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, 2022

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 whole warrant exercisable for one share of Voting Common Stock at an exercise price of $11.50	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, 2022 (the last business day of the registrant's most recently completed second fiscal quarter) was approximately $48.7 million based on the closing price of the registrant's common stock on June 30, 2022 of $1.93 per share, as reported by the Nasdaq Capital Market.

As of February 28, 2023, the number of shares of the registrant's common stock outstanding was 109,383,173 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

Portions of the registrant's Definitive Proxy Statement relating to the 2023 Annual Meeting of Stockholders, which will be filed with the Securities and Exchange Commission within 120 days after the end of the registrant's fiscal year ended December 31, 2022, are incorporated by reference into Part III of this Annual Report on Form 10-K.

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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. References to "Old Jasper" refer to the private Delaware corporation that is now our wholly-owned subsidiary and named Jasper Tx Corp. (formerly known as Jasper Therapeutics, Inc.).

On September 24, 2021, we consummated the previously announced Business Combination (pursuant to the Business Combination Agreement, dated May 5, 2021, by and among AMHC, Ample Merger Sub, Inc. ("Merger Sub") and Old Jasper). Pursuant to the terms of the Business Combination Agreement, a business combination (herein referred to as the "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.

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.

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, including those relating to the impact of the Business Combination on our business, financial condition, liquidity and results of operations;
- 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 of our product candidates;
- our ability to obtain and maintain regulatory approval for our product candidates;
- our ability to obtain funding for our operations;
- our projected financial information, anticipated growth rate and market opportunity;
- our ability to maintain the listing of our public securities on 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 existing license agreements and manufacturing arrangements; and
- the effect of the continuing COVID-19 pandemic on the foregoing.

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 by the continuing COVID-19 pandemic, 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 dedicated to enabling cures through therapeutics targeting mast and hemopoietic stem cells. We are focused on the development and commercialization of safer and more effective therapeutic agents for diseases such as Chronic Spontaneous Urticaria ("CSU"), Lower to Intermediate Risk Myelodysplastic Syndrome ("LR-MDS") and novel conditioning regimens for stem cell transplantation and ex-vivo gene therapy, a technique in which genetic manipulation of cells is performed outside of the body prior to transplantation.

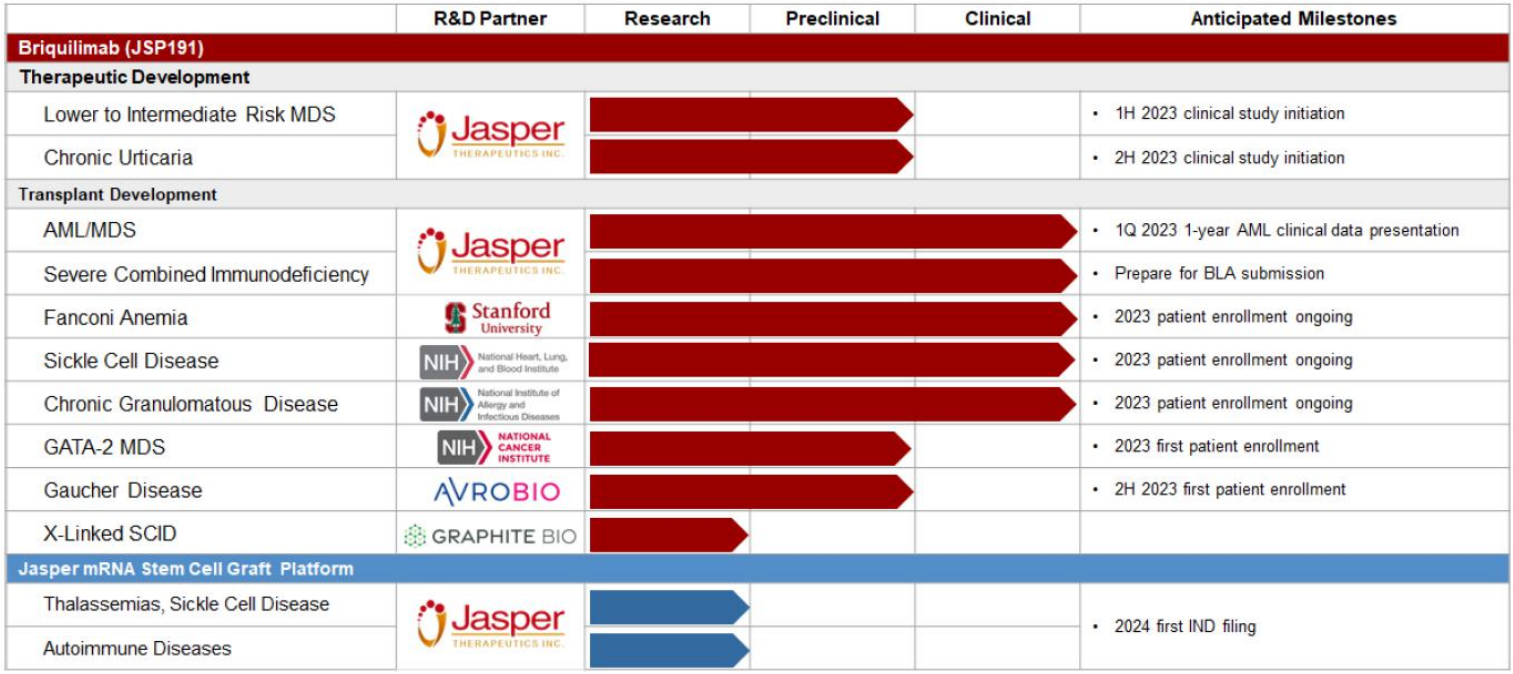
Our drug development pipeline includes multiple product candidates designed to target mast and/or hematopoietic stem cells. Our lead product candidate, briquilimab (formerly known as JSP191), is in clinical development as a novel therapeutic antibody that targets mast and stem cells in various diseases and as a conditioning agent to clear hematopoietic stem cells from bone marrow in patients prior to undergoing allogeneic stem cell therapy or stem cell gene therapy. We are also developing engineered hematopoietic stem cells product candidates reprogrammed using mRNA delivery ("mRNA stem cell platform") and gene editing that have a competitive advantage over endogenous hematopoietic stem cells ("HSCs") because they may permit higher levels of engraftment without the need for toxic conditioning. We also plan to continue to expand our pipeline to include other novel mast and stem cell therapies based on immune modulation, graft engineering or cell and gene therapies. Our goal is to expand the use of therapeutic agents targeting mast and stem cells as well as to expand curative stem cell transplants and gene therapies for all patients, including children and the elderly.

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, chronic inducible urticaria, allergic asthma, prurigo nodularis and eosinophilic esophagitis, the mast cell response is dysregulated and may lead to unwanted responses such as hives, airway constriction or conjunctivitis. Current therapeutic approaches to controlling mast cell response include anti-histamines to counteract the release of histamine by activated mast cells and anti-IgE antibody therapy to try to eliminate the antibodies responsible for triggering 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.

Myelodysplastic syndromes ("MDS") are a mixed group of hematological disorders characterized by decreased production of healthy blood and/or immune cells by the hematologic stem cells and eventual progression to Acute Myeloid Leukemia ("AML"). Patients with LR-MDS are typically treated with blood transfusions to augment poor bone marrow stem cell function or with growth factors, such as erythropoietin, to stimulate any remaining healthy bone marrow cells to increase production of blood or immune cells. The goals of current treatments are to delay the progression of the disease to AML and for an eventual donor stem cell transplant for eligible patients. We believe that novel approaches that directly target the diseased stem cells in the bone marrow of MDS patients may lead to better clinical outcomes such as decreased need for blood transfusions, decreased use of growth factors, and delayed disease progression.

Stem cell transplantation is among the most widely practiced forms of cellular therapy and has the potential to cure a wide variety of diseases, including cancers, genetic disorders and autoimmune diseases. A stem cell transplant procedure involves three main steps: (i) stem cells from the patient's or donor's bone marrow are collected; (ii) the patient's bone marrow is cleared of any remaining stem cells in order to make space to receive new transplanted stem cells, which is known as conditioning; and (iii) the new stem cells are transplanted into the patient via infusion where they fasten to, or engraft in, the bone marrow and grow into the blood and immune cells that form the basis of reset and rebuilt blood and immune systems. Transplants are either allogeneic or autologous, depending on the source of the new stem cells for the transplant. In an allogeneic transplant, patients receive cells from a stem cell donor. In an autologous transplant, the patient's own stem cells are used. Autologous transplants also include stem cell gene therapies, where cells are collected from the patient, edited to either enable a functioning gene or correct a defective gene, and then transplanted into the patient via infusion.

Currently, patients must receive highly toxic and potentially life-threatening conditioning agents to prepare their bone marrow for transplantation with either donor stem cells or their own gene-edited stem cells. Younger, fitter patients capable of surviving these toxic side effects are typically given myeloablative, or high-intensity, conditioning whereas older or less fit patients are typically given reduced intensity, but still toxic, conditioning which leads to less effective transplants. These toxicities include a range of acute and chronic effects to the gastrointestinal tract, kidneys, liver, lung, endocrine and neurologic tissues. Depending upon the conditioning regimen, fitness of the patient, and compatibility between the donor and recipient, the risk of transplant-related mortality ranges from 10% to more than 50% in older patients. Less toxic ways to condition patients have been developed to enable transplant for older patients or those with major comorbidities, but these regimens risk less potent disease elimination and higher rates of disease relapse. Even though stem cell therapy can be one of the most powerful forms of disease cure, these limitations of non-targeted conditioning regimens have seen little innovation over the past decade. We believe that novel targeting approaches to stem cell conditioning have the potential to reduce toxicities associated with current regimens and expand the use of allogeneic and gene modified transplant in multiple 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 receptor on mast and stem cells. The SCF/CD117 pathway is a survival signal for mast and stem cells and we believe that blocking this pathway may lead to depletion of these cells from skin and bone marrow environments. Currently, we are developing briquilimab as chronic therapy for CSU and LR-MDS. We are also developing briquilimab as a one-time conditioning therapy in various stem cell transplant settings such as severe combined immunodeficiency ("SCID") for which we are currently conducting a Phase 1/2 clinical trial in patients who have failed a previous stem cell transplant. Briquilimab is also being studied by our academic and institutional partners, Stanford University and National Institutes of Health ("NIH"), in other transplant settings, including Fanconi Anemia ("FA"), sickle cell disease ("SCD"), chronic granulomatous disease ("CGD") and GATA-2 Type MDS.

We are planning to evaluate briquilimab as a therapeutic in patients with CSU, a disorder of mast cells in the skin. Patients with CSU experience swelling, redness and itching of the skin that lasts at least six weeks due to either an unknown cause, Type I autoimmunity with Immunoglobulin E antibodies ("IgE") against self or Type IIb autoimmunity with activating antibodies directed at mast cells. 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. The biologic rationale for both of 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 omalizumab is designed to reduce IgE, which are thought to trigger mast cell activation. 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 effective therapy for CSU patients. We intend to study briquilimab monotherapy in CSU patients who are refractory to anti-histamine therapy.

We also plan to evaluate briquilimab as a therapeutic for certain patients with proliferative disorders of hematopoietic stem cells. MDS is a heterogeneous disorder of the bone marrow that typically occurs in an older population and can progress to AML. The Revised International Prognostic Scoring System ("IPSS-R") is a clinical assessment tool used to evaluate risk and prognosis of newly diagnosed patients. Patients with IPSS-R scores of low or very low are not typically referred for a stem cell transplant due to the risk of transplant-related toxicities from current conditioning regiments, infection and Graft vs Host Disease ("GvHD") outweighing the patient's expected survival with drug therapies. These patients typically suffer from anemia, thrombocytopenia or neutropenia and are given drug therapies such as an erythropoiesis stimulating agent ("ESA") to stimulate production of new cells to correct their blood deficiency. However, these agents do not target the diseased hematopoietic stem cell and patients who become refractory to ESA are dependent on routine blood transfusions, which are associated with poor survival rates. ESA-refractory lower-risk MDS patients have few treatment options and are a clinical unmet need.

Briquilimab and other anti-CD117 monoclonal antibodies have been shown to deplete normal and diseased MDS human hematopoietic stem cells in clinical and pre-clinical studies. In studies of non-human primates ("NHPs") and healthy human volunteers, administration of a single dose of briquilimab resulted in depletion of healthy hematopoietic stem cells followed by recovery in approximately six weeks. Additional recent clinical data in MDS patients undergoing stem cell transplants showed depletion of hematopoietic stem cells after administration of briquilimab alone. By depleting diseased and healthy hematopoietic stem cells, we believe that briquilimab may allow for preferential recovery of healthy hematopoietic stem cells and restoration of normal hematopoiesis. We intend to study briquilimab monotherapy in lower-risk MDS patients with documented cytopenia who are refractory to ESA therapy.

We are also developing briquilimab for SCID. 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 are currently conducting an open label Phase 1/2 clinical trial in SCID patients with a history of a prior allogeneic transplant for SCID but with poor graft outcomes. The primary goals of the study are to evaluate the safety of briquilimab in this population and to assess successful donor transplantation leading to improved immune function. Based on preliminary results from the ongoing trial, we believe briquilimab has demonstrated the ability to enable engraftment of donor HSCs as a single agent as determined by donor chimerism, or the percentage of bone marrow cells in the patient that are of donor origin after transplant. Seven out of the first ten T cell-negative, B cell-negative ("T-B-") SCID patients with prior allogeneic transplant achieved donor engraftment, naïve donor T cell production and demonstrated preliminary clinical improvement after re-transplantation using briquilimab-only conditioning. No briquilimab treatment-related serious adverse events ("SAEs") have been reported to date and pharmacokinetics have been consistent with earlier studies in healthy volunteers. We expect to complete enrollment in this Phase 1/2 clinical trial in 2023.

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.

We also are evaluating briquilimab in an open label Phase 1 clinical trial of donor stem cell transplant in patients with MDS or AML. The primary endpoints are to evaluate the safety, tolerability and pharmacokinetic parameters of briquilimab. In this clinical trial, 0.6 mg/kg briquilimab-based conditioning was well tolerated in all 31 MDS/AML patients as of December 31, 2022. Furthermore, it led to successful engraftment as demonstrated by sustained blood neutrophil count of >500 x 10^6 / L (Wolff 2002) in all 31 patients. Additionally, at one year post-transplant, eight of the twelve AML patients on study were alive and disease-free, without trace evidence of leukemic cells, or minimal residual disease ("MRD") as detected by cytogenetics, flow cytometry or next-generation sequencing, a secondary endpoint of the clinical study. No briquilimab-related SAEs have been reported. Among the twelve AML patients, three patients had disease relapse and one patient came off study due to late onset Grade 3 acute GvHD. We expect to present additional data from this study, including data from the MDS patients, in 2023.

We have entered into a clinical collaboration with Stanford University ("Stanford") to study briquilimab-based conditioning in patients with FA with bone marrow failure and who are eligible for stem cell transplant. This study is currently open for patient recruitment. The first two patients enrolled in this study have been transplanted and show 100% donor myeloid chimerism, a measurement of transplant efficacy, along with recovery of normal blood counts. We are also collaborating with the NIH to conduct clinical trials of briquilimab-based conditioning in patients with SCD, with CGD and with GATA-2 mutated MDS. The first three patients in the SCD study have shown full myeloid chimerism and increased production of hemoglobin compared to their pre-transplant baseline. We believe that briquilimab may also be useful for conditioning in allogenic transplant for other diseases beyond which we are currently studying, including autoimmune diseases. We also believe that targeted briquilimab-based conditioning may improve the efficacy and safety of gene therapies.

Our mRNA stem cell platform is designed to overcome key limitations of stem cell transplant and stem cell gene therapy. By using mRNA delivery and/or gene editing, we believe we can reprogram donor or gene corrected stem cells to have a transient proliferative and survival advantage over the patient's existing cells. We believe our initial preclinical experiments demonstrate that multiple different mRNAs can be used to improve engraftment of modified stem cells. One example is mRNA stem cell grafts that express certain variants of CXCR4, a cell surface protein involved in cellular homing to the bone marrow, which may lead to improved stem cell homing and engraftment in the bone marrow. Another example includes expression of a modified stem cell factor receptor that can lead to cell line proliferation independent of SCF concentration, enabling our mRNA stem cell grafts to outcompete unmodified HSCs through better survival and engraftment. Also, since briquilimab only blocks signaling through the SCF receptor, these mRNA stem cell grafts are not affected by briquilimab when used in combination. Other initial experiments have shown that mRNA can be used to express these receptor variants on the cell surface. We have also identified other potential receptor modifications that prevent the binding of briquilimab but retain the ability to bind SCF, therefore allowing the mRNA stem cell grafts to proliferate normally even in the presence of briquilimab.

We intend to become a fully integrated discovery, development and commercial company in the field of mast and stem cell therapeutics. We are developing our product candidates to be used individually or, in some cases, in combination with one another. For example, we believe our pipeline could be tailored to the patient-specific disease so that a patient may receive more than one of our therapies as part of his or her individual allogeneic or gene-edited stem cell therapy. 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 advance our pipeline and innovate through our research platform.

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 for the right to use briquilimab in the clearance of stem cells prior to the transplantation of HSCs. We also entirely own the intellectual property for our mRNA stem cell platform, which has been internally developed.

Our Product Pipeline

We are developing a portfolio of novel product candidates that we believe have the potential to meaningfully improve chronic mast and stem cell therapy for patients with certain blood disorders and autoimmune diseases. Additionally, we believe our product candidates have the potential to allow more patients with debilitating or life-threatening diseases to access a one-time, transformative blood and immune reset through transplant with better outcomes and reduced risk of toxicity and mortality versus current technologies. We are developing our product candidates so that they can be used individually or in combination with one another, such that patients may receive more than one of our therapies as part of their individual transplant journey. In addition to our first set of clinical product candidates, we are in the process of identifying several other potential candidates from our mRNA-modified hematopoietic stem cell platform.

Briquilimab

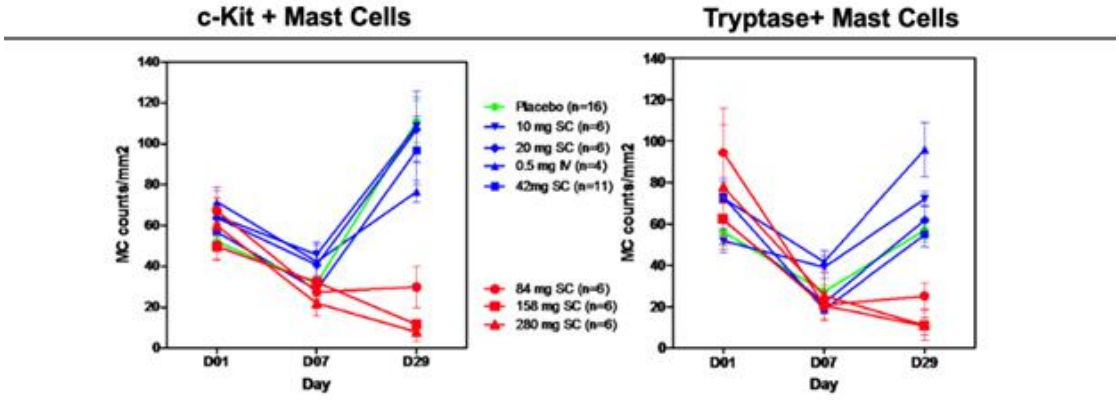
We believe briquilimab is a unique, humanized, monoclonal antibody that targets the underlying biology of mast cell and stem cell survival pathways to potentially improve the efficacy and safety of hematopoietic stem cell transplantation. Briquilimab is in development as a chronic therapy in CSU and LR-MDS, as well as a conditioning agent to clear hematopoietic stem cells from the bone marrow prior to transplant. Briquilimab binds to human CD117, a receptor for SCF, which is expressed on the surface of mast cells and hematopoietic stem and progenitor cells. The interaction of SCF and CD117 is required for mast and stem cells to survive. By blocking SCF from binding to CD117 and disrupting critical survival signals, briquilimab leads to the depletion of mast cells in the skin and stem cells in the bone marrow. Briquilimab is in development as a conditioning agent, both as a single agent and in combination with existing agents depending on the need in a particular transplant setting.

Briquilimab as a Primary Therapeutic for Disorders of Mast Cells

Mast cells are primary cells of the immune system derived from hematopoietic stem cells 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 triggered by an allergen specific to membrane-bound IgE antibodies, the mast cells are activated and release 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 anti-histamines. 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 CD117 receptor by inhibiting the binding of SCF, the ligand for the CD117 receptor. The interaction of SCF/CD117 on mast cells is critical for development, proliferation and survival. Without continued signaling through CD117, mast cells will undergo apoptosis and die. We have shown that a subcutaneous dosing of briquilimab leads to depletion of mast cells in the skin of healthy human volunteers for at least 29 days after a single administration. We believe that depletion of mast cells in the skin of patients with urticaria or prurigo nodularis and in the lungs of patients with allergic asthma has the potential to lead to improved disease control for those patients without adequate response to current therapies.



Briquilimab Phase 1a (N=71):

Reduction in SCF (c-Kit) positive and Tryptase positive mast cells in punch biopsy wound model

We intend to study briquilimab monotherapy in patients with CSU who are refractory to second generation anti-histamine agents. We plan to file an investigational new drug (“IND”) application with the FDA in the second quarter of 2023 with a potential study start in the third quarter of 2023.

Briquilimab as a Primary Therapeutic for Proliferative Disorders of the Stem Cells

A transforming event in hematopoietic stem cells can produce several different malignancies. Cancer stem cells can self-renew, have a prolonged survival rate and have the ability to give rise to cells with more differentiated characteristics. The idea that cancer is primarily driven by a smaller population of stem cells has important implications. For instance, many chemotherapies can shrink tumors or deplete downstream differentiated cells, but if the chemotherapies do not kill the cancer stem cells, the tumor will grow back.

