key employees, and scientific and medical advisors, and our inability to find suitable replacements, could result in delays in product development and harm our business.

We conduct our operations at our facility in the San Francisco Bay Area. This region is headquarters to many other biopharmaceutical companies and many academic and research institutions. Competition for skilled personnel in our market is intense and may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all. In addition, regulation or legislation impacting the workforce, such as the proposed rule published by the Federal Trade Commission which would, if issued, generally prevent employers from entering into non-compete with employees and require employers to rescind existing non-competes, may lead to increased uncertainty in hiring and competition for talent.

To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have provided stock options that vest over time. The value to employees of stock options that vest over time may be significantly affected by movements in our stock price that are beyond our control, and may at any time be insufficient to counteract more lucrative offers from other companies. Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us on short notice. In addition, we may experience employee turnover as a result of return to work policies or transitions away from remote work, which have impacted job market dynamics. New hires require training and take time before they achieve full productivity. New employees may not become as productive as we expect, and we may be unable to hire or retain sufficient numbers of qualified individuals. Although we have employment agreements with our key employees, these agreements provide for at-will employment, which means that any of our employees could leave our employment at any time, with or without notice. We do not maintain “key man” insurance policies on the lives of these individuals or the lives of any of our other employees. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level and senior managers as well as junior, mid-level and senior scientific and medical personnel.

***We and our management have a limited track record as an operating company. Failures in the operational execution of the expected business plans may have a material impact on our commercial prospects. Further, if we are not able to attract and retain highly-qualified personnel, we may not be able to successfully implement our business strategy.***

Our management team has worked together for only a limited period of time and has a limited track record of executing our business plan as a team. In addition, we have recently filled a number of positions in our finance and accounting staff. Accordingly, certain key personnel have only recently assumed the duties and responsibilities they are now performing, and it is difficult to predict whether our management team, individually and collectively, will be effective in operating our business. These changes may cause speculation and uncertainty regarding our commercial prospects and may cause or result in:

- disruption of our business or distraction of our employees and management;
- difficulty in recruiting, hiring, motivating, and retaining talented and skilled personnel;

- stock price volatility; and

- difficulty in negotiating, maintaining, or consummating business or strategic relationships or transactions.

If we are unable to mitigate these risks or to attract and retain highly qualified personnel, our revenue, operating results and financial condition may be adversely impacted.

***We will need to grow the size of our organization, and we may experience difficulties in managing this growth.***

As of December 31, 2025, we had 22 full-time employees. As our development, manufacturing and commercialization plans and strategies develop and we continue our operations as a public company, we expect to need and are actively recruiting additional managerial, operational, sales, marketing, financial and other personnel. Future growth would impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining and motivating additional employees;

- managing our internal development efforts effectively, including the clinical, the FDA and international regulatory review process for our product candidates, while complying with our contractual obligations to contractors and other third parties; and

- improving our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to commercialize our product candidates will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert a disproportionate amount of time to managing these growth activities.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants to provide certain services, including substantially all aspects of regulatory approval, clinical management and manufacturing. We cannot assure you that the services of independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by consultants is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval of our product candidates or otherwise advance our business. We cannot assure you that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, or at all. If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, or if we are not able to effectively build out new facilities to accommodate this expansion, we may not be able to successfully implement the tasks necessary for further development and commercialization of our product candidates and, accordingly, may not achieve our research, development and commercialization goals.

***Our insurance policies may be inadequate and potentially expose us to unrecoverable risks.***

We have limited director and officer insurance and commercial insurance policies. Any significant insurance claims would have a material adverse effect on our business, financial condition and results of operations. Insurance availability, coverage terms and pricing continue to vary with market conditions. We endeavor to obtain appropriate insurance coverage for insurable risks that we identify; however, we may fail to correctly anticipate or quantify insurable risks; we may not be able to obtain appropriate insurance coverage; and insurers may not respond as we intend to cover insurable events that may occur. We have observed rapidly changing conditions in the insurance markets relating to nearly all areas of traditional corporate insurance. Such conditions have resulted in higher premium costs, higher policy deductibles and lower coverage limits. For some risks, we may not have or maintain insurance coverage because of cost or availability.

***Our internal computer systems, or those of our third-party vendors, collaborators or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our product development programs, compromise sensitive information related to our business or prevent us from accessing critical information, potentially exposing us to liability or otherwise adversely affecting our business.***

Our internal computer systems and those of our current and any future third-party vendors, collaborators and other contractors or consultants are vulnerable to damage or interruption from computer viruses, computer hackers, malicious code, employee theft or misuse, denial-of-service attacks, sophisticated nation-state and nation-state-supported actors, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we seek to protect our information technology systems from system failure, accident and security breach, if such an event were to occur and cause interruptions in our operations, it could result in a disruption of our development programs and our business operations, whether due to a loss of our trade secrets or other proprietary information or other disruptions. For example, the loss of clinical trial data from future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. We have experienced cybersecurity incidents and expect that we will continue to be subject to cybersecurity attacks in the future. If we were to experience a significant cybersecurity breach of our information systems or data, the costs associated with the investigation, remediation and potential notification of the breach to counter-parties and data subjects could be material. In addition, our remediation efforts may not be successful. If we do not allocate and effectively manage the resources necessary to build and sustain the proper technology and cybersecurity infrastructure, we could suffer significant business disruption, including transaction errors, supply chain or manufacturing interruptions, processing inefficiencies, data loss or the loss of or damage to intellectual property or other proprietary information.

Although we take such steps to help protect confidential and other sensitive information from unauthorized access or disclosure, our information technology and infrastructure may be vulnerable to attacks by hackers or viruses, failures, or breaches due to third-party action, employee negligence or error, malfeasance, or other incidents or disruptions. For example, we could be the target of phishing attacks seeking confidential information regarding our employees. Furthermore, while we have implemented data privacy and security measures in an effort to comply with applicable laws and regulations relating to privacy and data protection, some health-related and other personal information or confidential information may be transmitted to us by third parties, who may not implement adequate security and privacy measures, and it is possible that laws, rules and regulations relating to privacy, data protection, or information security may be interpreted and applied in a manner that is inconsistent with our practices or those of third parties who transmit health-related and other personal information or confidential information to us.

To the extent that we or these third parties are found to have violated such laws, rules or regulations or that any disruption or security breach were to result in a loss of, or damage to, us or our third-party vendors', collaborators' or other contractors' or consultants' data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability including litigation exposure, penalties and fines, we could become the subject of regulatory action or investigation, our competitive position could be harmed and the further development and commercialization of our product candidates could be delayed. Any of the above could have a material adverse effect on our business, financial condition, results of operations or prospects.

***Artificial intelligence presents risks and challenges that can impact our business, including by posing security risks to our confidential information, proprietary information and personal data.***

Issues in the development and use of artificial intelligence, combined with an uncertain regulatory environment, may result in reputational harm, liability, or other adverse consequences to our business operations. As with many technological innovations, artificial intelligence presents risks and challenges that could impact our business. We may adopt and integrate generative artificial intelligence tools into our systems for specific use cases reviewed by legal and information security. Our vendors may incorporate generative artificial intelligence tools into their offerings without disclosing this use to us, and the providers of these generative artificial intelligence tools may not meet existing or rapidly evolving regulatory or industry standards with respect to privacy and data protection and may inhibit our or our vendors' ability to maintain an adequate level of service and experience. If we, our vendors, or our third-party partners experience an actual or perceived breach or privacy or security incident because of the use of generative artificial intelligence, we may lose valuable intellectual property and confidential information and our reputation and the public perception of the effectiveness of our security measures could be harmed. Further, bad actors around the world use increasingly sophisticated methods, including the use of artificial intelligence, to engage in illegal activities involving the theft and misuse of personal information, confidential information, and intellectual property. Any of these outcomes could damage our reputation, result in the loss of valuable property and information, and have a material adverse effect on our business, financial condition and results of operations.

***Unstable market and economic conditions may have serious adverse consequences on our business and financial condition.***

Our business, financial condition and results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. A severe or prolonged economic downturn could result in a variety of risks to our business, including our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers, service providers, manufacturers or other partners and there is a risk that one or more would not survive or be able to meet their commitments to us under such circumstances. There can be no assurances that further deterioration in the credit and financial markets and confidence in economic conditions will not occur.

For example, U.S. debt ceiling and budget deficit concerns have increased the possibility of additional credit-rating downgrades and economic slowdowns, or a recession in the United States. Although U.S. lawmakers passed legislation to raise the federal debt ceiling on multiple occasions, including a suspension of the federal debt ceiling in June 2023, ratings agencies have lowered or threatened to lower the long-term sovereign credit rating on the United States. The impact of this or any further downgrades to the U.S. government's sovereign credit rating or its perceived creditworthiness could adversely affect the U.S. and global financial markets and economic conditions. Absent further quantitative easing by the Federal Reserve, these developments could cause interest rates and borrowing costs to rise, which may negatively impact our results of operations or financial condition. Moreover, disagreement over the federal budget has caused the U.S. federal government to shut down for periods of time. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

Furthermore, the new U.S. administration has substantially departed from prior U.S. government international trade policies and has commenced activities to renegotiate, or potentially terminate, certain existing bilateral or multi-lateral trade agreements and treaties with foreign countries. In addition, the administration has initiated tariffs on certain foreign goods and continues to consider imposing additional tariffs. Related to this action, certain foreign governments, including China, have instituted or are considering imposing reciprocal tariffs on certain U.S. goods. It remains unclear what the new U.S. administration or foreign governments will or will not do with respect to tariffs or other international trade agreements and policies. A trade war or other governmental action related to tariffs or international trade agreements or policies has the potential to disrupt our research activities, affect our suppliers, increase the cost of materials purchased to manufacture our products, impact our ability to sell our products outside the United States or to sell our products outside the United States at competitive prices and/or to affect the United States or global economy or certain sectors thereof and, thus, could adversely impact our business and financial condition.

***Adverse developments affecting the financial services industry, such as actual events or concerns involving liquidity, defaults or non-performance by financial institutions or transactional counterparties, could adversely affect our current and projected business operations and its financial condition and results of operations.***

Actual events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market-wide liquidity problems. For example, on March 10, 2023, Silicon Valley Bank (SVB) was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation (FDIC) as receiver. Similarly, on March 12, 2023, Signature Bank and Silvergate Capital Corp. were each swept into receivership. Although a statement by the Department of the Treasury, the Federal Reserve and the FDIC stated all depositors of SVB would have access to all of their money after only one business day of closure, including funds held in uninsured deposit accounts, borrowers under credit agreements, letters of credit and certain other financial instruments with SVB, Signature Bank or any other financial institution that is placed into receivership by the FDIC may be unable to access undrawn amounts thereunder. If any of our lenders or counterparties to any such instruments were to be placed into receivership, we may be unable to access such funds. In addition, counterparties to SVB credit agreements and arrangements, and third parties such as beneficiaries of letters of credit (among others), may experience direct impacts from the closure of SVB and uncertainty remains over liquidity concerns in the broader financial services industry. Similar impacts have occurred in the past, such as during the 2008-2010 financial crisis.

Although we assess our banking relationships as we believe necessary or appropriate, our access to funding sources and other credit arrangements in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that affect us, the financial institutions with which we have credit agreements or arrangements directly, or the financial services industry or economy in general. These factors could include, among others, events such as liquidity constraints or failures, the ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, disruptions or instability in the financial services industry or financial markets, or concerns or negative expectations about the prospects for companies in the financial services industry. These factors could involve financial institutions or financial services industry companies with which we have financial or business relationships, but could also include factors involving financial markets or the financial services industry generally.

The results of events or concerns that involve one or more of these factors could include a variety of material and adverse impacts on our current and projected business operations and our financial condition and results of operations. These could include, but may not be limited to, the following:

- delayed access to deposits or other financial assets or the uninsured loss of deposits or other financial assets;
- loss of access to revolving existing credit facilities or other working capital sources and/or the inability to refund, roll over or extend the maturity of, or enter into new credit facilities or other working capital resources;
- potential or actual breach of contractual obligations that require us to maintain letters or credit or other credit support arrangements;
- potential or actual breach of financial covenants in our credit agreements or credit arrangements;
- potential or actual cross-defaults in other credit agreements, credit arrangements or operating or financing agreements; or
- termination of cash management arrangements and/or delays in accessing or actual loss of funds subject to cash management arrangements.

Any decline in available funding or access to our cash and liquidity resources could, among other risks, adversely impact our ability to meet our operating expenses, financial obligations or fulfill our other obligations, result in breaches of our financial and/or contractual obligations or result in violations of federal or state wage and hour laws. Any of these impacts, or any other impacts resulting from the factors described above or other related or similar factors not described above, could have material adverse impacts on our liquidity and our current and/or projected business operations and financial condition and results of operations.

In addition, any further deterioration in the macroeconomic economy or financial services industry could lead to losses or defaults by our customers or suppliers, which in turn, could have a material adverse effect on our current and/or projected business operations and results of operations and financial condition. For example, a customer may fail to make payments when due, default under their agreements with us, become insolvent or declare bankruptcy, or a supplier may determine that it will no longer deal with us as a customer. In addition, a customer or supplier could be adversely affected by any of the liquidity or other risks that are described above as factors that could result in material adverse impacts on our company, including but not limited to delayed access or loss of access to uninsured deposits or loss of the ability to draw on existing credit facilities involving a troubled or failed financial institution. Any customer or supplier bankruptcy or insolvency, or the failure of any customer to make payments when due, or any breach or default by a customer or supplier, or the loss of any significant supplier relationships, could result in material losses to our company and may have material adverse impacts on our business.

**Risks Related to Ownership of Our Common Stock and Warrants**

***If our operations and performance do not meet the expectations of investors or securities analysts or for other reasons, the market price of our securities may decline, and the market price of our common stock may continue to be volatile.***

Any of the factors listed below could have a negative impact on your investment in our securities, and our securities may trade at prices significantly below the price you paid for them. In such circumstances, the trading price of our securities may not recover and may experience a further decline.

Factors affecting the trading price of our securities may include:

- adverse regulatory decisions;
- any delay in our regulatory filings for our product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings, including without limitation the FDA's issuance of a "refusal to file" letter or a request for additional information;
- conflicts in the Middle East, the ongoing conflict between Ukraine and Russia. instability in Venezuela and other geopolitical conflicts and the global impact of restrictions and sanctions imposed on Russia and the impact thereof on the markets generally, including any adverse effects on macroeconomic conditions such as inflation;
- the commencement, enrollment or results of any future clinical trials we may conduct, or changes in the development status of our product candidates;
- adverse results from, delays in or termination of clinical trials;
- unanticipated serious safety concerns related to the use of our product candidates;
- lower than expected market acceptance of our product candidates following approval for commercialization;
- changes in financial estimates by us or by any securities analysts who might cover our stock;
- changes in the market valuations of similar companies;
- stock market price and volume fluctuations of comparable companies and, in particular, those that operate in the biopharmaceutical industry;
- publication of research reports about us or our industry or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- announcements by us or our competitors of significant acquisitions, strategic partnerships or divestitures;
- announcements of investigations or regulatory scrutiny of our operations or lawsuits filed against us;
- investors' general perception of our business or management;
- recruitment or departure of key personnel;
- overall performance of the equity markets;
- disputes or other developments relating to intellectual property rights, including patents, litigation matters and our ability to obtain, maintain, defend, protect and enforce patent and other intellectual property rights for our technologies;

- significant lawsuits, including patent or stockholder litigation;
- proposed changes to healthcare laws in the U.S. or foreign jurisdictions, or speculation regarding such changes;
- general political and economic conditions; and
- other events or factors, many of which are beyond our control.

In addition, the stock market in general, Nasdaq and pharmaceutical companies in particular have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. The trading price of our common stock is, and is likely to continue to be, volatile. For example, from January 2, 2025 to December 31, 2025, our closing stock price ranged from $1.58 to $21.09 per share. From January 2, 2026 to March 25, 2026, our closing stock price ranged from $1.09 to $2.05 per share. Broad market and industry factors may negatively affect the market price of our securities, regardless of our actual operating performance. As a result of this volatility, our stockholders may not be able to sell their common stock at or above the prices at which they purchased their shares. Moreover, in the past, stockholders have initiated class action lawsuits against pharmaceutical and biotechnology companies following periods of volatility in the market prices of these companies' stock. Such litigation, if instituted against us, could cause us to incur substantial costs and divert management's attention and resources from our business.

***Insiders have substantial control over us, which could limit your ability to affect the outcome of key transactions, including a change of control.***

As of January 31, 2026, our directors and executive officers and their affiliates beneficially owned approximately 15.1% of the outstanding shares of our common stock. As a result, these stockholders, if they act together, will be able to influence our management and affairs and all matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions, such as a merger or other sale of our company or our assets. This concentration of ownership may have the effect of delaying or preventing a change in control of our company or discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control, even if that change in control would benefit our other stockholders. This significant concentration of ownership may also adversely affect the trading price for our common stock because investors often perceive disadvantages in owning stock in companies with controlling stockholders.

***We have incurred and will continue to incur significant increased expenses and administrative burdens as a public company, which could negatively impact our business, financial condition and results of operations.***

We face increased legal, accounting, administrative and other costs and expenses as a public company. The Sarbanes-Oxley Act, including the requirements of Section 404, as well as rules and regulations subsequently implemented by the SEC, the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 and the rules and regulations promulgated and to be promulgated thereunder, and the securities exchanges, impose additional reporting and other obligations on public companies. Compliance with public company requirements increases costs and makes certain activities more time-consuming. Furthermore, if any issues in complying with those requirements are identified (for example, if a material weakness or significant deficiency is identified in the internal control over financial reporting), we could incur additional costs rectifying those issues, and the existence of those issues could adversely affect our reputation or investor perceptions of us. Risks associated with our status as a public company may make it more difficult to attract and retain qualified persons to serve on our board of directors or as executive officers. The reporting and other obligations imposed by these rules and regulations will continue to increase legal and financial compliance costs and the costs of related legal, accounting and administrative activities. These increased costs will require us to divert a significant amount of money that could otherwise be used to expand our business and achieve strategic objectives. Advocacy efforts by stockholders and third parties may also prompt additional changes in governance and reporting requirements, which could further increase costs.

***If we fail to comply with the continued listing requirements of the Nasdaq Capital Market, our common stock may be delisted and the price of our common stock and our ability to access the capital markets could be negatively impacted.***

We must continue to satisfy the Nasdaq Capital Market's continued listing requirements, including, among other things, a minimum closing bid price requirement of $1.00 per share for 30 consecutive business days. If a company fails for 30 consecutive business days to meet the $1.00 minimum closing bid price requirement, The Nasdaq Stock Market LLC ("Nasdaq") will send a deficiency notice to the company, advising that it has been afforded a "compliance period" of 180 calendar days to regain compliance with the applicable requirements.

A delisting of our common stock from the Nasdaq Capital Market could materially reduce the liquidity of our common stock and result in a corresponding material reduction in the price of our common stock. In addition, delisting could harm our ability to raise capital through alternative financing sources on terms acceptable to us, or at all, and may result in the potential loss of confidence by investors and employees.

On October 18, 2023, we received written notice from Nasdaq indicating that, for the last 30 consecutive business days, the bid price for our common stock had closed below the minimum $1.00 per share requirement for continued listing on the Nasdaq Capital Market under Nasdaq Listing Rule 5550(a)(2). In accordance with Nasdaq Listing Rule 5810(c)(3)(A), had been provided with an initial period of 180 calendar days, or until April 15, 2024, to regain compliance. On January 3, 2024, we filed a Certificate of Second Amendment to our Second Amended and Restated Certificate of Incorporation, as amended (the "Certificate of Amendment"), with the Secretary of State of the State of Delaware to effect a 1-for-10 reverse stock split (the "Reverse Split") of our voting common stock. The Reverse Stock Split was effective at 12:01 a.m., Eastern Time, on January 4, 2024. The Reverse Stock Split was intended for us to regain compliance with the minimum bid price requirement of $1.00 per share of our common stock for continued listing on the Nasdaq Capital Market. On January 19, 2024, we received a letter from Nasdaq notifying us that we regained full compliance with Nasdaq Listing Rule 5550(a)(2) after the closing bid price of our common stock had been at $1.00 per share or greater for ten consecutive business days from January 4, 2024 through January 18, 2024.

Even though we have regained compliance with the Nasdaq Capital Market's minimum closing bid price requirement, there is no guarantee that we will remain in compliance with such listing requirements or other listing requirements in the future. Any failure to maintain compliance with continued listing requirements of the Nasdaq Capital Market could result in delisting of our common stock from the Nasdaq Capital Market and negatively impact our company and holders of our common stock, including by reducing the willingness of investors to hold our common stock because of the resulting decreased price, liquidity and trading of our common stock, limited availability of price quotations and reduced news and analyst coverage. Delisting may adversely impact the perception of our financial condition, cause reputational harm with investors, our employees and parties conducting business with us and limit our access to debt and equity financing.

***Our failure to timely and effectively implement controls and procedures required by Section 404(a) of the Sarbanes-Oxley Act could negatively impact our business.***

Absent an applicable exemption, we are required to provide a management's attestation on internal controls over financial reporting, and we were not previously required to do this as a private company. The standards required for a public company under Section 404(a) of the Sarbanes-Oxley Act are significantly more stringent than those required of us when we were a privately held company. Management may not be able to effectively and timely implement controls and procedures that adequately respond to the increased regulatory compliance and reporting requirements. If we are not able to implement the additional requirements of Section 404(a) in a timely manner or with adequate compliance, we may not be able to assess whether our internal controls over financial reporting are effective, which may subject us to adverse regulatory consequences and could harm investor confidence and the market price of our securities.

***We are a "smaller reporting company" within the meaning of the Securities Act, and if we take advantage of certain exemptions from disclosure requirements available to smaller reporting companies, it could make our securities less attractive to investors.***

We are a "smaller reporting company" within the meaning of the Securities Act. As such, we are eligible for and intend to take advantage of certain exemptions from various reporting requirements applicable to other public companies that are not smaller reporting companies for as long as we continue to be a smaller reporting company, including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended, or the Sarbanes-Oxley Act, and (b) reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. In addition, for as long as we are deemed neither a large accelerated filer nor an accelerated filer, we will continue to use the exemption from compliance with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley.

We will remain a smaller reporting company and non-accelerated filer until we have a public float of $700 million or more and annual revenues of less than $100 million, or a public float of $250 million or more. We reassessed our public float as of June 30, 2025, and since it was less than $700 million and our annual revenues were less than $100 million, we have determined that we will continue as a smaller reporting company and a non-accelerated filer until at least December 31, 2026. We will need to reassess, as of June 30, 2026, whether we will continue to qualify as a smaller reporting company and a non-accelerated filer for filings beyond the fiscal year ending December 31, 2026.

We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

***If securities or industry analysts do not publish or cease publishing research or reports about us, our business, or our market, or if they change their recommendations regarding our securities adversely, the price and trading volume of our securities could decline.***

The trading market for our common stock will be influenced by the research and reports that industry or financial analysts publish about us or our business. Securities and industry analysts do not currently, and may never, publish research on us. If no or few analysts commence coverage of us, the trading price of our securities would likely decrease. Even if we do obtain analyst coverage, if one or more of the analysts covering our business downgrade their evaluations of our securities, the price of our securities could decline. If one or more of these analysts cease to cover our securities, we could lose visibility in the market for our securities, which in turn could cause the price of our securities to decline.

***Future sales, or the perception of future sales, by us or our stockholders in the public market, the issuance of rights to purchase our common stock, including pursuant to the 2024 Plan and the 2024 ESPP, and future exercises of registration rights could result in the additional dilution of the percentage ownership of our stockholders and cause the market price for our common stock to decline.***

The sale of shares of our common stock, convertible securities or other equity securities in the public market, or the perception that such sales could occur, could harm the prevailing market price of shares of our common stock. These sales, or the possibility that these sales may occur, also might make it more difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate. In addition, if we sell shares of our common stock, convertible securities or other equity securities, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights, preferences, and privileges senior to the holders of our common stock.

Pursuant to the Jasper Therapeutics, Inc. 2024 Equity Incentive Plan (the "2024 Plan"), which became effective on June 6, 2024, we are authorized to grant equity awards to our employees, directors and consultants. In addition, pursuant to the Jasper Therapeutics, Inc. 2024 Employee Stock Purchase Plan (the "2024 ESPP"), which became effective on June 6, 2024, we are authorized to sell shares to our employees. As of December 31, 2025, 843,360 shares and 920,827 shares of our common stock are reserved for future issuance under the 2024 Plan and the 2024 ESPP, respectively.

On March 14, 2022, the Compensation Committee of our Board of Directors (the "Compensation Committee") adopted the 2022 Inducement Equity Incentive Plan (the "2022 Inducement Plan"). On June 2, 2023, the Compensation Committee approved an amendment and restatement of our 2022 Inducement Plan to increase the maximum number of shares of our voting common stock available for grant by 250,000 shares of common stock to an aggregate of 550,000 shares of common stock. As of December 31, 2025, 132,769 shares of our common stock are available for future issuance under the 2022 Inducement Plan. The 2022 Inducement Plan has not been and will not be approved by our stockholders. Under the 2022 Inducement Plan, we can grant nonstatutory stock options, restricted stock awards, stock appreciation rights, restricted stock units, performance awards and other awards, but only to an individual, as a material inducement to such individual to enter into employment with us or an affiliate of ours, who (i) has not previously been an employee or director of ours or (ii) is rehired following a bona fide period of non-employment with us.

As of December 31, 2025, options to purchase an aggregate of 2,246, 206 shares of our common stock and 20,000 performance-based restricted stock units were outstanding.

Additionally, as of December 31, 2025, we had outstanding Pre-Funded Warrants to purchase up to an aggregate of 675,000 shares of common stock and Common Warrants to purchase up to an aggregate of 12,345,707 shares of common stock, which, if exercised, would further increase the number of shares of our common stock outstanding and the number of shares eligible for resale in the public market.

In the future, we may also issue our securities in connection with investments or acquisitions. The amount of shares of our common stock issued in connection with an investment or acquisition could constitute a material portion of our then-outstanding shares of our common stock. Any issuance of additional securities in connection with investments or acquisitions may result in additional dilution to our stockholders.