It has been shown that HSCs are the disease-initiating cells in cancers like MDS and that these pathogenic MDS HSCs outcompete normal HSCs present in the bone marrow of affected patients. Furthermore, these disease-initiating HSCs express CD117 and anti-CD117 antibodies can target and eradicate these pathogenic cells. This is especially significant in a disease like MDS where available therapies either lack disease-modifying activity or possess off-target toxicity, which prevents their use in older and/or fragile individuals who comprise most of the patients affected by MDS. Development of anti-CD117 monoclonal antibodies, which might be safely used to target MDS clones, would represent a major step forward for the treatment of this disease.

We plan to evaluate briquilimab as a therapeutic for certain MDS patients. The IPSS-R is a clinical assessment tool used to evaluate risk and prognosis of newly diagnosed patients. Patients with IPSS-R scores of low or very low are not typically referred to stem cell transplant due to the risk of transplant-related toxicities from current conditioning regiments, infection and GvHD outweighing the patient's expected survival with drug therapies. These patients typically suffer from anemia, thrombocytopenia or neutropenia and are given drug therapies such as an ESA to stimulate production of new cells to correct their blood deficiency. However, these agents do not target the diseased hematopoietic stem cell and patients who become refractory to ESA are dependent on routine blood transfusions, which are associated with poor survival rates. ESA refractory lower-risk MDS patients have few treatment options and are a clinical unmet need.

Briquilimab and other anti-CD117 monoclonal antibodies have been shown to deplete normal and diseased MDS human hematopoietic stem cells in clinical and pre-clinical studies. In studies in NHPs and healthy human volunteers, administration of a single dose of briquilimab resulted in depletion of healthy hematopoietic stem cells followed by recovery in approximately six weeks. Dr. Wendy Pang demonstrated at Stanford that briquilimab is capable of depleting MDS HSCs in vivo in a xenografted mouse model. New data from our MDS/AML trial of briquilimab as a conditioning agent have revealed that the antibody can have a direct depletion effect on CD34+CD45RA-CD117+ cells prior to administration of fludarabine or radiation. By depleting diseased and healthy hematopoietic stem cells, we believe that briquilimab may allow for preferential recovery of healthy hematopoietic stem cells and restoration of normal hematopoiesis.

We intend to study briquilimab monotherapy in lower-risk MDS patients with documented cytopenia who are refractory to ESA therapy. We plan to run the primary treatment study under the existing new drug application for MDS/AML and anticipate enrollment to begin in this single arm clinical trial in the first half of 2023.

mRNA Stem Cell Platform

Our mRNA stem cell grafts are designed to overcome key limitations of allogeneic donor and autologous gene-edited stem cell transplants. By delivering mRNA or modifying DNA, leading to expression of a modified receptor or protein, we can reprogram donor or gene-edited stem cells to have a transient proliferative and survival advantage over the patient's existing cells to permit higher levels of engraftment without the need for toxic conditioning of the patient. mRNA stem cell grafts have the potential to eliminate the need for donor T-cells, B-cells and NK-cells which are needed in unmodified donor HSC grafts to permit robust engraftment but can lead to GvHD, where the donor cells attack the patient's tissues, resulting in the need for long-term immunosuppression therapies.

Our Strategy

Our goal is to bring curative allogeneic and autologous hematopoietic cell transplant ("HCT") and gene therapy to more people by developing compounds that can make it safer and more effective. As part of our strategy, we aim to:

Build a leading biotechnology company to enable cures via immune modulation, graft engineering and cell and gene therapies. 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 improved therapeutics for mast and stem cell diseases and improved stem cell transplantation.

Advance the development of briquilimab as a chronic therapeutic targeted at mast and stem cell diseases. We are targeting disorders of mast and stem cells, including CSU and LR-MDS, with briquilimab as a repeat dose therapy. We believe that briquilimab may also be effective in other diseases of the mast or stem cell and we may consider expanding our efforts in additional indications.

Continue to develop briquilimab as a novel, targeted pre-transplant conditioning agent enabling more efficacious and safer HCT. Starting with our lead product candidate, briquilimab, we are advancing the field of HCT to address effective and safe pre-transplant conditioning in hematologic monogenic and malignant disorders as well as in autoimmune disease and gene therapy. Our initial focus is on SCID, AML, MDS and autologous gene-edited stem cell transplants.

Advance our mRNA platform to overcome the limitations of current allogeneic and autologous gene-edited stem cell transplants. We are developing enhanced stem cell therapies with transient proliferative advantages, which we believe may translate to superior efficacy and reduced GvHD compared to current standard of care therapies in allogenic and autologous gene therapy transplants.

Commercialize our product candidates to expand the use of effective and safe mast and stem 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 and accredited transplant centers and hospital-based prescribers who administer the majority of mast and stem 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 gene therapy 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 and stem cell therapies.

Our History and Team

Jasper was founded by Dr. Judith Shizuru, Professor of Medicine and Pediatrics at Stanford University, and Dr. Susan Prohaska, a Stanford-trained immunologist, stem cell biologist and drug developer, with the goal of bringing curative hematopoietic stem cell transplantation to more people by making it safer and more effective. We unite technologies from Stanford University and Amgen via expertise in stem cell transplantation, stem cell biology and drug development. Building on bone marrow niche-clearing technology from Stanford and with our lead compound briquilimab, Dr. Shizuru initiated a clinical program funded by the California Institute for Regenerative Medicine to safely condition patients with SCID prior to hematopoietic cell transplantation.

We have assembled a management team of experienced biopharma industry veterans. With this leadership, we believe we are well positioned to achieve our vision of revolutionizing hematopoietic cell transplantation with safer conditioning regimens. Ron Martell, our Chief Executive Officer, is an experienced biopharma veteran who has extensive experience in cellular therapies and oncology drug development. Prior to joining Jasper, Mr. Martell served as the President and CEO of MorphImmune, Inc., a private platform company advancing a highly specific targeting technology that uses a ligand-linked payload to reprogram the immune system. Previously, he was President and CEO of Nuvelution Pharma. He was also Co-Founder and Executive Chairman of Indapta, Orca Bio and Co-Founder and CEO of Achieve Life Sciences, where he led the merger of the company with Oncogenex. Mr. Martell has served as the CEO of three public biopharmaceutical companies, including Sevion and NeurogesX, and has overseen billions of dollars in industry transactions. Earlier in his career, Mr. Martell served as Senior Vice President of Commercial Operations at ImClone Systems, where he was instrumental in deals with Bristol-Myers Squibb and Merck KGaA and built ImClone Systems' worldwide operations to market and commercialize Erbitux®. He also served in various leadership positions with Genentech where, as Group Manager, Oncology, he was responsible for building the company's oncology franchise, including the launch of Herceptin® and Rituxan®.

Members of our management team have held leadership positions at companies that have successfully discovered, developed, and commercialized therapies for various cancers and devastating rare diseases. These companies include Roche, Johnson & Johnson, Genentech, Bristol-Myers Squibb, Imclone, Amgen, Portola, Alexion and many others.

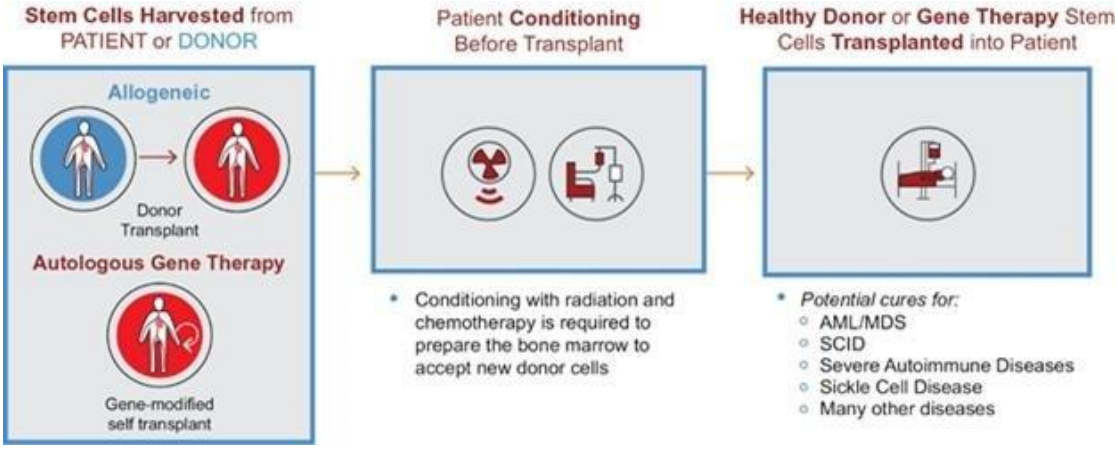
Background on Hematopoietic Stem Cell Therapy

HCT is among the most widely practiced forms of cellular therapy and has the potential to cure a wide variety of diseases. Currently, its use is limited to patients with severe disease burden due to the toxicities of current non-targeted conditioning regimens and the limitations of the transplant grafts themselves.

Stem cell transplants first require identification of a suitable donor and collection of the donor's stem cells, typically from blood. Then chemotherapy or radiation-based conditioning is used to clear the patient's bone marrow of existing diseased stem cells in order to make space to receive new transplanted stem cells. Finally, the donor or gene corrected stem cells are infused into the patient where they engraft into the bone marrow and produce new blood and immune cells that form the basis of a reset and rebuilt blood and immune system. All transplants are categorized as either autologous or allogeneic, depending on the source of the new stem cells for the transplant.

In an autologous transplant, which is used for conditions such as multiple myeloma, non-Hodgkin's lymphoma and certain autoimmune diseases, the patient's own stem cells are used. Autologous transplants also include stem cell gene therapies, in which cells are collected from the patient, edited to either insert a functioning gene into, or correct a defective gene within, such cells and then such cells are transplanted into the patient via infusion.

In an allogeneic transplant, used for conditions such as acute leukemias, MDS, genetic diseases and certain autoimmune diseases, patients receive cells from a stem cell donor. The preferred donor is a biological relative who has a well-matched immune system. The second option is a matched unrelated donor identified through a bone marrow donor registry. Transplant outcomes are not optimal with mismatched donors.



Current State of Conditioning Regimens

Currently, patients must receive highly toxic, potentially life-threatening and non-specific conditioning agents to prepare their bone marrow for transplantation with either donor stem cells or their own gene-edited stem cells. Current conditioning agents are genotoxic and are associated with major toxicities and adverse events such as oral mucositis, sepsis, veno-occlusive disease, bacteremia, pulmonary fibrosis, and GvHD in the near term. In the long term, patients must be counseled against risk of infertility of up to 70% and risk of secondary cancers of 5-10% after chemotherapy conditioning. Additionally, there is a treatment-related mortality risk associated with current conditioning regimens that ranges from 10% to more than 50% in older patients. Other limitations of chemotherapy-based conditioning include incomplete engraftment, transplant ineligibility and prolonged hospitalization.

Current State of Hematopoietic Stem Cell Grafts

Hematopoietic stem cell grafts currently have limitations around failed or poor engraftment with the risk of clinical relapse. Furthermore, GvHD is a high-risk short- and long-term adverse event associated with HCT as a result of donor T-cells, B-cells and NK-cells which are needed in unmodified donor HSC grafts to permit robust engraftment. Donor immune cells may react to the patient's tissues as foreign leading to GvHD whereas newly produced immune cells are trained by the patient's body to not act against the patient's own cells. Due to this risk, patients also need to undergo long-term immunosuppression.

Our Solution and Product Candidates

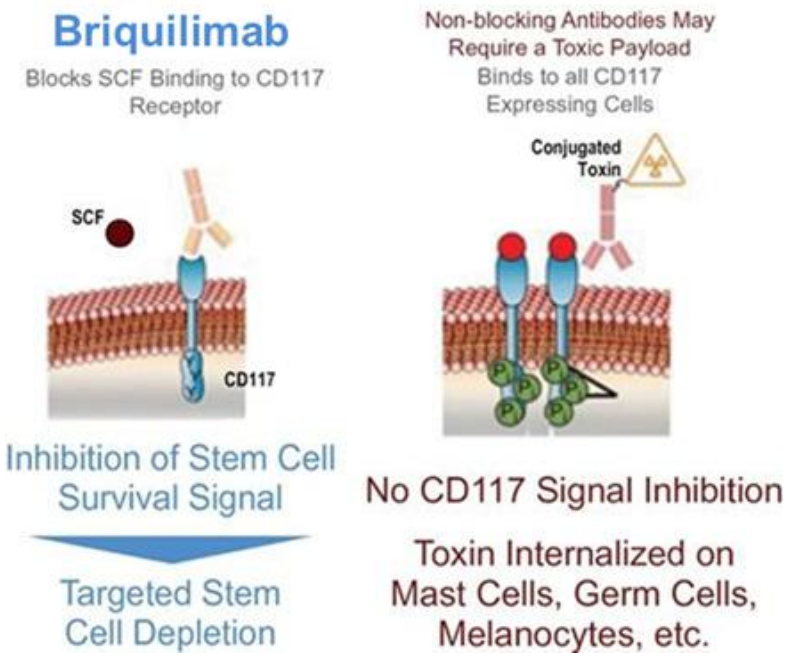
We are developing briquilimab as a conditioning agent that could significantly expand the eligible patient population for both allogeneic and autologous gene edited hematopoietic stem cell therapies in addition to our mRNA engineered hematopoietic stem cells that could result in better transplant efficacy with reduced complications. Currently, approximately 20,000 patients receive allogeneic and autologous gene therapy transplants each year in the major global markets (the United States, the United Kingdom, France, Germany, Spain, Italy and Japan), and we believe this may grow to 80,000 patients with safe conditioning and more effective grafts.

Briquilimab is a targeted anti-CD117 (stem cell factor receptor) antibody which we are currently evaluating in two clinical trials for conditioning prior to stem cell transplant in patients with SCID or with MDS/AML. Briquilimab is designed to bind to CD117 with a greater affinity than SCF. By blocking signaling of the stem cell factor receptor, briquilimab may lead to depletion of stem cell from the bone marrow. Briquilimab was also designed to minimize any interaction with the immune system thereby reducing the risk of immune activation via mast cells or other pathways normally activated by antibodies.

We believe these attributes will allow briquilimab to potentially be used as a monotherapy or in combination to deplete normal and diseased stem cells. The blocking of SCF by briquilimab may remove a critical survival signal on stem cells that leads to their depletion in the bone marrow. Furthermore, the mechanism of action ("MOA") of briquilimab on stem cells may be synergistic with other disruptors of stem cell survival such as radiation, azacytidine, and CD47. Our clinical strategy in SCD, AML and Higher Risk MDS aims to exploit this potentially synergistic mechanism to combine briquilimab and low dose radiation to fully clear both diseased and normal stem cells prior to transplantation of donor cells.

The monoclonal antibody isotype and other modifications of briquilimab were also chosen carefully to retain high affinity binding to the CD117 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, simply changing briquilimab from an IgG1 isotype to an IgG2 isotype would result in less potent inhibition of CD117, potentially decreasing the effect on mast and stem cell depletion. This finding and other data demonstrate that not all anti-CD117 antibodies behave equally or have the same MOA.

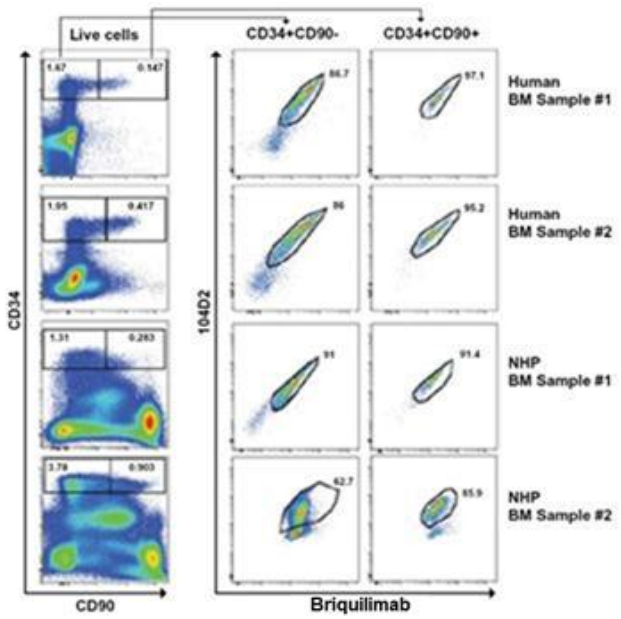
Other known approaches to target CD117, such as anti-CD117 antibodies linked to a toxin, may have off-target toxicity. In contrast to briquilimab, which provides a transient SCF signal blockade, a toxin linked anti-CD117 antibody requires internalization by CD117 expressing cells leading to cell death. Any CD117 expressing cell including stem cells, mast cells, germ cells and melanocytes may be affected by this mechanism. Furthermore, the complexity of an antibody-drug conjugate molecule adds to the manufacturing, clinical and regulatory risks of the drug development process, especially for a novel linker/payload combination that may be subject to different regulatory and Chemistry, Manufacturing and Controls reviews.



Preclinical Transplant Data for Briquilimab — General

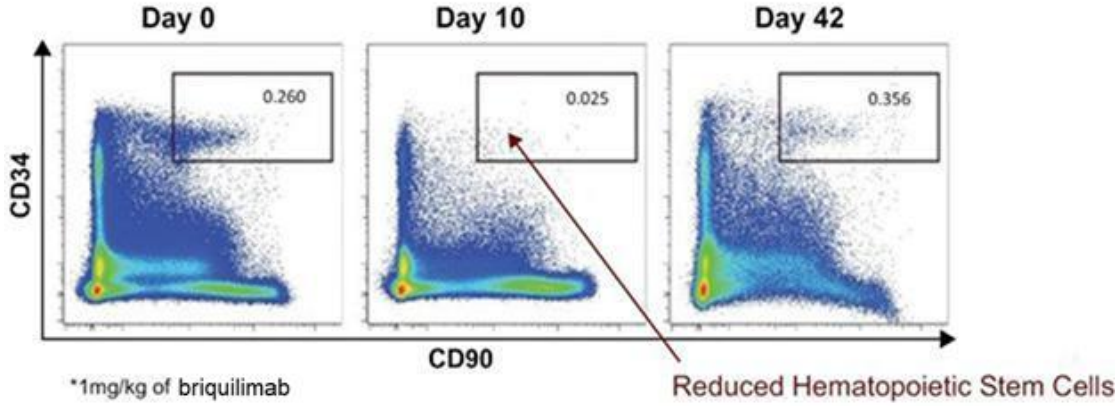
We conducted a preclinical study to determine if NHP HSCs are sufficiently similar to human HSCs to allow use of the same phenotype assays used in human studies to evaluate the effect of briquilimab on NHP hematopoiesis. This study tested, by flow cytometry, a technique used to measure physical and chemical characteristics of a population of cells, whether homologous subsets of NHP bone marrow express the same cellular markers as human HSCs (CD34, CD90, and CD117), and if the human antibody reagents used to identify these markers could also be used for NHP HSCs. Bone marrow samples (or bone marrow aspirates) of NHPs and humans were stained with the antibody reagents directed against human CD34, CD90, and CD117. HSCs in both human and NHP bone marrow were phenotypically identified using the anti-human antibodies against CD34 and CD90. A high percentage of human and NHP cells expressing CD34 and CD90 (also CD34+ and CD90+) also express CD117. Overall, we believe these data support the use of human antibody reagents for CD34 and CD90 to assess the effect of briquilimab on hematopoiesis in NHP in vitro and in vivo studies.

Figure 1: Briquilimab binds CD117 on CD34+CD90- and CD34+CD90+ cells in human and NHP bone marrow. Left panel: flow cytometric analysis of HSCs fluorescently labelled for CD34 and CD90. Right panel: the identified CD34+CD90- and CD34+CD90+ cells are then fluorescently labelled with 104D2 and briquilimab. Briquilimab and 104D2 non-competitively labeled the same population suggesting these antibodies bind different epitopes of NHP and human CD117.



Non-clinical studies in NHPs conducted at Stanford by Hye-Sook Kwon, Ph.D., now our Director, Biology and Translational Research, demonstrated briquilimab's ability to deplete bone marrow HSCs in a large animal model (Figure 2). Non-clinical studies in "humanized" mice demonstrated both depletion of human HSCs and engraftment of allogeneic donor HSCs. These studies supported the potential for briquilimab to deplete human stem cells prior to stem cell transplant in the IND filings for the ongoing clinical trials designed to assess the safety and efficacy of briquilimab in HSC transplants.

Figure 2: Representative flow cytometry analysis for cells fluorescently labeled with CD34 and CD90 on days 0, 10, and 42 post administration of 1.0 mg/kg briquilimab. CD34+ stem cells in the bone marrow of this NHP are transiently depleted. HSC depletion lasted up to 21 days in most animals and more than 42 days in one NHP receiving the highest dose.



Briquilimab for Severe Combined Immunodeficiency

SCID is a genetically heterogeneous group of over 20 monogenic conditions of the immune system characterized by the lack of normal T lymphocyte development, in addition to deficiencies of B cells, NK cells, or both in some forms which is currently curable only by hematopoietic cell transplant. The incidence of SCID is estimated at one in 80,000 live births across all ethnic groups. Due to the toxicities associated with the chemotherapy regimens used in standard allogeneic HCT to deplete endogenous HSC, some centers do not use conditioning regimens. SCID patients who undergo unconditioned HCT have relatively improved overall survival but often experience incomplete immune reconstitution characterized by inadequate T cell numbers and/or ongoing deficiency of B cell humoral immunity. This issue occurs more frequently in those patients who do not have a human leukocyte antigen-matched donor and who therefore receive T cell depleted haploidentical donor grafts.

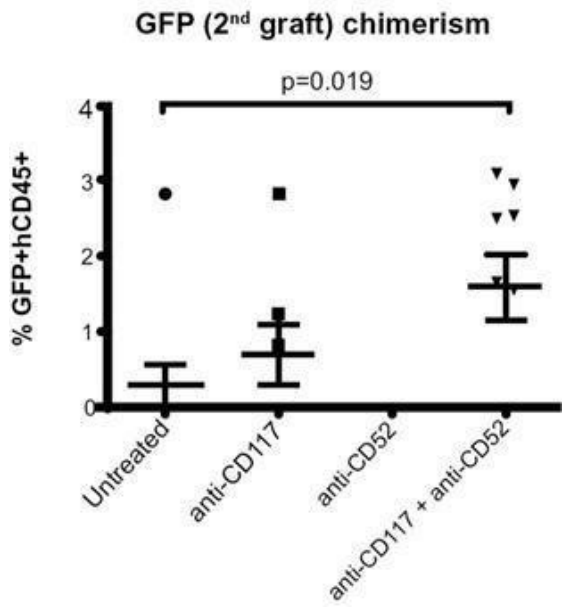
Patients who receive full or reduced doses of busulfan (a DNA damaging drug) tend to engraft well and have full lymphocyte reconstitution. However, due to busulfan's off-target toxic effects, these patients experience both short- and long-term complications. Since these patients receive busulfan as infants, they experience chronic complications such as growth retardation, cognitive defects, craniofacial abnormalities, liver toxicity, seizures and endocrine defects, including infertility, and increased cancer risk.

Pre-clinical Data for Briquilimab for Severe Combined Immunodeficiency

The ability of briquilimab to deplete human hematopoiesis was evaluated in humanized immune deficient mice that were stably engrafted with human hematopoietic grafts at Stanford by Aaron Logan, M.D., Ph.D., et al. The mice were treated with a single dose of either 0.5 or 3.0 mg/kg briquilimab. No significant differences in depletion of human cells and HSCs after six weeks of treatment were noted between the two dose levels of briquilimab. After a single treatment with briquilimab, mice were depleted of human cells in peripheral blood and bone marrow. Human HSCs and progenitor cells (CD45+CD34+CD117+) in the bone marrow were substantially decreased for six weeks after treatment with briquilimab.

To model human transplantation with a briquilimab-based conditioning regimen, humanized immune deficient mice that had been stably engrafted with human hematopoietic cells underwent a second transplant using conditioning with briquilimab with or without the addition of an anti-CD52 antibody (alemtuzumab) that depletes human lymphocytes. The second human HSC graft was from a different donor and hence, was allogeneic to the first human graft. This second donor graft was transduced with a lentiviral vector to express the marker green fluorescence protein ("GFP") to allow assessment of its engraftment. CD34+ GFP marked cells were injected into untreated control mice or mice that had been treated 23 – 25 days previously with briquilimab with or without anti-CD52. After six weeks, the blood of these secondarily transplanted mice was evaluated for evidence of GFP-marked second donor cells.

Figure 3: Briquilimab in addition to an anti-CD52 antibody demonstrated the highest level of engraftment. Engraftment was demonstrated by human CD45+ cells marked to express GFP.



Mice pre-treated with briquilimab and anti-CD52 demonstrated the highest level of engraftment, with 67% (six of nine) of human CD45+ cells also expressing GFP. In mice treated only with briquilimab, 43% (three of seven) were GFP positive. In control mice pre-treated with anti-CD52 alone, no mice (zero of seven) showed GFP expression, while 10% (one of ten) of the control mice not given any pre-treatment showed GFP expression (Figure 3).

We believe that this study can serve as a preclinical proof of concept of briquilimab conditioning enhanced engraftment with CD34+ progenitor cells in mice, suggesting it may be efficacious in an analogous clinical setting. Briquilimab appeared to be particularly effective in this setting when used along with an anti-CD52 antibody, which used a separate lymphodepleting agent to suppress rejection by the immune competent first allograft.

Clinical Data for Briquilimab for Severe Combined Immunodeficiency

We have an ongoing Phase 1/2 dose escalation open label clinical trial to evaluate briquilimab as the sole conditioning agent to achieve HSC engraftment in patients undergoing transplant for SCID. The primary endpoint in Phase 1 is to assess the safety and tolerability of briquilimab as a conditioning agent in SCID patients. The two primary efficacy endpoints in Phase 2 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 receive 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 will be followed for five years following transplant. This trial is currently open for enrollment at multiple clinical trial sites in the United States.

Other studies of SCID patients have shown functional T and B cell reconstitution in patients achieving long-term myeloid donor chimerism of at least 3%. SCID patients who fail to achieve durable donor cell engraftment from a first transplant may not be candidates for a second transplant using current conditioning agents due to the toxicity of the conditioning regimen and fragile nature of most SCID patients. These patients may remain on medically supportive immune therapies such as intravenous immunoglobulin ("IVIG") or receive an unconditioned "boost" transplant of donor cells which does not lead to sustained production of new immune cells.

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, 2022 in this open label clinical trial, ten T-B- SCID re-transplant patients have been treated in the ongoing SCID Phase 1/2 study. Seven of the ten transplanted patients have shown engraftment of donor cells and production of functional immune cells with up to three years of follow up. No briquilimab treatment-related SAEs have been reported through December 31, 2022 in this clinical trial.

We expect to complete enrollment in the Phase 1/2 clinical trial in 2023.

Briquilimab for Stem Cell Transplant in Acute Myeloid Leukemia and Myelodysplastic Syndrome

AML is a cancer of the blood and bone marrow, diagnosed in about 42,000 patients annually within the major global markets. It is primarily a disease of the elderly and is the most common type of acute leukemia diagnosed in adults. Patients with AML are deemed eligible for stem cell transplantation based on criteria which includes patient fitness (age and comorbidities) and response to initial treatment, comprising of about 40% of newly diagnosed AML patients. However, stem cell transplants are administered to approximately 40% of the eligible patient population due to current challenges with highly toxic conditioning regimens. Currently, approximately 8,000 patients with AML receive a stem cell transplant annually in the major global markets.

MDS is a group of disorders of the bone marrow where hematopoietic stem cells fail to properly differentiate into mature blood cells, leading to low blood cell count. Approximately 29,000 patients are diagnosed with MDS annually in the major global markets. Of all newly diagnosed MDS patients, about 35% have intermediate to higher-risk disease and about 30% of those are eligible for HCT based on age, comorbidities and blast count. However, about 60% of MDS patients do not receive transplants, even though they are otherwise eligible, due to the current challenges with highly toxic conditioning regimens. Currently, approximately 2,500 patients with MDS receive HCT each year.

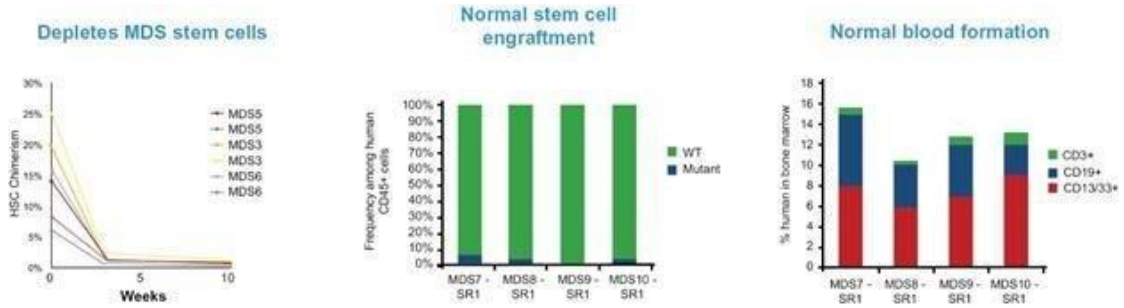
HCT offers the only known potentially curative therapy for many forms of AML and for MDS. Standard of care conditioning regimens can be divided into three groups: myeloablative conditioning, reduced intensity conditioning and non-myeloablative conditioning. Myeloablative conditioning with high dose busulfan, high dose melphalan or high dose radiation is the most aggressive approach and is associated with the lowest rates of disease relapse. However, due to significant toxicities, including treatment-related mortality, this approach is reserved for the most fit and younger patients. Reduced intensity conditioning with lower dose busulfan or lower dose melphalan can be used for a wider group of patients, but due to substantial toxicities, many patients remain ineligible. Non-myeloablative conditioning with low dose radiation (200 – 450 cGy, or centigray, a unit of radiation of exposure) is well tolerated but is associated with lower rates of successful donor chimerism and increased relapse rates compared to myeloablative or reduced-intensity conditioning.

Due to their age and co-morbidities, older (60 years and older) and less fit MDS and AML patients are typically unable to tolerate more intensive therapy and the toxicities associated with such treatments, and thus, have a worse prognosis than younger, fitter patients. Thus, safe and effective conditioning prior to HCT represents an unmet medical need for MDS and AML patients.

Preclinical Data for Briquilimab for Myelodysplastic Syndrome

Preclinical studies of immune deficient mice engrafted with MDS HSCs from patients with “high-risk and very high-risk disease” per IPSS-R criteria conducted at Stanford by Wendy Pang, M.D., Ph.D., now our Senior Vice President of Research and Translational Medicine, demonstrate the utility of anti-CD117 antibodies in the treatment of MDS. Mice xenografted with higher-risk MDS HSCs were treated with anti-human CD117 monoclonal antibody (“mAb”), SR-1 (the parent clone to briquilimab). Initial studies showed administration of either SR-1 or briquilimab resulted in well-tolerated and sustained depletion of MDS cells obtained from lower-risk MDS patients. Treatment of mice xenografted with higher-risk MDS HSCs cells resulted in transient depletion (Figure 4). Given the transient depletion of higher-risk MDS cells, studies were conducted to determine whether an anti-CD117 antibody followed by a normal human HSC allograft would lead to long-term disease amelioration of higher-risk disease. Results showed greater than 95% cytogenetically normal CD45+ cells 12 weeks after allograft transplant (Figure 4).

Figure 4: (A) CD117 mAb depletes MDS stem cells as demonstrated by decreasing HSC chimerism over time. (B) Normal stem cell engraftment occurs after stem cell depletion as shown by greater than 95% cytogenetically normal CD45+ cells 12 weeks after transplant in four higher-risk MDS-xenografted mice. (C) Normal blood formation results after stem cell engraftment with human cell lineages for T cells (CD3+), B cells (CD19+) and myeloid cells (CD13/33+) in the bone marrow of the four high-risk mice.



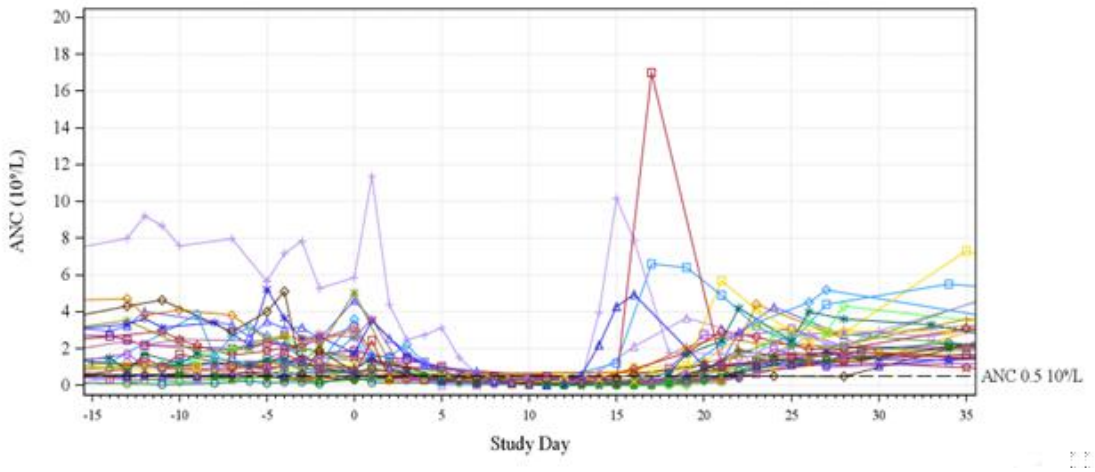
Mice xenografted with MDS HSCs from lower-risk or higher-risk patients were treated with SR-1 concurrently with an anti-mouse CD117 mAb, ACK2, to suppress endogenous mouse HSCs, and then transplanted with normal human UCB. Twelve weeks after this UCB HSC transplantation, both human myeloid and lymphoid cells like T cells and B cells were observed in the bone marrow (Figure 4), indicative of successful engraftment and sustained hematopoiesis by healthy UCB HSCs for both risk categories. Fluorescence in situ hybridization studies assessing clonal cytogenetic abnormalities confirmed that human CD45+ cells in both groups were predominantly (greater than 95%) cytogenetically normal in all SR-1 treated and UCB HSC engrafted mice. In contrast, MDS xenografted mice treated with the control antibody showed a persistence of high levels of MDS cells (greater than 95%) and were without second donor HSC engraftment.

Clinical Data for Briquilimab for Acute Myeloid Leukemia and Myelodysplastic Syndrome

We have an ongoing open label Phase 1 clinical trial to evaluate the safety and tolerability of briquilimab conditioning, in combination with low dose radiation (200-300 cGy) and fludarabine, in patients with AML or MDS undergoing blood stem cell transplantation. At clinical trial entry for the dose finding portion, all patients were transplant eligible but most still had evidence of measurable residual disease (MRD positive) as detected by cytogenetics, flow cytometry or next-generation sequencing. The dose of briquilimab is 0.6 mg/kg, fludarabine is administered at 30 mg/m2/day on transplant days -4, -3, and -2, and total body irradiation ("TBI") is delivered at 200 or 300 cGy on the day of transplant. The primary endpoints are to evaluate the safety, tolerability and pharmacokinetic parameters of briquilimab. Secondary endpoints include depletion of host HSCs, donor engraftment, donor chimerism, MRD clearance, non-relapse mortality, event-free survival and overall survival. Enrolled patients will be followed for one year. The overall study duration is anticipated to be approximately two years.

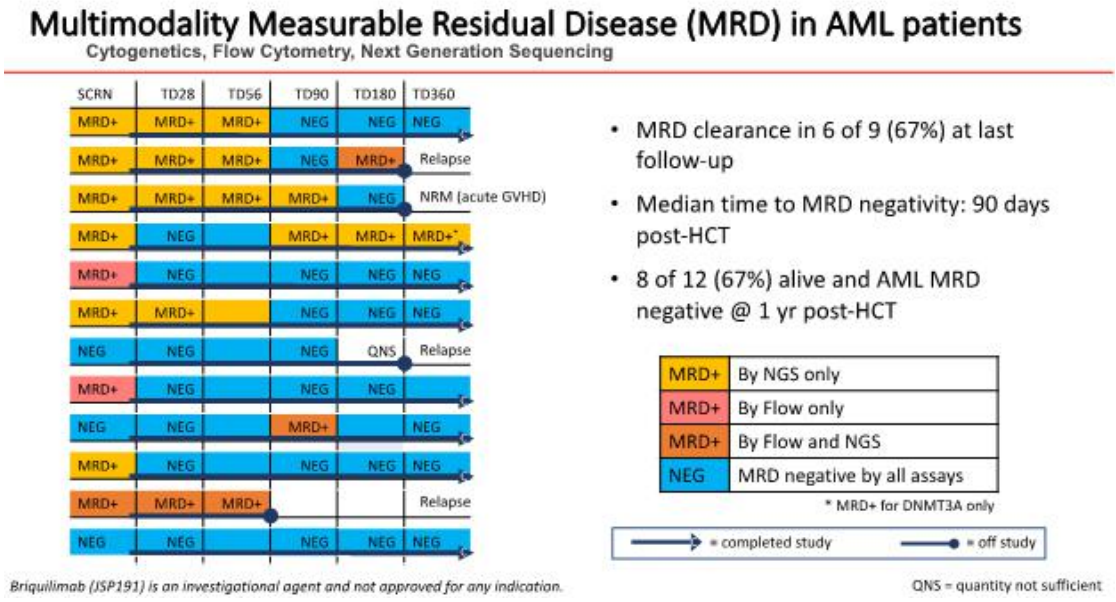
We have completed enrollment in this Phase 1 study. 31 MDS/AML patients have been enrolled. There were no briquilimab-related SAEs. All patients demonstrated a reduction of neutrophil counts ("ANC") below 500/uL following a single infusion of briquilimab (0.6 mg/kg) in combination with 200-300 cGy TBI and three days of 30 mg /m2/day fludarabine. Neutrophils are the most common type of white blood cell and are the first cells to engraft. Following transplant, all patients showed successful donor engraftment as evidenced by a recovery of neutrophil counts exceeding 500/uL in 13-24 days (Figure 5).

Figure 5: Neutrophil depletion and recovery in patients of the Phase 1 MDS/AML clinical trial. All patients demonstrated ANC greater than 500/uL within 13-24 days after transplant.



Subanalysis of the first twelve AML patients, median age of 70 years and all of whom were at least one year post-transplant, showed 67% relapse free survival, 75% overall survival and 8% non-relapse mortality at one year post-transplant. Nine of the twelve AML patients entered the trial with MRD, detected by either flow cytometry or next generation sequencing, and six of these patients no longer had evidence of MRD at one year post-transplant, with median time to MRD clearance of 90 days post-transplant (Figure 6). 67% of the AML patients are alive and without evidence of AML MRD at one year post-transplant. The trial has completed enrollment. We expect to present additional data from this study, including data from the MDS patients, in 2023.

Figure 6: Briquilimab MDS/AML Phase 1 preliminary clinical results in the first twelve AML patients.



No briquilimab-related SAEs have been reported, including no cases of oral mucositis, no cases of veno-occlusive disease. Among the 31 patients enrolled to date, there have been four cases of grade 2 acute GvHD, one case of late onset grade 3 GvHD, four cases of mild chronic GvHD and four cases of moderate chronic GvHD. SAEs have been reported in twenty patients, including infections, cardiovascular events, disease progression or relapse and secondary graft failure, which is loss of a previously functioning graft. None were related to treatment as determined by the investigator.

Briquilimab for Fanconi Anemia

FA is a rare but serious blood disorder that prevents bone marrow from making sufficient new red blood cells. It can also cause the bone marrow to make abnormal blood cells. FA typically presents at birth or early in childhood between five and ten years of age. Ultimately, it can lead to serious complications, including bone marrow failure, severe aplastic anemia and cancers such as AML and MDS. Treatment may include blood transfusions or medicine to create more red blood cells, but HCT is the only cure. Briquilimab for FA patients is being evaluated in a clinical trial collaboration with Stanford. Stanford has reported data for the first two patients, showing 100% donor myeloid chimerism and recovery of normal blood counts. Additional enrollment is ongoing.

Briquilimab for Sickle Cell Disease

SCD is an inherited blood disorder that affects the hemoglobin protein in red blood cells that delivers oxygen to tissues and organs. Approximately 300,000 infants are born with SCD annually worldwide, and the number of cases is expected to significantly increase. Currently, HCT is the only cure available for SCD. Allogeneic transplants as well as new autologous gene-edited transplants both currently rely on myeloablative conditioning with either busulfan or melphalan. We believe briquilimab could be a significant advance for patients, replacing these current agents which are known to be genotoxic and associated with limited efficacy and serious adverse effects, including veno-occlusive disease, infertility and secondary malignancies. Briquilimab for SCD patients is currently being evaluated in a clinical trial collaboration with the National Heart, Lung, and Blood Institute ("NHLBI"). The NHLBI has reported data for the first three patients in this study, showing 100% donor myeloid chimerism at 30 days and increased levels of hemoglobin versus pre-transplant baseline. Additional enrollment is ongoing.

Briquilimab for Chronic Granulomatous Disease

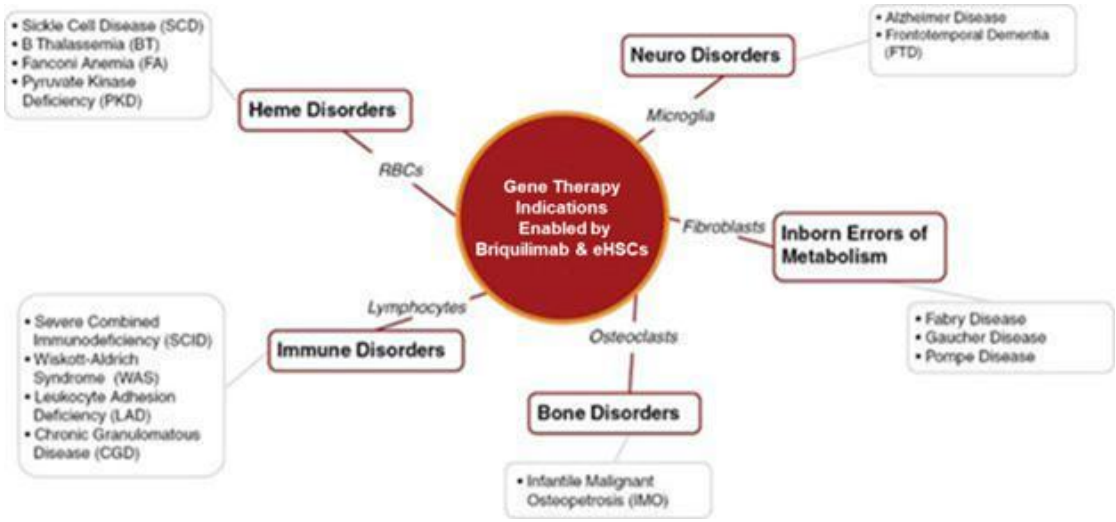
CGD is a rare, inherited disease of the immune system that develops in infancy or early childhood and results in severe and sometimes life-threatening infections. Allogeneic hematopoietic stem cell transplant is a proven cure for CGD. However, its use is limited because of the associated serious adverse effects and limited efficacy of current conditioning agents used to deplete stem cells in preparation for transplantation. Briquilimab for CGD patients will be evaluated in a clinical trial collaboration with the National Institute of Allergy and Infectious Diseases. Enrollment in this study is ongoing.