***Because there are no current plans to pay cash dividends on our common stock for the foreseeable future, you may not receive any return on investment unless you sell shares of our common stock for a price greater than that which you paid for it.***

We may retain future earnings, if any, for future operations, expansion and debt repayment and have no current plans to pay any cash dividends for the foreseeable future. Any decision to declare and pay dividends as a public company in the future will be made at the discretion of our board of directors and will depend on, among other things, our results of operations, financial condition, cash requirements, contractual restrictions and other factors that our board of directors may deem relevant. In addition, our ability to pay dividends may be limited by covenants of any existing and future outstanding indebtedness we or our subsidiaries incur. As a result, you may not receive any return on an investment in our common stock unless you sell your shares of our common stock for a price greater than that which you paid for it.

***Anti-takeover provisions in our Certificate of Incorporation and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.***

Our Certificate of Incorporation contains provisions that could delay or prevent a change of control of us or changes in our board of directors that our stockholders might consider favorable. Some of these provisions include:

- a board of directors divided into three classes serving staggered three-year terms, such that not all members of our board of directors will be elected at one time;
- a prohibition on stockholder action through written consent, which requires that all stockholder actions be taken at a meeting of our stockholders;

- a requirement that special meetings of stockholders be called only by the chairperson of our board of directors, the chief executive officer, the president, or by a majority of the total number of authorized directors;

- advance notice requirements for stockholder proposals and nominations for election to our board of directors;

- a requirement that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of not less than two-thirds of all outstanding shares of our voting stock then entitled to vote in the election of directors;

- a requirement of approval of not less than two-thirds of all outstanding shares of our voting stock to amend any bylaws by stockholder action or to amend specific provisions of our Certificate of Incorporation; and

- the authority of our board of directors to issue preferred stock on terms determined by our board of directors without stockholder approval and which preferred stock may include rights superior to the rights of the holders of our common stock.

In addition, because we are incorporated in the State of Delaware, we are governed by the provisions of Section 203 of the General Corporation Law of the State of Delaware ("DGCL"), which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These anti-takeover provisions and other provisions in our Certificate of Incorporation and Second Amended and Restated Bylaws (our "Bylaws") could make it more difficult for stockholders or potential acquirors to obtain control of our board of directors or initiate actions that are opposed by our then-current board of directors and could also delay or impede a merger, tender offer, or proxy contest involving us. These provisions could also discourage proxy contests and make it more difficult for you and other stockholders to elect directors of your choosing or cause us to take other corporate actions you desire. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline.

***Our Certificate of Incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.***

Our Certificate of Incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: (i) any derivative action or proceeding brought on our behalf; (ii) any action or proceeding asserting a claim of breach of a fiduciary duty owed by any of our current or former directors, officers, or other employees to us or our stockholders; (iii) any action or proceeding asserting a claim against us or any of our current or former directors, officers, or other employees, arising out of or pursuant to any provision of the DGCL, our Certificate of Incorporation or Bylaws; (iv) any action or proceeding to interpret, apply, enforce, or determine the validity of our Certificate of Incorporation or Bylaws; (v) any action or proceeding as to which the DGCL confers jurisdiction to the Court of Chancery of the State of Delaware; and (vi) any action asserting a claim against us or any of our directors, officers, or other employees governed by the internal affairs doctrine, in all cases to the fullest extent permitted by law and subject to the court's having personal jurisdiction over the indispensable parties named as defendants. These provisions would not apply to suits brought to enforce a duty or liability created by the Exchange Act. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our Certificate of Incorporation provides that the federal district courts of the United States of America shall be exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, including all causes of action asserted against any defendant named in such complaint. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our Certificate of Incorporation. This may require significant additional costs associated with resolving such action in other jurisdictions, and the provisions may not be enforced by a court in those other jurisdictions.

These exclusive forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, or other employees and may discourage these types of lawsuits. In addition, a stockholder that is unable to bring a claim in the judicial forum of its choosing may be required to incur additional costs in the pursuit of actions that are subject to these exclusive forum provisions, particularly if the stockholder does not reside in or near Delaware. Furthermore, the enforceability of similar choice of forum provisions in other companies' certificates of incorporation or bylaws has been challenged in legal proceedings, and it is possible that a court could find these types of provisions to be inapplicable or unenforceable. If a court were to find the exclusive forum provision contained in our Certificate of Incorporation to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with resolving such action in other jurisdictions, all of which could seriously harm our business.

***Any exercise of the outstanding warrants to purchase shares of our common stock would increase the number of shares eligible for future resale in the public market and result in dilution to our stockholders.***

Outstanding warrants to purchase an aggregate of 499,986 shares of our common stock became exercisable in accordance with the terms of the Warrant Agreement, dated November 19, 2019, between Continental Stock Transfer & Trust Company, as warrant agent, and us (the "Warrant Agreement") commencing on October 24, 2021 (the "Public Warrants"). As of December 31, 2025, 4,999,863 Public Warrants to purchase an aggregate of 499,986 shares of our common stock were outstanding. The exercise price of these Public Warrants is $115.00 per share for every ten Public Warrants. To the extent such Public Warrants are exercised, additional shares of our common stock will be issued, which will result in dilution to the holders of our common stock and increase the number of shares eligible for resale in the public market. Sales of substantial numbers of such shares in the public market or the fact that such Public Warrants may be exercised could adversely affect the prevailing market prices of our common stock. However, there is no guarantee that the Public Warrants will ever be in the money prior to their expiration, and as such, the Public Warrants may expire worthless. See below risk factor, "*The Public Warrants may never be in the money, they may expire worthless and the terms of the Public Warrants may be amended in a manner adverse to a holder if holders of at least 50% of the then-outstanding Public Warrants approve of such amendment*."

Additionally, as of December 31, 2025, we had outstanding Pre-Funded Warrants to purchase up to an aggregate of 675,000 shares of common stock and Common Warrants to purchase up to an aggregate of 12,345,707 shares of common stock, which, if exercised, would further increase the number of shares of our common stock outstanding and the number of shares eligible for resale in the public market. The exercise price of each Pre-Funded Warrant is $0.0001. Each Pre-Funded Warrant is exercisable at any time after the date of issuance, and will expire on the date it is exercised in full. The exercise price of each Common Warrant is $2.92. Each Common Warrant is exercisable commencing on the six month anniversary of the date of issuance and thereafter for a period of four years.

***The Public Warrants may never be in the money, they may expire worthless and the terms of the Public Warrants may be amended in a manner adverse to a holder if holders of at least 50% of the then-outstanding Public Warrants approve of such amendment.***

The Public Warrants were issued in registered form under the Warrant Agreement. The Warrant Agreement provides that the terms of the Public Warrants may be amended without the consent of any holder to cure any ambiguity or correct any defective provision or correct any mistake, but requires the approval by the holders of at least 50% of the then-outstanding Public Warrants to make any change that adversely affects the interests of the registered holders of Public Warrants. Accordingly, we may amend the terms of the Public Warrants in a manner adverse to a holder if holders of at least 50% of the then-outstanding Public Warrants approve of such amendment. Although our ability to amend the terms of the Public Warrants with the consent of at least 50% of the then-outstanding Public Warrants is unlimited, examples of such amendments could be amendments to, among other things, increase the exercise price of the Public Warrants, convert the Public Warrants into cash, shorten the exercise period, or decrease the number of shares of our common stock purchasable upon exercise of a Public Warrant.

***We may redeem your unexpired Public Warrants prior to their exercise at a time that is disadvantageous to you, thereby making your Public Warrants worthless.***

We have the ability to redeem outstanding Public Warrants at any time after they become exercisable and prior to their expiration, at a price of $0.10 per Public Warrant, provided that the last reported sales price of our common stock equals or exceeds $180.00 per share (as adjusted for share subdivisions, share dividends, rights issuances, subdivisions, reorganizations, recapitalizations, and the like) for any 20 trading days within a 30-trading-day period ending on the third trading day prior to the date we send the notice of redemption to the warrantholders. If and when the Public Warrants become redeemable by us, we may exercise our redemption right even if we are unable to register or qualify the underlying securities for sale under all applicable state securities laws. Redemption of the outstanding Public Warrants could force you to: (i) exercise your Public Warrants and pay the exercise price therefor at a time when it may be disadvantageous for you to do so; (ii) sell your Public Warrants at the then-current market price when you might otherwise wish to hold your Public Warrants; or (iii) accept the nominal redemption price that, at the time the outstanding Public Warrants are called for redemption, is likely to be substantially less than the market value of your Public Warrants.

In addition, we may redeem the Public Warrants at any time after they become exercisable and prior to their expiration at a price of $1.00 per Public Warrant upon a minimum of 30 days' prior written notice of redemption; provided that holders will be able to exercise their Public Warrants prior to redemption for a number of our common stock determined based on the redemption date and the fair market value of our common stock. The value received upon exercise of the Public Warrants (1) may be less than the value the holders would have received if they had exercised their Public Warrants at a later time where the underlying share price is higher and (2) may not compensate the holders for the value of the Public Warrants.

**ITEM 1B. UNRESOLVED STAFF COMMENTS**

None.

**ITEM 1C. CYBERSECURITY**

*Risk Management and Strategy*

Our Information Security team manages our Information Security Program, which is focused on assessing, identifying, and managing cyber risk and information security threats. We evaluate cybersecurity risk on an ongoing basis, and it is a risk monitored through our overall enterprise risk management program, including by the executive leadership and our Board of Directors (the "Board"), as described below under the sub-heading "*Governance*."

To proactively manage cybersecurity risk in our organization, our management team has instituted an Information Technology Security Policy that is available to all employees through our Quality Management System. We also conduct regular cybersecurity awareness and training campaigns for existing employees. Stakeholders can access Jasper's Information Technology helpdesk 24/7 online or by phone, to report any security incidents for escalation.

To proactively identify, mitigate, and prepare for potential cybersecurity incidents, we maintain a cyber incident response plan with formalized workflows and playbooks. We conduct simulation exercises involving employees at various levels of the organization. We also periodically engage external partners to conduct annual audits of our systems and test our Information Technology infrastructure. Through these channels and others, we work to proactively identify potential vulnerabilities in our information security system. We recognize that we are exposed to cybersecurity threats associated with our use of third-party service providers. To minimize the risk and vulnerabilities to our own systems stemming from such use, our Information Security team identifies, and addresses known cybersecurity threats and incidents at third-party service providers on a continuous basis. In addition, we strive to minimize cybersecurity risks when we first select or renew a vendor by including cybersecurity risk as part of our overall vendor evaluation and due diligence process.

Our risks associated with cybersecurity threats are set forth under "*Risk Factors*" in Part I, Item 1A in this report. Except as set forth therein, risks from cybersecurity threats, including as a result of any previous cybersecurity incidents, have not materially affected and are not reasonably likely to materially affect our company, including our business strategy, results of operations, or financial condition.

*Governance*

The Board, in coordination with the Audit Committee of the Board (the "Audit Committee"), oversees our risk management program, including the management of cybersecurity threats. The Board and the Audit Committee each receive regular presentations and reports on developments in the cybersecurity space, including risk management practices, recent developments, evolving standards, vulnerability assessments, third-party and independent reviews, the threat environment, technological trends, and information security issues encountered by our peers and third parties. The Board and the Audit Committee also receive prompt and timely information regarding any cybersecurity risk that meets pre-established reporting thresholds, as well as ongoing updates regarding any such risk. On an annual basis, the Board and the Audit Committee discuss our approach to overseeing cybersecurity threats with our CFO and other members of senior management. Our CEO, CFO and other members of our senior management collectively have several decades of experience managing risk at our company or similar companies and assessing cybersecurity threats.

## ITEM 2. PROPERTIES

We lease a total of approximately 25,900 square feet of space across two buildings for our headquarters in Redwood City, California under a single lease agreement that expires in August 2026. Thereafter, at our option, we may extend the term for an additional five years to August 2031. We believe that our existing facilities are adequate to meet our current needs, and that suitable additional alternative spaces will be available in the future on commercially reasonable terms.

## ITEM 3. LEGAL PROCEEDINGS

We, from time to time, may be party to litigation arising in the ordinary course of business. On September 19, 2025, a shareholder class action complaint captioned *Grant v. Jasper Therapeutics, Inc., et al.* (Case No. 25-cv-08010) was filed in the United States District Court for the Northern District of California against us and certain of our current and former officers. The complaint alleges that certain material misstatements or omissions related to the ongoing clinical studies of briquilimab were made in violation of federal securities laws. The plaintiffs are seeking unspecified monetary damages and an award of costs and expenses, including reasonable attorneys' fees, expert fees and other costs. On December 3, 2025, a stipulated order was entered appointing co-lead plaintiffs and approving their selection of co-lead counsel, and on December 16, 2025, a stipulated order was entered setting a schedule for the filing and responses to an amended complaint. Per the terms of the December 16, 2025 stipulated order, an amended complaint captioned *Allard, et al. v. Jasper Therapeutics, Inc., et al.* (Case No. 25-cv-08010) was filed, and defendants' responses to that amended complaint are due on or about April 20, 2026.

In addition, on November 5, 2025, a shareholder derivative complaint captioned *Bardauskas v. Martell, et al*. (Case No. 25-cv-09561) was filed in the United States District Court for the Northern District of California, and on December 22, 2025, another shareholder derivative complaint was filed in the same court and captioned *Walsh v. Martell, et al.* (Case No. 25-cv-10899). The derivative complaints name as defendants certain of our current and former officers and directors, and allege claims related to the allegations raised in the shareholder class action complaint. On January 21, 2026, a stipulated order was entered, among other things, consolidating and staying the derivative actions. We believe the claims raised in these lawsuits are without merit, and we intend to defend these matters vigorously. However, there can be no assurance that we will prevail. We are unable to determine whether any loss ultimately will occur or to estimate the range of such loss; therefore, no amount of loss has been accrued by us in our financial statements as of and for the year ended December 31, 2025. Regardless of outcome, litigation can have an adverse impact on us due to costs involved, diversion of management resources, negative publicity, reputational harm, and other factors.

From time to time, we may be party to other lawsuits in the ordinary course of business. We believe that we are not currently a party to any other legal proceedings which, individually or in the aggregate, would have a material adverse effect on our consolidated financial position, results of operations or cash flows.

## 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 and Public Warrants are currently listed on the Nasdaq Capital Market under the symbols "JSPR" and "JSPRW," respectively. As of March 20, 2026, there were 5 holders of record of our common stock and 1 holder of record of our Public Warrants.

Prior to the consummation of the Business Combination, AMHC's Class A Common Stock, units and warrants were listed on Nasdaq under the symbols "AMHCU," "AMHC" and "AMHCW," respectively.

**Dividend Policy**

We have never declared or paid any dividends on shares of our common stock. We anticipate that we will retain all of our future earnings, if any, to fund the development and growth of our business. Any future determination to pay dividends on our capital stock will be at the discretion of our board of directors ("Board"). It is the present intention of our Board to retain all earnings, if any, for use in our business operations and, accordingly, our Board does not anticipate declaring any dividends in the foreseeable future. Further, if we incur any indebtedness, our ability to declare dividends may be limited by restrictive covenants we may agree to in connection therewith.

**Performance Graph**

We were a smaller reporting company, as defined by Rule 12b-2 of the Securities Exchange Act of 1934, as amended, as of December 31, 2025, and are not required to provide a performance graph.

**Unregistered Sales of Equity Securities**

None.

**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 together with our consolidated financial statements and the related notes included* in Part II, Item 8 of *this Annual Report on Form 10-K. This discussion and analysis and other parts of this Annual Report on Form 10-K contain forward-looking statements based upon current beliefs, plans and expectations related to future events and our future financial performance that involve risks, uncertainties and assumptions, such as statements regarding our intentions, plans, objectives, expectations, forecasts and projections. Our actual results and the timing of selected events could differ materially from those anticipated in these forward-looking statements as a result of several factors, including those set forth under Part I, Item 1A, "Risk Factors" and elsewhere in this Annual Report on Form 10-K.*

### Overview

We are a clinical-stage biotechnology company focused on developing therapeutics targeting mast cell driven diseases such as Chronic Spontaneous Urticaria ("CSU"), Chronic Inducible Urticaria ("CIndU") and asthma. We may also consider additional indications in mast cell driven diseases for potential future development. We have also historically explored development programs in diseases where targeting diseased hemopoietic stem cells can provide benefits, such as stem cell transplant conditioning regimens, but those programs have been discontinued and we are exclusively focused on mast cell driven diseases.

Our lead product candidate, briquilimab, is a monoclonal antibody designed to block stem cell factor ("SCF") from binding to and signaling through the CD117 ("KIT") receptor on mast and stem cells. The SCF/KIT pathway is a survival signal for mast cells and we believe that blocking this pathway may lead to depletion of these cells throughout the body, including in the lungs and in the skin, which could lead to significant clinical benefit for patients with mast-cell driven diseases such as asthma and chronic urticarias. To that end, we are focusing on advancing a portfolio of clinical programs in mast cell driven diseases, highlights of which were as follows:

- We commenced the Phase 1b/2a BEACON study in CSU in late 2023 and in January 2025, we presented positive preliminary data from the first 8 dosing cohorts in the study (10mg, 40mg, 80mg Q8W, 120mg Q8W, 120mg Q12W, 180mg Q8W, 180mg Q12W, and 240mg single-dose). Average patient duration on study as of the cutoff date for the data presented was approximately 28 weeks. Highlights of the data were as follows:
  - Briquilimab demonstrated a rapid onset of clinical efficacy with clinical responses seen as early as 1 week post-dose and complete responses observed as early as week 2 post-dose.
  - Briquilimab drove deep and meaningful clinical responses with 100% complete responses through 8 weeks demonstrated at the 240mg dose level.
  - Briquilimab was well-tolerated and demonstrated a favorable safety profile:
    - KIT-related adverse events ("AEs") were generally transient, low-grade events;
    - The majority of AEs observed were resolved while on study prior to subsequent doses; and
    - No dose delays, missed doses or discontinuations were reported due to AEs possibly related to KIT blockade.

- In July 2025, we reported updated data from the Phase 1b/2a BEACON study in CSU with updates on the 240mg and 360mg single dose cohorts as well as the 240mg Q8W and the 240mg/180mg Q8W cohorts. Highlights of the data update were as follows:

    - Briquilimab administration continued to demonstrate deep and rapid disease control in the 240mg and 360mg single-dose cohorts with 8 of 9 (89%) of participants enrolled across both cohorts achieving a complete response, and with 7 of 9 (78%) achieving a clinical response by week 2.

    - Results from the 240mg Q8W and the 240mg/180mg Q8W dose cohorts demonstrated an atypical absence of UAS7 reduction in 11 of the 13 patients enrolled, and as a result, we launched an investigation into those two cohorts. Factors examined included clinical site conduct, site dosing procedures, patient selection criteria, as well as potential product lot variability in one lot of drug product first introduced into the BEACON study in those two cohorts. We also provided new clinical drug supply from a different lot for ongoing dosing of existing patients and subsequently enrolled an additional 10 patients in aggregate across those two cohorts.

- In December 2025, we reported the completion of the investigation into the confounded efficacy results reported in July 2025 from the 240mg Q8W and the 240mg/180mg Q8W cohorts of the BEACON study in CSU. Based on the work conducted, we concluded the anomalous efficacy results in these two cohorts was not the result of any issues with the investigational product used, or from drug substance ("DS") or drug product ("DP") manufacturing or distribution processes, but rather appeared to be an issue resulting from patient selection process/criteria at certain clinical sites participating in the study. This conclusion reflects, among other factors:

    - a comprehensive review of manufacturing and distribution records;

    - robust testing of multiple lots across the manufacturing and clinical supply chain;

    - independent, blinded testing of returned drug product samples from trial sites;

    - review of stability samples from the lots used in the two cohorts compared against other lots;

    - review of patient selection and enrollment processes;

    - review of investigational product handling and administration at the site level;

    - review of drug delivery methods (for example, injection site, needle and injection media); and

    - review of additional patient- and site-level data.

    The conclusions reached as a result of the investigation were supported by expert panels comprised of key opinion leaders in clinical development and antibody manufacturing experts that reviewed the findings and provided clinical operations and development recommendations on patient enrollment processes that are being integrated into the planned Phase 2b/3 CSU study to increase the likelihood that CSU patients enrolled in the study would be more likely to have mast cell driven disease.

- In January 2026, we reported updated data from the Phase 1b/2a BEACON study in CSU with updates on an additional 8 patients enrolled in the 240mg/180mg Q8W cohort (6 on briquilimab and 2 on placebo). Highlights of the data update were as follows:
    - Briquilimab demonstrated a rapid onset of clinical efficacy with clinical responses achieved by 5 of 6 participants (83%) by week 3;
    - Briquilimab drove deep and meaningful clinical responses with UAS7 reductions of as much as 29 points noted, and 4 of 6 participants (67%) reporting a complete response at 12 weeks.
    - Briquilimab continued to be well-tolerated and demonstrated a favorable safety profile:
        - KIT-related adverse events ("AEs") were generally transient, low-grade events;
        - The majority of AEs observed were resolved while on study prior to subsequent doses; and
        - No dose delays, missed doses or discontinuations were reported due to AEs possibly related to KIT blockade.
- In early 2024, we commenced the Phase 1b/2a SPOTLIGHT study in CIndU. In October 2024, we presented positive preliminary data on the 40mg and 120mg cohorts from the study showing the following for the 6-week preliminary analysis period following dosing, as follows:
    - Across the 40mg and 120mg dosing cohorts in the study, 14 of the 15 participants (93%) achieved a clinical response;
    - In the 120mg dose cohort, 10 of 12 participants (83%) experienced a complete response, and 1 participant experienced a partial response; and
    - Briquilimab was well-tolerated in the study, with KIT-related AEs being low-grade events, and no grade 3 or higher AEs possibly related to KIT blockade reported in any of the dose cohorts.
- In late 2024, we added a 180mg single dose cohort to the SPOTLIGHT study in CIndU. In June 2025, we reported positive preliminary data from the 180mg single dose cohort, the highlights of which were as follows:
    - Briquilimab treatment resulted in deep disease control at 180mg, with 12 of 12 participants (100%) enrolled in the cohort achieving a clinical response within the 8-week preliminary analysis period;
    - The efficacy observed was rapid and durable, with 8 of 12 participants (66%) achieving clinical response by week 2, and 7 of 12 participants (58%) maintaining clinical response through week 8; and
    - Briquilimab continued to be well tolerated in the study, with no SAEs and no grade 3 or higher AEs reported in the 180mg cohort.

- We also commenced an Open Label Extension study (the "OLE") in which patients in the BEACON study in CSU and the SPOTLIGHT study in CIndU are eligible to roll over to once they have completed their initial safety follow up period or experienced return of disease during the safety follow up period. All patients rolling over to the OLE study are treated with a 180mg Q8W dosing regimen. In January 2026, we reported preliminary data from the OLE study in both CSU and CIndU patients.

  Highlights of the clinical efficacy observed in CSU and CIndU participants for the OLE study released in January 2026 were as follows:

  - In CSU participants, briquilimab treatment resulted in deep and durable disease control in the OLE study with 27 of 36 participants (75%) achieving complete response or well controlled disease at the week 12 assessment; and

  - In CIndU participants, briquilimab treatment resulted in deep and durable disease control as well, with 11 of 17 participants (65%) achieving complete response or partial response at the week 16 assessment, which was 8 weeks following administration of the second dose.

  Across both CSU and CIndU participants in the OLE study, briquilimab continued to demonstrate a favorable safety profile:

  - KIT-related AEs were generally transient, low-grade events;

  - The majority of AEs observed were resolved while on study prior to subsequent doses;

  - One patient discontinued therapy due to taste disturbance potentially related to briquilimab; and

  - No other dose delays, missed doses or discontinuations were reported due to AEs possibly related to KIT blockade.

- In late 2024, we commenced a Phase 1b study in asthma, the "ETESIAN" study, which is a single dose double-blind, placebo-controlled challenge study seeking to demonstrate proof-of-concept in asthma utilizing a potential therapeutic dose to inform future trials in the broader asthma population. The study was conducted utilizing a single 180mg dose of subcutaneous briquilimab and key assessments included measuring improvements in Forced Expiratory Volume in 1 second ("$FEV_1$") in both Early Asthmatic Response ("EAR") measured at 6 weeks, and Late Asthmatic Response ("LAR") measured at 12 weeks, changes in airway hyperresponsiveness, mast cell depletion and recovery, and safety.

- In December 2025, we reported preliminary results from the ETESIAN study in 14 participants (7 receiving a single dose of 180mg briquilimab and 7 receiving placebo) who completed at least 7 weeks of allergen challenge testing following dosing with investigational product. Highlights of the clinical response observed in ETESIAN participants reported in December 2025 were as follows:

  - Compared to baseline, briquilimab reduced the allergen induced LAR (measured by the mean maximum percentage fall in $FEV_1$ (%Max $FEV_1$) and fall in area under the $FEV_1$ time response curve ("AUC")) at both 6 and 12 weeks. Patients who received briquilimab showed an improvement in the LAR %Max $FEV_1$ of 10.4% at 6 weeks and 8.7% at 12 weeks compared to baseline, as well as demonstrating an improvement in the LAR AUC of 25.4% at 6 weeks and 23.3% at 12 weeks.

  - Sputum eosinophils, a potential marker of inflammatory response, were also measured at various timepoints in conjunction with observing the EAR and LAR. Participants receiving briquilimab demonstrated notably lower eosinophil levels as compared to those receiving placebo, indicating a reduction in the inflammatory response to their allergen.

The positive proof of concept data generated in the ETESIAN study supports further development in the broader asthma population, however, advancing any future clinical studies in asthma would be based on an evaluation of the competitive landscape, the potential for strategic partnerships and capital availability.

Historically, we have also evaluated briquilimab as a one-time conditioning therapy for severe combined immunodeficiency ("SCID") patients undergoing a second stem cell transplant for which we conducted a Phase 1/2 clinical trial as well as via Investigator Sponsored Trials ("ISTs") in several other stem cell transplant indications. In July 2025, the SCID program and any remaining ISTs were discontinued to focus resources exclusively on our mast cell disease development portfolio.