Briquilimab for GATA-2 MDS

GATA-2 MDS is a type of MDS characterized by mutations in the GATA-2 gene resulting in complex phenotypes including increased risk of infection, deficiencies of immune cells such as B- and NK-cells and overall poor prognosis. Allogeneic stem cell transplant may be used to cure these patients; however, use of current conditioning agents can be difficult due to the fragile health status of these patients. Briquilimab-based conditioning for GATA-2 MDS patients will be evaluated in a clinical trial collaboration with the National Cancer Institute ("NCI"). We expect this study to start enrollment in 2022.

Briquilimab for Gene Therapy

Every gene therapy in academia or industry that modifies HSCs also requires pre-transplant conditioning to make space in the patient's bone marrow for the gene therapy to engraft. These types of gene therapies address a broad range of disease including heme disorders (e.g., SCD, beta thalassemia, FA), immune disorders (e.g., SCID, CGD, leukocyte adhesion deficiency), lysosomal storage disorders (e.g., Fabry, Gaucher, Pompe), neurologic disorders (e.g., frontotemporal dementia, amyotrophic lateral sclerosis) and bone disorders (e.g., infant malignant osteoporosis) to name a few. Toxic alkylators like busulfan are still the standard conditioning regimens on which these gene therapies rely. As a result, their curative benefit is limited to patients that can tolerate the conditioning. Furthermore, gene therapy trials have also been halted by the FDA due to secondary malignancies discovered in study patients, which is a well-known risk of genotoxic conditioning. We believe that a briquilimab based conditioning regimen may be an effective alternative to toxic alkylators like busulfan for conditioning prior to the infusion of gene modified stem cells and are exploring potential studies for this use.



mRNA-Modified Hematopoietic Stem Cell Therapy

Our mRNA platform includes multiple approaches to developing product candidates that are currently in preclinical development and are designed to overcome key limitations of allogeneic and autologous gene-edited stem cell grafts. By using mRNA delivery or gene editing we believe we can reprogram allogeneic donor or gene-edited stem cells to have a transient proliferative and survival advantage, potentially leading to higher engraftment rates and reduced or eliminated GvHD by elimination of co-transplanted donor immune cells in allogeneic transplants.

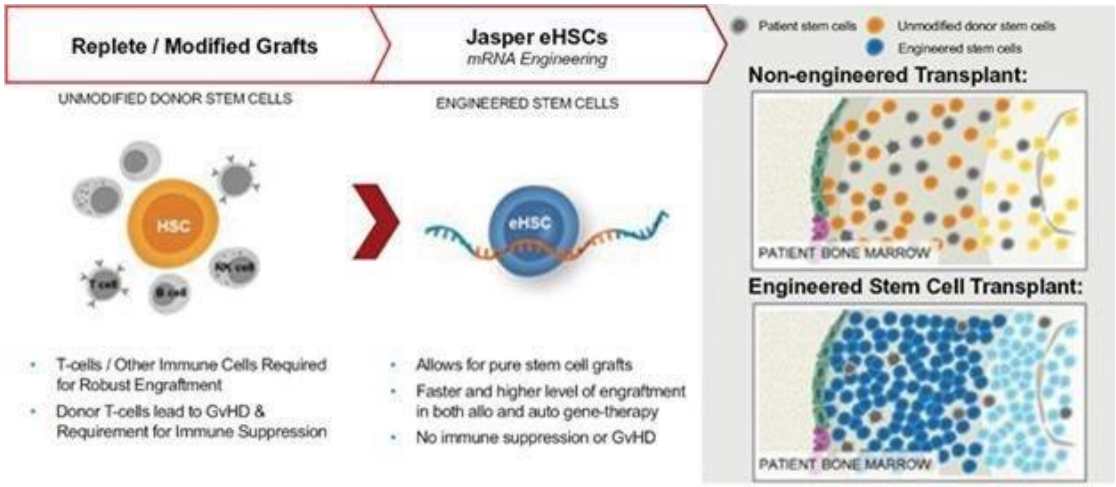
We are evaluating multiple approaches to use mRNA to increase engraftment of HSCs. One approach is to increase expression of CXCR4, a cell surface protein involved in cellular homing to the bone marrow. Another approach is to use mRNA to transiently increase expression of known variants of the stem cell factor receptor that signal independent of ligand (stem cell factor) concentration. Another approach in preclinical development is to use mRNA delivery or gene editing to express a variant of the stem cell factor receptor that is resistant to briquilimab. We are also working on other approaches to increase stem cell competitiveness that are not related to stem cell factor receptor signaling or cellular homing.

Initial in vitro experimental results in human cell lines show that expression of a constitutively active variant of the stem cell factor receptor can lead to cell line proliferation independent of stem cell factor concentration. In addition, these variant cells are not affected by briquilimab since the engineered cells proliferate independent of receptor signaling. Other in vitro experiments have shown that mRNA can be used to express these receptor variants and other target proteins, such as CXCR4, transiently on the cell surface. We have also identified potential receptor modifications that will keep stem cell factor binding intact but decrease or eliminate briquilimab binding.

In the setting of autologous gene edited stem cells, these technologies could lead to faster and more complete engraftment of edited cells without the need for toxic conditioning. Depending on the Jasper technology used, additional infusions of gene-modified cells may potentially be given to patients with low or fading responses to target protein production.

In the setting of allogeneic transplant, pure stem cell grafts can be used in place of today's replete or modified grafts. Similar to the autologous setting, we believe these technologies can lead to faster and more complete engraftment of donor stem cells without the need for toxic conditioning. In addition, by eliminating the need for donor passenger lymphocytes to drive engraftment, we can potentially eliminate the risk of GvHD and the need for long-term immune suppression. If approved, this approach may also increase the potential for use of partially matched grafts and expand the potential donor pool available for any given patient.

We are currently conducting an in-vivo preclinical assessment of various mRNA stem cell product constructs and plan to present data in 2023.



Opportunity Areas

There are other conditions and potential applications for briquilimab and the mRNA platform. We have assessed the existing therapeutic mast cell market, proliferative disorders of the stem cell and stem cell transplant market on a per-indication basis to estimate the potential number of patients that could benefit from our product candidates.

Mast Cell Disorders

Mast cells may also be the key cellular target for other inflammatory or autoimmune diseases such as chronic inducible urticaria ("CIndU"), prurigo nodularis, eosinophilic esophagitis, allergic asthma or inflammatory bowel disease. Similar to CSU, CIndU is characterized by development of hives and/or angioedema and redness in the skin. Unlike CSU, the trigger for CIndU patients can be diagnosed by assessment of various common provocations such as cold, heat, pressure, vibration and others. CIndU is thought to affect over one 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 anti-histamines and these patients could be eligible for biologic therapy depending on disease severity.

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 anti-histamines or biologics such as dupilumab.

Eosinophilic esophagitis is an immune disorder leading to build up of eosinophils in the esophagus and causes difficulty in eating, chronic reflux and/or the sensation of heartburn. Along with the buildup of eosinophils, there is typically buildup of other immune cells in the affected area including mast cells, basophils and lymphocytes. Patients may be treated with changes to diet, use of proton pump inhibitors, antihistamines and dupilumab.

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 may be responsive to agents that modulate mast cell response, including anti-histamines and anti IgE monoclonal antibody therapy.

Hematopoietic Stem Cell-Based Gene Therapies

The combination of stem cell transplantation and gene therapy has shown the potential to correct pathological genetic mutations but also the same limitations as unmodified stem cell transplantation, which include the toxicities of current conditioning agents. Furthermore, stem cell gene therapy requires larger doses of genetically modified stem cells for proper engraftment. We believe our product candidates can improve the field of stem cell gene therapy and address currently identified challenges.

In the United States alone, over 100,000 patients suffer from SCD, while about 52,000 patients are affected in the major markets in Europe. Approximately 58,000 patients from this pool are eligible for HCT or gene therapy as they have severe SCD.

Approximately 2,700 patients in the United States suffer from beta-thalassemia and about 16,000 in the European Union suffer from it annually. Approximately 70% of these patients can be classified to have beta-thalassemia major and, of that patient population, about 20%, or 2,600 patients, are eligible for stem cell transplant.

Agreements with Amgen

In November 2019, we entered into a worldwide exclusive license agreement with Amgen for briquilimab (formerly AMG-191 and JSP191) that 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 hematopoietic stem cells (c-kit)" granted by Stanford under the ISRA on June 2, 2020. As a result, we have worldwide exclusive rights to develop and commercialize briquilimab. 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 targeted conditioning program that contains patents and applications directed to humanized c-kit antibody. As of February 26, 2023, 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 February 26, 2023, this patent portfolio includes one issued U.S. patent and two European patents, as well as pending U.S., 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

We own eleven patent families directed to compositions and/or methods for hematopoietic stem cell transplantation, and one patent family directed to other methods of treating certain hematopoietic malignancies. These patent families include ten U.S. provisional applications, one U.S. utility application and three PCT applications. Any patents that grant from these applications would be expected to expire in 2042 or 2044, 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 is in 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 stem cell transplant and conditioning 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 two product candidates.

Competitors for our briquilimab CD117 targeted therapeutic program include the following:

- Celldex Therapeutics, Inc., which is developing an antibody to CD117 that is being studied in mast cell diseases;
- Acelyrin, Inc., which is developing an antibody to CD117 for mast cell diseases;
- Third Harmonic, Inc., which is developing small molecule inhibitors to CD117 for mast cell diseases;
- Allakos, Inc., which is developing an antibody to Siglec-8 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 for mast cell diseases;
- Gilead Sciences, Inc., which is developing an antibody to CD117 that may be used in combination with an antibody to CD47 for stem cell transplants;
- Actinium Pharmaceuticals, Inc., which is developing an antibody to CD45 that is fused to iodine-131 radioisotope for stem cell transplant;
- Beam Therapeutics, Inc., which is developing an antibody to CD117 that may be used in combination with their gene modified stem cells for gene therapy; and
- Molecular Templates Inc., which is developing an antibody to CD45 that is fused to an engineered Shiga-like toxin for stem cell transplant.

Competitors for our mRNA-modified stem cell therapy program include the following:

- Vor Biopharma, Inc., which is developing treatment-resistant marrow cells that enable CD33 targeted therapy;
- Sana Biotechnology, Inc., which is developing hypoimmune cells designed to evade rejection and enable persistence of differentiated cells;
- Ensoma Inc., which is developing viral vectors for delivery of cell modification payload in vivo;
- Orca Bio, which is developing precision allogeneic cell therapy products meant to safely and effectively replace a patient's blood and immune system; and
- Beam Therapeutics, Inc., which is developing stem cells designed to evade binding to their CD117 antibody for gene therapy.

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 while at Jasper, and while at Johnson & Johnson, AstraZeneca, Bristol-Myers Squibb, Portola, Amgen, Alexion and others. 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 two product candidates discovered through collaboration and our internal research efforts.

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 cGMP regulations for use in our clinical studies. 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 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.

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 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 IND application for human clinical testing, which must become effective before human clinical trials may begin;
- approval by an 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 cGCPs;
- 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 good clinical practices ("GCP"), and the integrity of clinical data in support of the BLA;
- payment of user 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. This order 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"). 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 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 trials 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. 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 are in full compliance 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 federal law, the submission of most BLAs is subject to an application user fee. 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 the 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. 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 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.

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 adverse reactions and production problems to the FDA, provide updated safety and efficacy information 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. 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:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning 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 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, as defined by such law, and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members.

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.

Employees and Human Capital

As of December 31, 2022, we employed 35 full-time employees. The 35 full-time employees were engaged in research and development, operations, finance, and business development. Eleven employees held Ph.D. degrees; one held M.D. degrees; and one held a VMD. 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, consultants and directors through the granting of stock-based compensation awards.

Facilities

We lease approximately 13,400 square feet of space for our headquarters in Redwood City, California under an 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.

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 (pursuant to the Business Combination Agreement, dated May 5, 2021, by and among AMHC, Merger Sub and Old Jasper). Pursuant to the terms of the Business Combination Agreement, 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 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.jaspertherapeutics.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 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. 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.
- 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.
    - We may not be successful in our efforts to identify, develop and commercialize 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.
    - Our mRNA stem cell platform is a novel technology that is not yet clinically validated for human use. The approaches we are taking to create mRNA stem cell grafts are unproven and may never lead to marketable products.
    - 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.

  - Stem cell transplant is a high-risk procedure with curative potential that may result in complications or adverse events for patients in our clinical trials or for patients that use any of our product candidates, if approved.

- 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 the 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 will 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. 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. For the years ended December 31, 2022 and 2021, we reported net losses of $37.7 million and $30.6 million, respectively. For the years ended December 31, 2022 and 2021, we reported negative operating cash flows of $45.9 million and $33.7 million, respectively. As of December 31, 2022, we had an accumulated deficit of $105.1 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 Chronic Spontaneous Urticaria ("CSU"), Lower to Intermediate Risk Myelodysplastic Syndrome ("LR-MDS") and other indications;
- continue the open label Phase 1/2 clinical trial for briquilimab for Severe Combined Immunodeficiency ("SCID"), and the open label Phase 1 clinical trial for briquilimab in patients with myelodysplastic syndrome ("MDS") or acute myeloid leukemia ("AML");
- 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;
- further develop our genome engineering capabilities;
- 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. As of December 31, 2022, our cash and cash equivalents were $38.3 million and we had an accumulated deficit of $105.1 million. Although we raised total estimated net proceeds of $101.4 million in January 2023 in connection with the issuance and sale of 69,000,000 shares of our common stock in an underwritten public offering and the issuance and sale of 2,337,496 shares pursuant to the ATM Prospectus Supplement (as defined below), 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, including any COVID-19-related delays or other effects on our development programs;
- the costs of continuing to build our technology platform, including in-licensing additional genome engineering technologies 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 ("FDA"), the European Medical 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 October 7, 2022, and which was declared effective on October 18, 2022 and will expire on October 18, 2025 (the "Shelf Registration Statement"). Pursuant to the Shelf Registration Statement, we may offer from time to time up to an aggregate of $150.0 million of securities, including any combination of common stock, preferred stock, debt securities, warrants, rights, units and depositary shares. On November 10, 2022, we entered into a Controlled Equity Offering^{SM} Sales Agreement with Cantor Fitzgerald & Co. (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 November 10, 2022, we filed under the Shelf Registration Statement a prospectus supplement with the SEC in connection with the ATM Offering (the "ATM Prospectus Supplement"), pursuant to which we may offer pursuant to the ATM Offering shares of our common stock having an aggregate offering price of up to $15.5 million. No securities were sold pursuant to the Shelf Registration Statement and the ATM Prospectus Supplement as of December 31, 2022. In January 2023, we issued and sold 2,337,496 shares of common stock pursuant to the ATM Prospectus Supplement for total estimated net proceeds of $4.5 million. In January 2023, we issued and sold 69,000,000 shares of our common stock in an underwritten public offering pursuant to the Shelf Registration Statement for total estimated net proceeds of $96.9 million pursuant to an underwriting agreement with Credit Suisse Securities (USA) LLC, William Blair & Company, L.L.C. and Oppenheimer & Co. Inc., as the representatives of the several underwriters named therein.

As of March 1, 2023, approximately $10.9 million remains allocated and available under the ATM Prospectus Supplement and approximately $31.0 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.

Our management believes that our existing cash and cash equivalents as of December 31, 2022, together with the cash proceeds received upon the closing of the public offering in January 2023, will be sufficient to fund our operating plan for at least twelve months from the date of filing of this Annual Report on Form 10-K. However, 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. If we are unable to obtain funding when and as needed on a timely basis, 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 affect our business, financial condition and results of operations. Any of the above events could significantly harm our business, prospects, financial condition and results of operations and cause the price of our common stock to decline.

We have a limited operating history and 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. Old Jasper was 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 young business, 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.

As a result of our history of losses and negative cash flows from operations, 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 raised substantial doubt about our ability to continue as a going concern beyond the 12-month period reported by us and our auditors in prior periods. While management believes that our existing cash and cash equivalents as of December 31, 2022, together with the cash proceeds received upon the closing of the public offering in January 2023, will be sufficient to fund our operating plan for at least twelve months from the date of filing of this Annual Report on Form 10-K, 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 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.

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.

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, 2022, we had net operating loss carryforwards for federal income tax purposes of $68.8 million that can be carried forward indefinitely. As of December 31, 2022, we had net operating loss carryforwards for state income tax purposes of $120.0 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. 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, 2022.

Our business could be adversely affected by the effects of health pandemics or epidemics, including the current COVID-19 pandemic and future outbreaks of the disease, in regions where we or third parties on which we rely have concentrations of clinical trial sites or other business operations.

Our business could be adversely affected by the effects of health pandemics or epidemics, including the current COVID-19 pandemic and future outbreaks of the disease, including any variants thereof. For example, enrollment in clinical trials may be delayed. Although we have reopened our offices and some employees have transitioned back to working on site, there is a lack of uniformity of restrictions and requirements among our clinical trial sites, and future restrictions could be imposed. This uncertainty and the evolving nature of policies and restrictions may negatively impact productivity, disrupt our business and further delay clinical programs and timelines, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course, which could negatively impact our business, operating results and financial condition.

The spread of COVID-19, which has caused a broad impact globally, may affect us economically. While the potential economic impact brought by, and the duration of, the COVID-19 pandemic may be difficult to assess or predict, it has resulted in significant disruption of global financial markets. This disruption, if sustained or recurrent, could make it more difficult for us to access capital, which could in the future negatively affect our liquidity. In addition, a recession or market correction resulting from the spread of COVID-19 or the global impacts thereof could materially affect our business and the value of our common stock. These effects could have an adverse impact on our operations.

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.

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 investigational 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 willingness of clinical investigators to place patients in the clinical trials, and the willingness of patients to enroll in a clinical trial studying a first-in-human cell therapy;

- the initiation and successful patient enrollment and completion of additional clinical trials of briquilimab in CSU and LR-MDS on a timely basis;
- the frequency and severity of adverse events in the clinical trials;
- the successful and timely completion of our ongoing Phase 1/2 clinical trial of briquilimab for the treatment of SCID;
- 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, under the FDA's current Good Clinical Practices ("cGCPs") 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 results of clinical trials conducted by third parties in hematopoietic cell transplant ("HCT") if such trials result in changes to the standard of care for HCT or otherwise cause us to change our clinical trial protocols;
- 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.

We may not be successful in our efforts to identify, develop and commercialize 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 identify, develop and commercialize additional product candidates based on, or complementary with, our technology platform. While we are currently initiating clinical trials in LR-MDS and CSU this year, are currently conducting a Phase 1/2 clinical trial of briquilimab as a conditioning agent prior to allogenic transplant for SCID patients, and are planning a registrational package of briquilimab as a conditioning agent prior to allogenic re-transplant in SCID patients, our other product development programs, including our mRNA stem cell platform, are still in the research or preclinical stage of development. Our research programs may fail to identify additional product candidates for clinical development for a number of reasons. Our research methodology may be unsuccessful in identifying potential product candidates, our potential product candidates 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, although we believe our technology platform will position us to rapidly expand our portfolio of product candidates beyond our current product candidates, our ability to expand our portfolio may never materialize.

If any of these events occur, we may be forced to abandon our research or development efforts for a program or programs, which would have a material adverse effect on our business, financial condition, results of operations and prospects. Research programs to identify 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 January 10, 2023, we announced, as part of an overall portfolio prioritization, that we will focus on the development of our lead product candidate, briquilimab (formerly known as JSP191), in chronic mast and stem cell diseases as well as a conditioning agent for stem cell transplant in rare diseases. This portfolio includes a new program as a therapeutic for patients with CSU, along with our existing programs for briquilimab as a therapeutic for patients with LR-MDS and as a conditioning agent for stem cell transplant in patients with sickle cell disease, Fanconi anemia or severe combined immunodeficiency. Our resource allocation decisions may cause us to fail to capitalize on viable commercial medicines or profitable market opportunities. 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.

Our mRNA stem cell platform is a novel technology that is not yet clinically validated for human use. The approaches we are taking to create mRNA stem cell grafts are unproven and may never lead to marketable products.

We are developing mRNA stem cell grafts for transplant into the human body. Although there have been significant advances in the field of use of RNA or DNA to edit cells ex vivo prior to transplant in recent years, these technologies have only more recently been applied to HSCs, and our approach is new and unproven. The scientific evidence to support the feasibility of developing mRNA stem cell grafts is both preliminary and limited. Successful development of mRNA stem cell grafts by us will require solving a number of challenges, including:

- obtaining regulatory authorization from the FDA and other regulatory authorities;
- identifying appropriate molecular or genetic targets for modification within HSCs;
- developing and deploying consistent and reliable processes for procuring cells from consenting third-party donors, isolating HSCs from such donor cells, modifying target molecules within such HSCs, storing and transporting the resulting mRNA stem cell grafts for therapeutic use and finally infusing these mRNA stem cell grafts into patients;
- utilizing these mRNA stem cell graft product candidates in combination or in sequence with companion therapeutics, which may increase the risk of adverse side effects;
- avoiding potential complications of mRNA stem cell graft transplants, including failure to engraft, rejection by host or lack of functionality, any of which could result in serious side effects or death;
- educating medical personnel regarding the potential side effect profile of our product candidates, particularly those that may be unique to our mRNA stem cell grafts;
- understanding and addressing variability in the quality of a donor's cells, which could ultimately affect our ability to manufacture product in a reliable and consistent manner;

- developing processes for the safe administration of mRNA stem cell graft product candidates, including long-term follow-up and registries, for all patients who receive these product candidates;
- relying on third parties to find suitable healthy donors;
- manufacturing product candidates to our specifications and in a timely manner to support our clinical trials and, if approved, commercialization;
- sourcing clinical and, if approved by applicable regulatory authorities, commercial supplies for the materials used to manufacture and process product candidates;
- developing a manufacturing process and distribution network that can provide a stable supply with a cost of goods that allows for an attractive return on investment; and
- establishing sales and marketing capabilities ahead of and after obtaining any regulatory approval to gain market acceptance, and obtaining coverage, adequate reimbursement and pricing by third-party payors and governmental healthcare programs.

We may decide to alter or abandon our initial mRNA stem cell grafts platform as new data become available and we gain experience in developing mRNA stem cell grafts. We cannot be sure that our programs will yield satisfactory products that are safe and effective, scalable or profitable in our initial indication or any other indication we pursue.

Moreover, actual or perceived safety issues, including as a result of adverse developments in our mRNA stem cell graft platform or in genome engineering programs undertaken by third parties or of the adoption of novel approaches to treatment, may adversely influence the willingness of subjects to participate in our clinical trials, or, if one of our product candidates is approved by applicable regulatory authorities, of physicians to subscribe to the novel treatment mechanics or of patients to provide consent to receive a novel treatment despite its regulatory approval. The FDA or other applicable regulatory authorities may require specific post-market studies or additional information that communicates the benefits or risks of our products. New data may reveal new risks of our product candidates at any time prior to or after regulatory approval.

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 and our other product candidates, and our mRNA stem cell platform or other cell-based companion 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.

There have been no clinical trials of our mRNA stem cell platform. In the genetic medicine field, there have been several significant adverse events from genetically engineered treatments in the past, including reported cases of leukemia and death. There can be no assurance that our mRNA stem cell grafts will not cause undesirable side effects, as improper modification of a patient's DNA could lead to lymphoma, leukemia or other cancers, or other aberrantly functioning cells.

A significant risk in any genetically engineered product candidate is that "off-target" gene alterations may occur, which could cause serious adverse events, undesirable side effects or unexpected characteristics. Although we and others have demonstrated the ability to improve the specificity of gene alterations in a laboratory setting, we cannot be certain that off-target alterations will not occur in any of our planned or future clinical trials, and the lack of observed side effects in preclinical studies does not guarantee that such side effects will not occur in human clinical trials.

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, gene therapy or genome engineering fields, 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 genome engineering as a treatment approach;
- 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;
- potential disruptions caused by the COVID-19 pandemic, including difficulties in initiating clinical sites, enrolling and retaining participants, diversion of healthcare resources away from clinical trials, travel or quarantine policies that may be implemented, and other factors;
- 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;
- the requirement for HCT to be performed in centers that specialize in this procedure; and
- changes to diagnostic technologies, methodologies or criteria used to identify HCT patients at high risk for relapse.

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. Ethical, social and legal concerns about genetic medicines generally and genome engineering technologies specifically could result in additional regulations restricting or prohibiting the marketing of our product candidates. 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;
- public attitudes regarding genetic medicine generally and genome engineering technologies specifically;
- the willingness of the target patient population to try novel biologics and of physicians to prescribe these treatments, as well as their willingness to accept an intervention that involves the alteration of the patient's gene;
- 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 genome engineering, autoimmune and oncology fields are 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 for our conditioning program for CD-117, a receptor for stem cell factor ("SCF") that is expressed on the surface of hematopoietic stem and progenitor cells, include the following:

- Celldex Therapeutics, Inc., which is developing an antibody to CD117 that is being studied in mast cell diseases;
- Acelyrin, Inc., which is developing an antibody to CD117 for mast cell diseases;
- Third Harmonic, Inc., which is developing small molecule inhibitors to CD117 for mast cell diseases;
- Allakos, Inc., which is developing an antibody to Siglec-8 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 for mast cell diseases;
- Gilead Sciences, Inc., which is developing an antibody to CD117 that may be used in combination with an antibody to CD47 for stem cell transplants;
- Actinium Pharmaceuticals, Inc., which is developing an antibody to CD45 that is fused to iodine-131 radioisotope for stem cell transplant;
- Beam Therapeutics, Inc., which is developing an antibody to CD117 that may be used in combination with their gene modified stem cells for gene therapy; and
- Molecular Templates Inc., which is developing an antibody to CD45 that is fused to an engineered Shiga-like toxin for stem cell transplant.

Competitors for our mRNA-modified stem cell therapy program include the following:

- Vor Biopharma, Inc., which is developing treatment-resistant marrow cells that enable CD33 targeted therapy;
- Sana Biotechnology, Inc., which is developing hypoimmune cells designed to evade rejection and enable persistence of differentiated cells;
- Ensoma Inc., which is developing viral vectors for delivery of cell modification payload in vivo;
- Orca Bio, which is developing precision allogeneic cell therapy products meant to safely and effectively replace a patient's blood and immune system; and
- Beam Therapeutics, Inc., which is developing stem cells designed to evade binding to their CD117 antibody for gene therapy.

Adverse public perception of genetic medicines, and genome engineering in particular, may negatively impact regulatory approval of, and/or demand for, our potential products.

Some of our mRNA stem cell grafts or other cell-based therapeutics we develop may be created by altering the human genome. The clinical and commercial success of our potential products will depend in part on public understanding and acceptance of the use of genome engineering for the prevention or treatment of human diseases. Public attitudes may be influenced by claims that genome engineering is unsafe, unethical or immoral, and, consequently, our current or future product candidates may not gain the acceptance of the public or the medical community. Adverse public attitudes may adversely impact our ability to enroll clinical trials. Moreover, our success will depend upon physicians prescribing, and their patients being willing to receive, treatments that involve the use of product candidates in lieu of, or in addition to, existing treatments with which they are already familiar and for which greater clinical data may be available.

In addition, genome engineering technology is subject to public debate and heightened regulatory scrutiny due to ethical concerns relating to the application of genome engineering technology to human embryos or the human germline. For example, in the United States, germline alteration for clinical application has been expressly prohibited since enactment of a December 2015 FDA ban on such activity. Prohibitions are also in place in the United Kingdom, across most of Europe, in China and many other countries around the world. In the United States, the National Institutes of Health ("NIH") has announced that the agency would not fund any use of gene engineering technologies in human embryos, noting that there are multiple existing legislative and regulatory prohibitions against such work, including the Dickey-Wicker Amendment, which prohibits the use of appropriated funds for the creation of human embryos for research purposes or for research in which human embryos are destroyed. Adverse events in our preclinical studies or clinical trials or those of our competitors or of academic researchers utilizing genome engineering technologies, even if not ultimately attributable to product candidates we may identify and develop, and the accompanying publicity could result in increased governmental regulation, unfavorable public perception, potential regulatory delays in the testing or approval of potential product candidates we may identify and develop, stricter labeling requirements for those product candidates that are approved and a decrease in demand for any such product candidates.

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. Moreover, unlike chemical and other biological pharmaceuticals, the physical and chemical properties of a gene-engineered cell therapies cannot be fully characterized. 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.

mRNA stem cell grafts consist of engineered human cells, and the process of manufacturing such product candidates is complex, concentrated with a limited number of suppliers, highly regulated and subject to numerous risks. Manufacturing such product candidates involves harvesting cells from a donor or from the patient, altering the cells *ex vivo* using genome engineering technology, cryopreservation, storage and eventually shipment and infusing the cell product into the patient's body. Our manufacturing process will be susceptible to product loss or failure, or product variation that may negatively impact patient outcomes, due to logistical issues associated with the collection of starting material from the donor, shipping such material to the manufacturing site, shipping the final product back to the clinical trial recipient, preparing the product for administration, infusing the patient with the product, manufacturing issues or different product characteristics resulting from the differences in donor starting materials, variations between reagent lots, interruptions in the manufacturing process, contamination, equipment or reagent failure, improper installation or operation of equipment, vendor or operator error, inconsistency in cell growth and variability in product characteristics. our manufacturing process, like that of a number of other cell therapy companies, is also characterized by limited numbers of suppliers, and in some cases sole source suppliers, with the manufacturing capabilities and know-how to create or source the materials, such as donor marrow cells and electroporation machines, used in our cell manufacturing. While we pursue multiple sources for the critical components of our manufacturing process, we may not be successful in securing these additional sources at all or on a timely basis. If microbial, viral or other contaminations are discovered in our product candidates or in any of the manufacturing facilities in which our product candidates or other materials are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination.

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. For example, our products are considered to contain genetically modified organisms or cells, which are regulated in different ways depending upon the country in which preclinical research or clinical trials are conducted. 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, which may be particularly challenging for some of the rare genetically defined diseases we are targeting in our most advanced programs, 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.

Stem cell transplant is a high-risk procedure with curative potential that may result in complications or adverse events for patients in our clinical trials or for patients that use any of our product candidates, if approved.

Stem cell transplant has the potential to cure patients across multiple diseases, but its use carries with it risks of toxicity, serious adverse events and death. Because many of our therapies are used to prepare or treat patients undergoing stem cell transplant, patients in our clinical trials or patients that use any of our product candidates may be subject to many of the risks that are currently inherent to this procedure. In particular, stem cell transplant involves certain known potential post-procedure complications that may manifest several weeks or months after a transplant and that may be more common in certain patient populations. For example, up to 20% of patients with inherited metabolic disorders treated with a transplant experience primary engraftment failure, resulting in severe complications, including death. Another example is autoimmune cytopenia, a known and severe frequent complication of the transplant procedure in patients with non-malignant diseases, such as inherited metabolic diseases, that can result in death. There is also a risk of graft-versus-host disease, a potentially serious complication in which the grafted cells attack and damage the patient's healthy cells, which can be severe and sometimes life-threatening. If these or other serious adverse events, undesirable side effects, or unexpected characteristics are identified during the development of any of our product candidates, we may need to limit, delay or abandon our further clinical development of those product candidates, even if such events, effects or characteristics were the result of stem cell transplant or related procedures generally, and not directly or specifically caused or exacerbated by our product candidates. All serious adverse events or unexpected side effects are continually monitored per the clinical trial's approved protocol. If serious adverse events are determined to be directly or specifically caused or exacerbated by our product candidates, we would follow the trial protocol's requirements, which call for our data safety monitoring committee to review all available clinical data in making a recommendation regarding the trial's continuation.

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.

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. 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. 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.

The regulatory landscape that will govern our product candidates is uncertain; regulations relating to more established cellular therapy products are still developing, and changes in regulatory requirements could result in delays or discontinuation of development of our product candidates or unexpected costs in obtaining regulatory approval. The FDA and other governing bodies may disagree with our regulatory plan, and we may fail to obtain regulatory approval of our product candidates.

Because our product candidates and technology platform involve genetic and cellular engineering, we are subject to many of the challenges and risks that other genetically engineered biologics and cellular therapies face, including:

- regulatory requirements or guidance regarding the requirements governing genetic and cellular engineering products have changed and may continue to change in the future;
- to date, only a limited number of products that involve genetic or cellular engineering have been approved globally;
- improper modulation of a gene sequence, including unintended alterations or insertion of a sequence into certain locations in a patient's chromosomes, could lead to cancer, other aberrantly functioning cells or other diseases, as well as death;
- corrective expression of a missing protein, or deletion of an existing protein, in patients' cells could result in the protein or cell being recognized as foreign, and lead to a sustained immunological reaction against the expressed protein or expressing cells, which could be severe or life-threatening;
- regulatory agencies may require extended follow-up observation periods of patients who receive treatment using genetic or cellular engineering products including, for example, the FDA's recommended 15-year follow-up observation period for these patients, and we will need to adopt such observation periods for our product candidates if required by the relevant regulatory agency, which could vary by country or region; and
- the fields of genetic and cellular engineering are subject to a number of intellectual property disputes.

The regulatory requirements that will govern any mRNA stem cell grafts or other novel genetically engineered product candidates we develop may change. Within the broader genetic medicine field, we are aware of a limited number of gene therapy products that have received marketing authorization from the FDA and the EMA. Even with respect to more established products that fit into the categories of gene therapies or cell therapies, the regulatory landscape is still developing. Regulatory requirements governing gene therapy products and cell therapy products have changed frequently and will likely continue to change in the future. Moreover, there is substantial, and sometimes uncoordinated, overlap in those responsible for regulation of existing gene therapy products and cell therapy products. For example, in the United States, the FDA has established the Office of Tissues and Advanced Therapies ("OTAT") within its Center for Biologics Evaluation and Research ("CBER") to consolidate the review of gene therapy and related products, and the Cellular, Tissue and Gene Therapies Advisory Committee to advise CBER on its review. In addition to FDA oversight and oversight by IRBs under guidelines promulgated by the NIH, gene therapy clinical trials are also subject to review and oversight by an institutional biosafety committee ("IBC"), a local institutional committee that reviews and oversees research utilizing recombinant or synthetic nucleic acid molecules at that institution. Before a clinical study can begin at any institution, that institution's IRB and its IBC assess the safety of the research and identify any potential risk to public health or the environment. While the NIH guidelines are not mandatory unless the research in question is being conducted at or sponsored by institutions receiving NIH funding of recombinant or synthetic nucleic acid molecule research, many companies and other institutions not otherwise subject to the NIH guidelines voluntarily follow them. Moreover, serious adverse events or developments in clinical trials of gene or cellular therapy product candidates conducted by others may cause the FDA or other regulatory bodies to initiate a clinical hold on our clinical trials or otherwise change the requirements for approval of any of our product candidates. Although the FDA decides whether individual gene or cellular therapy protocols may proceed, the review process and determinations of other reviewing bodies can impede or delay the initiation of a clinical trial even if the FDA has reviewed the trial and approved its initiation.

The same applies in the European Union. The EMA's Committee for Advanced Therapies ("CAT") is responsible for assessing the quality, safety and efficacy of advanced-therapy medicinal products. The role of the CAT is to prepare a draft opinion on an application for marketing authorization for a cell or gene therapy or other novel therapeutic medicinal candidate that is submitted to the Committee for Medicinal Products for Human Use ("CHMP") before CHMP adopts its final opinion. In the European Union, the development and evaluation of an advanced therapeutic medicinal product must be considered in the context of the relevant European Union guidelines. The EMA may issue new guidelines concerning the development and marketing authorization for these medicinal products and require that we comply with these new guidelines. As a result, the procedures and standards applied to gene and cell therapy products may be applied to our mRNA stem cell grafts, but that remains uncertain at this point.

Adverse developments in post-marketing experience or in clinical trials conducted by others of gene therapy products, cell therapy products or products developed through the application of a genome engineering technology may cause the FDA, the EMA and other regulatory bodies to revise the requirements for development or approval of our mRNA stem cell grafts may develop or limit the use of products utilizing genome engineering technologies, either of which could materially harm our business. In addition, the clinical trial requirements of the FDA, the EMA and other regulatory authorities and the criteria these regulators use to determine the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty and intended use and market of the potential products. The regulatory approval process for novel product candidates, such as our mRNA stem cell grafts, can be more expensive and take longer than for other, better known or more extensively studied pharmaceutical or other product candidates. Regulatory agencies administering existing or future regulations or legislation may not allow production and marketing of products utilizing genome engineering technology in a timely manner or under technically or commercially feasible conditions. In addition, regulatory action or private litigation could result in expenses, delays or other impediments to our product candidate development, research programs or the commercialization of resulting products.

The regulatory review committees and advisory groups described above and the new guidelines they promulgate may lengthen the regulatory review process, require us to perform additional studies or trials, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of these treatment candidates, or lead to significant post-approval limitations or restrictions. Currently, OTAT requires a 15-year follow-up for each patient who receives a genetically engineered cell or gene therapy. This requirement applies to all patients treated in trials during clinical development prior to approval. Following approval, such prolonged follow-up could continue to be required. As we advance our product candidates and research programs, we will be required to consult with these regulatory and advisory groups and to comply with applicable guidelines. If we fail to do so, we may be required to delay or discontinue development of our mRNA stem cell grafts and any other product candidates we identify and develop.

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, open label Phase 1/2 and Phase 1 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.

Negative public opinion of gene therapy and increased regulatory scrutiny of gene therapy and genetic research may adversely impact public perception of our future product candidates.

Our potential therapeutic products involve introducing genetic material into patients' cells. The clinical and commercial success of our potential products will depend in part on public acceptance of the use of gene therapy and gene regulation for the prevention or treatment of human diseases. Public attitudes may be influenced by claims that gene therapy and gene regulation are unsafe, unethical or immoral, and, consequently, our products may not gain the acceptance of the public or the medical community. Adverse public attitudes may adversely impact our ability to enroll clinical trials. Moreover, our success will depend upon physicians prescribing, and their patients being willing to receive, treatments that involve the use of product candidates we may develop in lieu of, or in addition to, existing treatments with which they are already familiar and for which greater clinical data may be available.

More restrictive government regulations or negative public opinion would have a negative effect on our business or financial condition and may delay or impair the development and commercialization of our product candidates or demand for any products once approved. For example, in 2003, trials using early versions of murine gamma-retroviral vectors, which integrate with, and thereby alter, the host cell's DNA, have led to several well-publicized adverse events, including reported cases of leukemia. Adverse events in our clinical trials, even if not ultimately attributable to our product candidates, and the resulting publicity could result in increased governmental regulation, unfavorable public perception, potential regulatory delays in the testing or approval of our product candidates, stricter labeling requirements for those product candidates that are approved, and a decrease in demand for any such product candidates. The risk of cancer remains a concern for gene therapy, and we cannot assure that it will not occur in any of our planned or future clinical trials. In addition, there is the potential risk of delayed adverse events following exposure to gene therapy products due to persistent biological activity of the genetic material or other components of products used to carry the genetic material. If any such adverse events occur, commercialization of our product candidates or further advancement of our clinical trials could be halted or delayed, which would have a negative impact on our business and operations.

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.

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.

The regenerative medicine advanced therapy ("RMAT") designation by the FDA 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 an RMAT designation for our product candidates if the clinical data support such a designation for one or more product candidates. An RMAT is defined as cell and gene therapies, therapeutic tissue engineering products, human cell and tissue products, and combination products using any such therapies or products. Gene therapies, including genetically modified cells that lead to a durable modification of cells or tissues may meet the definition of a regenerative medicine therapy. The RMAT program is intended to facilitate efficient development and expedite review of RMATs, which are intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition and for which preliminary clinical evidence indicates that the drug has the potential to address unmet medical needs for such disease or condition. A biologics license application for a regenerative medicine therapy that has received RMAT designation may be eligible for priority review or accelerated approval. An RMAT may be eligible for priority review if it treats a serious condition and, if approved, would provide a significant improvement in the safety or effectiveness of the treatment of the condition. An RMAT may be eligible for accelerated approval through surrogate or intermediate endpoints reasonably likely to predict long-term clinical benefit or reliance upon data obtained from a meaningful number of sites. Benefits of such designation also include early interactions with the FDA to discuss any potential surrogate or intermediate endpoint to be used to support accelerated approval. A regenerative medicine therapy with RMAT designation that is granted accelerated approval and is subject to post-approval requirements may fulfill such requirements through the submission of clinical evidence from clinical trials, patient registries, or other sources of real world evidence, such as electronic health records; the collection of larger confirmatory data sets; or post-approval monitoring of all patients treated with such therapy prior to its approval.

Designation as an RMAT is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for designation as a RMAT, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of RMAT designation for our product candidates may not result in a faster development process, review or approval compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify for RMAT designation, the FDA may later decide that the biological products no longer meet 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 issued recent draft 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.

In 2017, Congress passed the FDA Reauthorization Act of 2017 (the "FDARA"). FDARA, among other things, codified the FDA's pre-existing regulatory interpretation to require that a drug sponsor demonstrate the clinical superiority of an orphan drug that is otherwise the same as a previously approved drug for the same rare disease in order to receive orphan drug exclusivity. Under omnibus legislation signed by President Trump on December 27, 2020, the requirement for a product to show clinical superiority applies to any drug and biologic that received orphan drug designation before enactment of FDARA in 2017 but has not yet been approved or licensed by the FDA. We do not know if, when, or how the FDA may change the orphan drug regulations and policies in the future, and it is uncertain how any changes might affect our business. Depending on what changes the FDA may make to its orphan drug regulations and policies, our business could be adversely impacted.

Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new biologics or modifications to cleared or approved biologics to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have furloughed critical FDA 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.

Separately, in response to the COVID-19 pandemic, on March 10, 2020, the FDA announced its intention to postpone most inspections of foreign manufacturing facilities, and on March 18, 2020, the FDA temporarily postponed routine surveillance inspections of domestic manufacturing facilities. Subsequently, on July 10, 2020, the FDA announced its intention to resume certain on-site inspections of domestic manufacturing facilities subject to a risk-based prioritization system. Increased cases associated with a COVID-19 variant led the FDA to again pause inspections, although the FDA announced in February 2022 that it would resume routine domestic surveillance inspections and that it would proceed with certain foreign surveillance inspections where country conditions permit. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

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 penalties up to and including criminal prosecution.

We and our CROs will be required to comply with regulations, including cGCPs 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 cGCP regulations through periodic inspections of clinical trial sponsors, principal investigators and trial sites. If we or our CROs fail to comply with applicable cGCPs, 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 cGCPs. 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 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 C-kit antibody. We also rely on our license agreement with Stanford, whereby we license a patent portfolio applicable to our targeted conditioning and Stem Cell Graft programs 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. For example, we employ a range of genome engineering technologies that are owned by third parties in our preclinical studies, as well as to manufacture the supply of mRNA stem cell grafts or other cell therapies used for clinical trials and, if approved, for commercialization of our product candidates. 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. Although we try to ensure that our employees and consultants do not use the proprietary information or know-how of others in their work for us, 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, a new unitary patent system will likely be introduced by the end of 2023, which would significantly impact European patents, including those granted before the introduction of such a system. Under the unitary patent system, European applications will soon have the option, upon grant of a patent, of becoming a Unitary Patent which will be 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 will 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 any potential changes.