We intend to become a fully integrated discovery, development and commercial company in the field of mast cell therapeutics. We are developing our product candidates to be used individually or, in some cases, in combination with other therapeutics. Our goal is to advance our product candidates through regulatory approval and bring them to the commercial market based on the data from our clinical trials and communications with regulatory agencies and payor communities. We expect to continue to broaden our pipeline with additional mast cell indications and next-generation products by leveraging our research organization.

We have an exclusive license agreement with Amgen Inc. ("Amgen") for the development and commercialization of the briquilimab monoclonal antibody in all indications and territories worldwide. We also have an exclusive license agreement with Stanford University for the right to use briquilimab in the clearance of diseased stem cells prior to the transplantation of hematopoietic stem cells.

**Recent Developments**

On July 8, 2025, we implemented a corporate reorganization to extend our cash runway, including a workforce reduction of approximately 50% of our workforce, representing 22 employees. The reorganization was substantially completed during the third quarter of 2025. In connection with this corporate reorganization, we refined our operating plan to focus on our briquilimab clinical development programs in chronic urticaria, halted enrollment in our Phase 1b ETESIAN study in asthma, and ended our other clinical and preclinical programs. The total cost related to the workforce reduction was approximately $2.3 million, all of which represented cash-based expenditure related primarily to severance payments. For the year ended December 31, 2025, we recorded restructuring charges of $1.8 million and $0.5 million as research and development expenses and general and administrative expenses, respectively, in our consolidated statements of operations and comprehensive loss.

On September 18, 2025, we entered into an underwriting agreement with TD Securities (USA) LLC as the representative of the several underwriters named therein, relating to an underwritten public offering. On September 22, 2025, we closed the offering and issued an aggregate of 11,670,707 shares of common stock, pre-funded warrants to purchase 675,000 shares of common stock and common warrants to purchase 12,345,707 shares of common stock for net proceeds of $27.5 million.

In December 2025, our board of directors approved a plan to cease operations of our vivarium and to terminate three of the four remaining research personnel associated with those operations. As a result of this decision, we recognized an impairment loss of $1.1 million for certain fixed assets and the right of use asset that were abandoned.

We have incurred significant losses and negative cash flows from operations since our inception. During the years ended December 31, 2025 and 2024 we incurred net losses of $75.8 million and $71.3 million, respectively. We generated negative operating cash flows of $77.2 million and $62.6 million for the years ended December 31, 2025 and 2024, respectively. As of December 31, 2025, we had an accumulated deficit of $316.7 million.

We had cash and cash equivalents of $28.7 million as of December 31, 2025. We expect to continue to incur substantial losses for the foreseeable future, and our transition to profitability will depend upon successful development, approval and commercialization of our product candidates and upon achievement of sufficient revenues to support our cost structure. We do not expect to generate any revenue from commercial product sales unless and until we successfully complete development and obtain regulatory approval for one or more of our product candidates. We may never achieve profitability, and unless we do and until then, we will need to continue to raise additional capital. Accordingly, based on our current operating plan, and along with our history of operating losses, our current cash and cash equivalents will not be sufficient to fund our ongoing operations for a period of at least twelve months from the date the consolidated financial statements included in this Annual Report on Form 10-K are issued.

Our management plans to monitor expenses and raise additional capital through a combination of public and private equity, debt financings, strategic alliances or licensing arrangements. Our ability to access capital when needed is not assured and, if capital is not available to us when, and in the amounts, needed, we may be required to significantly curtail, delay or discontinue one or more of our research or development programs or the commercialization of any product candidate, or be unable to expand our operations or otherwise capitalize on our business opportunities, as desired, which could materially harm our business, financial condition and results of operations.

We expect our expenses will increase substantially in connection with our ongoing and planned activities, as we:

- advance product candidates through preclinical studies and clinical trials;
- procure the manufacture of supplies for our preclinical studies and clinical trials;
- acquire, validate, and develop additional product candidates;
- attract, hire and retain additional personnel;
- operate as a public company;
- implement operational, financial and management systems;
- pursue regulatory approval for any product candidates that successfully complete clinical trials;
- establish a sales, marketing, and distribution infrastructure to commercialize any product candidate for which we may obtain marketing approval and related commercial manufacturing build-out; and
- obtain, maintain, expand, and protect our portfolio of intellectual property rights.

We do not currently own or operate any manufacturing facility. We rely on contract manufacturing organizations (“CMOs”) to produce our drug candidates in accordance with the FDA’s current good manufacturing practices (“cGMP”) regulations for use in our clinical trials. The manufacture of pharmaceuticals is subject to extensive cGMP regulations, which impose various procedural and documentation requirements and govern all areas of record keeping, production processes and controls, personnel and quality control. Under our license agreement with Amgen, we have received a substantial amount of drug product to support initiation of our planned clinical trials of briquilimab. In November 2019, we entered into development and manufacturing agreements with Lonza Sales AG (“Lonza”) relating to the manufacturing of briquilimab and product quality testing. The facility of Lonza in Slough, United Kingdom is responsible for production and testing of drug substance. The facility of Lonza in Stein, Switzerland is responsible for production and testing of drug product. Labelling, packaging and storage of finished drug product is provided by PCI Pharma Services, in San Diego, California. Our agreement with Lonza includes certain limitations on our ability to enter into supply arrangements with any other supplier without Lonza’s consent. In addition, Lonza has the right to increase the prices it charges us for certain supplies depending on a number of factors, some of which are outside of our control. In addition, given drug substance and drug product manufacturing and testing with Lonza currently occurs outside the United States, drug product imported into the United States for clinical or commercial use could be subject to significant tariffs in the current political environment.

We do not currently have sales and marketing infrastructure to support commercial launch of our product candidates, if approved. We may build such capabilities in North America prior to potential launch of briquilimab. Outside of North America, we may rely on licensing, co-sale and co-promotion agreements with strategic partners for the commercialization of our product candidates. If we build a commercial infrastructure to support marketing in North America, such commercial infrastructure could be expected to include a targeted sales force supported by sales management, internal sales support, an internal marketing group and distribution support. To develop the appropriate commercial infrastructure internally, we would have to invest financial and management resources, some of which would have to be deployed prior to any confirmation that briquilimab will be approved.

Because of the numerous risks and uncertainties associated with product development, we are unable to 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 revenue from the sale of our product candidates, 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 may be forced to reduce our operations.

**Components of Results of Operations**

***Operating Expenses***

*Research and Development*

The largest component of our total operating expenses since our inception has been research and development activities, including the preclinical and clinical development of our product candidates. Research and development expenses consist primarily of compensation and benefits for research and development employees, including stock-based compensation; expenses incurred under agreements with contract research organizations ("CROs") and investigative sites that conduct preclinical studies and clinical trials; the costs of acquiring and manufacturing clinical trial materials and other supplies; payments under licensing and research and development agreements; other outside services and consulting costs; and facilities, information technology and overhead expenses. Research and development costs are expensed as incurred.

Research and development costs include:

- program costs, including costs incurred under agreements with third-party CROs, CMOs and other third parties;
- employee-related costs, including salaries, benefits and stock-based compensation expense for our research and development personnel; and
- other expenses and allocated overheads incurred in connection with our research and development programs.

We expect our research and development expenses to increase substantially for the foreseeable future as we advance our product candidates into and through preclinical studies and clinical trials, pursue regulatory approval of our product candidates and expand our pipeline of product candidates. The process of conducting the necessary preclinical and clinical research to obtain regulatory approval is costly and time-consuming. The actual probability of success for our product candidates may be affected by a variety of factors, including the safety and efficacy of our product candidates, early clinical data, investment in our clinical programs, competition, manufacturing capability and commercial viability. We may never succeed in achieving regulatory approval for any of our product candidates. As a result of the uncertainties discussed above, we are unable to determine the duration and completion costs of our research and development projects or if, when and to what extent we will generate revenue from the commercialization and sale of our product candidates, if approved.

Our future research and development costs may vary significantly based on factors, such as:

- the scope, rate of progress, expense and results of our discovery and preclinical development activities;
- the costs and timing of our chemistry, manufacturing and controls activities, including fulfilling cGMP-related standards and compliance, and identifying and qualifying suppliers;
- per patient clinical trial costs;
- the number of trials required for approval;
- the number of sites included in our clinical trials;
- the countries in which the trials are conducted;
- delays in adding a sufficient number of trial sites and recruiting suitable patients to participate in our clinical trials;
- the number of patients that participate in the trials;
- the number of doses that patients receive;
- patient drop-out or discontinuation rates;
- potential additional safety monitoring requested by regulatory agencies;
- the duration of patient participation in the trials and follow up;
- the cost and timing of manufacturing our product candidates;
- the phase of development of our product candidates;
- the efficacy and safety profile of our product candidates;
- the timing, receipt, and terms of any approvals from applicable regulatory authorities, including the FDA and non-U.S. regulators;
- maintaining a continued acceptable safety profile of our product candidates following approval, if any, of our product candidates;
- significant and changing government regulation and regulatory guidance;
- changes in the standard of care on which a clinical development plan was based, which may require new or additional trials;
- the extent to which we establish additional strategic collaborations or other arrangements; and
- the impact of any business interruptions to our operations or to those of the third parties with whom we work, particularly in light of geopolitical and macroeconomic trends.

*General and Administrative*

General and administrative expenses consist primarily of personnel costs and expenses, including salaries, employee benefits, and stock-based compensation for our executive and other administrative personnel; legal services, including relating to intellectual property and corporate matters; accounting, auditing, consulting and tax services; insurance; and facility and other allocated costs not otherwise included in research and development expenses. We expect our general and administrative expenses to increase substantially for the foreseeable future as we anticipate an increase in our personnel headcount to support expansion of research and development activities, as well as to support our operations generally. We also expect to continue to incur significant expenses associated with being a public company, including costs related to accounting, audit, legal, regulatory, and tax-related services associated with maintaining compliance with applicable Nasdaq and SEC requirements; additional director and officer insurance costs; and investor and public relations costs.

*Total Other Income, Net*

Total other income, net includes foreign currency transactions gains and losses, interest income, offering costs on the common warrants recognized as other expense, and changes in the fair value of warrant liability. Earnout liability and warrant liability were classified as liabilities in our consolidated financial statements and were re-measured at each reporting period end. The earnout liability expired in September 2024 as the common stock price targets were not achieved prior to the expiration of the earnout period.

**Results of Operations**

***Comparison of the Years Ended December 31, 2025 and 2024***

The following table summarizes our results of operations for the years ended December 31, 2025 and 2024 (in thousands):

| | Year Ended December 31, | | Change | Change |
|---|---|---|---|---|
| | 2025 | 2024 | $ | % |
| Operating expenses | | | | |
| Research and development | $ 63,104 | $ 55,821 | $ 7,283 | 13 |
| General and administrative | 20,779 | 20,418 | 361 | 2 |
| Total operating expenses | 83,883 | 76,239 | 7,644 | 10 |
| Loss from operations | (83,883) | (76,239) | (7,644) | 10 |
| Interest income | 1,741 | 5,058 | (3,317) | (66) |
| Change in fair value of warrant liability | 8,528 | — | 8,528 | 100 |
| Other expense, net | (2,187) | (88) | (2,099) | NM |
| Total other income, net | 8,082 | 4,970 | 3,112 | 63 |
| Net loss and comprehensive loss | $ (75,801) | $ (71,269) | $ (4,532) | 6 |

NM = Not meaningful

***Research and Development Expenses***

The following table summarizes our research and development expenses for the periods indicated (in thousands, except percentages):

| | Year Ended December 31, | | Change | Change |
|---|---|---|---|---|
| | 2025 | 2024 | $ | % |
| Personnel-related costs | $ 15,146 | $ 14,941 | $ 205 | 1 |
| General and overhead costs | 6,323 | 6,612 | (289) | (4) |
| Program costs | 41,635 | 34,268 | 7,367 | 21 |
| Total research and development expenses | $ 63,104 | $ 55,821 | $ 7,283 | 13 |

Research and development expenses increased by $7.3 million, from $55.8 million for the year ended December 31, 2024 to $63.1 million for the year ended December 31, 2025.

Personnel-related costs, including employee payroll and related expenses, increased by $0.2 million, from $14.9 million for the year ended December 31, 2024 to $15.1 million for the year ended December 31, 2025. We recognized $1.8 million related to severance costs due to the restructuring of our operations in July 2025. As we stopped hiring, our personnel-related costs decreased by $1.6 million in 2025 as compared to 2024. Stock-based compensation expenses, included in personnel-related costs, were $2.0 million for each of the years ended December 31, 2025 and 2024.

General and overhead costs, which include common facilities, human resources and information technology related expenses allocated to research and development, decreased by $0.3 million, from $6.6 million for the year ended December 31, 2024 to $6.3 million for the year ended December 31, 2025, primarily due to decreased allocated overheads to research and development costs following our corporate reorganization in July 2025.

Program costs increased by $7.3 million, from $34.3 million for the year ended December 31, 2024 to $41.6 million for the year ended December 31, 2025. Clinical program expenses primarily consisted of expenses incurred under agreements with CROs, consultants, other professional services, in vivo study costs and lab supplies. Clinical program expenses increased primarily due to an increase in CRO expenses of $3.5 million from $13.9 million for the year ended December 31, 2024 to $17.4 million for the year ended December 31, 2025 and an increase in the in vivo study costs of $2.4 million from $1.0 million for the year ended December 31, 2024 to $3.4 million for the year ended December 31, 2025.

Our program costs for the year ended December 31, 2025 and 2024 were as follows (in thousands):

| | Year Ended December 31, | | Change | Change |
|---|---|---|---|---|
| | 2025 | 2024 | $ | % |
| Briquilimab platform | $ 6,727 | $ 5,637 | $ 1,090 | 19 |
| CMO | 12,912 | 9,500 | 3,412 | 36 |
| CSU | 12,047 | 10,689 | 1,358 | 13 |
| Asthma | 4,971 | 1,975 | 2,996 | 152 |
| CindU | 3,294 | 2,234 | 1,060 | 47 |
| SCID | 1,466 | 2,409 | (943) | (39) |
| MDS/AML | 218 | 1,824 | (1,606) | (88) |
| Total program costs | $ 41,635 | $ 34,268 | $ 7,367 | 21 |

At the program level, the increase in clinical program expenses was primarily driven by higher costs related to the briquilimab platform, CMO product development and manufacturing expenses not allocated to specific programs, and the CSU, CindU, and asthma programs. Enrollment in the ETESIAN study for the asthma program, which began in late 2024, was halted in July 2025 after it was determined that the clinical material used in the study was supplied from a drug product lot under investigation due to an atypical lack of efficacy observed in two cohorts of the BEACON study, in which material from the same lot was also used. In July 2025, we discontinued the SCID program. We incurred restructuring charges of approximately $1.8 million during the year ended December 31, 2025 in connection with halting enrollment in the clinical trial for our asthma program and discontinuing the SCID program, included in research and development expenses, and we do not expect to incur significant costs related to these programs in the future. We substantially discontinued the MDS/AML program in late 2024 and do not expect to incur significant costs related to this program in the future.

***General and Administrative Expenses***

General and administrative expenses increased by $0.4 million, from $20.4 million for the year ended December 31, 2024 to $20.8 million for the year ended December 31, 2025. Employee payroll and related expenses increased by $0.3 million, from $11.4 million for the year ended December 31, 2024 to $11.7 million for the year ended December 31, 2025, due to increased stock-based compensation expense. Stock-based compensation expenses, included in employee payroll and related expenses, were $4.1 million and $3.7 million for the years ended December 31, 2025 and 2024, respectively. Expenses related to professional consulting services were $7.3 million and $7.2 million for the years ended December 31, 2025 and 2024, respectively. Other expenses were $1.8 million for each of the years ended December 31, 2025 and 2024.

***Total Other Income, Net***

Total other income, net increased by $3.1 million, from $5.0 million for the year ended December 31, 2024 to $8.1 million for the year ended December 31, 2025.

Interest income decreased by $3.4 million, from $5.1 million for the year ended December 31, 2024 to $1.7 million for the year ended December 31, 2025, primarily due to lower cash balances invested in money market funds.

In connection with our underwritten public offering in September 2025, we issued common stock warrants, which are accounted for as liabilities at fair value, and remeasured at each reporting period until their exercise or expiration. We use Black-Scholes pricing model to estimate fair value of these warrants at each reporting date. Changes in our common stock price, volatility and estimated term may significantly impact the fair value of warrant liability. See Note 3, Fair Value Measurements, in our consolidated financial statements included elsewhere in this Annual Report on Form 10-K for additional details. The change in fair value of warrant liability of $8.5 million represents a decrease in the fair value of common stock warrants from the issuance date of September 22, 2025 to December 31, 2025.

Other expense includes $2.0 million offering costs associated with our underwritten public offering, which was closed in September 2025.

**Liquidity and Capital Resources**

As of December 31, 2025, we had $28.7 million of cash and cash equivalents.

In order to assist in funding our future operations, including our planned clinical trials, on March 19, 2025, we filed a new universal shelf registration statement on Form S-3 (the “Shelf Registration Statement”) with the SEC, which was declared effective on March 26, 2025 and superseded our prior universal shelf registration statement. As of December 31, 2025, we can sell from time to time up to $263.5 million of common stock, preferred stock, debt securities, warrants, rights, units and depositary shares comprised of any combination of these securities, for our own account in one or more offerings under the Shelf Registration Statement. The terms of any offering under the Shelf Registration Statement will be established at the time of such offering and will be described in a prospectus supplement to the Shelf Registration Statement filed with the SEC prior to the completion of any such offering.

On March 19, 2025, we entered into an Open Market Sale Agreement[SM] with Jefferies LLC ("Jefferies"), pursuant to which we may offer and sell through or to Jefferies, as sales agent or principal, shares of common stock from time to time (the "ATM Offering"). On March 26, 2025, we filed with the SEC a prospectus under the New S-3 in connection with the ATM Offering (the "ATM Prospectus"), pursuant to which we may offer and sell shares of common stock having an aggregate offering price of up to $100.0 million. As of December 31, 2025, we issued and sold an aggregate of 1,231,447 shares of common stock for net proceeds of approximately $6.5 million pursuant to the ATM Prospectus.

On September 18, 2025, we entered into an underwriting agreement with TD Securities (USA) LLC as the representative of the several underwriters named therein, relating to an underwritten public offering under the Shelf Registration Statement. On September 22, 2025, we closed the offering and issued an aggregate of 11,670,707 shares of common stock, pre-funded warrants to purchase 675,000 shares of common stock and common stock warrants to purchase 12,345,707 shares of common stock, for net proceeds of approximately $27.5 million.

As of December 31, 2025, $93.5 million remains allocated and available under the ATM Prospectus and $170.0 million remains available and unallocated under the Shelf Registration Statement.

***Future Funding Requirements***

Our primary uses of cash are to fund our operations, which consist primarily of research and development expenditures related to our programs and, to a lesser extent, general and administrative expenditures. We anticipate that we will continue to incur significant expenses for the foreseeable future as we continue to advance our product candidates, expand our corporate infrastructure, operate as a public company, further our research and development initiatives for our product candidates, scale our laboratory and manufacturing operations, and incur marketing costs associated with potential commercialization. We are subject to all the risks typically related to the development of new drug candidates, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. We anticipate that we will need substantial additional funding in connection with our continuing operations.

We have incurred significant losses and negative cash flows from operations since our inception. As of December 31, 2025, we had an accumulated deficit of $316.7 million. Given our recurring losses from operations and negative cash flows, and based on our current operating plan, we have concluded that there is substantial doubt about our ability to continue as a going concern within one year from the date of filing of this Annual Report on Form 10-K. We expect to finance our future cash needs through equity or debt financings, collaborations or a combination of these approaches. The sale of equity or convertible debt securities may result in dilution to our stockholders, and, in the case of preferred equity securities or convertible debt, those securities could provide for rights, preferences or privileges senior to those of our common stock. Debt financings may subject us to covenant limitations or restrictions on our ability to take specific actions, such as incurring additional debt or making capital expenditures. Our ability to raise additional funds may be adversely impacted by negative global economic conditions and any disruptions to and volatility in the credit and financial markets in the United States and worldwide or other factors. There can be no assurance that we will be successful in acquiring additional funding at levels sufficient to fund our operations or on terms favorable or acceptable to us. If we are unable to obtain adequate financing when needed or on terms favorable or acceptable to us, we may be forced to delay, reduce the scope of or eliminate one or more of our research and development programs.

Our future financing requirements will depend on many factors, including:

- the timing, scope, progress, results and costs of research and development, preclinical and non-clinical studies and clinical trials for our current and future product candidates;

- the number, scope and duration of clinical trials required for regulatory approval of our current and future product candidates;

- the outcome, timing and costs of seeking and obtaining regulatory approvals from the FDA and comparable foreign regulatory authorities for our product candidates, including any requirement to conduct additional studies or generate additional data beyond that which we currently expect would be required to support a marketing application;
- the costs of manufacturing clinical and commercial supplies of our current and future product candidates;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive marketing approval;
- any product liability or other lawsuits related to our product candidates;
- the revenue, if any, received from commercial sales of any product candidates for which we may receive marketing approval;
- our ability to establish a commercially viable pricing structure and obtain approval for coverage and adequate reimbursement from third-party and government payers;
- the costs to establish, maintain, expand, enforce and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with licensing, preparing, filing, prosecuting, defending and enforcing our patents or other intellectual property rights;
- expenses incurred to attract, hire and retain skilled personnel; and
- the costs of operating as a public company.

A change in the outcome of any of these or other variables could significantly change the costs and timing associated with the development of our product candidates. Furthermore, our operating plans may change in the future, and we may need additional funds to meet operational needs and capital requirements associated with such change.

***Contractual Obligations and Commitments***

We enter into contracts in the normal course of business with CROs for clinical trials, with CMOs for clinical supplies manufacturing and with other vendors for preclinical studies, supplies and other services and products for operating purposes. These contracts generally provide for termination on notice or may have a potential termination fee if a purchase order is cancelled within a specified time, and therefore are cancelable contracts. We do not expect any such contract terminations and did not have any non-cancellable obligations under these agreements as of December 31, 2025.

*Leases*

As of December 31, 2025, we leased approximately 25,900 square feet of space for our headquarters in Redwood City, California. The lease expires in August 2026. We have an option to extend the term for an additional five years to August 2031. In addition to base rent, we pay our share of operating expenses and taxes. As of December 31, 2025, our rent commitments under the lease agreement were $1.3 million within the next 12 months from December 31, 2025.

*Stanford License Agreements*

In March 2021, we entered into an exclusive license agreement with Stanford (the "2021 Stanford License Agreement"). In July 2023, we entered into an amendment to the 2021 Stanford License Agreement to modify certain milestones set forth thereunder. Pursuant to the 2021 Stanford License Agreement we are required to pay annual license maintenance fees, beginning on the first anniversary of the effective date of the agreement and ending upon the first commercial sale of a product, method, or service in the licensed field of use, as follows: $25,000 for each first and second year, $35,000 for each third and fourth year, and $50,000 at each anniversary thereafter ending upon the first commercial sale. We are also obligated to pay late-stage clinical development milestone payments and first commercial sales milestone payments of up to $9.0 million in total. We will also pay low single-digit royalties on net sales of licensed products. All products were in development as of December 31, 2025, and no such royalties were due as of such date and no milestones were achieved.

In December 2024, we entered into a co-exclusive license agreement with Stanford (the "2024 Stanford License Agreement"). Pursuant to the 2024 Stanford License Agreement, we are required to pay a license issuance fee of $75,000, which was paid in January 2025, and annual license maintenance fees, beginning on the first anniversary of the effective date of the agreement: $25,000 for each of the first through third years, $50,000 for each of the fourth through sixth years and $65,000 at each anniversary thereafter. As of December 31, 2025, we recognized $25,000 related to the annual license maintenance fees as research and development expense in the statement of operations and comprehensive loss and as accounts payable in the consolidated balance sheet. As of December 31, 2024, we recognized $75,000 related to the license issue fee as research and development expense in the statement of operations and comprehensive loss and as accrued expenses and other current liabilities in the consolidated balance sheet. We are also obligated to pay clinical development milestone payments of up to $1.3 million and sales milestone payments of up to $7.0 million in total. We will also pay low single-digit royalties on net sales of licensed products. All products are in development as of December 31, 2025, and no such royalties were due as of such date and no milestones were achieved.

***Cash Flows***

The following table summarizes our sources and uses of cash for the periods presented (in thousands):

| | Year ended December 31, | |
|---|---|---|
| | **2025** | **2024** |
| Net cash used in operating activities | $ (77,161) | $ (62,602) |
| Net cash provided by (used in) investing activities | 5 | (532) |
| Net cash provided by financing activities | 34,211 | 47,884 |
| Net (decrease) increase in cash and cash equivalents and restricted cash | $ (42,945) | $ (15,250) |

*Cash Flows from Operating Activities*

Net cash used in operating activities was $77.2 million and $62.6 million for the years ended December 31, 2025 and 2024, respectively.

Cash used in operating activities in the year ended December 31, 2025 was primarily due to our net loss for the period of $75.8 million, partially offset by non-cash items totaling $3.6 million and a net change of $4.9 million in our net operating assets and liabilities. The non-cash amounts consisted of $6.7 million related to stock-based compensation expense, $2.0 million related to offering costs recognized as expense, $1.1 million related to depreciation and amortization expense, impairment loss of $1.1 million and $1.2 million non-cash lease expense, partially offset by change in fair value of warrant liability of $8.5 million. The changes in our net operating assets and liabilities were primarily due to an increase of $2.2 million in accounts payable and a decrease of $0.7 million in other non-current assets, offset by a decrease of $4.4 million in accrued expenses and other current liabilities, an increase of $1.8 million in prepaid expenses and other current assets, and a decrease of $1.7 million in operating lease liability.

Cash used in operating activities in the year ended December 31, 2024 was primarily due to our net loss for the period of $71.3 million, adjusted by non-cash net loss of $8.5 million and a net change of $0.2 million in our net operating assets and liabilities. The non-cash amounts consisted of $6.6 million related to stock-based compensation expense, $1.4 million related to depreciation and amortization expense and $0.5 million non-cash lease expense. The changes in our net operating assets and liabilities were primarily due to an increase of $2.9 million in accrued expenses and other current liabilities and a decrease of $0.5 million in other non-current assets, offset by an increase of $2.1 million in prepaid expenses and other current assets, a decrease of $1.0 million in operating lease liability and a decrease of $0.1 million in accounts payable.

*Cash Flows from Investing Activities*

Cash provided by investing activities was less than $0.1 million for the year ended December 31, 2025, which primarily consisted of proceeds from sales of property and equipment.

Cash used in investing activities was $0.5 million for the year ended December 31, 2024, principally consisting of purchases of property and equipment.

*Cash Flows from Financing Activities*

Cash provided by financing activities for the year ended December 31, 2025 was $34.2 million, which consisted of net proceeds of $27.5 million from the issuance of common stock and warrants through the underwritten offering under the Shelf Registration Statement, net proceeds of $6.5 million from the issuance and sale of shares of common stock under the ATM Offering and proceeds from issuance of common stock pursuant to our employee stock purchase plan of $0.2 million.

Cash provided by financing activities for the year ended December 31, 2024 was $47.9 million, which consisted primarily of net proceeds from the issuance and sale of shares of common stock in an underwritten public offering of $47.2 million, cash received from the exercise of stock options of $0.3 million and cash received from the issuance of common stock in connection with purchases under our employee stock purchase plan of $0.4 million.

**Critical Accounting Policies and Significant Judgments and Estimates**

Our critical accounting policies are disclosed in Note 2 of the notes to the consolidated financial statements included in Part II, Item 8 of this Annual Report on Form 10-K.

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these consolidated 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 consolidated financial statements, as well as the reported 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 consolidated financial statements included in Part II, Item 8 of this Annual Report on Form 10-K, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our consolidated financial statements.

***Warrants to Purchase Common Stock***

We account for issued warrants as either equity-classified or liability-classified instruments based on an assessment of the warrant's specific terms and applicable authoritative guidance included in Accounting Standards Codification ("ASC") Topic 480, Distinguishing Liabilities from Equity ("ASC 480"), and ASC Topic 815, Derivatives and Hedging ("ASC 815"). The assessment considers whether the warrants are freestanding financial instruments pursuant to ASC 480, whether the warrants meet the definition of a liability pursuant to ASC 480, and whether the warrants meet all of the requirements for equity classification under ASC 815. This assessment, which requires the use of professional judgment, is conducted at the time of warrant issuance and as of each subsequent reporting period end date while the warrants are outstanding. Warrants that meet all of the criteria for equity classification are required to be recorded as a component of additional paid-in capital at the time of issuance, or when the conditions for equity classification are met and are not subsequently remeasured. Warrants that do not meet the required criteria for equity classification are classified as liabilities at fair value. The warrants are subsequently remeasured at each reporting date with changes in fair value recorded in the consolidated statements of operations and comprehensive loss until exercise or expiration.

We use the Black-Scholes pricing model to determine the fair value of warrant liability. Inputs used to determine estimated fair value of the warrant liability include the fair value of the underlying stock at the valuation date, the term of the warrants, and the expected volatility of the underlying stock. The significant unobservable input used in the fair value measurement of the warrant liability is the estimated term of the warrants. The estimates of fair value are uncertain and changes in any of the estimated inputs used as of the date of this report could have resulted in significant adjustments to the fair value. We recorded a change in fair value of warrant liability of $8.5 million for the year ended December 31, 2025.

***Accrued Research and Development Expenses***

We have entered into various agreements with outsourced vendors, including CROs and CMOs. Research and development expenses are recognized as services are performed and as costs occur. We make significant judgments and estimates in determining the accrual balance in each reporting period. As actual costs become known, we adjust our accruals. Although we do not expect our estimates to be materially different than the actual amounts incurred, such estimates for the status and timing of services performed relative to the actual status and timing of services performed may vary and could result in us reporting amounts that are too high or too low in any one period. Our accrual is dependent, in part, upon the receipt of timely and accurate reporting from CROs, CMOs, and other third-party vendors. Variations in the assumptions used to estimate accruals including, but not limited to, the number of patients enrolled, the rate of patient enrollment and the actual services performed, may vary from our estimates, resulting in adjustments to clinical trial expenses in future periods. Payments made under these arrangements in advance of the performance of the related services are recorded as prepaid expenses and other current assets until the services are rendered. To date, there have been no material differences between estimates of such expenses and the amounts actually incurred.

***Stock-Based Compensation***

We measure stock-based awards made to employees and non-employees based on the estimated fair values of the awards as of the grant dates using the Black-Scholes option-pricing model. The model requires management to make a number of assumptions including common stock fair value, expected volatility, expected term, risk-free interest rate and expected dividend yield.

*Expected Volatility* — Expected volatility is estimated by studying the volatility of the prices of shares of common stock of comparable public companies for similar terms.

*Expected Term* — Expected term represents the period that our stock-based awards are expected to be outstanding and is determined using the simplified method.

*Risk-Free Interest Rate* — The risk-free interest rate is based on the U.S. Treasury zero-coupon issued in effect at the time of grant for periods corresponding with the expected term of the option.

*Expected Dividend* — The Black-Scholes valuation model calls for a single expected dividend yield as an input. To date, we have not declared or paid any dividends.

*Common Stock Fair Value* — We estimate the fair value of our common stock based on the closing quoted market price of our common stock as reported on the Nasdaq Capital Market.

We recorded stock-based compensation expense of $6.7 million and $6.6 million for the years ended December 31, 2025 and 2024, respectively. As of December 31, 2025, there was $9.1 million of total unrecognized compensation expense, which we expect to recognize over a remaining weighted-average period of 2.50 years. We expect to continue to grant equity-based awards in the future, and to the extent that we do, our stock-based compensation expense recognized in future periods will likely increase.

**Recently Issued Accounting Pronouncements**

See Note 2 to the consolidated financial statements included in Part II, Item 8 of this Annual Report on Form 10-K for more information regarding recently issued accounting pronouncements.

**Smaller Reporting Company Status**

Previously, we were an emerging growth company as defined by the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"). The JOBS Act exempts emerging growth companies from being required to comply with new or revised financial accounting standards until private companies (that is, those that have not had a U.S. Securities Act of 1933, as amended, registration statement declared effective or do not have a class of securities registered under the Securities Exchange Act of 1934, as amended (the "Exchange Act")) are required to comply with the new or revised financial accounting standards. The JOBS Act provides that a company can elect to opt out of the extended transition period and comply with the requirements that apply to non-emerging growth companies but any such election to opt out is irrevocable. As of December 31, 2024, we ceased to be an emerging growth company.

We are now a "smaller reporting company," as defined in Item 10(f)(1) of Regulation S-K. Smaller reporting companies may take advantage of certain reduced disclosure obligations, including, among other things, providing only two years of audited financial statements. We will remain a smaller reporting company until the last day of the fiscal year in which (i) the market value of our common stock held by non-affiliates exceeds $250 million as of the last business day of our second fiscal quarter, or (ii) our annual revenue exceeded $100 million during such completed fiscal year and the market value of our common stock held by non-affiliates exceeds $700 million as of the last business day of our second fiscal quarter.

## ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

***Interest Rate Risk***

We had cash and cash equivalents of $28.7 million as of December 31, 2025, which consisted of checking account and money market funds. Historical fluctuations in interest rates have not been significant for us, and we believe a hypothetical 10% change in interest rates during any of the periods presented would not have had a material effect on our consolidated financial statements included in Part II, Item 8 of this Annual Report on Form 10-K. We had no outstanding debt as of December 31, 2025. To minimize risk in the future, we intend to maintain our portfolio of cash equivalents in institutional market funds that are composed of U.S. Treasury and U.S. Treasury-backed repurchase agreements or short-term U.S. Treasury securities.

***Foreign Currency Exchange Risk***

All of our employees are currently located in the United States; however, we do utilize certain vendors outside of the United States for our manufacturing of drug substances and clinical supplies. As such, our expenses are denominated in both U.S. dollars and foreign currencies. Therefore, our operations are and will continue to be subject to fluctuations in foreign currency exchange rates. To date, foreign currency transaction gains and losses have not been material to our consolidated financial statements, and we have not had a formal hedging program with respect to foreign currency. We believe a hypothetical 10% change in exchange rates during any of the periods presented would not have a material effect on our consolidated financial statements included in Part II, Item 8 of this Annual Report on Form 10-K.

***Effects of Inflation***

Inflation generally affects us by increasing our cost of labor and in the future our clinical trial costs. We believe that inflation has not had a material effect on our consolidated financial statements included in Part II, Item 8 of this Annual Report on Form 10-K.

**ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

**JASPER THERAPEUTICS, INC.**

**INDEX TO THE FINANCIAL STATEMENTS**

## Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of Jasper Therapeutics, Inc.

***Opinion on the Financial Statements***

We have audited the accompanying consolidated balance sheet of Jasper Therapeutics, Inc. and its subsidiary (the "Company") as of December 31, 2025 and 2024, and the related consolidated statements of operations and comprehensive loss, of stockholders' equity and of cash flows for the years then ended, 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 2024, and the results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

*Substantial Doubt About the Company's Ability to Continue as a Going Concern*

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the consolidated financial statements, the Company has incurred significant losses and negative cash flows from operations since its inception that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

***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.

***Critical Audit Matters***

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that (i) relates to accounts or disclosures that are material to the consolidated financial statements and (ii) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

*Certain Research and Development Expenses*

As described in Note 2 to the consolidated financial statements, research and development expenses are charged to expense when incurred. As disclosed by management, research and development costs include program costs, including costs incurred under agreements with third-party contract research organizations (CROs), contract manufacturing organizations (CMOs) and other third parties. The Company's research and development expense for the year ended December 31, 2025 was $63.1 million, a majority of which relates to certain research and development expenses.

The principal consideration for our determination that performing procedures relating to certain research and development expenses is a critical audit matter is a high degree of auditor effort in performing procedures related to certain of the Company's research and development expenses.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included, among others, testing certain research and development expenses on a sample basis by obtaining and inspecting source documents, such as the underlying third-party agreements and invoices received.

/s/ PricewaterhouseCoopers LLP
San Jose, California
March 30, 2026

We have served as the Company's auditor since 2021.

**JASPER THERAPEUTICS, INC.**
**CONSOLIDATED BALANCE SHEETS**
***(in thousands, except share and per share data)***

| | December 31, | |
|---|---|---|
| | **2025** | **2024** |
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 28,692 | $ 71,637 |
| Prepaid expenses and other current assets | 5,953 | 4,174 |
| Total current assets | 34,645 | 75,811 |
| Property and equipment, net | 102 | 1,875 |
| Operating lease right-of-use assets | 502 | 976 |
| Restricted cash | 417 | 417 |
| Other non-current assets | 113 | 820 |
| Total assets | $ 35,779 | $ 79,899 |
| **Liabilities and Stockholders' Equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 6,220 | $ 4,027 |
| Current portion of operating lease liabilities | 1,235 | 1,089 |
| Accrued expenses and other current liabilities | 5,745 | 10,121 |
| Total current liabilities | 13,200 | 15,237 |
| Non-current portion of operating lease liabilities | — | 724 |
| Warrant liability | 16,164 | — |
| Other non-current liabilities | 2,264 | 2,264 |
| Total liabilities | 31,628 | 18,225 |
| Commitments and contingencies (Note 8) | | |
| Stockholders' equity | | |
| Preferred stock: $0.0001 par value — 10,000,000 shares authorized at December 31, 2025 and 2024; none issued and outstanding at December 31, 2025 and 2024 | — | — |
| Common stock: $0.0001 par value — 492,000,000 shares authorized at December 31, 2025 and 2024; 27,996,819 and 15,022,122 shares issued and outstanding at December 31, 2025 and 2024, respectively | 3 | 2 |
| Additional paid-in capital | 320,818 | 302,541 |
| Accumulated deficit | (316,670) | (240,869) |
| Total stockholders' equity | 4,151 | 61,674 |
| Total liabilities and stockholders' equity | $ 35,779 | $ 79,899 |

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

**JASPER THERAPEUTICS, INC.**
**CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS**
***(in thousands, except share and per share data)***

| | Year Ended December 31, | |
|---|---|---|
| | **2025** | **2024** |
| Operating expenses | | |
| Research and development | $ 63,104 | $ 55,821 |
| General and administrative | 20,779 | 20,418 |
| Total operating expenses | 83,883 | 76,239 |
| Loss from operations | (83,883) | (76,239) |
| Interest income | 1,741 | 5,058 |
| Change in fair value of warrant liability | 8,528 | — |
| Other expense, net | (2,187) | (88) |
| Total other income, net | 8,082 | 4,970 |
| Net loss and comprehensive loss | $ (75,801) | $ (71,269) |
| Net loss per share attributable to common stockholders, basic and diluted | $ (3.95) | $ (4.89) |
| Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted | 19,168,110 | 14,584,870 |

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

**JASPER THERAPEUTICS, INC.**
**CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY**
***(in thousands, except share data)***

| | Common Stock | | Additional Paid-In | Accumulated | Total Stockholders' |
|---|---|---|---|---|---|
| | Shares | Amount | Capital | Deficit | Equity |
| **Balance as of December 31, 2023** | 11,163,896 | $ 1 | $ 248,039 | $ (169,600) | $ 78,440 |
| Issuance of common stock upon exercise of stock options | 33,735 | — | 329 | — | 329 |
| Issuance of common stock through underwritten offering, net of discounts and commissions and issuance costs of $3.3 million | 3,900,000 | 1 | 47,194 | — | 47,195 |
| Issuance of common stock pursuant to Employee Stock Purchase Plan | 29,491 | — | 360 | — | 360 |
| Forfeiture of shares subject to earnout | (105,000) | — | — | — | — |
| Stock-based compensation expense | — | — | 6,619 | — | 6,619 |
| Net loss | — | — | — | (71,269) | (71,269) |
| **Balance as of December 31, 2024** | 15,022,122 | 2 | 302,541 | (240,869) | 61,674 |
| Issuance of common stock and pre-funded warrants through underwritten offering, net of issuance costs of $0.4 million | 11,670,707 | 1 | 4,867 | — | 4,868 |
| Issuance of common stock through ATM line, net of commissions and issuance costs of $0.3 million | 1,231,447 | — | 6,454 | — | 6,454 |
| Issuance of common stock for vested restricted stock units | 12,000 | — | — | — | — |
| Issuance of common stock pursuant to Employee Stock Purchase Plan | 60,543 | — | 243 | — | 243 |
| Stock-based compensation expense | — | — | 6,713 | — | 6,713 |
| Net loss | — | — | — | (75,801) | (75,801) |
| **Balance as of December 31, 2025** | 27,996,819 | $ 3 | $ 320,818 | $ (316,670) | $ 4,151 |

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

**JASPER THERAPEUTICS, INC.**
**CONSOLIDATED STATEMENTS OF CASH FLOWS**
***(in thousands)***

| | Year Ended December 31, | |
|---|---|---|
| | **2025** | **2024** |
| **Cash flows used in operating activities** | | |
| Net loss | $ (75,801) | $ (71,269) |
| Adjustments to reconcile net loss to net cash used in operating activities | | |
| Depreciation and amortization expense | 1,056 | 1,373 |
| Impairment of long-lived assets | 1,112 | — |
| Non-cash lease expense | 1,164 | 491 |
| Stock-based compensation expense | 6,713 | 6,619 |
| Change in fair value of warrant liability | (8,528) | — |
| Offering costs recognized in other expense, net | 2,046 | — |
| Changes in operating assets and liabilities: | | |
| Prepaid expenses and other current assets | (1,779) | (2,123) |
| Other non-current assets | 707 | 523 |
| Accounts payable | 2,193 | (122) |
| Accrued expenses and other current liabilities | (4,374) | 2,879 |
| Operating lease liability | (1,670) | (973) |
| Net cash used in operating activities | (77,161) | (62,602) |
| **Cash flows provided by (used in) investing activities** | | |
| Purchases of property and equipment | (7) | (552) |
| Proceeds from sales of property and equipment | 12 | 20 |
| Net cash provided by (used in) investing activities | 5 | (532) |
| **Cash flows from financing activities** | | |
| Proceeds from issuance of common stock through ATM offering, net | 6,454 | — |
| Proceeds from issuance of common stock and warrants through underwritten offering, net | 27,514 | 47,195 |
| Proceeds from exercise of common stock options | — | 329 |
| Proceeds from issuance of common stock pursuant to Employee Stock Purchase Plan | 243 | 360 |
| Net cash provided by financing activities | 34,211 | 47,884 |
| Net decrease in cash, cash equivalents and restricted cash | (42,945) | (15,250) |
| Cash, cash equivalents and restricted cash at beginning of the year | 72,054 | 87,304 |
| Cash, cash equivalents and restricted cash at end of the year | $ 29,109 | $ 72,054 |
| **Supplemental and non-cash items reconciliations:** | | |
| Right-of-use asset obtained in exchange for lease liabilities | $ 1,092 | $ — |
| Warrant liability recognized in connection with underwritten offering | $ 24,692 | $ — |

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

## NOTE 1. ORGANIZATION AND DESCRIPTION OF BUSINESS

### *Description of Business*

Jasper Therapeutics, Inc. and its consolidated subsidiary, Jasper Tx Corp. (collectively, "Jasper" or the "Company"), is a clinical-stage biotechnology company focused on developing therapeutics targeting mast cell driven diseases, such as chronic spontaneous urticaria, chronic inducible urticaria and asthma. Briquilimab has been evaluated in clinical studies in chronic spontaneous urticaria, chronic inducible urticaria and allergic asthma. The Company's clinical development activities are currently focused on chronic urticarias, and while the clinical data generated in allergic asthma supports further development in the broader asthma population, advancing any future clinical studies in asthma would be based on an evaluation of the competitive landscape, the potential for strategic partnerships and capital availability. The Company has also historically explored diseases where targeting diseased hematopoietic stem cells can provide benefits, such as stem cell transplant conditioning regimens, but is currently focused on development of briquilimab in mast cell driven diseases.

The Company is headquartered in Redwood City, California. The Company is a Delaware corporation and was incorporated in March 2018. In September 2021, the Company completed a merger with Amplitude Healthcare Acquisition Corporation and became a public company.

## NOTE 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

### *Basis of Presentation*

The consolidated financial statements and accompanying notes have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") and applicable rules and regulations of the U.S. Securities and Exchange Commission (the "SEC") for financial reporting.

The financial statements are consolidated for the years ended December 31, 2025 and 2024, and include the accounts of Jasper Therapeutics, Inc. and its wholly-owned subsidiary, Jasper Tx Corp, which had no operations during the periods presented.

### *Going Concern*

In accordance with Accounting Standards Codification ("ASC") Topic 205-40, Going Concern, the Company evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about its ability to continue as a going concern within one year after the date that the consolidated financial statements are issued. This evaluation initially does not take into consideration the potential mitigating effect of the Company's plans that have not been fully implemented as of the date the financial statements are issued. When substantial doubt exists under this methodology, the Company evaluates whether the mitigating effect of its plans sufficiently alleviates substantial doubt about its ability to continue as a going concern. The mitigating effect of the Company's plans, however, is only considered if both (1) it is probable that the plans will be effectively implemented within one year after the date that the financial statements are issued, and (2) it is probable that the plans, when implemented, will mitigate the relevant conditions or events that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that the consolidated financial statements are issued. In performing this analysis, the Company excluded certain elements of its operating plan that cannot be considered probable.

The Company has incurred significant losses and negative cash flows from operations since its inception. During the years ended December 31, 2025 and 2024, the Company incurred net losses of $75.8 million and $71.3 million, respectively. During the years ended December 31, 2025 and 2024, the Company had negative operating cash flows of $77.2 million and $62.6 million, respectively. As of December 31, 2025, the Company had an accumulated deficit of $316.7 million. The Company expects to continue to incur substantial losses, and its ability to achieve and sustain profitability will depend on the successful development, approval, and commercialization of product candidates and on the achievement of sufficient revenues to support the Company's cost structure.

Management expects to finance the Company's future cash needs through equity or debt financings, collaborations or a combination of these approaches. However, due to several factors, including those outside management's control, there can be no assurance that the Company will be able to complete additional financings. The Company's ability to raise additional funds may be adversely impacted by negative global economic conditions and any disruptions to and volatility in the credit and financial markets in the United States and worldwide or other factors. There can be no assurance that the Company will be successful in acquiring additional funding at levels sufficient to fund its operations or on terms favorable or acceptable to the Company. If the Company is unable to obtain adequate financing when needed or on terms favorable or acceptable to it, the Company may be forced to delay, reduce the scope of or eliminate one or more of its research and development programs. The Company concluded the likelihood that its plan to successfully obtain sufficient funding or adequately delay or reduce expenditures, while reasonably possible, is less than probable. As of December 31, 2025, the Company had cash and cash equivalents of $28.7 million. The Company's management expects that the existing cash and cash equivalents will not be sufficient to fund the Company's operating plans for at least twelve months from the issuance date of these consolidated financial statements. Accordingly, the Company has concluded that substantial doubt exists about its ability to continue as a going concern.

The consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the ordinary course of business. The consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of the uncertainties described above.

***Reverse Stock Split***

On January 4, 2024, the Company effected a 1-for-10 reverse stock split (the "Reverse Stock Split") of its common stock. The par value per share and the number of authorized shares were not adjusted as a result of the Reverse Stock Split. The shares of common stock underlying outstanding stock options, common stock warrants 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. In addition, the shares available for grants under the Company's incentive plans were adjusted as a result of the Reverse Stock Split.

***Use of Estimates***

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make estimates, assumptions and judgements that affect the reported amounts of assets and liabilities and disclosure of contingent liabilities as of the date of the consolidated financial statements and the reported amounts of income and expenses during the reporting periods. Significant estimates and assumptions made in the consolidated financial statements include but are not limited to, the determination of the accrued research and development expenses, the measurement of stock-based compensation expense and the valuation of warrant liability. The Company evaluates its estimates and assumptions on an ongoing basis using historical experience and other factors and adjusts those estimates and assumptions when facts and circumstances dictate. Actual results could materially differ from those estimates.

***Cash, Cash Equivalents, and Restricted Cash***

The following table provides a reconciliation of cash and cash equivalents and restricted cash reported within the consolidated balance sheets that sum to the total amount shown in the consolidated statements of cash flows (in thousands):

| | December 31, | |
|---|---|---|
| | **2025** | **2024** |
| Cash and cash equivalents | $ 28,692 | $ 71,637 |
| Restricted cash | 417 | 417 |
| Total cash, cash equivalents and restricted cash | $ 29,109 | $ 72,054 |

Cash and cash equivalents consist of cash held in operating accounts and investments in money market funds. Restricted cash relates to the letter of credit secured in conjunction with the operating lease (Note 8).

***Concentrations of Credit Risk and Other Risks and Uncertainties***

The Company's cash and cash equivalents are maintained with financial institutions in the United States of America. Cash balances are held at financial institutions and account balances may exceed federally insured limits. To date, the Company has not experienced any losses on its cash, cash equivalents and marketable securities' balances and periodically evaluates the creditworthiness of its financial institutions.

The Company is subject to risks common to companies in the development stage, including, but not limited to, development and regulatory approval of new product candidates, development of markets and distribution channels, dependence on key personnel, and the ability to obtain additional capital as needed to fund its product plans. To achieve profitable operations, the Company must successfully develop and obtain requisite regulatory approvals for, manufacture, and market its product candidates. There can be no assurance that any such product candidate can be developed and approved or manufactured at an acceptable cost and with appropriate performance characteristics, or that such product will be successfully marketed. These factors could have a material adverse effect on the Company's future financial results.

Products developed by the Company require approval from the U.S. Food and Drug Administration (the "FDA") or other international regulatory agencies prior to commercial sales. There can be no assurance that the Company's future products will receive the necessary clearances. If the Company were denied such clearances or such clearances were delayed, it could have a materially adverse impact on the Company.

***Property and Equipment, Net***

Property and equipment, net is stated at cost less accumulated depreciation and amortization. Depreciation and amortization are recorded using the straight-line method over the estimated useful lives of the assets, generally 3 to 5 years. Leasehold improvements are amortized over the shorter of the estimated useful life of the asset or the remaining term of the lease. Upon the sale or retirement of assets, the cost and related accumulated depreciation and amortization are removed from the balance sheets and the resulting gain or loss is reflected in the consolidated statements of operations and comprehensive loss. Maintenance and repairs are charged to operations as incurred.

***Impairment of Long-Lived Assets***

The Company reviews its long-lived assets for impairment, principally property and equipment, whenever events or changes in business circumstances indicate the carrying amount of an asset may not be fully recoverable. Recoverability of assets held and used is measured by comparing the carrying amount of an asset to future net cash flows expected to be generated by the asset. If the Company determines that the carrying value of long-lived assets may not be recoverable, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value of the assets. Fair value is determined through various valuation techniques, principally discounted cash flow models, to assess the fair values of long-lived assets.

The Company recognized an impairment loss of $1.1 million for the year ended December 31, 2025, which was recorded in research and development and general and administrative expenses in the consolidated statements of operations and comprehensive loss in the amounts of $0.8 million and $0.3 million, respectively (see Note 16). The Company did not record any impairment of long-lived assets during the year ended December 31, 2024.

***Leases***

The Company determines whether an arrangement is or contains a lease at the inception of the arrangement and whether such a lease is classified as a financing lease or operating lease at the commencement date of the lease. Leases with a term greater than one year are recognized on the balance sheet as operating right-of-use assets, current portion of operating lease liabilities and non-current portion of operating lease liabilities. The Company elected not to recognize the right-of-use assets and lease liabilities for leases with lease terms of 12 months or less (short-term leases). Lease liabilities and their corresponding right-of-use assets are recorded based on the present value of lease payments over the expected lease term. As the interest rate implicit in the Company's lease contracts is not readily determinable, the Company utilizes a collateralized incremental borrowing rate based on the information available at the commencement date to determine the present value of lease payments. Certain adjustments to the right-of-use asset may be required for items such as initial direct costs paid or incentives received and impairment charges if the Company determines the right-of-use asset is impaired.