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. In the U.S., recently enacted legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. 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 and the Biden administration have each 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. To those ends, in October 2020, the FDA issued final guidance that describes procedures drug manufacturers can follow to facilitate importation of prescription drugs, including biological products, that are FDA-approved, manufactured abroad, authorized for sale in any foreign country, and originally intended for sale in that foreign country.

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 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, 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, which shall take 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 an estimated $4,000 a year in 2024 and, thereafter beginning in 2025, at $2,000 a year.

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 information 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 further laws and regulations limiting the processing of personal data, including genetic, biometric or health data.

Further, Brexit has led and could also lead to legislative and regulatory changes and may increase our compliance costs. As of January 1, 2021 and the expiry of transitional arrangements agreed to between the United Kingdom and the European Union, 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), exposing us to two parallel regimes, each of which authorizes similar fines and other potentially divergent enforcement actions for certain violations. On June 28, 2021, the European Commission adopted an Adequacy Decision for the United Kingdom, allowing for the relatively free exchange of personal information between the European Union and the United Kingdom, however, the European Commission may suspend the Adequacy Decision if it considers that the United Kingdom no longer provides for an adequate level of data protection. Other jurisdictions outside the European Union are similarly introducing or enhancing privacy and data security laws, rules and regulations.

Similar actions are either in place or under way in the United States. There are a broad variety of data protection 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. The Federal Trade Commission 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. For example, the California Consumer Privacy Act — which went into effect on January 1, 2020 — is creating similar risks and obligations as those created by the GDPR, though the California Consumer Privacy Act does exempt certain information collected as part of a clinical trial subject to the Federal Policy for the Protection of Human Subjects (the Common Rule). As of January 1, 2023, the California Consumer Privacy Act (as amended by the California Privacy Rights Act) is in full effect, with enforcement by California's dedicated privacy enforcement agency expected to start later in 2023. While California was first among the states in adopting comprehensive data privacy legislation similar to the GDPR, many other states are following suit. For example, four other states have adopted such laws, taking effect from January 1, 2023 (in Virginia) and throughout the next year in Utah, Colorado, and Connecticut. Many other states are considering similar legislation. A broad range of legislative measures also have been introduced at the federal level. Accordingly, failure to comply with federal and state laws (both those currently in effect and future legislation) regarding privacy and security of personal information 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 information, 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.

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, 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 information from our clinical trials, 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.

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.

Previously enacted state laws in California seek to impose gender and diversity quotas for boards of directors of public companies headquartered in California.

In September 2018, California enacted Senate Bill 826 ("SB 826"), which generally required public companies with principal executive offices in California to have at least two female directors on its board of directors if the company has at least five directors, and at least three female directors on its board of directors if the company has at least six directors. On May 13, 2022, the Los Angeles Superior Court declared SB 826 unconstitutional and, although the California Secretary of State has directed counsel to file an appeal of decision, the State of California is currently precluded from enforcing SB 826.

Additionally, on September 30, 2020, California enacted Assembly Bill 979 ("AB 979"), which generally required public companies with principal executive offices in California to include specified numbers of directors from "underrepresented communities". A director from an "underrepresented community" means a director who self-identifies as Black, African American, Hispanic, Latino, Asian, Pacific Islander, Native American, Native Hawaiian, Alaska Native, gay, lesbian, bisexual or transgender. By December 31, 2021, each public company with principal executive offices in California was required to have at least one director from an underrepresented community. By December 31, 2022, a public company with more than four but fewer than nine directors would have been required to have a minimum of two directors from underrepresented communities, and a public company with nine or more directors would have been required to have a minimum of three directors from underrepresented communities. On April 1, 2022, the Los Angeles Superior Court declared AB 979 unconstitutional and, although the California Secretary of State has filed a notice of appeal in the case, the State of California is currently precluded from enforcing AB 979.

If the State of California successfully appeals the court decisions regarding SB 826 or AB 979, we cannot assure that we can recruit, attract and/or retain qualified members of the board and meet gender or diversity quotas as previously required by SB 826 or AB 979, and our board of directors does not currently satisfy the quota previously required under SB 826. A failure to comply with any such quota requirement could result in fines from the California Secretary of State, and our reputation may be adversely affected.

Investors' expectations of our performance relating to environmental, social and governance factors may impose additional costs and expose us to new risks.

There is an increasing focus from certain investors, employees, regulators and other stakeholders concerning corporate responsibility, specifically related to environmental, social and governance ("ESG") factors. Some investors and investor advocacy groups may use these factors to guide investment strategies and, in some cases, investors may choose not to invest in our company if they believe our policies relating to corporate responsibility are inadequate. Third-party providers of corporate responsibility ratings and reports on companies have increased to meet growing investor demand for measurement of corporate responsibility performance, and a variety of organizations currently measure the performance of companies on such ESG topics, and the results of these assessments are widely publicized. Investors, particularly institutional investors, use these ratings to benchmark companies against their peers and if we are perceived as lagging with respect to ESG initiatives, certain investors may engage with us to improve ESG disclosures or performance and may also make voting decisions, or take other actions, to hold us and our board of directors accountable. In addition, the criteria by which our corporate responsibility practices are assessed may change, which could result in greater expectations of us and cause us to undertake costly initiatives to satisfy such new criteria. If we elect not to or are unable to satisfy such new criteria, investors may conclude that our policies with respect to corporate responsibility are inadequate.

We may face reputational damage in the event our corporate responsibility initiatives or objectives do not meet the standards set by our investors, stockholders, lawmakers, listing exchanges or other constituencies, or if we are unable to achieve an acceptable ESG or sustainability rating from third-party rating services. A low ESG or sustainability rating by a third-party rating service could also result in the exclusion of our common stock from consideration by certain investors who may elect to invest with our competition instead. Ongoing focus on corporate responsibility matters by investors and other parties as described above may impose additional costs or expose us to new risks. Any failure or perceived failure by us in this regard could have a material adverse effect on our reputation and on our business, share price, financial condition, or results of operations, including the sustainability of our business over time.

In addition, the SEC has announced proposed rules that, among other matters, will establish a framework for reporting of climate-related risks. To the extent the proposed rules impose additional reporting obligations, we could face increased costs. Separately, the SEC has also announced that it is scrutinizing existing climate-change related disclosures in public filings, increasing the potential for enforcement if the SEC were to allege our existing climate disclosures are misleading or deficient.

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 the ongoing "great resignation" occurring throughout the U.S. economy, which has 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, 2022, we had 35 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, 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. 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.

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

As widely reported, global credit and financial markets have experienced volatility and disruptions in the past several years and especially in 2020, 2021 and 2022 due to the impacts of the COVID-19 pandemic, and, more recently, the ongoing conflict between Ukraine and Russia and the global impact of restrictions and sanctions imposed on Russia, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. There can be no assurances that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment or continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and share price and could require us to delay or abandon clinical development plans.

The impact of the Russian invasion of Ukraine on the global economy, energy supplies and raw materials is uncertain, but may prove to negatively impact our business and operations.

The short and long-term implications of Russia's invasion of Ukraine are difficult to predict at this time. We continue to monitor any adverse impact that the outbreak of war in Ukraine and the subsequent institution of sanctions against Russia by the United States and several European and Asian countries may have on the global economy in general, on our business and operations and on the businesses and operations of our suppliers and other third parties with which we conduct business. For example, the continuing conflict has resulted and may continue to result in increased inflation, escalating energy prices and constrained availability, and thus increasing costs, of raw materials. We will continue to monitor this fluid situation and develop contingency plans as necessary to address any disruptions to our business operations as they develop. To the extent the war in Ukraine may adversely affect our business as discussed above, it may also have the effect of heightening many of the other risks described herein. Such risks include, but are not limited to, adverse effects on macroeconomic conditions, including inflation; disruptions to our technology infrastructure, including through cyberattack, ransom attack, or cyber-intrusion; adverse changes in international trade policies and relations; disruptions in global supply chains; and constraints, volatility, or disruption in the capital markets, any of which could negatively affect our business and financial condition.

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;
- the impacts of the ongoing COVID-19 pandemic and related restrictions;
- the ongoing conflict between Ukraine and Russia 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 September 24, 2021, the date of the closing of the Business Combination, to December 31, 2022, our closing stock price ranged from $0.46 to $16.42 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 December 31, 2022, our directors and executive officers and their affiliates beneficially owned approximately 28.8% 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. A number of those requirements require us to carry out activities we had not done previously. For example, we have adopted new charters for our board committees and adopted some new disclosure controls and procedures. In addition, expenses associated with SEC reporting requirements will be incurred. 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. It is also more expensive to obtain director and officer liability insurance. 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 additional reporting and other obligations imposed by these rules and regulations will 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 November 3, 2022, 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), we were provided with an initial period of 180 calendar days, or until May 2, 2023, to regain compliance. On January 18, 2023, 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 3, 2023 through January 17, 2023.

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 an "emerging growth company" within the meaning of the Securities Act, and if we take advantage of certain exemptions from disclosure requirements available to emerging growth companies, it could make our securities less attractive to investors and may make it more difficult to compare our performance to the performance of other public companies.

We are an "emerging growth company" as defined in Section 2(a)(19) of the U.S. Securities Act of 1933, as amended (the "Securities Act"), as modified by the JOBS 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 emerging growth companies for as long as we continue to be an emerging growth company, including, but not limited to, (a) not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, (b) reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and (c) exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. As a result, our stockholders may not have access to certain information they may deem important. We will remain an emerging growth company until the earlier of (i) the last day of the fiscal year (a) following November 22, 2024, (b) in which we have total annual gross revenue of at least $1.235 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common equity that is held by non-affiliates exceeds $700 million as of the last business day of our most recently completed second fiscal quarter; and (ii) the date on which we have issued more than $1.00 billion in non-convertible debt securities during the prior three-year period. We cannot predict whether investors will find our securities less attractive because we will rely on these exemptions. If some investors find our securities less attractive as a result of our reliance on these exemptions, the trading prices of our securities may be lower than they otherwise would be; there may be a less active trading market for our securities; and the trading prices of our securities may be more volatile.

Further, Section 102(b)(1) of 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 Securities Act registration statement declared effective or do not have a class of securities registered under 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 an election to opt out is irrevocable. We have opted to take advantage of the exemption for complying with new or revised accounting standards within the same time periods as private companies, which means that when a standard is issued or revised and it has different application dates for public or private companies, we, as an emerging growth company, can adopt the new or revised standard at the time private companies adopt the new or revised standard. This may make comparison of our consolidated financial statements with another public company that is neither an emerging growth company nor an emerging growth company that has opted out of using the extended transition period difficult or impossible because of the potential differences in accounting standards used.

Even after we no longer qualify as an emerging growth company, we may continue to qualify as a "smaller reporting company," which would allow us to continue to take advantage of many of the same exemptions from disclosure requirements, including reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. If we cease to be an emerging growth company and do not qualify as a smaller reporting company, we will no longer be able to take advantage of certain exemptions from reporting discussed above, including not being able to take advantage of extended transition periods for the adoption of new or modified accounting standards, and, absent other exemptions or relief available from the SEC, we will also be required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act if we are no longer a non-accelerated filer at such time. We will incur additional expenses in connection with such compliance, and our management will need to devote additional time and effort to implement and comply with such requirements.

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 Equity Incentive Plan and the 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. 2021 Equity Incentive Plan (the "Equity Incentive Plan"), which became effective on September 23, 2021, we are authorized to grant equity awards to our employees, directors and consultants. In addition, pursuant to the Jasper Therapeutics, Inc. 2021 Employee Stock Purchase Plan (the "ESPP"), which became effective on September 23, 2021, we are authorized to sell shares to our employees. As of February 28, 2023, 2,796,855 shares and 1,249,573 shares of our common stock are reserved for future issuance under the Equity Incentive Plan and the ESPP, respectively. In addition, the Equity Incentive Plan and ESPP provide for annual automatic increases in the number of shares reserved thereunder, in each case, beginning on January 1, 2022. As a result of such annual increases, our stockholders may experience additional dilution, which could cause the price of our common stock to fall.

On March 14, 2022, the Compensation Committee of our board of directors adopted the 2022 Inducement Equity Incentive Plan (the "2022 Inducement Plan"). As of February 28, 2023, 201,841 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, 2022, options to purchase an aggregate of 6,169,180 shares of our common stock and restricted stock units with respect to an aggregate of 2,617,445 shares were outstanding, and we have granted additional options to purchase shares of our common stock after this date.

Pursuant to the Amended and Restated Registration Rights Agreement entered into in connection with the Business Combination, certain of our stockholders can demand that we register their registrable securities under certain circumstances and will each also have piggyback registration rights for these securities. In addition, we are required to file and maintain an effective registration statement under the Securities Act covering such securities and certain of our other securities. We filed a registration statement on October 18, 2021, which was first amended on March 29, 2022 and further amended on October 7, 2022, in order to satisfy the foregoing obligations and we have currently registered for resale an aggregate of 36,019,362 shares of our common stock, including up to 4,999,863 shares of our common stock issuable upon exercise of our outstanding warrants. The registration of these securities permits the public sale of such securities, subject to certain contractual restrictions on transfer imposed by the Amended and Restated Registration Rights Agreement and the Business Combination Agreement, which contractual restrictions on transfer terminated on March 23, 2022. The presence of these additional shares of our common stock trading in the public market may have an adverse effect on the market price of our securities.

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 Second Amended and Restated Certificate of Incorporation (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 chairman 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 4,999,883 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, 2022, Public Warrants to purchase 4,999,863 shares of our common stock were outstanding. The exercise price of these Public Warrants is $11.50 per share. 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*."

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 $0.01 per Public Warrant, provided that the last reported sales price of our common stock equals or exceeds $18.00 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 your Public Warrants at any time after they become exercisable and prior to their expiration at a price of $0.10 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 2. PROPERTIES

We lease approximately 13,400 square feet of space for our headquarters in Redwood City, California under an 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 are not currently a party to any material legal proceedings. From time to time, we may be subject to various legal proceedings and claims that arise in the ordinary course of our business activities.

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 February 28, 2023, there were 15 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.

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 dedicated to enabling cures through therapeutics targeting mast and hemopoietic stem cells. We are focused on the development and commercialization of safer and more effective therapeutic agents for diseases such as Chronic Spontaneous Urticaria ("CSU"), Lower to Intermediate Risk Myelodysplastic Syndrome ("LR-MDS") and novel conditioning regimens for stem cell transplantation and ex-vivo gene therapy, a technique in which genetic manipulation of cells is performed outside of the body prior to transplantation.

Our drug development pipeline includes multiple product candidates designed to target mast and/or hematopoietic stem cells. Our lead product candidate, briquilimab (formerly known as JSP191), is in clinical development as a novel therapeutic antibody that targets mast and stem cells in various diseases and as a conditioning agent to clear hematopoietic stem cells from bone marrow in patients prior to undergoing allogeneic stem cell therapy or stem cell gene therapy. We are also developing engineered hematopoietic stem cells product candidates reprogrammed using mRNA delivery ("mRNA stem cell platform") and gene editing that have a competitive advantage over endogenous hematopoietic stem cells ("HSCs") because they may permit higher levels of engraftment without the need for toxic conditioning. We also plan to continue to expand our pipeline to include other novel mast and stem cell therapies based on immune modulation, graft engineering or cell and gene therapies. Our goal is to expand the use of therapeutic agents targeting mast and stem cells as well as to expand curative stem cell transplants and gene therapies for all patients, including children and the elderly.

Our lead product candidate, briquilimab, is a monoclonal antibody designed to block stem cell factor ("SCF") from binding to and signaling through the CD117 receptor on mast and stem cells. The SCF/CD117 pathway is a survival signal for mast and stem cells and we believe that blocking this pathway may lead to depletion of these cells from skin and bone marrow environments. Currently, we are developing briquilimab as chronic therapy for CSU and LR-MDS. We are also developing briquilimab as a one-time conditioning therapy in various stem cell transplant settings such as severe combined immunodeficiency ("SCID") for which we are currently conducting a Phase 1/2 clinical trial in patients who have failed a previous stem cell transplant. Briquilimab is also being studied by our academic and institutional partners, Stanford University and National Institutes of Health, in other transplant settings, including Fanconi Anemia, sickle cell disease ("SCD"), chronic granulomatous disease and GATA-2 Type myelodysplastic syndromes ("MDS").

We intend to become a fully integrated discovery, development and commercial company in the field of mast and stem cell therapeutics. We are developing our product candidates to be used individually or, in some cases, in combination with one another. For example, we believe our pipeline could be tailored to the patient-specific disease so that a patient may receive more than one of our therapies as part of his or her individual allogeneic or gene-edited stem cell therapy. 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 advance our pipeline and innovate through our research platform.

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 for the right to use briquilimab in the clearance of stem cells prior to the transplantation of HSCs. We also entirely own the intellectual property for our mRNA stem cell platform, which has been internally developed.

AMHC was incorporated in the State of Delaware in August 2019. Old Jasper was incorporated in the State of Delaware in March 2018 and did not have any significant operations or research and development activities until November 2019, when it entered into a license agreement with Amgen for a license to certain patents and know-how related to Amgen's proprietary monoclonal antibody known as AMG-191, which we later renamed as JSP191 and then briquilimab.

On September 24, 2021 (the "Closing Date"), we consummated the previously announced Business Combination pursuant to the terms of the Business Combination Agreement, dated as of May 5, 2021 (the "BCA"), by and among AMHC, Merger Sub, and Old Jasper. Pursuant to the terms of the BCA, on the Closing Date, (i) Merger Sub merged with and into Old Jasper (the "Merger"), with Old Jasper as the surviving company in the Merger, and, after giving effect to the Merger, Old Jasper became a wholly-owned subsidiary of AMHC and changed its name to "Jasper Tx Corp.", and (ii) AMHC changed its name to "Jasper Therapeutics, Inc.".

Since Old Jasper's inception in March 2018, we have devoted substantially all of our resources to performing research and development, enabling manufacturing activities in support of our product development efforts, hiring personnel, acquiring and developing our technology and product candidates, performing business planning, establishing our intellectual property portfolio, raising capital and providing general and administrative support for these activities. We do not have any products approved for sale and have not generated any revenue from product sales. We expect to continue to incur significant and increasing expenses and substantial losses for the foreseeable future as we continue our development of and seek regulatory approvals for our product candidates and commercialize any approved products, seek to expand our product pipeline and invest in our organization. We expect to incur increased expenses associated with operating as a public company, including significant legal, audit, accounting, regulatory, tax-related, director and officer insurance, investor relations and other expenses.

We have incurred significant losses and negative cash flows from operations since our inception. During the years ended December 31, 2022 and 2021, we incurred net losses of $37.7 million and $30.6 million, respectively. We generated negative operating cash flows of $45.9 million and $33.7 million for the years ended December 31, 2022 and 2021, respectively. As of December 31, 2022, we had an accumulated deficit of $105.1 million.

We had cash and cash equivalents of $38.3 million as of December 31, 2022. Management expects that our existing cash and cash equivalents, together with the total estimated net proceeds of $101.4 million from our public offering in January 2023 and the sale of shares pursuant to the ATM Offering in January 2023, will be sufficient to fund our operating plan for at least twelve months from the date of filing of this Annual Report on Form 10-K. Therefore, based on management's updated evaluation of our ability to continue as a going concern, management has concluded the factors that previously raised substantial doubt about our ability to continue as a going concern no longer exist as of the issuance date of our consolidated financial statements included in Part II, Item 8 of this Annual Report on Form 10-K. 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.

Our management plans to monitor expenses and raise additional capital through a combination of public and private equity, debt financings, strategic alliances, and 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, discover, 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 studies. 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.

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.

Business Impact of the COVID-19 Pandemic

While conditions related to the COVID-19 pandemic improved in 2022 compared to 2021, the pandemic continues to be dynamic and near-term challenges across the economy remain. While our operations to date have not been significantly impacted by the COVID-19 pandemic any continuing impact of the COVID-19 pandemic and its downstream effects, such as healthcare and vendor staffing shortages and general disruption to the U.S. healthcare system, on our financial performance will depend on future developments, including the duration and spread of the pandemic, its impact on our clinical trial enrollment, trial sites, contract research organizations ("CROs"), CMOs, and other third parties with whom we do business, its impact on regulatory authorities and our key scientific and management personnel, progress and effectiveness of vaccination and related governmental advisories and restrictions. These developments and the impact of the COVID-19 pandemic and its downstream effects on the financial markets and the overall economy are highly uncertain and cannot be predicted. If the financial markets or the overall economy continue to be impacted by the COVID-19 pandemic and its downstream effects, our business may be materially adversely affected. We will continue to actively monitor the effects of the COVID-19 pandemic and its downstream effects and will continue to take appropriate steps to attempt to mitigate the impacts to our employees, business, financial condition and operations.

Business Impact of the Geopolitical Events

We are unable to predict the effect that geopolitical events, including the conflict in Ukraine, global inflation and rising interest rates, may have on our operations. To the extent that geopolitical events adversely affect our business prospects, financial condition, and results of operations, they may also have the effect of exacerbating many of the other risks described or referenced in the section titled "Risk Factors" in this Annual Report on Form 10-K such as those relating to the supply of materials for our product candidates, and the timing and possible disruptions of our ongoing and future preclinical studies and clinical trials, and our access to the financial markets.

Amgen License Agreement

In November 2019, we entered into a worldwide exclusive license agreement with Amgen for briquilimab (formerly AMG-191 and JSP191) that 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 hematopoietic stem cells (c-kit)" granted by Stanford under the ISRA on June 2, 2020. As a result, we have worldwide exclusive rights to develop and commercialize briquilimab. The issued U.S. patents would be expected to expire in 2027, absent any applicable patent term extensions.