The Company considers the lease term to be the noncancelable period that it has the right to use the underlying asset, together with any periods where it is reasonably certain it will exercise an option to extend (or not terminate) the lease. Periods covered by an option to extend (or not terminate) the lease in which the exercise of the option is controlled by the lessor are included in the lease term.

Rent expense for operating leases is recognized on a straight-line basis over the lease term and is presented in operating expenses on the consolidated statements of operations and comprehensive loss. The Company has elected to not separate lease and non-lease components for its real estate leases and has instead accounted for each separate lease component and the non-lease components associated with that lease component as a single lease component. Variable lease payments are recognized as lease expense as incurred and are presented in operating expenses on the consolidated statements of operations and comprehensive loss.

The Company had no finance leases as of December 31, 2025 and 2024.

***Fair Value of Financial Instruments***

The Company's financial instruments consist of cash and cash equivalents, prepaid expenses and other current assets, accounts payable, accrued expenses and other current liabilities, warrant liability and other non-current liabilities. Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. The carrying amounts of cash, prepaid expenses and other current assets, accounts payable, accrued expenses and other current liabilities, approximate fair value due to their short-term maturities.

***Warrants to Purchase Common Stock***

The Company accounts for issued warrants as either equity-classified or liability-classified instruments based on an assessment of the warrant's specific terms and applicable authoritative guidance included in ASC Topic 480, Distinguishing Liabilities from Equity ("ASC 480"), and ASC Topic 815, Derivatives and Hedging ("ASC 815"). The assessment considers whether the warrants are freestanding financial instruments pursuant to ASC 480, whether the warrants meet the definition of a liability pursuant to ASC 480, and whether the warrants meet all of the requirements for equity classification under ASC 815. This assessment, which requires the use of professional judgment, is conducted at the time of warrant issuance and as of each subsequent reporting period end date while the warrants are outstanding. Warrants that meet all of the criteria for equity classification are required to be recorded as a component of additional paid-in capital at the time of issuance, or when the conditions for equity classification are met and are not subsequently remeasured. Warrants that do not meet the required criteria for equity classification are classified as liabilities at fair value. The warrants are subsequently remeasured at each reporting date with changes in fair value recorded in the consolidated statements of operations and comprehensive loss until exercise or expiration.

***Accrued Research and Development Expenses***

The Company has entered into various agreements with outsourced vendors, contract manufacturing organizations and contract research organizations. The Company makes estimates of accrued research and development expenses as of each balance sheet date based on facts and circumstances known at that time. The Company periodically confirms the accuracy of its estimates with the service providers and makes adjustments, if necessary. Research and development accruals are estimated based on the level of services performed, progress of the studies, including the phase or completion of events, and contracted costs. The estimated costs of research and development services provided, but not yet invoiced, are included in accrued expenses on the consolidated balance sheets. If the actual timing of the performance of services or the level of effort varies from the original estimates, the Company will adjust the accrual accordingly. Payments made under these arrangements in advance of the performance of the related services are recorded as prepaid expenses and other current assets until the services are rendered. To date, there have been no material differences between estimates of such expenses and the amounts actually incurred.

***Research and Development***

The Company expenses research and development ("R&D") expenses as incurred. R&D expenses consist primarily of personnel-related expenses, clinical trials, engineering and product development costs to support regulatory clearance of, and related regulatory compliance for, the Company's products. Specifically, R&D expenses that support regulatory approval of, and related regulatory compliance for, the Company's products include costs associated with the Company's clinical trials, consisting of clinical trial design, clinical site establishment and management, clinical data management, travel expenses and the costs of products used for the Company's clinical trials. Personnel-related expenses include salaries, benefits, bonuses and stock-based compensation of the Company's R&D employees. Non personnel-related expenses include costs of outside consultants, testing, materials and supplies, and allocated overhead. The Company allocates overhead related to rent, facility costs, information technology and human resources costs. R&D expenses are charged to expense when incurred.

***General and Administrative***

General and administrative expenses include compensation, employee benefits and stock-based compensation for executive management, finance administration and human resources, allocated facility and information technology costs, professional service fees and other general overhead costs, including allocated depreciation to support the Company's operations.

***Stock-Based Compensation***

The Company measures its stock options granted to employees and non-employees based on the estimated fair values of the awards as of the grant date using the Black-Scholes option-pricing model. The model requires management to make a number of assumptions, including expected volatility, expected term, risk-free interest rate and expected dividend yield. For restricted stock unit awards, the estimated fair value is the fair market value of the underlying stock on the grant date. The Company expenses the fair value of its equity-based compensation awards on a straight-line basis over the requisite service period, which is the period in which the related services are received. The Company accounts for award forfeitures as they occur. The expense for stock-based awards with performance conditions is recognized when it is probable that a performance condition is met during the vesting period.

***Income Taxes***

The Company accounts for income taxes using the asset and liability method. The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the consolidated financial statements or tax returns. Deferred tax assets and liabilities are determined based on the difference between the consolidated financial statements and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse.

In evaluating the ability to recover its deferred income tax assets, the Company considers all available positive and negative evidence, including its operating results, ongoing tax planning, and forecasts of future taxable income on a jurisdiction-by-jurisdiction basis. In the event the Company determines that it would be able to realize its deferred income tax assets in the future in excess of their net recorded amount, it would make an adjustment to the valuation allowance that would reduce the provision for income taxes. Conversely, if all or part of the net deferred tax assets are determined not to be realizable in the future, an adjustment to the valuation allowance would be charged to the provision of income taxes in the period when such determination is made. As of December 31, 2025 and 2024, the Company has recorded a full valuation allowance on its deferred tax assets.

Tax benefits related to uncertain tax positions are recognized when it is more likely than not that a tax position will be sustained during an audit. Interest and penalties related to unrecognized tax benefits are included within the provision for income tax. To date, there have been no interest or penalties recorded in relation to unrecognized tax benefits.

***Foreign Currency Transactions***

Transactions denominated in foreign currencies are initially measured in U.S. dollars using the exchange rate on the date of the transaction. Foreign currency denominated monetary assets and liabilities are subsequently re-measured at the end of each reporting period using the exchange rate at that date, with the corresponding foreign currency transaction gain or loss recorded in the consolidated statements of operations and comprehensive loss and consolidated statements of cash flows. Nonmonetary assets and liabilities are not subsequently re-measured.

***Comprehensive Loss***

Comprehensive loss represents all changes in stockholders' equity except those resulting from distributions to stockholders. There have been no items qualifying as other comprehensive income (loss) during the years ended December 31, 2025 and 2024, and therefore, the Company's comprehensive loss was the same as its reported net loss.

***Net Loss per Share Attributable to Common Stockholders***

Basic net loss per common share is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding during the period, without consideration of potentially dilutive securities. The Pre-Funded Warrants (see Note 7) are included in the computation of basic net loss per share because their exercise price is negligible and they are fully vested and exercisable at any time after the original issuance date. Diluted net loss per share is computed by dividing the net loss attributable to common 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 the diluted net loss per share calculation, the restricted stock units, the Public Warrants (see Note 9), the Common Warrants (see Note 7) and stock options are considered to be potentially dilutive securities.

Basic and diluted net loss attributable to common stockholders per share is presented in conformity with the two-class method required for participating securities. The Company considers the Common Warrants to be participating securities as the holders are entitled to receive dividends on a pari passu basis in the event that a dividend is paid on common stock. The Company's participating securities do not have a contractual obligation to share in the Company's losses. As such, the net loss is attributed entirely to common stockholders. For the years ended December 31, 2025 and 2024, the diluted net loss per common share was the same as basic net loss per share of common stock, as the impact of potentially dilutive securities was antidilutive to the net loss per common share. The performance restricted stock units are contingently issuable shares and are not included in the diluted net loss per share calculation until contingencies are resolved.

***Segment Reporting***

The Company has one reportable and operating segment. Financial information about the Company's operating segment is presented in Note 15.

***Recent Accounting Pronouncements***

*Recent Accounting Pronouncements Adopted*

In December 2023, the Financial Accounting Standards Board (the "FASB") issued Accounting Standards Update ("ASU") No. 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures. This ASU requires public entities, on an annual basis, to provide disclosure of specific categories in the rate reconciliation, as well as disclosure of income taxes paid disaggregated by jurisdiction. ASU No. 2023-09 is effective for fiscal years beginning after December 15, 2024, with early adoption permitted. The Company adopted ASU No. 2023-09 as of December 31, 2025 on a prospective basis. Additional required disclosures have been included in Note 12.

*Accounting Pronouncements Not Yet Adopted*

In November 2024, the FASB issued ASU No. 2024-03, Income Statement-Reporting Comprehensive Income-Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses, to improve financial reporting by requiring that public business entities disclose additional information about specific expense categories in the notes to financial statements at interim and annual reporting periods. In January 2025, the FASB issued ASU No. 2025-01, Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures (Subtopic 220-40): Clarifying the Effective Date ("ASU 2025-01"). The amendments do not change or remove current expense disclosure requirements; however, the amendments affect where such information appears in the notes to financial statements because entities are required to include certain current disclosures in the same tabular format disclosure as the other disaggregation requirements in the amendments. The amendments are effective for annual reporting periods beginning after December 15, 2026, and interim reporting periods beginning after December 15, 2027. Early adoption is permitted. The Company is currently evaluating the impact of adopting this ASU to its consolidated financial statements.

In September 2025, the FASB issued ASU No. 2025-06, Intangibles - Goodwill and Other - Internal - Use Software (Subtopic 350-40): Targeted Improvements to the Accounting for Internal-Use Software ("ASU 2025-06"). The amendments in ASU 2025-06 remove all references to prescriptive and sequential software development stages. This ASU requires entities to begin capitalizing software costs when management authorizes and commits to funding the software project, and it is probable that the project will be completed, and the software will be used for its intended purpose. ASU 2025-06 is effective for fiscal years beginning after December 15, 2027, including interim periods within those fiscal years. Early adoption is permitted. The Company is currently evaluating the impact of adopting this ASU to its consolidated financial statements.

In December 2025, the FASB issued ASU No. 2025-10, Accounting for Government Grants Received by Business Entities (Topic 832). This ASU provides recognition, measurement, presentation, and disclosure requirements for government grants, including guidance for grants related to an asset and grants related to income. ASU No. 2025-10 is effective for fiscal years beginning after December 15, 2028, including interim periods within those fiscal years. Early adoption is permitted. The Company is currently evaluating the impact of adopting this ASU to its consolidated financial statements.

In December 2025, the FASB issued ASU No. 2025-11, Interim Reporting: Narrow-Scope Improvements (Topic 270). This ASU improves clarity for interim financial reporting requirements under the existing guidance within ASC Topic 270, by creating a comprehensive list of interim disclosure requirements, clarifying scope and applicability, along with adding a principle to disclose all material events that have occurred since the most recently filed Annual Report on Form 10-K. ASU No. 2025-11 is effective for interim reporting for fiscal years beginning after December 15, 2027, with early adoption permitted. The Company is currently evaluating the impact of adopting this ASU to its consolidated financial statements.

**NOTE 3. FAIR VALUE MEASUREMENTS**

The Company measures certain financial assets and liabilities at fair value on a recurring basis. Fair value is an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or a liability. A three-tier fair value hierarchy is established as a basis for considering such assumptions and for inputs used in the valuation methodologies in measuring fair value:

- Level 1 – Inputs are unadjusted, quoted prices in active markets for identical assets or liabilities at the measurement date;

- Level 2 – Inputs are observable, unadjusted quoted prices in active markets for similar assets or liabilities, unadjusted quoted prices for identical or similar assets or liabilities in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the related assets or liabilities; and

- Level 3 – Unobservable inputs that are significant to the measurement of the fair value of the assets or liabilities that are supported by little or no market data.

In determining fair value, the Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible as well as considers counterparty credit risk in its assessment of fair value.

Assets and liabilities measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires management to make judgments and consider factors specific to the asset or liability.

The fair value of Level 1 securities is determined using quoted prices in active markets for identical assets. Level 1 securities consist of highly liquid money market funds. In addition, restricted cash collateralized by money market funds is a financial asset measured at fair value and is a Level 1 financial instrument under the fair value hierarchy.

Financial assets and liabilities are considered Level 2 when their fair values are determined using inputs that are observable in the market or can be derived principally from or corroborated by observable market data, such as pricing for similar securities, recently executed transactions, cash flow models with yield curves, and benchmark securities. In addition, Level 2 financial instruments are valued using comparisons to like-kind financial instruments and models that use readily observable market data as their basis. The Company had no financial instruments classified at Level 2 as of December 31, 2025 and 2024.

Financial assets and liabilities are considered Level 3 when their fair values are determined using pricing models, discounted cash flow methodologies, or similar techniques and at least one significant model assumption or input is unobservable. As of December 31, 2025, the Company's Level 3 liabilities consisted of the warrant liability. The Company had no financial instruments classified at Level 3 as of December 31, 2024.

There were no transfers within the hierarchy during the years ended December 31, 2025 and 2024.

The following tables set forth the fair value of the Company's financial assets and liabilities measured on a recurring basis by level within the fair value hierarchy (in thousands):

| | December 31, 2025 | | | |
|---|---|---|---|---|
| | **Level 1** | **Level 2** | **Level 3** | **Total** |
| Financial assets | | | | |
| Money market funds | $ 27,692 | $ — | $ — | $ 27,692 |
| Total fair value of assets | $ 27,692 | $ — | $ — | $ 27,692 |
| | | | | |
| Financial liabilities | | | | |
| Warrant liability | $ — | $ — | $ 16,164 | $ 16,164 |
| Total fair value of financial liabilities | $ — | $ — | $ 16,164 | $ 16,164 |

| | December 31, 2024 | | | |
|---|---|---|---|---|
| | **Level 1** | **Level 2** | **Level 3** | **Total** |
| Financial assets | | | | |
| Money market funds | $ 70,637 | $ — | $ — | $ 70,637 |
| Total fair value of assets | $ 70,637 | $ — | $ — | $ 70,637 |

During the year ended December 31, 2025, the changes in the Company's warrant liability were as follows (in thousands):

| | Warrant Liability |
|---|---|
| **Fair Value as of December 31, 2024** | $ — |
| Issuance of warrants | 24,692 |
| Change in the fair value | (8,528) |
| **Fair Value as of December 31, 2025** | $ 16,164 |

The Company uses the Black-Scholes pricing model to determine the fair value of its warrant liability using Level 3 inputs. Inputs used to determine estimated fair value of the warrant liability include the fair value of the underlying stock at the valuation date, the term of the warrants, and the expected volatility of the underlying stock. The significant unobservable input used in the fair value measurement of the warrant liability is the estimated term of the warrants. The estimates of fair value are uncertain and changes in any of the estimated inputs used as of the date of this report could have resulted in significant adjustments to the fair value.

The key inputs into valuation models used to estimate the fair value of the warrant liability as of September 22, 2025, the issuance date, and as of December 31, 2025 were as follows:

| | December 31, 2025 | September 22, 2025 |
|---|---|---|
| Common stock price | $ 1.83 | $ 2.59 |
| Expected term (in years) | 4.22 | 4.5 |
| Expected volatility | 113.30% | 113.00% |
| Risk-free interest rate | 3.66% | 3.58% |

**NOTE 4. CONSOLIDATED BALANCE SHEET COMPONENTS**

***Prepaid expenses and other current assets***

The following table summarizes the details of prepaid expenses and other current assets as of the dates set forth below (in thousands):

| | December 31, | |
|---|---|---|
| | 2025 | 2024 |
| Research and development prepaid expenses | $ 4,320 | $ 2,604 |
| Prepaid insurance | 866 | 784 |
| Prepaid travel expenses | 103 | 140 |
| Other prepaid expenses and current assets | 664 | 646 |
| Total | $ 5,953 | $ 4,174 |

***Property and equipment, net***

The following table summarizes the details of property and equipment, net as of the dates set forth below (in thousands):

| | December 31, | |
|---|---|---|
| | 2025 | 2024 |
| Leasehold improvements | $ 2,711 | $ 2,711 |
| Lab equipment | 1,513 | 2,049 |
| Office furniture & fixtures | 522 | 522 |
| Computer equipment | 170 | 310 |
| Capitalized software | — | 90 |
| Property and equipment, gross | 4,916 | 5,682 |
| Less: accumulated depreciation and amortization | (4,814) | (3,807) |
| Property and equipment, net | $ 102 | $ 1,875 |

Depreciation and amortization expense for the years ended December 31, 2025 and 2024 was $1.1 million and $1.4 million, respectively.

In December 2025, the Company reviewed its long-lived assets for impairment and recognized an impairment loss of $0.7 million to write off certain property and equipment assets to zero, as these assets were abandoned after the Company's restructuring of its research and development organization in the fourth quarter of 2025 (see Note 16). The impairment loss of $0.6 million and $0.1 million were recorded in research and development and general and administrative expenses, respectively, in the consolidated statements of operations and comprehensive loss for the year ended December 31, 2025.

***Accrued expenses and other current liabilities***

The following table summarizes the details of accrued expenses and other current liabilities as of the dates set forth below (in thousands):

| | December 31, | |
|---|---|---|
| | **2025** | **2024** |
| Research and development accrued expenses | $ 3,775 | $ 6,424 |
| Accrued employee and related compensation expenses | 1,589 | 3,100 |
| Accrued legal and professional expenses | 261 | 178 |
| Other | 120 | 419 |
| Total | $ 5,745 | $ 10,121 |

**NOTE 5. CIRM GRANT**

In November 2020, California Institute for Regenerative Medicine ("CIRM") awarded the Company $2.3 million in support of the research project related to a monoclonal antibody that depletes blood stem cells and enables chemotherapy-free transplants. The award is payable to the Company upon achievement of milestones that are primarily based on patient enrollment in the Company's clinical trials. CIRM could permanently cease disbursements if milestones are not met within four months of the scheduled completion date. Additionally, if CIRM determines, in its sole discretion, that the Company has not complied with the terms and conditions of the grant, CIRM may suspend or permanently cease disbursements. Funds received under this grant may only be used for allowable project costs specifically identified with the CIRM-funded project. Such costs can include, but are not limited to, salary for personnel, itemized supplies, consultants, and itemized clinical study costs. Under the terms of the grant, both CIRM and the Company will co-fund the research project and the amount of the Company's co-funding requirement is predetermined as a part of the award. Under the terms of the CIRM grant, the Company is obligated to pay royalties and licensing fees based on 0.1% of net sales of CIRM-funded inventions per $1.0 million of CIRM grant. As an alternative to revenue sharing, the Company has the option to convert the award to a loan. In the event the Company exercises its right to convert the award to a loan, it would be obligated to repay the loan within ten business days of making such election. Repayment amounts vary dependent on when the award is converted to a loan, ranging from 60% of the award granted to amounts received plus interest at the rate of the three-month LIBOR rate plus 25% per annum. Since the Company may be required to repay some or all of the amounts awarded by CIRM, the Company accounted for this award as a liability. Given the uncertainty in amounts due upon repayment, the Company has recorded amounts received without any discount or interest recorded, and upon determination of amounts that would become due, the Company will adjust accordingly. In the absence of explicit U.S. GAAP guidance on contributions received by business entities from government entities, the Company has applied to the CIRM grant the recognition and measurement guidance in Accounting Standards Codification Topic 958-605 by analogy. The Company has received an aggregate of $2.3 million from CIRM through December 31, 2025. As of December 31, 2025, the CIRM grant has been closed and there are no further amounts available for future distribution to the Company under the grant. As of each of December 31, 2025 and 2024, the amount of CIRM grant received of $2.3 million is included in other non-current liabilities in the consolidated balance sheets.

**NOTE 6. SIGNIFICANT AGREEMENTS**

***Stanford License Agreements***

In March 2021, the Company entered into an exclusive license agreement with Stanford (the "2021 Stanford License Agreement"). In July 2023, the Company entered into an amendment to the 2021 Stanford License Agreement to modify certain milestones set forth thereunder. The Company received a worldwide, exclusive license, with a right to sublicense, for briquilimab in the field of depleting endogenous blood stem cells in patients for whom hematopoietic cell transplantation is indicated. Stanford transferred to the Company certain know-how and patents related to briquilimab (together, the "Licensed Technology"). Under the terms of this agreement, the Company is required to use commercially reasonable efforts to develop, manufacture, and sell licensed product and to develop markets for a licensed product. In addition, the Company is required to use commercially reasonable efforts to meet the milestones as specified in the agreement over the six years from execution of the 2021 Stanford License Agreement and must notify Stanford in writing as each milestone is met.

The Company is obligated to pay annual license maintenance fees, beginning on the first anniversary of the effective date of the agreement and ending upon the first commercial sale of a product, method, or service in the licensed field of use, as follows: $25,000 for each first and second year, $35,000 for each third and fourth year and $50,000 at each anniversary thereafter ending upon the first commercial sale. The Company is also obligated to pay late-stage clinical development milestone payments and first commercial sales milestone payments of up to $9.0 million in total. The Company will also pay low single-digit royalties on net sales of licensed products, if approved. The Company paid $35,000 in annual license maintenance fees in each of April 2025 and March 2024, which were recognized as research and development expense in the consolidated statements of operations and comprehensive loss for the years ended December 31, 2025 and 2024.

The 2021 Stanford License Agreement expires on a country-by-country basis on the last-to-expire valid claim of a licensed patent in such country. The Company may terminate the agreement by giving Stanford written notice at least 12 months in advance of the effective date of termination. The Company may also terminate the agreement solely with respect to any particular patent application or patent by giving Stanford written notice at least 60 days in advance of the effective date of termination. Stanford may terminate the agreement after 90 days from a written notice by Stanford, specifying a problem, including a delinquency on any report required pursuant to the agreement or any payment, missing a milestone or a material breach, unless the Company remediates the problem in that 90-day period.

In December 2024, the Company entered into a co-exclusive license agreement with Stanford (the "2024 Stanford License Agreement"). The Company received a co-exclusive license in the United States, with a right to sublicense, for a certain patent to be used in the field of the treatment and prevention of human diseases, including the use of anti-CD117 antibodies (other than JSP191) for the purpose of depleting endogenous blood stem cells in patients for whom hematopoietic cell transplantation is indicated (the "Co-Exclusive Licensed Field of Use") and an exclusive license in the United States for the use of the same patent in the field provided in the 2021 Stanford License Agreement (the "Exclusive Licensed Field of Use"). Stanford will have at most one other commercial license for the licensed patent in the Co-Exclusive Licensed Field of Use. Under the terms of this agreement, the Company is required to use commercially reasonable efforts to develop, manufacture, and sell a licensed product and to develop markets for a licensed product. In addition, the Company is required to use commercially reasonable efforts to meet the milestones as specified in the agreement over approximately 4.5 years from the execution of the agreement and must notify Stanford in writing when, and if, each milestone is met.

The Company was obligated to pay a license issue fee of $75,000, following the execution of the agreement, which was paid in January 2025. The Company is also obligated to pay annual license maintenance fees, beginning on the first anniversary of the effective date of the agreement, as follows: $25,000 for each of the first through third years, $50,000 for each of the fourth through sixth years and $65,000 at each anniversary thereafter. The Company is also obligated to pay clinical development milestone payments of up to $1.3 million and sales milestone payments of up to $7.0 million in total. The Company will pay low single-digit royalties on net sales of licensed products, if approved. The Company will pay Stanford a portion of sublicensee consideration if a sublicense is granted. As of December 31, 2025, the Company recognized $25,000 related to the annual license maintenance fee as research and development expense in the statement of operations and comprehensive loss and as accounts payable in the consolidated balance sheet. As of December 31, 2024, the Company recognized $75,000 related to the license issue fee as research and development expense in the statement of operations and comprehensive loss and as accrued expenses and other current liabilities in the consolidated balance sheet.

The Company may terminate the agreement by giving Stanford written notice at least 30 days in advance of the effective date of termination. Stanford may terminate the agreement by giving the Company 90 days written notice for a problem, including a delinquency on any report required pursuant to the agreement, missing a milestone or a material breach, and by giving the Company 30 days written notice for a payment default, unless the Company remediates the problem in that 90-day or 30-day period.

**NOTE 7. WARRANTS**

In September 2025, in connection and together with the issuance of 11,670,707 shares of the Company's voting common stock through the underwritten offering (the "September 2025 Offering"), the Company issued pre-funded warrants to purchase 675,000 shares of common stock (the "Pre-Funded Warrants") and common stock warrants to purchase 12,345,707 shares of common stock (the "Common Warrants"). See Note 9 for additional details about the September 2025 Offering.

***Pre-Funded Warrants***

The exercise price of each Pre-Funded Warrant is $0.0001 per share. The Pre-Funded Warrants are exercisable at the option of each holder in whole or in part at any time after their original issuance and have no expiration date. The Pre-Funded Warrants may be exercised by means of cash or the cashless settlement of the net number of shares of common stock determined according to a formula set forth in the Pre-Funded Warrants. However, a holder will not be entitled to exercise any portion of any Pre-Funded Warrant that, upon giving effect to such exercise, would cause the aggregate number of shares of common stock beneficially owned by such holder (together with its affiliates) to exceed 4.99% (or, at the election of the holder, 9.99% or 19.99%) of the number of issued and outstanding shares of common stock following such exercise. However, any holder of a Pre-Funded Warrant may increase or decrease such percentage to any other percentage not in excess of 19.99%, provided that the holder shall provide written notice at least 61 days' prior written notice to the Company prior to the date such increase shall be effective.

Pursuant to the terms of the Pre-Funded Warrant, upon the consummation of a Fundamental Transaction, as defined in the Pre-Funded Warrants, the holders of the Pre-Funded Warrants are entitled to receive, upon exercise of the Pre-Funded Warrants, the kind and amount of securities, cash or other property that such holders would have received had they exercised the Pre-Funded Warrants immediately prior to such Fundamental Transaction, without regard to any limitations on exercise contained in the Pre-Funded Warrants.

The Company concluded that the Pre-Funded Warrants met the equity indexation criteria and the Pre-Funded Warrants are therefore accounted for in stockholders' equity. The Company recorded $0.3 million to additional paid-in capital upon issuance of the Pre-Funded Warrants.

As of December 31, 2025, none of the Pre-Funded Warrants have been exercised.