Stanford License Agreement

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.

Collaboration and Clinical Trial Agreements

Collaboration with Stanford University

Effective September 2020, we entered into a sponsored research agreement with Stanford, pursuant to which Stanford will execute a Phase 1/2 clinical trial utilizing briquilimab to treat Fanconi Anemia patients in Bone Marrow Failure requiring allogeneic transplant with non-sibling donors at Stanford Lucile Packard Children's Hospital. As consideration for the services performed by Stanford under this agreement, we will pay Stanford a total of $0.9 million over approximately three years upon the achievement of the first development and clinical milestone, including FDA filings and patients' enrollment. The first $0.3 million milestone was achieved in 2020 and paid by us in February 2021. The second $0.3 million milestone was achieved in February 2022 and paid by us in March 2022. The third milestone is based on the progress of the clinical trials and will be recognized when achieved.

Other Collaboration and Clinical Trial Agreements

We have other collaboration and clinical trial agreements, including with Graphite Bio, Inc. and AVROBIO, Inc., to study briquilimab as targeted, non-toxic conditioning for investigational gene therapies. These collaborations are non-exclusive, and we have agreed with these collaborators to provide materials to use by the collaborators in their products' development studies and clinical studies. We also have a clinical trial agreement with the National Cancer Institute ("NCI") for the clinical development of briquilimab for the treatment of GATA2 deficiency, whereby NCI will perform the preclinical studies and submit an IND for this indication to the FDA, and we will provide materials to use in such studies.

We have also entered into clinical trial agreements with the National Heart, Lung, and Blood Institute ("NHLBI") and the National Institute of Allergy and Infectious Diseases ("NIAID"), pursuant to which NHLBI and NIAID will serve as the IND sponsors of a Phase 1/2 clinical trial to evaluate briquilimab as a targeted, non-toxic conditioning regimen prior to allogeneic transplant for SCD and for chronic granulomatous disease, respectively. Each party incurs its own costs under these agreements.

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 CROs and investigative sites that conduct preclinical and clinical studies; the costs of acquiring and manufacturing clinical study 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.

External research and development costs include:

- costs incurred under agreements with third-party CROs, CMOs and other third parties that conduct preclinical and clinical activities on our behalf and manufacture our product candidates;
- costs associated with acquiring technology and intellectual property licenses that have no alternative future uses;
- consulting fees associated with our research and development activities; and
- other costs associated with our research and development programs, including laboratory materials and supplies.

Internal research and development costs include:

- 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 the current COVID-19 pandemic environment.

General and Administrative

General and administrative expenses consist primarily of personnel costs and expenses, including salaries, employee benefits, 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.

Other Income (Expense), Net

Other income (expense), net includes foreign currency transactions gains and losses, interest income, changes in the fair value of our derivative tranche liabilities, which were settled in February 2021, changes in the fair value of common stock warrant liability and earnout liability, which were recorded at the closing of the Business Combination. These financial instruments were classified as liabilities in our consolidated balance sheets and re-measured at each reporting period end until they are exercised, settled or have expired.

Results of Operations

Comparison of the Years Ended December 31, 2022 and 2021

The following table summarizes our results of operations for the years ended December 31, 2022 and 2021 (in thousands):

	Year Ended December 31,		Change	Change
	2022	2021	$	%
Operating expenses				
Research and development	$ 34,627	$ 25,421	$ 9,206	36
General and administrative	16,569	11,412	5,157	45
Total operating expenses	51,196	36,833	14,363	39
Loss from operations	(51,196)	(36,833)	(14,363)	39
Change in fair value of common stock warrant liability	7,200	500	6,700	*
Change in fair value of earnout liability	5,725	9,277	(3,552)	(38)
Change in fair value of derivative liability	—	(3,501)	3,501	(100)
Other income (expense), net	586	(80)	666	*
Total other income, net	13,511	6,196	7,315	118
Net loss and comprehensive loss	$ (37,685)	$ (30,637)	$ (7,048)	23

* *not meaningful*

Research and Development Expenses

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

	Year Ended December 31,		Change	Change
	2022	2021	$	%
External costs:				
CRO, CMO and other third-party preclinical studies and clinical trials	$ 13,817	$ 15,271	$ (1,454)	(10)
Consulting costs	4,639	3,205	1,434	45
Other research and development costs, including laboratory materials and supplies	3,322	479	2,843	*
Total external costs	21,778	18,955	2,823	15
Internal costs:				
Personnel-related costs	8,326	5,339	2,987	56
Facilities and overhead costs	4,523	1,127	3,396	301
Total internal costs	12,849	6,466	6,383	99
Total research and development expense:	$ 34,627	$ 25,421	$ 9,206	36

* *not meaningful*

Research and development expenses increased by $9.2 million, from $25.4 million for the year ended December 31, 2021 to $34.6 million for the year ended December 31, 2022.

External CRO, CMO and other third-party preclinical studies and clinical trials expenses decreased by $1.5 million, from $15.3 million for the year ended December 31, 2021 to $13.8 million for the year ended December 31, 2022. The decrease is primarily due to a $0.4 million decrease in CRO expenses, a $0.3 million decrease in expenses related to pre-clinical studies, a $0.2 million decrease in Chemistry, Manufacturing and Controls expenses and a $0.6 million decrease in other third-party research and development expenses. Expenses related to professional consulting services increased by $1.4 million, from $3.2 million for the year ended December 31, 2021 to $4.6 million for the year ended December 31, 2022. The increase was related to external consulting incurred to supplement our research and development personnel. Other external research and development costs increased by $2.8 million from $0.5 million for the year ended December 31, 2021 to $3.3 million for the year ended December 31, 2022 due to increases in purchases of laboratory materials, supplies and services and other miscellaneous costs.

Our external costs by program for the years ended December 31, 2022 and 2021 were as follows (in thousands):

	Year Ended December 31,	
	2022	2021
Briquilimab platform	$ 11,358	$ 11,035
MDS/AML clinical trial	4,725	3,829
SCID clinical trial	2,566	2,840
Other	3,129	1,251
Total external costs	$ 21,778	$ 18,955

Personnel-related costs, including employee payroll and related expenses increased by $3.0 million, from $5.3 million for the year ended December 31, 2021 to $8.3 million for the year ended December 31, 2022, as a result of hiring additional employees in our research and development organization. Stock-based compensation expenses related to awards granted to our employees and directors increased by $0.7 million, from $0.6 million for the year ended December 31, 2021 to $1.3 million for the year ended December 31, 2022. Facilities and overheads include common facilities, human resources and information technology related expenses allocated to research and development. These costs increased by $3.4 million, from $1.1 million for the year ended December 31, 2021 to $4.5 million for the year ended December 31, 2022 as a result of hiring additional employees in our research and development organization and it being the first full year of allocated overhead expenses.

General and Administrative Expenses

General and administrative expenses increased by $5.2 million, from $11.4 million for the year ended December 31, 2021 to $16.6 million for the year ended December 31, 2022. Employee payroll and related expenses increased by $2.9 million, from $2.3 million for the year ended December 31, 2021 to $5.2 million for the year ended December 31, 2022, as a result of $1.5 million of higher stock based compensation and continued hiring of executives and administrative employees. Expenses related to professional consulting services increased by $1.9 million, from $6.4 million for the year ended December 31, 2021 to $8.3 million for the year ended December 31, 2022 due to increased spending on consulting, recruiting, legal, audit, accounting and other services to support our growing operations as a public company. Other expenses, including insurance, office supplies, subscriptions and other miscellaneous expenses, increased by $0.4 million for the year ended December 31, 2022 as compared to expenses for the year ended December 31, 2021, as we continued expanding our operations to support our business strategy and product development.

Other Income, Net

Total other income, net increased by $7.3 million, from $6.2 million net income for the year ended December 31, 2021 to $13.5 million for the year ended December 31, 2022.

As of December 31, 2022, we have outstanding warrants to purchase an aggregate of 4,999,863 shares of our common stock, which were recognized upon the closing of the Business Combination on September 24, 2021. The warrants were concluded to be derivative financial instruments and are measured at fair value at each reporting period end until these are exercised, have expired or are redeemed. These warrants are publicly traded, and the fair value is estimated using the closing price of a warrant at the period end. We recognized $7.2 million and $0.5 million of other income related to the decrease in the fair value of the common stock warrants for the years ended December 31, 2022 and 2021, respectively due to the decrease in the closing prices of the warrants during the respective period.

Upon the closing of the Business Combination on September 24, 2021, we recognized earnout liability related to the Sponsor Earnout Shares placed in escrow. These shares will be released from escrow upon achieving agreed upon common stock price targets within the specified period. This liability is recorded at fair value using Monte Carlo simulation model and is re-measured at each period end until shares are released or forfeited. The significant inputs used in the Monte Carlo model include the expected volatility of our common stock and the expected term when shares will be released. We recognized $5.7 million and $9.3 million of other income related to the decrease in the fair value of the earnout liability for the year ended December 31, 2022 and 2021, respectively, primarily as a result of the decrease in our common stock price, which decreased the estimated liability related to the earnout provision.

We recognized a loss of $3.5 million during the year ended December 31, 2021 related to the change in fair value of our derivative tranche liability and did not have such expense in the 2022 period, as the derivative was settled in February 2021 and was no longer outstanding.

Liquidity and Capital Resources

Prior to the closing of the Business Combination, we funded our operations primarily from the issuance of redeemable convertible preferred stock shares and the issuance of convertible promissory notes. We also received net cash proceeds of $95.3 million at the closing of the Business Combination. As of December 31, 2022, we had $38.3 million of cash and cash equivalents.

In order to assist in funding our future operations, including our planned clinical trials, on October 7, 2022, we filed a universal shelf registration statement on Form S-3 with the SEC, and which was declared effective on October 18, 2022 and will expire on October 18, 2025 (the "Shelf Registration Statement"), which allows us to, from time to time, offer up to $150.0 million of securities, including any combination of common stock, preferred stock, debt securities, warrants, rights, units and depositary shares. We believe that the Shelf Registration Statement will provide us with the flexibility to raise additional capital to finance our operations as needed. From time to time, we may offer securities under our Shelf Registration Statement in response to market conditions or other circumstances if we believe such a plan of financing is in the best interests of our stockholders. 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 November 10, 2022, we entered into a Controlled Equity Offering^{SM} Sales Agreement (the "Sales Agreement") with Cantor Fitzgerald & Co. (the "Agent"), pursuant to which we may offer and sell through or to the Agent, as sales agent or principal, shares of our voting common stock from time to time (the "ATM Offering"). The Agent will use commercially reasonable efforts consistent with its normal sales and trading practices to sell shares from time to time, based upon our instructions (including any price or size limits or other customary parameters or conditions we may impose). We will pay a commission equal to 3.0% of the aggregate gross proceeds of any shares sold through the Agent pursuant to the Sales Agreement. We are not obligated to sell any shares under the Sales Agreement unless it is terminated earlier. The Sales Agreement will continue until all shares available under the Sales Agreement have been sold. On November 10, 2022, we filed under the Shelf Registration Statement a prospectus supplement with the SEC in connection with the ATM Offering (the "ATM Prospectus Supplement"), pursuant to which we may offer and sell shares of common stock having an aggregate offering price of up to $15.5 million. As of December 31, 2022, there have been no sales under the Sales Agreement and, as of December 31, 2022, the full capacity remained available for issuance. In January 2023, we issued and sold an aggregate of 2,337,496 shares of our common stock pursuant to the ATM Prospectus Supplement for total estimated net proceeds of $4.5 million.

In January 2023, we issued and sold 69,000,000 shares of our common stock in an underwritten public offering (the "Public Offering") for total estimated net proceeds of $96.9 million pursuant to an underwriting agreement with Credit Suisse Securities (USA) LLC, William Blair & Company, L.L.C. and Oppenheimer & Co. Inc., as the representatives of the several underwriters named therein.

As of March 1, 2023, approximately $10.9 million remains allocated and available under the ATM Prospectus Supplement and approximately $31.0 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, 2022, we had an accumulated deficit of $105.1 million. Based on our current operating plan, we have concluded that our existing cash and cash equivalents will be sufficient to fund our current operating plan for at least the twelve months from the date of filing of this Annual Report on Form 10-K. We have based these estimates on our current assumptions, which may require future adjustments based on our ongoing business decisions.

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 do not have any non-cancellable obligations under these agreements as of December 31, 2022.

Leases

In August 2020 and January 2022, we leased approximately 13,400 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, 2022, our rent commitments under the lease agreement are $1.1 million within the next 12 months from December 31, 2022, and $3.1 million for the remainder of the lease term.

Stanford Sponsored Research Agreement

Effective September 2020, we entered into a sponsored research agreement with Stanford for a research program related to the treatment of Fanconi Anemia patients in Bone Marrow Failure requiring allogeneic transplant with non-sibling donors at Stanford Lucile Packard Children's Hospital using briquilimab. As consideration for the services performed by Stanford under this sponsored research agreement, we will pay Stanford a total of $0.9 million over approximately 3 years upon the achievement of development and clinical milestones, including FDA filings and patients' enrollment. In February 2021, we paid $0.3 million related to the achievement of the first milestone under this agreement. In February 2022, the second milestone was achieved, and we paid $0.3 million in March 2022. The third milestone is based on the progress of the clinical trials and will be recognized when achieved.

Stanford License Agreement

In March 2021, we entered into the Stanford License Agreement, pursuant to which 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 milestones 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 are in development as of December 31, 2022, 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,	
	2022	2021
Net cash used in operating activities	$ (45,858)	$ (33,678)
Net cash used in investing activities	(576)	(2,428)
Net cash provided by financing activities	55	100,969
Net (decrease) increase in cash and cash equivalents and restricted cash	$ (46,379)	$ 64,863

Cash Flows from Operating Activities

Net cash used in operating activities was $45.9 million and $33.7 million for the years ended December 31, 2022 and 2021, respectively.

Cash used in operating activities in the year ended December 31, 2022 was primarily due to our net loss for the period of $37.7 million, adjusted by non-cash net gain of $7.5 million and a net change of $0.6 million in our net operating assets and liabilities. The non-cash amounts consisted of $12.9 million net gain related to the changes in fair value of common stock warrant liability and the earnout liability, reduced by non-cash expenses, which included $4.1 million related to stock-based compensation expense, $1.0 million related to depreciation and amortization expense and $0.3 million non-cash lease expense. The changes in our net operating assets and liabilities were primarily due to a decrease of $2.2 million in accounts payable, an increase of $0.7 million in other receivables, and a decrease of $0.6 million in operating lease liability, partially offset by an increase of $1.7 million in other non-current liabilities, an increase of $0.8 million in accrued expenses and other current liabilities and a decrease of $0.3 million in prepaid expenses and other current assets.

Cash used in operating activities in the year ended December 31, 2021 was primarily due to our net loss for the period of $30.6 million adjusted by non-cash net gain charges of $4.7 million and a net change of $1.6 million in our net operating assets and liabilities. The non-cash charges consisted of $6.3 million net gain related to the changes in fair value of a derivative liability, common stock warrant liability and the earnout liability, reduced by non-cash expenses, which included $1.0 million related to stock-based compensation expense, $0.4 million related to depreciation and amortization expense and $0.2 million related to non-cash lease expense. The changes in our net operating assets and liabilities were primarily due to an increase of $2.9 million in accounts payable due to the timing of payments to our vendors, an increase of $1.0 million in accrued expenses and other current liabilities and a decrease of $0.6 million in other receivables, partially offset by $2.2 million increase in prepaid expenses and other current assets, a $0.3 million increase in other non-current assets, a decrease in other non-current liabilities of $0.2 million and a decrease in operating lease liability of $0.1 million.

Cash Flows from Investing Activities

Cash used in investing activities was $0.6 million and $2.4 million for the years ended December 31, 2022 and 2021, respectively, which primarily consisted of purchases of the lab equipment and leasehold improvements.

Cash Flows from Financing Activities

Cash provided by financing activities for the year ended December 31, 2022 was $0.1 million, which primarily consisted of cash received from exercise of stock options and the purchase of shares under our employee stock purchase plan.

Cash provided by financing activities for the year ended December 31, 2021 was $101.0 million, which consisted of $95.3 million net cash proceeds received at the closing of the Business Combination, which included the PIPE Financing, $10.8 million net proceeds received in February 2021 upon the issuance of Series A-1 redeemable convertible preferred stock shares and $0.2 million of cash received from the exercise of stock options. Cash received was reduced by $5.3 million related to expenses paid by us related to the Business Combination.

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.

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.

Earnout Liability

Upon the closing of the Business Combination, we recognized Sponsor Earnout Shares placed in escrow as a contingent earnout liability. These contingently issuable shares are classified as a liability on the balance sheets and are subject to re-measurement at each balance sheet date and at the settlement date. Any change in fair value is recognized in the consolidated statements of operations and comprehensive loss.

We utilize the Monte Carlo simulation model, which uses a distribution of potential outcomes on a monthly basis over the earnout period prioritizing the most reliable information available. The assumptions utilized in the calculation are based on the achievement of certain stock price milestones, including our current common stock price, expected volatility, risk-free rate and expected term. We determine expected stock volatility based on the historical volatility of the prices of shares of common stock of publicly traded peer companies. We estimate the risk-free interest rate by reference to the U.S. Treasury yield curve over the expected term. The expected term equals the remaining contractual term of the escrow, which ends on September 24, 2024. Common stock fair value equals the closing price of our common stock on the Nasdaq Capital Market at the valuation date. An increase or decrease in the common stock fair value and volatility assumptions will significantly increase or decrease the recorded liability, respectively.

As of December 31, 2022, we estimated the fair value of the contingent earnout liability to be less than $0.1 million. We recognized $5.7 million of other income related to the decrease in the fair value of the earnout liability for the year ended December 31, 2022, primarily as a result of the decrease in our common stock price, which decreased the estimated liability.

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. Prior to the closing of the Business Combination, we determined the fair value of our common stock using methodologies, approaches, and assumptions consistent with the American Institute of Certified Public Accountants Accounting and Valuation Guide, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*. We recognized stock-based compensation expense on a straight-line basis over the requisite service period, which is the period in which the related services are received. We account for 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.

We recorded stock-based compensation expense of $4.1 million and $1.0 million for the years ended December 31, 2022 and 2021, respectively. As of December 31, 2022, there was $8.2 million of total unrecognized compensation expense, which we expect to recognize over a remaining weighted-average period of 2.3 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.

JOBS Act

The Jumpstart Our Business Startups Act of 2012 (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. We have opted to take advantage of the exemption for complying with new or revised accounting standards within the same time periods as private companies, which means that when a standard is issued or revised and it has different application dates for public or private companies, we, as an emerging growth company, can adopt the new or revised standard at the time private companies adopt the new or revised standard. This may make comparison of our consolidated financial statements with another public company that is neither an emerging growth company nor an emerging growth company that has opted out of using the extended transition period difficult or impossible because of the potential differences in accounting standards used.

We will remain an emerging growth company until the earlier of: (i) the last day of the fiscal year (a) following November 22, 2024, (b) in which we have total annual gross revenue of at least $1.235 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common equity that is held by non-affiliates exceeds $700 million as of the last business day of its most recently completed second fiscal quarter; and (ii) the date on which we have issued more than $1.00 billion in non-convertible debt securities during the prior three-year period. References herein to "emerging growth company" have the meaning associated with it in the JOBS Act.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Risk

We had cash and cash equivalents of $38.3 million as of December 31, 2022, 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, 2022. 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% chance 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.

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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 sheets of Jasper Therapeutics, Inc. and its subsidiary (the "Company") as of December 31, 2022 and 2021, and the related consolidated statements of operations and comprehensive loss, of redeemable convertible preferred stock and stockholders' equity (deficit) 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, 2022 and 2021, 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.

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.

Emphasis of Matter

As discussed in Note 1 to the consolidated financial statements, the Company will need to raise additional financing to continue its products' development for the foreseeable future.