***Common Warrants***

The exercise price of each Common Warrant is $2.92 per share. Each Common Warrant is exercisable commencing on the six month anniversary of the date of issuance and thereafter for a period of four years. The Common Warrants may be exercised by means of cash or the cashless settlement of the net number of shares of common stock determined according to a formula set forth in the Common Warrants. However, a holder will not be entitled to exercise any portion of any Common Warrant that, upon giving effect to such exercise, would cause the aggregate number of shares of common stock beneficially owned by such holder (together with its affiliates) to exceed 4.99% (or, at the election of the holder, 9.99% or 19.99%) of the number of issued and outstanding shares of common stock following such exercise. However, any holder of a Common Warrant may increase or decrease such percentage to any other percentage not in excess of 19.99%, provided that the holder shall provide written notice at least 61 days' prior written notice to the Company prior to the date such increase shall be effective.

Pursuant to the terms of the Common Warrant, upon the consummation of a Fundamental Transaction, as defined in the Common Warrants, the holders of the Common Warrants are entitled to receive, upon exercise of the Common Warrant, the kind and amount of securities, cash or other property that such holders would have received had they exercised the Pre-Funded Warrants immediately prior to such Fundamental Transaction, without regard to any limitations on exercise contained in the Pre-Funded Warrants or the holder may require the Company or the successor entity to repurchase the unexercised portion of the Common Warrant for its Black Scholes Value, as defined in the Common Warrant; provided, however, if the holder shall only be entitled to receive from the Company or any successor entity the same type or form of consideration (and in the same proportion) at the Black Scholes Value of the unexercised portion of the Common Warrant, that is being offered and paid to the holders of common stock of the Company in connection with the Fundamental Transaction, whether that consideration be in the form of cash, shares or any combination thereof, or whether the holders of common stock are given the choice to receive from among alternative forms of consideration in connection with the Fundamental Transaction; provided, further, that if holders of common stock of the Company are not offered or paid any consideration in such Fundamental Transaction, such holders of common stock will be deemed to have received common stock of the successor entity (which successor entity may be the Company following such Fundamental Transaction) in such Fundamental Transaction.

The Company concluded that the Common Warrants did not meet the equity indexation criteria due to the certain inputs to estimate the number of shares issuable in a Fundamental Transaction and the Common Warrants are therefore accounted for as liabilities. The Company recorded $24.7 million to warrant liability upon issuance of the outstanding Common Warrants. The Company estimated fair value of the Common Warrants at the issuance date using the Black-Scholes valuation model and will remeasure the liability at each reporting date. The Company recorded a change in fair value of warrant liability of $8.5 million in its consolidated statement of operations and comprehensive loss for the year ended December 31, 2025. Refer to Note 3 for assumptions used to estimate the Common Warrants fair value.

As of December 31, 2025, none of the Common Warrants have been exercised.

## NOTE 8. COMMITMENTS AND CONTINGENCIES

### *Operating Leases*

As of December 31, 2025, the Company leased approximately 25,900 square feet of laboratory and office space in Redwood City, California, under an operating lease that expires in August 2026.

In conjunction with signing the lease, the Company secured a letter of credit in favor of the lessor in the amount of $0.4 million. The funds related to this letter of credit are presented as restricted cash on the Company’s consolidated balance sheets. The lease agreement includes an escalation clause for increased base rent and a renewal provision allowing the Company to extend this lease for an additional 60 months at the prevailing rental rate, which the Company is not reasonably certain to exercise. In addition to base rent, the Company pays its share of operating expenses and taxes.

In March 2025, the Company extended its existing short-term lease for 12,500 square feet of laboratory and office space in Redwood City, California, through August 2026. As a result, the Company recorded a right-of-use asset and lease liability of $1.1 million in March 2025.

In December 2025, in connection with the cessation of the Company’s vivarium operations and consolidation of personnel office space, the Company ceased use of a portion of its leased headquarters space. As a result, the right-of-use asset associated with that lease was impaired and the Company recognized an impairment loss of $0.4 million for the year ended December 31, 2025, recorded in research and development expense and general and administrative expense in the consolidated statements of operations and comprehensive loss in the amounts of $0.2 million each.

The Company also pays variable costs related to its share of operating expenses and taxes. These variable costs are recorded as lease expense as incurred and presented as operating expenses in the consolidated statements of operations and comprehensive loss.

The components of lease costs, which were included in the Company's consolidated statements of operations and comprehensive loss, are as follows (in thousands):

| | Year ended December 31, | |
|---|---|---|
| | 2025 | 2024 |
| **Lease cost** | | |
| Operating lease cost | $ 1,314 | $ 672 |
| Short-term lease cost | 169 | 354 |
| Variable lease cost | 674 | 438 |
| **Total lease cost** | $ 2,157 | $ 1,464 |

Supplemental information related to the Company's operating leases is as follows:

| | Year ended December 31, | |
|---|---|---|
| | 2025 | 2024 |
| Cash paid for amounts included in the measurement of lease liabilities (in thousands) | $ 1,823 | $ 1,153 |
| Weighted average remaining lease term (years) | 0.64 | 1.61 |
| Weighted average discount rate | 8.00% | 8.00% |

The following table summarizes a maturity analysis of the Company's operating lease liabilities showing the aggregate lease payments as of December 31, 2025 (in thousands):

| | Amount |
|---|---|
| Year Ending December 31, 2026 | $ 1,260 |
| Total undiscounted lease payments | 1,260 |
| Less imputed interest | (25) |
| Total discounted lease payments | 1,235 |
| Less current portion of lease liability | (1,235) |
| Noncurrent portion of lease liability | $ — |

***License Agreements***

In March 2021, the Company entered into the 2021 Stanford License Agreement (Note 6), which was amended in July 2023, pursuant to which the Company is required to pay annual license maintenance fees, clinical development and commercial sales milestone payments of up to an aggregate of $9.0 million, and low single-digit royalties on net sales of licensed products. All products were in development as of December 31, 2025, and no royalties were due as of such date. The Company paid $35,000 in annual license maintenance fees in each of April 2025 and March 2024, which were recognized as a research and development expense in the consolidated statements of operations and comprehensive loss for the years ended December 31, 2025 and 2024. As of December 31, 2025 and 2024, no milestones were probable to be achieved and payable.

In December 2024, the Company entered into the 2024 Stanford License Agreement (Note 6), pursuant to which the Company is required to pay a license issue and annual license maintenance fees, clinical development and commercial sales milestone payments of up to an aggregate of $8.3 million and low single-digit royalties on net sales of licensed products. As of December 31, 2025, the Company recognized $25,000 related to the annual license maintenance fee as research and development expense in the statement of operations and comprehensive loss and as accounts payable in the consolidated balance sheet. All products were in development as of December 31, 2025, and no royalties were due as of such date. As of December 31, 2025, no milestones were probable to be achieved and payable.

***Legal Proceedings***

The Company, from time to time, may be party to litigation arising in the ordinary course of business. On September 19, 2025, a shareholder class action complaint captioned *Grant v. Jasper Therapeutics, Inc., et al.* (Case No. 25-cv-08010) was filed in the United States District Court for the Northern District of California against us and certain of the Company's current and former officers. The complaint alleges that certain material misstatements or omissions related to the ongoing clinical trials of briquilimab were made in violation of federal securities laws. The plaintiffs are seeking unspecified monetary damages and an award of costs and expenses, including reasonable attorneys' fees, expert fees and other costs. On December 3, 2025, a stipulated order was entered appointing co-lead plaintiffs and approving their selection of co-lead counsel, and on December 16, 2025, a stipulated order was entered setting a schedule for the filing and responses to an amended complaint. Per the terms of the December 16, 2025 stipulated order, an amended complaint captioned *Allard, et al. v. Jasper Therapeutics, Inc., et al.* (Case No. 25-cv-08010) was filed, and defendants' responses to that amended complaint are due on or about April 20, 2026.

In addition, on November 5, 2025, a shareholder derivative complaint captioned *Bardauskas v. Martell, et al*. (Case No. 25-cv-09561) was filed in the United States District Court for the Northern District of California , and on December 22, 2025, another shareholder derivative complaint was filed in the same court and captioned *Walsh v. Martell, et al.* (Case No. 25-cv-10899). The derivative complaints name as defendants certain of the Company's current and former officers and directors, and allege claims related to the allegations raised in the shareholder class action complaint. On January 21, 2026, a stipulated order was entered, among other things, consolidating and staying the derivative actions. The Company believes the claims raised in these lawsuits are without merit, and intends to defend these matters vigorously. However, there can be no assurance that the Company will prevail. The Company is unable to determine whether any loss ultimately will occur or to estimate the range of such loss; therefore, no amount of loss has been accrued in the Company's financial statements as of and for the year ended December 31, 2025. Regardless of outcome, litigation can have an adverse impact on the Company due to costs involved, diversion of management resources, negative publicity, reputational harm, and other factors.

The Company believes that it is not currently a party to any other legal proceedings which, individually or in the aggregate, would have a material adverse effect on its consolidated financial position, results of operations or cash flows.

***Guarantees and Indemnifications***

In the normal course of business, the Company enters into agreements that contain a variety of representations and provide for general indemnification. The Company's exposure under these agreements is unknown because it involves claims that may be made against the Company in the future. To date, the Company has not paid any claims or been required to defend any action related to its indemnification obligations. As of December 31, 2025 and 2024, the Company does not have any material indemnification claims that were probable or reasonably possible and consequently has not recorded related liabilities.

**NOTE 9. COMMON STOCK**

The Company is authorized to issue 490,000,000 shares of voting common stock, 2,000,000 shares of non-voting common stock, and 10,000,000 shares of undesignated preferred stock. There were 27,996,819 shares of voting common stock, no shares of non-voting common stock and no shares of preferred stock issued and outstanding as of December 31, 2025.

Holders of the voting common stock and the non-voting common stock have similar rights, except that non-voting stockholders are not entitled to vote, including for the election of directors. Holders of voting common stock do not have conversion rights, while holders of non-voting common stock have the right to convert each share of non-voting common stock held by such holder into one share of voting common stock at such holder's election by providing written notice to the Company, provided that as a result of such conversion, such holder, together with its affiliates, would not beneficially own in excess of 9.9% of the Company's voting common stock following such conversion. There were no outstanding shares of non-voting common stock as of December 31, 2025 and 2024.

As of December 31, 2025 and 2024, the Company had common stock reserved for future issuance as follows:

| | December 31, | |
|---|---|---|
| | 2025 | 2024 |
| Outstanding and issued common stock options | 2,246,206 | 1,628,378 |
| Outstanding and issued restricted stock units | 198,900 | — |
| Outstanding and issued performance-based restricted stock units | 20,000 | 20,000 |
| Shares issuable upon exercise of Public Warrants (1) | 499,986 | 499,986 |
| Shares issuable upon exercise of Common Warrants | 12,345,707 | — |
| Shares issuable upon exercise of Pre-Funded Warrants | 675,000 | — |
| Shares available for grant under Equity Incentive Plans | 843,360 | 1,791,291 |
| Shares available for grant under Employee Stock Purchase Plans | 920,827 | 981,370 |
| Shares available for grant under 2022 Inducement Equity Incentive Plan | 132,769 | 16,885 |
| Total shares of common stock reserved | 17,882,755 | 4,937,910 |

(1) The Company has 4,999,863 outstanding warrants to purchase an aggregate of 499,986 shares of its common stock (the "Public Warrants"). A holder may purchase one share of the Company's common stock for every ten Public Warrants at an exercise price of $115.00 per share. The Public Warrants are publicly traded and exercisable during the exercise period, which commenced on October 24, 2021 and ends on September 24, 2026, for cash or, in certain circumstances, on a cashless basis. The Public Warrants were reclassified to equity in January 2023.

***Shelf Registration Statement***

On April 28, 2023, the Company filed a shelf registration statement on Form S-3 (the "Prior S-3") with the SEC, which was declared effective on May 5, 2023. The Company could sell from time to time up to $250.0 million of common stock, preferred stock, debt securities, warrants, rights, units or depositary shares comprised of any combination of these securities, for the Company's own account in one or more offerings under the Prior S-3.

On March 19, 2025, the Company filed a new shelf registration statement on Form S-3 (the "New S-3") with the SEC, which was declared effective on March 26, 2025 and superseded the Prior S-3. As of December 31, 2025, the Company can sell up to $263.5 million of common stock, preferred stock, debt securities, warrants, rights, units and depositary shares comprised of any combination of these securities in one or more offerings under the New S-3. The terms of any offering under the New S-3 will be established at the time of such offering and will be described in a prospectus supplement to the New S-3 filed with the SEC prior to the completion of any such offering.

***ATM Offerings***

On March 19, 2025, the Company entered into an Open Market Sale Agreement[SM] with Jefferies LLC ("Jefferies"), pursuant to which the Company may offer and sell through or to Jefferies, as sales agent or principal, shares of common stock from time to time (the "ATM Offering"). On March 26, 2025, the Company filed with the SEC a prospectus under the New S-3 in connection with the ATM Offering (the "ATM Prospectus"), pursuant to which the Company may offer and sell shares of common stock having an aggregate offering price of up to $100.0 million. As of December 31, 2025, the Company issued and sold an aggregate of 1,231,447 shares of common stock for net proceeds of approximately $6.5 million pursuant to the ATM Prospectus.

As of December 31, 2025, $93.5 million remained available under the ATM Prospectus.

***Underwritten Offerings***

In February 2024, the Company entered into an underwriting agreement with Cowen and Company, LLC and Evercore Group L.L.C., as the representatives of the several underwriters named therein, related to an underwritten offering under the Prior S-3 of 3,900,000 shares of common stock. The Company received net proceeds of $47.2 million.

On September 18, 2025, the Company entered into an underwriting agreement with TD Securities (USA) LLC as the representative of the several underwriters, relating to an underwritten public offering under the New S-3 of an aggregate of 11,670,707 shares of common stock, Pre-Funded Warrants to purchase 675,000 shares of common stock and Common Warrants to purchase 12,345,707 shares of common stock. The Company received net proceeds of $27.5 million.

As of December 31, 2025, $170.0 million remained available and unallocated under the New S-3.

**NOTE 10. STOCK-BASED COMPENSATION**

On June 6, 2024, the Company's 2024 Equity Incentive Plan (the "2024 Plan") and the 2024 Employee Stock Purchase Plan (the "2024 ESPP") were approved by its stockholders and became effective, superseding and replacing the Company's 2021 Equity Incentive Plan (the "2021 Plan") and the 2021 Employee Stock Purchase Plan (the "2021 ESPP"), respectively. No further awards or purchase rights will be granted under the 2021 Plan or the 2021 ESPP.

Under the 2024 Plan, the Company can grant incentive stock options, nonstatutory stock options, restricted stock awards, stock appreciation rights, restricted stock units ("RSUs"), performance restricted stock units ("PSUs"), and other stock-based awards to employees, directors, and consultants. Under the 2024 ESPP, the Company can grant purchase rights to employees to purchase shares of common stock at a purchase price which is equal to 85% of the fair market value of common stock on the offering date or on the exercise date, whichever is lower.

On March 14, 2022, the Compensation Committee of the Board (the "Compensation Committee") adopted the 2022 Inducement Equity Incentive Plan (the "2022 Inducement Plan") and on June 2, 2023, the Compensation Committee approved an amendment and restatement of the 2022 Inducement Plan. Under the 2022 Inducement Plan, the Company may grant nonstatutory stock options, restricted stock awards, stock appreciation rights, RSUs, performance awards and other awards, but only to an individual, as a material inducement to such individual to enter into employment with the Company or an affiliate of the Company, who (i) has not previously been an employee or director of the Company or (ii) is rehired following a bona fide period of non-employment with the Company.

Stock options under the 2024 Plan and the 2022 Inducement Plan may be granted for periods of up to 10 years and at prices no less than 100% of the fair market value of the shares on the date of grant, provided, however, that the exercise price of an incentive stock option (which cannot be granted pursuant to the 2022 Inducement Plan) granted to a 10% stockholder may not be less than 110% of the fair market value of the shares. Stock options granted to employees and non-employees generally vest ratably over four years.

As of December 31, 2025, 2,750,719 shares were reserved for issuance under the 2024 Plan, of which 843,360 shares were available for future grant and 1,907,359 shares were subject to outstanding options and RSUs, including performance-based awards of 50,894 shares. As of December 31, 2025, options to purchase 140,516 shares of common stock remained outstanding and unexercised, and continue to be governed by the 2019 Equity Incentive Plan (the "2019 EIP"). As of December 31, 2025, 29,802 shares have been issued under the 2021 ESPP and 79,173 shares have been issued under the 2024 ESPP. As of December 31, 2025, 1,000,000 shares were reserved under the 2024 ESPP and 920,827 shares were available for future issuance. As of December 31, 2025, 550,000 shares were reserved for issuance under the 2022 Inducement Plan, of which 132,769 shares were available for future grant and 417,231 shares were subject to outstanding stock options.

***Stock Option Activity***

The following table summarizes the stock option activities, including performance-based stock options, under the 2024 Plan, the 2021 Plan, the 2022 Inducement Plan and the 2019 EIP for the year ended December 31, 2025:

| | Options Outstanding | Weighted Average Exercise Price | Weighted Average Remaining Contractual Life (Years) | Aggregate Intrinsic Value (in thousands) |
|---|---|---|---|---|
| Balance, December 31, 2024 | 1,628,378 | $ 19.79 | 8.31 | $ 6,608 |
| Options granted | 1,269,200 | $ 5.95 | | |
| Options cancelled/forfeited | (651,372) | $ 13.75 | | |
| Balance, December 31, 2025 | 2,246,206 | $ 13.72 | 4.81 | $ — |
| Vested and expected to vest, December 31, 2025 | 2,246,206 | $ 13.72 | 4.81 | $ — |
| Exercisable, December 31, 2025 | 906,750 | $ 20.32 | 3.89 | $ — |

The aggregate intrinsic value represents the difference between the estimated fair value of the underlying common stock and the exercise price of outstanding, in-the-money options. The total intrinsic value of the options exercised during the year ended December 31, 2024 was $0.5 million. No options were exercised during the year ended December 31, 2025.

The total fair value of options that vested during the years ended December 31, 2025 and 2024 was $7.5 million and $5.5 million, respectively. The weighted-average grant date fair value of options granted during the years ended December 31, 2025 and 2024 was $4.73 and $16.89 per share, respectively.

Unamortized stock-based compensation expense as of December 31, 2025 was $8.9 million, which is expected to be recognized over a weighted-average period of 2.5 years.

***Performance-Based Stock Options***

The following table provides a summary of performance-based stock options activity under the 2024 Plan and the 2021 Plan during the year ended December 31, 2025:

| | Options Outstanding | Weighted Average Exercise Price | Weighted Average Remaining Contractual Life (Years) | Aggregate Intrinsic Value (in thousands) |
|---|---|---|---|---|
| Balance, December 31, 2024 | 45,894 | 13.95 | 6.04 | $ 438 |
| Options forfeited | (15,000) | 27.60 | | |
| Balance, December 31, 2025 | 30,894 | 7.33 | 4.43 | — |
| Vested and expected to vest, December 31, 2025 | 30,894 | 7.33 | 4.43 | — |
| Exercisable, December 31, 2025 | 30,894 | 7.33 | 4.43 | — |

***Restricted Stock Units (RSUs)***

The following table provides a summary of RSU activity under the 2024 Plan during the year ended December 31, 2025:

| | Number of Share | Weighted-Average Grant Date Fair Value |
|---|---|---|
| Unvested restricted stock units at December 31, 2024 | — | $ — |
| Granted | 275,250 | $ 6.00 |
| Vested | (12,000) | $ 5.94 |
| Forfeited | (64,350) | $ 6.00 |
| Unvested restricted stock units at December 31, 2025 | 198,900 | $ 6.00 |

***Performance Restricted Stock Units (PSUs)***

In June 2024, the Company granted PSUs for 20,000 shares that will vest in full if the closing price of the Company's common stock on the Nasdaq Capital Market reaches or exceeds $35.00 per share (subject to adjustment for recapitalizations, stock splits and similar transactions) for thirty consecutive calendar days within two years from the grant date. If the vesting condition is not met within two years from the grant date, the PSUs will be forfeited. The Company concluded that issued PSUs are equity-based awards and include a market based vesting condition. The Company used a Monte Carlo simulation model to estimate the fair value of the PSUs with the following assumptions: common stock fair value of $23.95, which was the closing market price of the Company's common stock at the grant date, volatility of 133.00%, risk free rate of 4.87%, and vesting term of 2.0 years. Total estimated fair value of $0.4 million was recognized as stock-based compensation expense over 0.4 years, the derived requisite service period from the grant date.

The was no PSU activities during the year ended December 31, 2025. As of December 31, 2025 and 2024, the Company has unvested outstanding PSUs for 20,000 shares with the weighted-average grant date fair value of $21.90 per share.

***Employee Stock Purchase Plans***

The Company issued 60,543 and 29,491 shares of common stock under the 2024 ESPP and 2021 ESPP during the years ended December 31, 2025 and 2024, respectively, and recognized $0.5 million and $0.2 million compensation expense related to the 2024 ESPP and 2021 ESPP during the years ended December 31, 2025 and 2024, respectively. There was no unamortized stock-based compensation for shares issuable under the 2021 ESPP as of December 31, 2025. There was $0.2 million unamortized stock-based compensation for shares issuable under the 2024 ESPP as of December 31, 2025, which is expected to be recognized over a weighted-average period of 1.9 years. The Company recorded less than $0.1 million in accrued expenses and other current liabilities related to contributions withheld as of December 31, 2025.

***Stock-Based Compensation Expense***

The following table presents stock-based compensation expenses related to options, PSUs and RSUs granted to employees and non-employees, employee stock purchase plan awards and restricted common stock shares issued to founders (in thousands):

| | Year Ended December 31, | |
|---|---|---|
| | 2025 | 2024 |
| General and administrative | $ 4,718 | $ 4,580 |
| Research and development | 1,995 | 2,039 |
| Total | $ 6,713 | $ 6,619 |

The Company recognized $0.2 million and $0.5 million of stock-based compensation expense related to performance-based options, PSUs and RSUs during the years ended December 31, 2025 and 2024, respectively.

***Valuation of Stock Options***

The grant date fair value of stock options was estimated using a Black-Scholes option-pricing model with the following assumptions:

| | Year Ended December 31, | |
|---|---|---|
| | **2025** | **2024** |
| Expected term (in years) | 5.27 – 6.08 | 5.50 – 6.08 |
| Expected volatility | 97.37% – 99.81% | 95.80% – 123.10% |
| Risk-free interest rate | 3.82% – 4.35% | 3.63% – 4.50% |
| Expected dividend yield | — | — |

The determination of the fair value of stock options on the date of grant using a Black-Scholes option-pricing model is affected by the estimated fair value of the Company's common stock, as well as assumptions regarding a number of variables that are complex, subjective and generally require significant judgment to determine. The Company estimates the fair value of its common stock based on the closing quoted market price of its common stock as reported on the Nasdaq Capital Market.

*Expected Term*

The expected term represents the period that the options granted are expected to be outstanding and is determined using the simplified method (based on the mid-point between the vesting date and the end of the contractual term) as the Company has concluded that its stock option exercise history does not provide a reasonable basis upon which to estimate expected term.

*Expected Volatility*

The Company derived the expected volatility from the average historical volatilities over a period approximately equal to the expected term of comparable publicly traded companies within its peer group that were deemed to be representative of future stock price trends. The Company will continue to apply this process until a sufficient amount of historical information regarding the volatility of its own stock price becomes available.

*Risk-Free Interest Rate*

The risk-free interest rate is based on the U.S. Treasury rate, with maturities similar to the expected term of the stock options.

*Expected Dividend Yield*

The Company does not anticipate paying any dividends in the foreseeable future and, therefore, uses an expected dividend yield of zero.

***Valuation of ESPP Awards***

The grant date fair value of ESPP awards granted under the 2024 ESPP was estimated using a Black-Scholes option-pricing model with the following assumptions:

| | Year Ended December 31, | |
|---|---|---|
| | **2025** | **2024** |
| Expected term (in years) | 0.49 – 2.00 | 0.38 – 2.00 |
| Expected volatility | 104.93% – 155.78% | 67.74% – 154.96% |
| Risk-free interest rate | 3.54% – 4.31% | 4.13% –5.36% |
| Expected dividend yield | — | — |

## NOTE 11. NET LOSS PER SHARE ATTRIBUTABLE TO COMMON STOCKHOLDERS

The following table sets forth the computation of basic and diluted net loss per share attributable to common stockholders (in thousands, except share and per share data):

| | Year Ended December 31, | |
|---|---|---|
| | 2025 | 2024 |
| Numerator: | | |
| Net loss attributable to common stockholders | $ (75,801) | $ (71,269) |
| Denominator: | | |
| Weighted average common shares outstanding | 19,168,110 | 14,661,468 |
| Less: Shares subject to earnout | — | (76,598) |
| Weighted average shares used to compute basic and diluted net loss per share | 19,168,110 | 14,584,870 |
| Net loss per share attributable to common stockholders – basic and diluted | $ (3.95) | $ (4.89) |

The potential shares of common stock that were excluded from the computation of diluted net loss per share attributable to common stockholders for the periods presented because including them would have had an antidilutive effect were as follows:

| | December 31, | |
|---|---|---|
| | 2025 | 2024 |
| Outstanding and issued common stock options | 2,246,206 | 1,628,378 |
| Outstanding and issued restricted stock units | 198,900 | — |
| Shares issuable upon exercise of Public Warrants | 499,986 | 499,986 |
| Shares issuable upon exercise of Common Warrants | 12,345,707 | — |
| Unvested performance-based restricted stock units | 20,000 | 20,000 |
| **Total** | **15,310,799** | **2,148,364** |

## NOTE 12. INCOME TAXES

During the years ended December 31, 2025 and 2024, the Company did not incur any tax expense or benefit as the Company operated with taxable losses and provided a full valuation allowance.

The following table is a reconciliation of the U.S. federal statutory rate of 21% to the Company's effective rate for the year ended December 31, 2025 in accordance with the guidance in ASU No. 2023-09:

| | Year Ended December 31, | |
|---|---|---|
| | 2025 | |
| Tax at the federal statutory rate | $ (15,918) | 21.00% |
| Nondeductible items | | |
| Stock-based compensation | 1,178 | (1.55) |
| Change in fair value of warrant liability | (1,791) | 2.36 |
| Other permanent differences | 32 | (0.05) |
| Research and development credits | (1,308) | 1.73 |
| Change in valuation allowance | 17,807 | (23.49) |
| State taxes | — | — |
| Provision for income taxes | $ — | — |

The following table presents a reconciliation of the income tax expense computed at the statutory federal rate and the Company's income tax expense for the year ended December 31, 2024 (in thousands):

| | Year Ended December 31, 2024 |
|---|---|
| Federal statutory tax rate | $ (14,966) |
| State taxes | (2) |
| Research and development credits | (1,492) |
| Stock-based compensation | 986 |
| Other permanent differences | 353 |
| Change in valuation allowance | 15,123 |
| Provision for income taxes | $ 2 |

Significant components of the Company's net deferred tax assets (liabilities) as of December 31, 2025 and 2024 were as follows (in thousands):

| | December 31, | |
|---|---|---|
| | 2025 | 2024 |
| **Deferred tax assets:** | | |
| Accrued expenses and other | $ 242 | $ 479 |
| Intangibles | 286 | 287 |
| Net operating losses | 48,712 | 31,820 |
| Research and development credits | 7,079 | 6,031 |
| Stock-based compensation | 1,371 | 1,146 |
| Lease liability | 259 | 382 |
| Section 195 start-up amortization | 193 | 211 |
| Capitalized section 174 | 19,112 | 21,128 |
| Other | 542 | 340 |
| Total deferred tax assets | 77,796 | 61,824 |
| Valuation allowance | (77,691) | (61,590) |
| Total net deferred tax assets | 105 | 234 |
| Deferred tax liabilities: | | |
| Right-of-use asset | (105) | (206) |
| Fixed assets | — | (28) |
| Total deferred tax liabilities | (105) | (234) |
| **Net deferred tax assets** | $ — | $ — |

A valuation allowance is provided when it is more likely than not that some portion of the deferred tax assets will not be realized. The Company believes that, based on a number of factors such as the history of operating losses, it is more likely than not that the deferred tax assets will not be fully realized, such that a full valuation allowance has been recorded. The valuation allowance increased by $16.1 million and $15.1 million for the years ended December 31, 2025 and 2024, respectively.

The following table sets forth the Company's federal and state net operating loss carryforwards as of December 31, 2025 (in thousands):

| | Amount | Expiration Years |
|---|---|---|
| Net operating losses, Federal | $ 210,421 | Do not expire |
| Net operating losses, states primarily California | $ 64,946 | 2038-2042 |
| Tax credits, Federal | $ 6,630 | 2040-2045 |
| Tax credits, state | $ 4,680 | N/A |

As of December 31, 2025, the Company had research and development credit carryforwards of approximately $2.1 million and $1.4 million available to reduce future taxable income, if any, for both federal and California state income tax purposes, respectively. The federal research and development credit carryforwards begin expiring in 2040, and California credits carryforward indefinitely.

Utilization of the net operating loss carryforwards and research credit carryforwards may be subject to an annual limitation due to the ownership percentage change limitations provided by the Internal Revenue Code, as amended ("IRC"), and similar state provisions. Annual limitations may result in the expiration of the net operating losses and tax credit carryforwards before they are utilized. As of December 31, 2022, the Company has completed an IRC Section 382 analysis from inception through the year ended December 31, 2022. The Company experienced an ownership change on November 21, 2019 related to Series A redeemable convertible preferred stock financing. Any net operating loss generated in excess of the $2.9 million will be permanently limited for California tax purposes. The Company reduced its California net operating loss deferred tax assets balance by the permanently limited amount of $0.6 million. Net federal operating losses are not limited as they can be carried forward indefinitely. The Company experienced an additional ownership change on September 24, 2021 in connection with the business combination with Amplitude Healthcare Acquisition Corporation, a special purpose acquisition company. Any further potential ownership change will be evaluated through a section 382 study. However, the Company does not expect there are additional tax attributes that will expire unused before the expiration periods.

***Uncertain Tax Positions***

A reconciliation of the beginning and ending balances of the unrecognized tax benefits during the periods ended December 31, 2025 and 2024 is as follows (in thousands):

| | Year Ended December 31, | |
|---|---|---|
| | 2025 | 2024 |
| Balance at beginning of year | $ 3,059 | $ 2,420 |
| Additions based on tax positions related to current year | 709 | 639 |
| Lapse of the applicable statute of limitations | (90) | — |
| Balance at end of year | $ 3,678 | $ 3,059 |

The Company recognizes interest accrued related to unrecognized tax benefits and penalties as income tax expense. Related to the unrecognized tax benefits noted above, the Company did not accrue any penalties or interest during tax year 2025 and 2024.

The Company is subject to examination by the United States federal and state tax authorities for the tax years 2022 and later. State income tax returns are generally subject to examination for a period of four years after filing of the respective return. 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 and state tax authorities to the extent utilized in a future period. No income tax returns are currently under examination by taxing authorities.

On July 4, 2025, new legislation was enacted in the United States which includes significant provisions, including, but not limited to, modifications of capitalization of research and development expenses and accelerated fixed asset depreciation. The legislation has multiple effective dates, with certain provisions effective in 2025 and others implemented through 2027. The Company has evaluated the impact of new legislation and determined that it does not have a material impact on the Company's consolidated financial statements.

**NOTE 13. 401(K) SAVINGS PLAN**

The Company has a retirement and savings plan under Section 401(k) of the IRC (the "401(k) Plan"), covering all U.S. employees. The 401(k) Plan allows employees to make pre-tax contributions up to the maximum allowable amount set by the Internal Revenue Service. The Company may make contributions to the 401(k) Plan at its discretion. $0.2 million contributions were made to the 401(k) Plan by the Company for each of the years ended December 31, 2025 and 2024.

**NOTE 14. RELATED PARTIES**

The Company entered into consulting agreements with two founders, one of whom is also a member of the Company's Board of Directors (the "Board"), and each of whom also received founders' common stock shares for services and assigned patents. The Company recorded $0.3 million for advisory and consulting services performed by Professor Judith Shizuru, one of the founders of the Company and a member of the Board, as research and development expenses in the consolidated statements of operations and comprehensive loss for the year ended December 31, 2024. No expense was recorded for advisory and consulting services performed by Dr. Shizuru during the year ended December 31, 2025.

The Company recorded $0.1 million in accounts payable and accrued expenses related to advisory and consulting services performed by Dr. Shizuru as of December 31, 2024, and no expenses were recorded in accounts payable and accrued expenses as of December 31, 2025. Also, the Company's Licensed Technology from Stanford (see Note 6) was created in the Stanford laboratory of Dr. Shizuru.

In the first quarter of 2024, a senior executive of the Company joined the board of directors of an information technology service provider that the Company has utilized to support a broad array of the Company's systems infrastructure as well as for general information technology support services. For the years ended December 31, 2025 and 2024, the Company incurred $0.9 million and $1.4 million, respectively, for various information technology support services performed by this service provider. As of December 31, 2025 and 2024, there was $0.1 million and less than $0.1 million, respectively, of accounts payable recognized in the consolidated balance sheets.

**NOTE 15. SEGMENT INFORMATION**

The Company has determined it operates as a single operating and reportable segment, which is the research and development of therapeutic products in the fields of chronic urticaria and asthma. The Company's chief operating decision maker, its Chief Executive Officer (the "CEO"), manages the Company's operations on a consolidated basis. The CEO assesses the segment's performance and allocates resources based on review of various development, manufacturing and clinical programs expenses, along with the segment's personnel and general and overhead costs.

In addition to the significant expense categories included within net loss presented in the Company's consolidated statements of operations and comprehensive loss, see below for disaggregated amounts that comprise total operating expenses:

| | Year Ended December 31, | |
|---|---|---|
| | 2025 | 2024 |
| Personnel-related costs | $ 27,497 | $ 27,615 |
| Facilities and overhead costs | 14,751 | 14,356 |
| | | |
| Program costs | | |
| Briquilimab platform | 6,727 | 5,637 |
| CMO | 12,912 | 9,500 |
| CSU | 12,047 | 10,689 |
| Asthma | 4,971 | 1,975 |
| CIndU | 3,294 | 2,234 |
| SCID | 1,466 | 2,409 |
| MDS/AML | 218 | 1,824 |
| Total program costs | 41,635 | 34,268 |
| Total operating expense | 83,883 | 76,239 |
| Other income, net | 8,082 | 4,970 |
| Net loss | $ (75,801) | $ (71,269) |

All long-lived assets are located in the United States.

**NOTE 16. RESTRUCTURING**

In July 2025, the Company implemented and substantially completed a corporate reorganization to extend its cash runway, including a workforce reduction of approximately 50% of its workforce, representing 22 employees. In connection with this corporate reorganization, the Company refined its operating plan to focus on its briquilimab clinical development programs in chronic urticaria and halted enrollment in its Phase 1b asthma study and discontinued its other clinical and preclinical programs. As a result, management performed a long-lived assets impairment assessment and concluded that no impairment charges were necessary at the time. The total cost related to the workforce reduction was approximately $2.3 million, primarily related to severance payments.

In December 2025, the Board approved a plan to cease operations of the Company's vivarium and to terminate three research personnel associated with those operations. The Company determined that certain fixed assets and its right-of-use asset related to those operations were abandoned. Accordingly, the Company recognized an impairment loss of $1.1 million.

The restructuring and impairment charges are included in the Company's consolidated statements of operations and comprehensive loss for the year ended December 31, 2025, as follows (in thousands):

| | Restructuring cost | Impairment loss |
|---|---|---|
| Research and development | $ 1,780 | $ 806 |
| General and administrative | 473 | 306 |
| Total | $ 2,253 | $ 1,112 |

**NOTE 17. SUBSEQUENT EVENTS**

In January 2026, Ron Martell ceased serving as the Company's Chief Executive Officer and President. Pursuant to the Amended and Restated Employment Agreement, dated as of June 10, 2024, between the Company and Mr. Martell (the "Martell Employment Agreement"), Mr. Martell's departure from the Company constitutes a termination without Cause (as defined in the Martell Employment Agreement), and, in accordance therewith, Mr. Martell will be entitled to receive an amount equal to 18 months of his base salary, payable in accordance with the Company's payroll cycle, and the Company shall pay COBRA premiums for Mr. Martell and his covered dependents for a period of up to 18 months.

Jeet Mahal, the Company's Chief Operating Officer, was appointed as the Company's Chief Executive Officer and President. In connection with this appointment, Mr. Mahal's annualized salary was increased to $600,000 and he will be eligible to receive an annual performance bonus of up to 50% of his base salary.

## 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***

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Our disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports we file under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. As required by Rule 13a-15(b) or Rule 15d-15(b) promulgated by the SEC under the Exchange Act, we carried out an evaluation, under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this Annual Report on Form 10-K. Based on the foregoing, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective as of the end of the period covered by this Annual Report on Form 10-K at the reasonable assurance level.

***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 such term is defined in Exchange Act Rules 13a-15(f) and 15d-15(f). Our management conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2025 based on the criteria established in *Internal Control - Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission.

Based on the results of its evaluation, management concluded that our internal control over financial reporting was effective as of December 31, 2025.

***Attestation Report of the Registered Public Accounting Firm***

This Annual Report on Form 10-K does not include an attestation report of our registered public accounting firm regarding internal control over financial reporting because as a smaller reporting company we are not subject to Section 404(b) of the Sarbanes-Oxley Act of 2002.

***Changes in Internal Controls***

There have been no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended December 31, 2025 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## ITEM 9B. OTHER INFORMATION

During the fiscal quarter ended December 31, 2025, none of our directors or officers (as defined in Section 16 of the Securities Exchange Act of 1934, as amended) adopted or terminated any contract, instruction or written plan for the purchase or sale of our securities that was intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) or any "non-Rule 10b5-1 trading arrangement," as defined in Item 408(a) of Regulation S-K.

## ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

## PART III

### ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this item will be contained in our definitive proxy statement on Schedule 14A to be filed with the Securities and Exchange Commission in connection with our 2026 annual meeting of stockholders (the "2026 Proxy Statement"), which we expect to file not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K, and is incorporated in this report by reference. To the extent that we do not file the 2026 Proxy Statement by such date, we will file an amendment to this Annual Report on Form 10-K that includes the information required by this Item 10.

### ITEM 11. EXECUTIVE COMPENSATION

The information required by this item is incorporated by reference from the information contained in the 2026 Proxy Statement, which we expect to file not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K. To the extent that we do not file the 2026 Proxy Statement by such date, we will file an amendment to this Annual Report on Form 10-K that includes the information required by this Item 11.

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

The information required by this item is incorporated by reference from the information contained in the 2026 Proxy Statement, which we expect to file not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K. To the extent that we do not file the 2026 Proxy Statement by such date, we will file an amendment to this Annual Report on Form 10-K that includes the information required by this Item 12.

### ITEM 13. CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

The information required by this item is incorporated by reference from the information contained in the 2026 Proxy Statement, which we expect to file not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K. To the extent that we do not file the 2026 Proxy Statement by such date, we will file an amendment to this Annual Report on Form 10-K that includes the information required by this Item 13.

## PART IV

### ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by this item is incorporated by reference from the information contained in the 2026 Proxy Statement, which we expect to file not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K. To the extent that we do not file the 2026 Proxy Statement by such date, we will file an amendment to this Annual Report on Form 10-K that includes the information required by this Item 14.

### ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

***(a)(1) Financial Statements***

Our Financial Statements are listed in the "Index to the Financial Statements" of Jasper Therapeutics, Inc. in Part II, Item 8 of this Annual Report on Form 10-K.

***(a)(2) Financial Statement Schedules***

All financial statement schedules have been omitted because they are not required, not applicable, or the required information is included in the consolidated financial statements or notes thereto included in Part II, Item 8 of this Annual Report on Form 10-K.

***(a)(3) Exhibits***

The following exhibits are filed herewith or incorporated herein by reference:

| | | Incorporated by Reference | | | |
|---|---|---|---|---|---|
| **Exhibit Number** | **Description** | **Form** | **File Number** | **Filing Date** | **Exhibit** |
| 2.1+ | Business Combination Agreement, dated as of May 5, 2021, by and among Amplitude Healthcare Acquisition Corporation, Ample Merger Sub, Inc., and Jasper Therapeutics, Inc. | 8-K | 001-39138 | 5/6/2021 | 2.1 |
| 3.1 | Second Amended and Restated Certificate of Incorporation of the Registrant. | 8-K | 001-39138 | 9/29/2021 | 3.1 |
| 3.2 | Certificate of Amendment to the Second Amended and Restated Certificate of Incorporation, dated June 8, 2023. | 8-K | 001-39138 | 6/8/2023 | 3.1 |
| 3.3 | Certificate of Second Amendment to the Second Amended and Restated Certificate of Incorporation of Jasper Therapeutics, Inc., filed with the Secretary of State of the State of Delaware on January 3, 2024. | 8-K | 001-39138 | 1/3/2024 | 3.1 |
| 3.4 | Third Amended and Restated Bylaws of the Registrant. | 8-K | 001-39138 | 2/17/2023 | 3.1 |
| 4.1 | Form of Warrant Agreement, dated November 19, 2019, by and between the Registrant and Continental Stock Transfer & Trust Company, as warrant agent. | 8-K | 001-39138 | 11/25/2019 | 4.1 |
| 4.2 | Specimen Warrant Certificate. | S-1/A | 333-234324 | 11/6/2019 | 4.3 |
| 4.3 | Form of Pre-Funded Warrant to Purchase Common Stock. | 8-K | 001-39138 | 9/19/2025 | 4.1 |
| 4.4 | Form of Common Warrant. | 8-K | 001-39138 | 9/19/2025 | 4.2 |
| 4.5* | Description of Securities of Jasper Therapeutics, Inc. | | | | |
| 10.1 | Jasper Therapeutics, Inc. 2021 Equity Incentive Plan | 8-K | 001-39138 | 9/29/2021 | 10.3 |
| 10.2 | Amended and Restated Registration Rights Agreement, dated September 24, 2021. | 8-K | 001-39138 | 9/29/2021 | 10.2 |
| 10.3# | Jasper Therapeutics, Inc. 2024 Equity Incentive Plan. | S-8 | 333-280039 | 6/7/2024 | 4.3 |
| 10.4# | Form of Stock Option Award Agreement under the Jasper Therapeutics, Inc. 2024 Equity Incentive Plan. | S-8 | 333-280039 | 6/7/2024 | 4.4 |
| 10.5# | Form of Restricted Stock Unit Award Agreement under the Jasper Therapeutics, Inc. 2024 Equity Incentive Plan. | S-8 | 333-280039 | 6/7/2024 | 4.5 |
| 10.6# | Form of Restricted Stock Award Agreement under the Jasper Therapeutics, Inc. 2024 Equity Incentive Plan. | S-8 | 333-280039 | 6/7/2024 | 4.6 |
| 10.7# | Jasper Therapeutics, Inc. 2024 Employee Stock Purchase Plan. | S-8 | 333-280039 | 6/7/2024 | 4.7 |

| | | | | | |
|---|---|---|---|---|---|
| 10.8# | Jasper Therapeutics, Inc. 2022 Amended and Restated Inducement Equity Incentive Plan. | 8-K | 001-39138 | 6/8/2023 | 10.1 |
| 10.9# | Jasper Therapeutics, Inc. 2022 Inducement Equity Incentive Plan Form of Stock Option Agreement and Terms and Conditions of Stock Option Grant. | S-8 | 333-263702 | 3/18/2022 | 10.6 |
| 10.10# | Jasper Therapeutics, Inc. 2022 Inducement Equity Incentive Plan Form of Restricted Stock Unit Agreement and Terms and Conditions of Restricted Stock Unit Grant. | S-8 | 333-263702 | 3/18/2022 | 10.7 |
| 10.11# | Jasper Therapeutics, Inc. 2019 Equity Incentive Plan. | S-4/A | 333-256875 | 7/19/2021 | 10.12 |
| 10.12# | Amended and Restated Employment Agreement, dated as of June 10, 2024, by and between Jasper Therapeutics, Inc. and Ronald Martell. | 8-K | 001-39138 | 6/12/2024 | 10.3 |
| 10.13# | Amended and Restated Employment Agreement, dated as of June 10, 2024, by and between Jasper Therapeutics, Inc. and Herb Cross. | 8-K | 001-39138 | 6/12/2024 | 10.4 |
| 10.14# | Amended and Restated Employment Agreement, dated as of June 10, 2024, by and between Jasper Therapeutics, Inc. and Jeet Mahal. | 8-K | 001-39138 | 6/12/2024 | 10.5 |
| 10.15# | Consulting Agreement, dated December 16, 2019, by and between Jasper Therapeutics, Inc. and Judith Shizuru, M.D., Ph.D. | S-4/A | 333-256875 | 8/9/2021 | 10.29 |
| 10.16# | Jasper Therapeutics, Inc. Non-Employee Director Compensation Policy. | 10-K | 001-39138 | 2/28/2025 | 10.17 |
| 10.17# | Form of Indemnification Agreement by and between Jasper Therapeutics, Inc. and each of its directors and executive officers. | S-4/A | 333-256875 | 7/19/2021 | 10.28 |
| 10.18^ | Exclusive License Agreement, dated November 21, 2019, by and between Jasper Therapeutics, Inc. and Amgen Inc. | S-4/A | 333-256875 | 8/9/2021 | 10.13 |
| 10.19 | Assignment Agreement, dated as of November 21, 2019, by and between Jasper Therapeutics, Inc. and Amgen Inc. | S-4/A | 333-256875 | 8/9/2021 | 10.14 |
| 10.20^ | Investigator Sponsored Research Agreement, Amgen Protocol No. 20119244, effective as of June 18, 2013, between Jasper Therapeutics, Inc., as successor in interest to Amgen Inc., and The Board of Trustees of the Leland Stanford Junior University for Stanford University. | S-4/A | 333-256875 | 8/9/2021 | 10.15 |
| 10.21^ | Amendment #1 to the Investigator Sponsored Research Agreement, Amgen Protocol No. 20119244, dated February 27, 2017, between Jasper Therapeutics, Inc., as successor in interest to Amgen Inc., and The Board of Trustees of the Leland Stanford Junior University for Stanford University. | S-4/A | 333-256875 | 8/9/2021 | 10.16 |
| 10.22^ | Amendment #2 to the Investigator Sponsored Research Agreement, Amgen Protocol No. 20119244, dated November 15, 2017, between Jasper Therapeutics, Inc., as successor in interest to Amgen Inc., and The Board of Trustees of the Leland Stanford Junior University for Stanford University. | S-4/A | 333-256875 | 8/9/2021 | 10.17 |
| 10.23^ | Quality Agreement, dated October 7, 2015, by and between Jasper Therapeutics, Inc., as successor in interest to Amgen Inc., and The Board of Trustees of the Leland Stanford Junior University for Stanford University. | S-4/A | 333-256875 | 8/9/2021 | 10.18 |
| 10.24^ | Exclusive License Agreement, effective as of March 25, 2021, by and between Jasper Therapeutics, Inc. and The Board of Trustees of the Leland Stanford Junior University. | S-4/A | 333-256875 | 8/9/2021 | 10.19 |
| 10.25^ | Amendment No. 1 to the Exclusive License Agreement, dated July 27, 2023, between Stanford University and Jasper Therapeutics, Inc. | 10-Q | 001-39138 | 8/11/2023 | 10.2 |
| 10.26^ | Sponsored Research Agreement, effective September 1, 2020, by and between Jasper Therapeutics, Inc. and The Board of Trustees of the Leland Stanford Junior University. | S-4/A | 333-256875 | 8/9/2021 | 10.20 |

| | | | | | |
|---|---|---|---|---|---|
| 10.27^ | Development and Manufacturing Services Agreement, dated November 29, 2019, by and between Jasper Therapeutics, Inc. and Lonza Sales AG. | S-4/A | 333-256875 | 8/20/2021 | 10.25 |
| 10.28^ | Amendment No. 1 to Development and Manufacturing Services Agreement, executed April 24, 2020 by and between Jasper Therapeutics, Inc. and Lonza Sales AG. | S-4/A | 333-256875 | 8/20/2021 | 10.26 |
| 10.29^ | Amendment No. 2 to Development and Manufacturing Services Agreement, executed December 1, 2020, by and between Jasper Therapeutics, Inc. and Lonza Sales AG. | S-4/A | 333-256875 | 8/20/2021 | 10.27 |
| 10.30 | Open Market Sale Agreement℠, dated as of March 19, 2025, by and between Jasper Therapeutics, Inc. and Jefferies LLC. | S-3 | 333-285914 | 3/19/2025 | 1.2 |
| 19.1 | Jasper Therapeutics, Inc. Insider Trading Policy. | 10-K | 001-39138 | 2/28/2025 | 19.1 |
| 21.1 | List of Subsidiaries of the Registrant. | 8-K | 001-39138 | 9/29/2021 | 21.1 |
| 23.1* | Consent of Independent Registered Public Accounting Firm. | | | | |
| 31.1* | Certification of the Principal Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934. | | | | |
| 31.2* | Certification of the Principal Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934. | | | | |
| 32.1** | Certification of the Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. | | | | |
| 97 | Jasper Therapeutics, Inc. Clawback Policy | 10-K | 001-39138 | 3/5/2024 | 97 |
| 101.INS* | Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document. | | | | |
| 101.SCH* | Inline XBRL Taxonomy Extension Schema Document. | | | | |
| 101.CAL* | Inline XBRL Taxonomy Extension Calculation Linkbase Document. | | | | |
| 101.DEF* | Inline XBRL Taxonomy Extension Definition Linkbase Document. | | | | |
| 101.LAB* | Inline XBRL Taxonomy Extension Label Linkbase Document. | | | | |
| 101.PRE* | Inline XBRL Taxonomy Extension Presentation Linkbase Document. | | | | |
| 104* | Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101). | | | | |

+ The annexes, schedules, and certain exhibits to the Business Combination Agreement have been omitted pursuant to Item 601(b)(2) of Regulation S-K. The Registrant hereby agrees to furnish supplementally a copy of any omitted annex, schedule or exhibit to the SEC upon request.

# Indicates a management contract or compensatory plan or arrangement.

^ Certain identified information has been omitted pursuant to Item 601(b)(10) of Regulation S-K because such information is both (i) not material and (ii) of the type that the Registrant treats as private or confidential. The Registrant hereby undertakes to furnish supplemental copies of the unredacted exhibit upon request by the SEC.

* Filed herewith.

** Furnished herewith.

**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, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: March 30, 2026

**JASPER THERAPEUTICS, INC.**

By: /s/ Jeet Mahal
Jeet Mahal
Chief Executive Officer

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

| Signature | Title | Date |
|---|---|---|
| /s/ Jeet Mahal<br>Jeet Mahal | President, Chief Executive Officer and Director<br>(Principal Executive Officer) | March 30, 2026 |
| /s/ Herb Cross<br>Herb Cross | Chief Financial Officer<br>(Principal Accounting and Financial Officer) | March 30, 2026 |
| /s/ Thomas G. Wiggans<br>Thomas G. Wiggans | Chairperson of the Board | March 30, 2026 |
| /s/ Scott Brun, M.D.<br>Scott Brun, M.D. | Director | March 30, 2026 |
| /s/ Vishal Kapoor<br>Vishal Kapoor | Director | March 30, 2026 |
| /s/ Svetlana Lucas, Ph.D.<br>Svetlana Lucas, Ph.D. | Director | March 30, 2026 |
| /s/ Christian W. Nolet<br>Christian W. Nolet | Director | March 30, 2026 |
| /s/ Judith Shizuru, M.D., Ph.D.<br>Judith Shizuru, M.D., Ph.D. | Director | March 30, 2026 |
| /s/ Kurt von Emster<br>Kurt von Emster | Director | March 30, 2026 |

**Exhibit 4.5**

# DESCRIPTION OF SECURITIES OF JASPER THERAPEUTICS, INC.

The following summary of certain provisions of the securities of Jasper Therapeutics, Inc. (the "Company") does not purport to be complete and is subject to the Company's Second Amended and Restated Certificate of Incorporation, as amended (the "Certificate of Incorporation"), the Company's Third Amended and Restated Bylaws (the "Bylaws") and the provisions of applicable law. Copies of the Certificate of Incorporation and the Bylaws are filed as exhibits to the Company's Annual Report on Form 10-K to which this document is an exhibit.

## Authorized and Outstanding Stock

The Certificate of Incorporation authorizes the issuance of 502,000,000 shares of common stock of which: (a) 490,000,000 shall be voting common stock, par value $0.0001 per share (the "Voting Common Stock") and (b) 2,000,000 shall be non-voting common stock, par value $0.0001 per share (the "Non-Voting Common Stock" and, together with the Voting Common Stock, the "Common Stock"), and 10,000,000 shares of undesignated preferred stock, par value $0.0001 per share (the "Preferred Stock").

## Common Stock

Under the Certificate of Incorporation, holders of Voting Common Stock and Non-Voting Common Stock have identical rights other than with respect to voting and conversion rights, each as described below. There were no shares of Non-Voting Common Stock outstanding as of March 27, 2026.

### *Voting Rights*

Except as otherwise expressly provided in the Certificate of Incorporation or as required by applicable law, on any matter that is submitted to a vote by the Company's stockholders, holders of Voting Common Stock will be entitled to one vote per share of Voting Common Stock, and holders of Non-Voting Common Stock will not be entitled to any votes per share of Non-Voting Common Stock, including for the election of directors.

### *Conversion Rights*

Holders of Voting Common Stock do not have conversion rights, while holders of Non-Voting Common Stock have the right to convert each share of Non-Voting Common Stock held by such holder into one share of Voting Common Stock at such holder's election by providing written notice to the Company, provided that as a result of such conversion, such holder, together with its affiliates and any members of a Schedule 13(d) group with such holder, would not beneficially own in excess of 9.9% of Voting Common Stock following such conversion. However, this ownership limitation may be increased to any other percentage designated by such holder of Non-Voting Common Stock (and applicable only to such holder) upon 61 days' prior written notice to the Company or decreased to any other percentage designated by such holder of Non-Voting Common Stock (and applicable only to such holder) at any time upon prior written notice to the Company. Holders of Non-Voting Common Stock are also permitted to make certain transfers to non-affiliates upon which such transferred shares would immediately convert to shares of Voting Common Stock upon the written request of the original holder and the written certification from the transferee holder of its non-affiliation with the original holder of such Non-Voting Common Stock.

### *Dividends*

Holders of Common Stock are entitled to receive ratably any dividends declared by the Company's Board of Directors (the "Board") or a committee thereof out of funds legally available for that purpose, subject to any preferential dividend rights of any then outstanding Preferred Stock. The Common Stock does not have preemptive rights or other subscription rights or redemption or sinking fund provisions.

***Liquidation, Dissolution and Winding Up***

In the event of the Company's voluntary or involuntary liquidation, dissolution or winding up, its net assets will be distributed pro rata to the holders of Common Stock, subject to any liquidation preference of any then outstanding Preferred Stock. The holders of Non-Voting Common Stock will rank on parity with holders of Voting Common Stock as to such distributions.

***Preemptive or Other Rights***

Holders of Common Stock have no preemptive or other subscription rights, and there are no sinking fund or redemption provisions applicable to the Common Stock.

***Election of Directors***

The Board is divided into three classes, Class I, Class II and Class III, with only one class of directors being elected in each year and each class serving a three-year term. There is no cumulative voting with respect to the election of directors.

***Listing***

The Voting Common Stock is listed on the Nasdaq Capital Market under the symbol "JSPR."

**Preferred Stock**

The Certificate of Incorporation provides that shares of Preferred Stock may be issued from time to time in one or more series. The Board is authorized to fix the number of shares applicable to any such series of Preferred Stock and to determine or alter for each such series, such voting powers, full or limited, or no voting powers, and such designation, preferences, and relative, participating, optional or other rights and such qualifications, limitations or restrictions thereof. The Board will be able to, without stockholder approval, issue Preferred Stock with voting and other rights that could adversely affect the voting power and other rights of the holders of Common Stock and could have anti-takeover effects. The ability of the Board to issue Preferred Stock without stockholder approval could have the effect of delaying, deferring or preventing a change of control of the Company or the removal of existing management. As of March 27, 2026, there were no shares of Preferred Stock outstanding.

**Certain Anti-Takeover Provisions of Delaware Law**

***Special Meetings of Stockholders***

The Bylaws provide that special meetings of stockholders may be called only by a majority vote of the Board, by the Chairman of the Board, or by the Company's Chief Executive Officer. The Bylaws limit the business that may be conducted at an annual meeting of stockholders to those matters properly brought before the meeting.

***Advance Notice Requirements for Stockholder Proposals and Director Nominations***

The Bylaws provide that stockholders seeking to bring business before an annual meeting of stockholders, or to nominate candidates for election as directors at an annual meeting of stockholders, must provide timely notice of their intent in writing. To be timely under the Bylaws, a stockholder's notice will generally need to be received by the corporate secretary at the Company's principal executive offices not later than the close of business on the $90^{th}$ day nor earlier than the close of business on the $120^{th}$ day prior to the first anniversary of the preceding year's annual meeting; provided, however, that in the event the date of the annual meeting is advanced more than 30 days prior to or delayed by more than 60 days after the anniversary of the preceding year's annual meeting, or if no annual meeting was held in the preceding year, notice by the stockholder to be timely must be so received not earlier than the close of business on the $120^{th}$ day prior to such annual meeting and not later than the close of business on the later of the $90^{th}$ day prior to such annual meeting and the $10^{th}$ day following the day on which notice of the date of such annual meeting was mailed or public announcement of the date of such meeting is first made, whichever first occurs. Pursuant to Rule 14a-8 of the Exchange Act, stockholders seeking to have proposals included in the Company's annual proxy statement must comply with the notice periods contained therein. The Bylaws specify certain requirements as to the form and content of a stockholders' meeting. These provisions may preclude the Company's stockholders from bringing matters before an annual meeting of stockholders or from making nominations for directors at an annual meeting of stockholders.

***Authorized but Unissued Shares***

The authorized but unissued Common Stock and Preferred Stock are available for future issuances without stockholder approval and could be utilized for a variety of corporate purposes, including future offerings to raise additional capital, acquisitions and employee benefit plans. The existence of authorized but unissued and unreserved Common Stock and Preferred Stock could render more difficult or discourage an attempt to obtain control of the Company by means of a proxy contest, tender offer, merger or otherwise.

***Written Consent by Stockholders***

The Certificate of Incorporation and the Bylaws provide that no action shall be taken by the Company's stockholders except at an annual or special meeting of stockholders called in accordance with the Bylaws, and no action shall be taken by the stockholders by written consent or electronic transmission.

***Amendments to Certificate of Incorporation and Bylaws***

The Certificate of Incorporation requires the affirmative vote of the holders of at least 66⅔% of the voting power of all of the then-outstanding shares of the Company's capital stock entitled to vote generally in the election of directors, voting together as a single class to alter, amend or appeal Articles V (regarding directors), VI (regarding indemnification), VII (exclusive forum) or VIII (regarding amendments of the Certificate of Incorporation) of the Certificate of Incorporation (provided that as of September 24, 2024, such reference to "66⅔%" shall be deemed to be "50%").

The Bylaws provide that they may be adopted, amended, or repealed by the Company's stockholders by the affirmative vote of the holders of at least 66⅔% of the voting power of all of the Company's then outstanding capital stock entitled to vote generally in the election of directors, voting together as a single class (provided that as of September 24, 2024, such reference to "66⅔%" shall be deemed to be "50%").

***Removal of Directors***

The Certificate of Incorporation provides that, subject to the rights of any series of Preferred Stock, directors may be removed at any time, but only for cause and only by the affirmative vote of 66⅔% of the voting power of all then outstanding capital stock entitled to vote generally at an election of directors, voting together as a single class (provided that as of September 24, 2024, such reference to "66⅔%" shall be deemed to be "50%").

***Exclusive Forum Selection***

The Certificate of Incorporation and the Bylaws provide that the Court of Chancery of the State of Delaware will be the sole and exclusive forum for the following claims or causes of actions or proceedings under Delaware statutory or common law: (i) any derivative action or claim brought on the Company's behalf; (ii) any action or proceeding asserting a claim of breach of a fiduciary duty owed by any of the Company's current or former directors, officers or other employees to the Company or its stockholders; (iii) any action or proceeding asserting a claim against the Company or any of its current or former directors, officers or other employees, arising out of or pursuant to any provision of the General Corporate Law of the State of Delaware ("DGCL"), the Certificate of Incorporation or the Bylaws; (iv) any action asserting a claim against the Company or any of its directors, officers, or other employees governed by the internal-affairs doctrine or otherwise related to the Company's internal affairs; (v) any action or claim to interpret, apply, enforce or determine the validity of the Certificate of Incorporation or the Bylaws; and (vi) any action or claim as to which the DGCL confers jurisdiction to the Court of Chancery of the State of Delaware, in all cases to the fullest extent permitted by law and subject to the court having personal jurisdiction over the indispensable parties named as defendants. Further, pursuant to the Certificate of Incorporation and the Bylaws, these foregoing provisions would not apply to suits brought to enforce a duty or liability created by the Exchange Act, the Securities Act or any other claim for which the federal courts have exclusive jurisdiction. Any person or entity holding, owning or otherwise acquiring any interest in shares of the Company's capital stock shall be deemed to have notice of and to have consented to such provisions.

Although the Company believes these provisions benefit the Company by providing increased consistency in the application of Delaware law in the types of lawsuits to which they apply, a court may determine that these provisions are unenforceable, and to the extent they are enforceable, the provisions may have the effect of discouraging lawsuits against the Company's directors and officers, although the Company's stockholders will not be deemed to have waived the Company's compliance with federal securities laws and the rules and regulations thereunder. Additionally, the Company cannot be certain that a court will decide that these provisions are either applicable or enforceable, and if a court were to find the choice of forum provisions contained in the Certificate of Incorporation and the Bylaws to be inapplicable or unenforceable in an action, the Company may incur additional costs associated with resolving such action in other jurisdictions, which could harm its business, operating results and financial condition.

The Certificate of Incorporation provides that the exclusive forum provision will be applicable to the fullest extent permitted by applicable law. Section 27 of the Exchange Act creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder. As a result, the exclusive forum provision will not apply to suits brought to enforce any duty or liability created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. Accordingly, both state and federal courts have jurisdiction to entertain such claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, the Certificate of Incorporation and the Bylaws provide that the federal district courts of the United States are the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, including all causes of action asserted against any defendant named in such complaint.

***Section 203 of the Delaware General Corporation Law***

The Company is subject to provisions of Section 203 of the DGCL regulating corporate takeovers under the Certificate of Incorporation. This statute prevents certain Delaware corporations, under certain circumstances, from engaging in a "business combination" with:

- a stockholder who owns 15% or more of the Company's outstanding voting stock (otherwise known as an "interested stockholder");
- an affiliate of an interested stockholder; or
- an associate of an interested stockholder, for three years following the date that the stockholder became an interested stockholder.

A "business combination" includes a merger or sale of more than 10% of the Company's assets. However, the above provisions of Section 203 do not apply if:

- the Board approves the transaction that made the stockholder an "interested stockholder," prior to the date of the transaction;
- after the completion of the transaction that resulted in the stockholder becoming an interested stockholder, that stockholder owned at least 85% of the Company's voting stock outstanding at the time the transaction commenced, other than statutorily excluded shares of common stock; or
- on or subsequent to the date of the transaction, the Company's initial business combination is approved by the Board and authorized at a meeting of the Company's stockholders, and not by written consent, by an affirmative vote of at least two-thirds of the outstanding voting stock not owned by the interested stockholder.

Under certain circumstances, this provision will make it more difficult for a person who would be an "interested stockholder" to effect various business combinations with the Company for a three-year period. This provision may encourage companies interested in acquiring the Company to negotiate in advance with the Board because the stockholder approval requirement would be avoided if the Board approves either the business combination or the transaction which results in the stockholder becoming an interested stockholder. These provisions also may have the effect of preventing changes in the Board, and may make it more difficult to accomplish transactions which stockholders may otherwise deem to be in their best interests.

**Limitation on Liability and Indemnification of Directors and Officers**

The Certificate of Incorporation eliminates directors' liability for monetary damages to the fullest extent permitted by applicable law and eliminates officers' personal liability to the Company or its stockholders for monetary damages for breach of fiduciary duty as an officer. The Certificate of Incorporation and the Bylaws require the Company to indemnify and advance expenses to, to the fullest extent permitted by applicable law, its directors and officers. The Certificate of Incorporation and the Bylaws authorize the Board to determine whether to indemnify and advance expenses to, as set forth in the DGCL or any other applicable law, the Company's employees and other agents. Further, the Certificate of Incorporation prohibits any retroactive changes to the rights or protections or increase the liability of any director or officer in effect at the time of the alleged occurrence of any act or omission to act giving rise to liability or indemnification. The Company believes that these provisions in the Certificate of Incorporation and the Bylaws are necessary to attract and retain qualified persons as directors and officers. However, these provisions may discourage stockholders from bringing a lawsuit against the Company's directors for breach of their fiduciary duty. These provisions also may have the effect of reducing the likelihood of derivative litigation against directors and officers, even though such an action, if successful, might otherwise benefit the Company and its stockholders. Furthermore, a stockholder's investment may be adversely affected to the extent the Company pays the costs of settlement and damage awards against directors and officers pursuant to these indemnification provisions.

**Public Warrants**

As of March 27, 2026, the Company had 4,999,863 outstanding warrants to purchase an aggregate of 499,986 shares of Voting Common Stock (the "Public Warrants") with an exercise price of $115.00 per share for every ten Public Warrants, all of which are currently excisable. The Public Warrants will expire on September 24, 2026, at 5:00 p.m., New York City time, or earlier upon redemption or liquidation.

If the Voting Common Stock is at the time of any exercise of a Public Warrant not listed on a national securities exchange such that it satisfies the definition of a "covered security" under Section 18(b)(1) of the Securities Act, the Company may, at its option, require holders of Public Warrants who exercise their Public Warrants to do so on a "cashless basis" in accordance with Section 3(a)(9) of the Securities Act and, in the event the Company so elects, the Company will not be required to file or maintain in effect a registration statement, but the Company will be required to use its best efforts to register or qualify the shares under applicable blue sky laws to the extent an exemption is not available. Once the Public Warrants become exercisable, the Company may call the Public Warrants for redemption:

- in whole and not in part;
- at a price of $0.10 per warrant;
- upon not less than 30 days' prior written notice of redemption to each warrant holder; and
- if, and only if, the reported last sale price of Voting Common Stock equals or exceeds $180.00 per share (as adjusted for stock splits, stock dividends, reorganizations, recapitalizations and the like) for any 20 trading days within a 30-trading day period ending three business days before the Company sends the notice of redemption to the warrant holders.

If and when the Public Warrants become redeemable by the Company, it may exercise its redemption right if the issuance of shares of Voting Common Stock upon exercise of the Public Warrants is not exempt from registration or qualification under applicable state blue sky laws or the Company is unable to effect such registration or qualification.

The Company has established the last of the redemption criterion discussed above to prevent a redemption call unless there is at the time of the call a significant premium to the warrant exercise price. If the foregoing conditions are satisfied and the Company issues a notice of redemption of the Public Warrants, each warrant holder will be entitled to exercise its Public Warrant prior to the scheduled redemption date. However, the price of Voting Common Stock may fall below the $180.00 redemption trigger price (as adjusted for stock splits, stock dividends, reorganizations, recapitalizations and the like) as well as the $115.00 warrant exercise price after the redemption notice is issued.

If the Company calls the Public Warrants for redemption as described above, the Company's management will have the option to require any holder that wishes to exercise its Public Warrant to do so on a "cashless basis." In determining whether to require all holders to exercise their Public Warrants on a "cashless basis," the Company's management will consider, among other factors, the Company's cash position, the number of Public Warrants that are outstanding and the dilutive effect on its stockholders of issuing the maximum number of shares of Voting Common Stock issuable upon the exercise of the Public Warrants. If the Company's management takes advantage of this option, all holders of Public Warrants would pay the exercise price by surrendering their Public Warrants for that number of shares of Voting Common Stock equal to the quotient obtained by dividing (x) the product of the number of shares of Voting Common Stock underlying the Public Warrants, multiplied by the excess of the "fair market value" (defined below) over the exercise price of the Public Warrants by (y) the fair market value. The "fair market value" shall mean the average last reported sale price of Voting Common Stock for the 10 trading days ending on the third trading day prior to the date on which the notice of redemption is sent to the holders of Public Warrants. If the Company's management takes advantage of this option, the notice of redemption will contain the information necessary to calculate the number of shares of Voting Common Stock to be received upon exercise of the Public Warrants, including the "fair market value" in such case. Requiring a cashless exercise in this manner will reduce the number of shares to be issued and thereby lessen the dilutive effect of a Public Warrant redemption. The Company believes this feature is an attractive option if the Company does not need the cash from the exercise of the Public Warrants after the closing.

A holder of a Public Warrant may notify the Company in writing in the event it elects to be subject to a requirement that such holder will not have the right to exercise such Public Warrant, to the extent that after giving effect to such exercise, such person (together with such person's affiliates), to the Public Warrant agent's actual knowledge, would beneficially own in excess of 4.8% or 9.8% (or such other amount as a holder may specify) of the shares of Voting Common Stock outstanding immediately after giving effect to such exercise.

If the number of outstanding shares of Voting Common Stock is increased by a stock dividend payable in shares of Voting Common Stock, or by a split-up of shares of Voting Common Stock or other similar event, then, on the effective date of such stock dividend, split-up or similar event, the number of shares of Voting Common Stock issuable on exercise of each Public Warrant will be increased in proportion to such increase in the outstanding shares of Voting Common Stock. A rights offering to holders of Voting Common Stock entitling holders to purchase shares of Voting Common Stock at a price less than the fair market value will be deemed a stock dividend of a number of shares of Voting Common Stock equal to the product of (i) the number of shares of Voting Common Stock actually sold in such rights offering (or issuable under any other equity securities sold in such rights offering that are convertible into or exercisable for Voting Common Stock) multiplied by (ii) one minus the quotient of (x) the price per share of Voting Common Stock paid in such rights offering divided by (y) the fair market value. For these purposes (i) if the rights offering is for securities convertible into or exercisable for Voting Common Stock, in determining the price payable for Voting Common Stock, there will be taken into account any consideration received for such rights, as well as any additional amount payable upon exercise or conversion and (ii) fair market value means the volume weighted average price of Voting Common Stock as reported during the ten (10) trading day period ending on the trading day prior to the first date on which the shares of Voting Common Stock trade on the applicable exchange or in the applicable market, regular way, without the right to receive such rights.

In addition, if the Company, at any time while the Public Warrants are outstanding and unexpired, pays a dividend or makes a distribution in cash, securities or other assets to the holders of Voting Common Stock on account of such shares of Voting Common Stock (or other shares of the Company's capital stock into which the Public Warrants are convertible), other than (a) as described above, or (b) certain ordinary cash dividends, then the warrant exercise price will be decreased, effective immediately after the effective date of such event, by the amount of cash and/or the fair market value of any securities or other assets paid on each share of Voting Common Stock in respect of such event.

If the number of outstanding shares of Voting Common Stock is decreased by a consolidation, combination, reverse stock split or reclassification of shares of Voting Common Stock or other similar event, then, on the effective date of such consolidation, combination, reverse stock split, reclassification or similar event, the number of shares of Voting Common Stock issuable on exercise of each Public Warrant will be decreased in proportion to such decrease in outstanding shares of Voting Common Stock.

Whenever the number of shares of Voting Common Stock purchasable upon the exercise of the Public Warrants is adjusted, as described above, the warrant exercise price will be adjusted by multiplying the warrant exercise price immediately prior to such adjustment by a fraction (x) the numerator of which will be the number of shares of Voting Common Stock purchasable upon the exercise of the Public Warrants immediately prior to such adjustment, and (y) the denominator of which will be the number of shares of Voting Common Stock purchasable immediately thereafter.

In case of any reclassification or reorganization of the outstanding shares of Voting Common Stock (other than those described above or that solely affects the par value of such shares of Voting Common Stock), or in the case of any merger or consolidation of the Company with or into another corporation (other than a consolidation or merger in which the Company is the continuing corporation and that does not result in any reclassification or reorganization of outstanding shares of Voting Common Stock), or in the case of any sale or conveyance to another corporation or entity of the assets or other property of the Company as an entirety or substantially as an entirety in connection with which the Company is dissolved, the holders of the Public Warrants will thereafter have the right to purchase and receive, upon the basis and upon the terms and conditions specified in the Public Warrants and in lieu of the shares of Voting Common Stock immediately theretofore purchasable and receivable upon the exercise of the rights represented thereby, the kind and amount of shares of stock or other securities or property (including cash) receivable upon such reclassification, reorganization, merger or consolidation, or upon a dissolution following any such sale or transfer, that the holder of the Public Warrants would have received if such holder had exercised their Public Warrants immediately prior to such event. If less than 70% of the consideration receivable by the holders of Voting Common Stock in such a transaction is payable in the form of common stock in the successor entity that is listed for trading on a national securities exchange or is quoted in an established over-the-counter market, or is to be so listed for trading or quoted immediately following such event, and if the registered holder of the Public Warrant properly exercises the Public Warrant within thirty days following public disclosure of such transaction, the Public Warrant exercise price will be reduced as specified in the warrant agreement, dated as of November 19, 2019, by and between the Company and Continental Stock Transfer & Trust Company, as warrant agent ("Warrant Agreement") based on the Black-Scholes value (as defined in the Warrant Agreement) of the Public Warrant. The Public Warrants will be issued in registered form under the Warrant Agreement. The Warrant Agreement provides that the terms of the Public Warrants may be amended without the consent of any holder to cure any ambiguity or correct any defective provision, but requires the approval by the holders of at least 50% of the then outstanding Public Warrants to make any change that adversely affects the interests of the registered holders of Public Warrants.

The Public Warrants may be exercised upon surrender of the warrant certificate on or prior to the expiration date at the offices of the warrant agent, with the exercise form on the reverse side of the warrant certificate completed and executed as indicated, accompanied by full payment of the exercise price (or on a cashless basis, if applicable), by certified or official bank check payable to the Company, for the number of Public Warrants being exercised. The warrant holders do not have the rights or privileges of holders of Voting Common Stock or any voting rights until they exercise their Public Warrants and receive shares of Voting Common Stock. After the issuance of shares of Voting Common Stock upon exercise of the Public Warrants, each holder will be entitled to one vote for each share held of record on all matters to be voted on by stockholders.

No fractional shares will be issued upon exercise of the Public Warrants. If, upon exercise of the Public Warrants, a holder would be entitled to receive a fractional interest in a share, the Company will, upon exercise, round down to the nearest whole number of shares of Voting Common Stock to be issued to the warrant holder.

***Listing***

The Public Warrants are listed on the Nasdaq Capital Market under the symbol "JSPRW."

**Warrants**

As of March 27, 2026, in addition to the Public Warrants, the Company had outstanding warrants to purchase up to an aggregate of 13,020,707 shares of Voting Common Stock, as follows:

- common warrants to purchase up to an aggregate of 12,345,707 shares of Voting Common Stock with an exercise price of $2.92 per share, all of which are currently exercisable (subject to certain beneficial ownership limitations) and expire on March 22, 2030 (the "Common Warrants"); and

- pre-funded warrants to purchase up to an aggregate of 675,000 shares of Voting Common Stock, with an exercise price of $0.0001 per share, all of which are currently exercisable (subject to certain beneficial ownership limitations) and expire on the date the applicable warrant is exercised in full (the "Pre-Funded Warrants").

The Common Warrants and the Pre-Funded Warrants contain provisions for the adjustment of the exercise price and the number of shares issuable upon exercise of the applicable warrant in the event of stock dividends, stock splits or similar transactions. In addition, the Common Warrants and the Pre-Funded Warrants contain a "cashless exercise" feature that allows the holders thereof to exercise the warrants without a cash payment to the Company under certain circumstances. The Common Warrants and the Pre-Funded Warrants also contain provisions that provide certain rights to the warrantholders in the event of a fundamental transaction, including a merger or consolidation with or into another entity, such as:

- the right to receive the same amount and kind of consideration paid to the holders of Voting Common Stock in the fundamental transaction; or

- solely with respect to the Common Warrants, the right to require the Company to repurchase the unexercised portion of certain warrants at the warrant's respective fair value using the Black Scholes option pricing formula.

**Exhibit 23.1**

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (No. 333-285914) and Form S-8 (File No. 333-277674, 333-280039, 333-263702, 333-270361, 333-263773 and 333-273941) of Jasper Therapeutics, Inc., of our report dated March 30, 2026 relating to the financial statements, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP
San Jose, California
March 30, 2026

**Exhibit 31.1**

**CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER**
**Pursuant to Rule 13a-14(a) adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002**

I, Jeet Mahal, certify that:

1. I have reviewed this Annual Report on Form 10-K of Jasper Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Jeet Mahal
Jeet Mahal
*President, Chief Executive Officer, and Director*
(Principal Executive Officer)

Dated: March 30, 2026

**Exhibit 31.2**

**CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER**
**Pursuant to Rule 13a-14(a) adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002**

I, Herb Cross, certify that:

1. I have reviewed this Annual Report on Form 10-K of Jasper Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Herb Cross
Herb Cross
*Chief Financial Officer and Corporate Secretary*
(Principal Financial Officer)

Dated: March 30, 2026

**Exhibit 32.1**

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

In connection with the Annual Report on Form 10-K of Jasper Therapeutics, Inc. (the "Company") for the period ended December 31, 2025 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to their knowledge that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

By: /s/ Jeet Mahal
Jeet Mahal

President and Chief Executive Officer
*(Principal Executive Officer)*
March 30, 2026

By: /s/ Herb Cross
Herb Cross

Chief Financial Officer and Corporate Secretary
*(Principal Financial Officer)*
March 30, 2026

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

This certification accompanies the Report, is not deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Report), irrespective of any general incorporation language contained in such filing.