/s/ PricewaterhouseCoopers LLP
San Jose, California
March 8, 2023

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,	
	2022	**2021**
Assets		
Current assets:		
Cash and cash equivalents	$ 38,250	$ 84,701
Other receivables	663	—
Prepaid expenses and other current assets	2,818	3,130
Total current assets	41,731	87,831
Property and equipment, net	3,568	3,686
Operating lease right-of-use assets	1,886	1,147
Restricted cash	417	345
Other non-current assets	759	645
Total assets	$ 48,361	$ 93,654
Liabilities, Preferred Stock and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,768	$ 3,919
Current portion of operating lease liabilities	865	505
Accrued expenses and other current liabilities	4,432	3,596
Total current liabilities	7,065	8,020
Non-current portion of operating lease liabilities	2,786	2,380
Common stock warrant liability	150	7,350
Earnout liability	18	5,743
Other non-current liabilities	2,353	643
Total liabilities	12,372	24,136
Commitments and contingencies (Note 9)		
Stockholders' equity		
Preferred stock: $0.0001 par value — 10,000,000 shares authorized at December 31, 2022 and 2021; none issued and outstanding at December 31, 2022 and 2021	—	—
Common stock: $0.0001 par value — 492,000,000 shares authorized at December 31, 2022 and 2021, respectively; 38,045,677 and 37,855,114 shares issued and outstanding at December 31, 2022 and 2021, respectively	4	4
Additional paid-in capital	141,120	136,964
Accumulated deficit	(105,135)	(67,450)
Total stockholders' equity	35,989	69,518
Total liabilities, preferred stock and stockholders' equity	$ 48,361	$ 93,654

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,	
	2022	**2021**
Operating expenses		
Research and development	$ 34,627	$ 25,421
General and administrative	16,569	11,412
Total operating expenses	51,196	36,833
Loss from operations	(51,196)	(36,833)
Change in fair value of common stock warrant liability	7,200	500
Change in fair value of earnout liability	5,725	9,277
Change in fair value of derivative liability	—	(3,501)
Other income (expense), net	586	(80)
Total other income, net	13,511	6,196
Net loss and comprehensive loss	$ (37,685)	$ (30,637)
Net loss per share attributable to common stockholders, basic and diluted	$ (1.03)	$ (2.69)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	36,482,761	11,393,753

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

JASPER THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)
(in thousands, except share data)

	Preferred Stock		Common Stock		Additional Paid-In	Accumulated	Total Stockholders' Equity
	Shares[(1)]	Amount	Shares[(1)]	Amount	Capital	Deficit	(Deficit)
Balance as of January 1, 2021	15,480,195	$ 43,840	2,770,702	$ 1	$ 1,682	$ (36,813)	$ (35,130)
Issuance of common stock upon exercise of stock options	—	—	323,740	—	235	—	235
Issuance of common stock upon exercise of common stock warrants	—	—	110	—	1	—	1
Issuance of Series A-1 redeemable convertible preferred stock for cash	4,042,565	10,750	—	—	—	—	—
Settlement of the redeemable convertible preferred stock tranche liability	—	11,659	—	—	—	—	—
Conversion of redeemable convertible preferred stock into common stock in connection with the Reverse Recapitalization (Note 3)	(19,522,760)	(66,249)	21,722,661	2	66,247	—	66,249
Issuance of common stock upon the Reverse Recapitalization and PIPE Financing, net of issuance costs	—	—	13,037,901	1	67,741	—	67,742
Vesting of founders' restricted stock	—	—	—	—	10	—	10
Stock-based compensation expense	—	—	—	—	1,048	—	1,048
Net loss	—	—	—	—	—	(30,637)	(30,637)
Balance as of December 31, 2021	—	$ —	37,855,114	$ 4	$ 136,964	$ (67,450)	$ 69,518
Issuance of common stock upon exercise of stock options	—	—	37,387	—	27	—	27
Issuance of common stock upon exercise of common stock warrants	—	—	20	—	—	—	—
Issuance of common stock pursuant to Employee Stock Purchase Plan	—	—	59,434	—	28	—	28
RSU settlements	—	—	93,722	—	—	—	—
Vesting of founders' restricted stock	—	—	—	—	10	—	10
Stock-based compensation expense	—	—	—	—	4,091	—	4,091
Net loss	—	—				(37,685)	(37,685)
Balance as of December 31, 2022	—	$ —	38,045,677	$ 4	$ 141,120	$ (105,135)	$ 35,989

(1) The shares of the Company's common and redeemable convertible preferred stock, prior to the Reverse Recapitalization (as defined in Note 1) have been retroactively restated to reflect the exchange ratio of 0.282378, except for 100 shares of Series A-2 redeemable convertible preferred stock as described in Note 3.

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,	
	2022	**2021**
Cash flows used in operating activities		
Net loss	$ (37,685)	$ (30,637)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization expense	975	377
Non-cash lease expense	335	189
Stock-based compensation expense	4,091	1,048
Change in fair value of derivative liability	—	3,501
Change in fair value of common stock warrant liability	(7,200)	(500)
Change in fair value of earnout liability	(5,725)	(9,277)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	312	(2,212)
Other receivables	(663)	600
Other non-current assets	(114)	(347)
Accounts payable	(2,151)	2,938
Accrued expenses and other current liabilities	836	959
Operating lease liability	(589)	(117)
Other non-current liabilities	1,720	(200)
Net cash used in operating activities	(45,858)	(33,678)
Cash flows used in investing activities		
Purchases of property and equipment	(576)	(2,428)
Net cash used in investing activities	(576)	(2,428)
Cash flows from financing activities		
Net proceeds from Reverse Recapitalization and PIPE Financing (Note 3)	—	95,271
Payment of Reverse Recapitalization related expenses	—	(5,288)
Proceeds from issuance of redeemable convertible preferred stock, net of issuance costs	—	10,750
Proceeds from exercise of common stock options	27	235
Proceeds from issuance of common stock upon ESPP purchase	28	—
Proceeds from exercise of common stock warrants	—	1
Net cash provided by financing activities	55	100,969
Net (decrease) increase in cash, cash equivalents and restricted cash	(46,379)	64,863
Cash, cash equivalents and restricted cash at beginning of the year	85,046	20,183
Cash, cash equivalents and restricted cash at end of the year	$ 38,667	$ 85,046

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,	
	2022	**2021**
Supplemental and non-cash items reconciliations:		
Right-of-use asset obtained in exchange for lease liabilities	$ 1,074	$ —
Non-cash leasehold improvements	$ (281)	$ 1,378
Vesting of founders' restricted stock	$ 10	$ 10
Conversion of redeemable convertible preferred stock into common stock in connection with Reverse Recapitalization	$ —	$ (66,249)
Deferred issuance costs reclassified to additional paid in capital	$ —	$ 5,288
Net liabilities assumed upon the closing of Reverse Recapitalization	$ —	$ (7,222)
Recognition of earnout liability	$ —	$ 15,020
Settlement of derivative tranche liability	$ —	$ (11,659)
Letter of credit issued in connection with lease recognition	$ 72	$ —

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. ("Jasper" or the "Company"), formerly known as Amplitude Healthcare Acquisition Corporation ("AMHC"), is a clinical-stage biotechnology company dedicated to enabling cures through therapeutics targeting mast and hemopoietic stem cells. The Company is focused on the development and commercialization of safer and more effective therapeutic agents for diseases such as Chronic Spontaneous Urticaria, Lower to Intermediate Risk Myelodysplastic Syndrome and novel conditioning regimens for stem cell transplantation and ex-vivo gene therapy, a technique in which genetic manipulation of cells is performed outside of the body prior to transplantation. The Company is headquartered in Redwood City, California.

On September 24, 2021 (the "Closing Date"), the Company consummated the previously announced business combination (the "Business Combination" or "Reverse Recapitalization" for accounting purposes) pursuant to the terms of the Business Combination Agreement, dated as of May 5, 2021 (the "BCA"), by and among AMHC, Ample Merger Sub, Inc., a then-wholly-owned subsidiary of AMHC ("Merger Sub"), and the pre-Business Combination Jasper Therapeutics, Inc. (now named Jasper Tx Corp.) ("Old Jasper"). Pursuant to the terms of the BCA, on the Closing Date, (i) Merger Sub merged with and into Old Jasper, with Old Jasper as the surviving company in the Business Combination, and, after giving effect to such Business Combination, Old Jasper became a wholly-owned subsidiary of AMHC and changed its name to "Jasper Tx Corp.", and (ii) AMHC changed its name to "Jasper Therapeutics, Inc.".

In addition, concurrently with the execution of the BCA, certain investors ("PIPE Investors") entered into Subscription Agreements with AMHC whereby such investors subscribed for the purchase of an aggregate of 10,000,000 shares of AMHC's Class A Common Stock at a price of $10.00 per share for aggregate gross proceeds of $100.0 million ("PIPE Financing"). The PIPE Financing was consummated concurrently with the closing of the Business Combination.

Please refer to Note 3, "Reverse Recapitalization", for further details of the Business Combination.

Liquidity and Going Concern

The Company has incurred significant losses and negative cash flows from operations since its inception. During the years ended December 31, 2022 and 2021, the Company incurred net losses of $37.7 million and $30.6 million, respectively. During the years ended December 31, 2022 and 2021, the Company had negative operating cash flows of $45.9 million and $33.7 million, respectively. As of December 31, 2022, the Company had an accumulated deficit of $105.1 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.

As of December 31, 2022, the Company had cash and cash equivalents of $38.3 million. The Company's management expects that the existing cash and cash equivalents, together with the total estimated net proceeds of $101.4 million from the public offering that closed in January 2023 and the sale of shares of common stock pursuant to the ATM Prospectus Supplement in January 2023, will be sufficient to fund the Company's operating plans for at least twelve months from the issuance date of these consolidated financial statements. Therefore, based on management's updated evaluation of the Company's ability to continue as a going concern, management has concluded the factors that previously raised substantial doubt about the Company's ability to continue as a going concern no longer exist as of the issuance date of these consolidated financial statements. However, the Company will need to raise additional financing to continue its products' development for the foreseeable future, and will continue to need to do so until it becomes profitable. The Company's management plans to monitor expenses and raise additional capital through a combination of public and private equity, debt financings, strategic alliances, and licensing arrangements. The Company's ability to access capital when needed is not assured and, if capital is not available to the Company when, and in the amounts needed, the Company may be required to significantly curtail, delay or discontinue one or more of its research or development programs or the commercialization of any product candidate, or be unable to expand its operations or otherwise capitalize on the Company's business opportunities, as desired, which could materially harm the Company's business, financial condition and results of operations.

The consolidated financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The consolidated financial statements do not reflect any adjustments relating to the recoverability and reclassifications of assets and liabilities that might be necessary if the Company is unable to continue as a going concern.

Coronavirus Pandemic

While conditions related to the COVID-19 pandemic improved in 2022 compared to 2021, the pandemic continues to be dynamic, and near-term challenges across the economy remain. While the Company's operations to date have not been significantly impacted by the continuing COVID-19 pandemic, it cannot at this time predict the specific extent, duration, or full impact that the COVID-19 pandemic will have on its business, financial condition and operations, as the ongoing effects of COVID-19 remain difficult to predict due to numerous uncertainties, including the severity, duration and resurgence of the outbreak, new variants and the contagiousness of these new variants, the effectiveness of health and safety measures, including vaccines and therapies, government and community responses, the pace and strength of the economic recovery, supply chain pressures, and potential delays in enrollment in clinical trials, among others. The impact of the COVID-19 pandemic on the Company's financial performance will depend on future developments, including the duration and spread of the pandemic, its impact on the Company's clinical trial enrollment, trial sites, contract research organizations ("CROs"), contract manufacturing organizations ("CMOs"), and other third parties with whom it does business, its impact on regulatory authorities and the Company's key scientific and management personnel, progress and effectiveness of vaccinations and related governmental advisories and restrictions. These developments and the impact of the COVID-19 pandemic on the financial markets and the overall economy are highly uncertain and cannot be predicted. The Company will continue to actively monitor the effects of the COVID-19 pandemic and will continue to take appropriate steps to attempt to mitigate the impacts to its employees, business, financial condition and operations.

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 for financial reporting.

The financial statements are consolidated for the years ended December 31, 2022 and 2021, and include the accounts of Jasper Therapeutics, Inc. (i.e., formerly known as AMHC) and its wholly-owned subsidiary, Jasper Tx Corp., following the Reverse Recapitalization as further discussed in Note 3, "Reverse Recapitalization". All intercompany transactions and balances have been eliminated upon consolidation.

All historical share data and per-share amounts were retrospectively adjusted to reflect the effect of the exchange ratio of 0.2823780 per one share, which was determined at the closing of the Reverse Recapitalization, except for the 100 shares of Series A-2 redeemable convertible preferred stock. The Series A-2 shares were not subject to the exchange ratio as a part of the recapitalization; rather, the shares were converted into 2,200,000 shares of common stock upon the closing of the Business Combination.

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 valuation of common and redeemable convertible preferred stock before the Reverse Recapitalization, the determination of the incremental borrowing rate used for operating lease liabilities, valuation of derivative liability before the Reverse Recapitalization, valuation of earnout liability and the measurement of stock-based compensation expense. 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,	
	2022	**2021**
Cash and cash equivalents	$ 38,250	$ 84,701
Restricted cash	417	345
Total cash, cash equivalents and restricted cash	$ 38,667	$ 85,046

Cash and cash equivalents consist of checking account and investments in money market funds with an original maturity of three months or less at the time of purchase. The recorded carrying amount of cash and cash equivalents approximates their fair value. Restricted cash relates to the letter of credit secured in conjunction with the operating lease (Note 9).

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. Management believes that these financial institutions are financially sound. The Company has not experienced any losses on its cash and cash equivalents.

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 ("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 did not record any impairment of long-lived assets during the years ended December 31, 2022 and 2021.

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 has no finance leases as of December 31, 2022 and 2021.

Fair Value of Financial Instruments

The Company's financial instruments consist of cash and cash equivalents, other receivables, prepaid expenses and other current assets, accounts payable, accrued expenses and other current liabilities, common stock warrant liability, earnout 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, other receivables, prepaid expenses and other current assets, accounts payable, accrued expenses and other current liabilities, approximate fair value due to their short-term maturities.

Common Stock Warrant Liability

The Company has outstanding warrants to purchase 4,999,863 shares of its common stock (the "Common Stock Warrants"), all of which were issued in connection with AMHC's initial public offering and entitle a holder to purchase one share of the Company's common stock at an exercise price of $11.50 per share. The Common Stock 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 Common Stock Warrants are accounted as derivative financial instruments. As long as the Company continues to have shares of non-voting common stock outstanding, the Common Stock Warrants do not meet the equity classification guidance and are accounted as liabilities at fair value. The Common Stock 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. Upon conversion of all outstanding shares of non-voting common stock into shares of voting common stock, the Common Stock Warrants will meet the equity classification guidance and will be reclassified to equity at the then-current fair value. On January 31, 2023, 911,022 outstanding shares of the Company's non-voting common stock were converted into 911,022 shares of the Company's voting common stock per the holder's request, leaving no shares of non-voting common stock remaining outstanding as of January 31, 2023.

Earnout Liability

At the closing of the Business Combination, the Company recognized the earnout liability related to the Sponsor Support Agreement, dated May 5, 2021 and amended on September 24, 2021, by and among the Company, Amplitude Healthcare Holdings LLC (the "Sponsor") and Old Jasper (as amended, the "Sponsor Support Agreement"), pursuant to which 1,050,000 shares of common stock that were previously issued to the Sponsor were placed in escrow (the "Earnout Shares"). These shares will be released from escrow upon achieving agreed upon common stock price targets during the specified periods and in three tranches. In accordance with Accounting Standards Codification ("ASC") Topic 815-40, the Earnout Shares are not indexed to the common stock and therefore are accounted as a liability at fair value at the Closing Date and subsequently remeasured at each reporting date with changes in fair value recorded in the consolidated statements of operations and comprehensive loss. The Company will reassess the classification of the Earnout Shares as triggering events are met or expire.

Accrued Research and Development Expenses

The Company has entered into various agreements with outsourced vendors, CMOs and CROs. 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 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 studies, 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 studies, 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 overheads 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 common stock fair value, 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, 2022 and 2021, 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 (deficit) except those resulting from distributions to stockholders. There have been no items qualifying as other comprehensive income (loss) during the years ended December 31, 2022 and 2021, 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. 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 redeemable convertible preferred stock, common stock subject to repurchase, common stock subject to restricted stock awards, the Earnout Shares, the Common Stock Warrants 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 all series of its redeemable convertible preferred stock, common stock subject to repurchase, common stock subject to restricted stock awards and the Earnout Shares 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, 2022 and 2021, 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 Earnout Shares and common stock subject to restricted stock awards 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 determined it operates as a single operating and reportable segment. The Company's chief operating decision maker, its President and Chief Executive Officer, manages the Company's operations on a consolidated basis for the purposes of allocating resources. All long-lived assets are located in the United States.

Recent Accounting Pronouncements

In December 2019, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2019-12, Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes, which removes certain exceptions to the general principles in Topic 740 and improves consistent application of and simplifies U.S. GAAP for other areas of Topic 740 by clarifying and amending existing guidance. For public companies, this ASU is effective for fiscal years beginning after December 15, 2020. For all other entities, this ASU is effective for fiscal years beginning after December 15, 2021, and interim periods within fiscal years beginning after December 15, 2022. Early adoption is permitted. The Company adopted this ASU on January 1, 2022. The adoption of this ASU did not have a material effect on the Company's consolidated financial statements and related disclosures.

In November 2021, the FASB issued ASU No. 2021-10, Government Assistance (Topic 832): Disclosures by Business Entities about Government Assistance, which requires annual disclosures about certain types of government assistance received. ASU No. 2021-10 is effective for fiscal years beginning after December 15, 2021. The Company adopted this ASU on January 1, 2022. The adoption of this ASU resulted in additional disclosures related to the CIRM grant (Note 6). The adoption of this ASU did not have a material effect on the Company's consolidated financial statements.

New Accounting Pronouncements Not Yet Adopted

In June 2022, the FASB issued ASU No. 2022-03, Fair Value Measurement (Topic 820): Fair Value Measurement of Equity Securities Subject to Contractual Sales Restrictions, which (1) clarifies the guidance in Topic 820 on the fair value measurement of an equity security that is subject to contractual restrictions that prohibit the sale of an equity security and (2) requires specific disclosures related to such an equity security. The Company does not expect the adoption of this ASU to have a significant impact on the Company's consolidated financial statements.

In March 2020, the FASB issued ASU No. 2020-04, Reference Rate Reform (Topic 848): Facilitation of the Effects of Reference Rate Reform on Financial Reporting, which provides optional expedients and exceptions for applying U.S. GAAP to contracts, hedging relationships and other transactions affected by reference rate reform if certain criteria are met. The amendments in this ASU were effective for all entities as of March 12, 2020 through December 31, 2022; however, in December 2022, the FASB issued ASU No. 2022-06, Reference Rate Reform (Topic 848): Deferral of the Sunset Date of Topic 848, which extended the sunset date from December 31, 2022 to December 31, 2024. An entity may elect to apply the amendments for contract modifications by Topic or Industry Subtopic as of any date from the beginning of an interim period that includes or is subsequent to March 12, 2020, or prospectively from the date that the financial statements are available to be issued. Once elected for a Topic or an Industry Subtopic, the amendments must be applied prospectively for all eligible contract modifications for that Topic or Industry Subtopic. The Company is currently evaluating the effect of ASU No. 2020-04 on its consolidated financial statements.

NOTE 3. REVERSE RECAPITALIZATION

On the Closing Date, the Company consummated the Business Combination in accordance with the BCA. Merger Sub merged with Old Jasper, with Old Jasper as the surviving company and as a wholly-owned subsidiary of AMHC. AMHC was renamed Jasper Therapeutics, Inc., and Old Jasper was renamed Jasper Tx Corp.

In accordance with the BCA, at the closing of the Business Combination, each share of Old Jasper common stock and Old Jasper redeemable convertible preferred stock outstanding immediately prior to the closing was automatically cancelled, extinguished and converted into the number of shares of the Company's common stock or, in certain circumstances, the Company's non-voting common stock, based on Old Jasper's equity value of $275.0 million divided by $10.00. The exchange ratio agreed between the parties was one-for-0.282378 share of the Company's common stock for all Old Jasper stockholders, except for Amgen Inc. ("Amgen"). Amgen's 100 shares of Series A-2 redeemable convertible preferred stock were converted into 2,200,000 shares of the Company's common stock, which represented 8% of the Old Jasper equity value, as per the terms of the Amgen's agreement with Old Jasper. Each vested and unvested option to purchase shares of Old Jasper's common stock outstanding at the closing of the Business Combination was converted into a comparable option to purchase shares of the Company's common stock, with the same terms after giving effect of the exchange ratio. Each unvested award of restricted shares of Old Jasper common stock outstanding immediately prior to the closing was converted into a comparable right to receive restricted shares of the Company's common stock, after giving effect of the same exchange ratio.

In accordance with the Sponsor Support Agreement, 1,050,000 shares received by the Sponsor were placed in escrow and will be released upon meeting triggering events as defined in the agreement and as described in Note 8 below.

The Business Combination is accounted for as a reverse recapitalization under U.S. GAAP and Old Jasper was determined to be the acquiror. Accordingly, for accounting purposes, the consolidated financial statements of the Company represent a continuation of the financial statements of Old Jasper with the Business Combination being treated as the equivalent of the Company issuing stock for the net assets of AMHC, accompanied by a reverse recapitalization. The net assets of AMHC are stated at historical costs, with no goodwill or other intangible assets recorded. Operations prior to the Business Combination are presented as those of Old Jasper.

In connection with the Business Combination, the Company received $95.3 million in net cash proceeds. This amount was comprised of $5.5 million of cash held in AMHC's trust account from its initial public offering (after payment of redemptions and public offering expenses paid at the closing of the Business Combination) and $100.0 million of cash received by AMHC in connection with the PIPE Financing, net of AMHC's transaction costs and placement agents' fees of $9.0 million and operating expense payments of $1.2 million. The Company incurred $5.3 million of transaction costs, consisting of legal, professional, and banking fees, which were recorded as a reduction to additional paid-in capital.

At the Closing Date, the Company also recognized AMHC's net assets of $0.6 million, the fair value of common stock warrant liability of $7.9 million, and the fair value of earnout liability of $15.0 million.

The number of shares of common stock issued and outstanding immediately following the consummation of the Business Combination was:

	Number of Shares
Common stock of AMHC outstanding prior to the Business Combination	12,500,000
Less: shares forfeited by the Sponsor	(200,000)
Less: redemption of AMHC shares	(9,262,099)
Common stock of AMHC	3,037,901
Shares issued in the PIPE Financing	10,000,000
Business Combination and PIPE Financing shares	13,037,901
Old Jasper shares	24,778,409
Total shares of common stock immediately after the Business Combination	37,816,310

NOTE 4. 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, 2022 and 2021.

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. Level 3 liabilities that are measured at fair value on a recurring basis included the derivative tranche liability, which was extinguished in February 2021, and earnout liability, which was recognized in connection with the Business Combination in September 2021.

During the periods presented, the Company has not changed the manner in which it values liabilities that are measured at estimated fair value using Level 3 inputs. There were no transfers within the hierarchy during the years ended December 31, 2022 and 2021.

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, 2022			
	Level 1	**Level 2**	**Level 3**	**Total**
Financial assets				
Money market funds	$ 37,250	$ -	$ -	$ 37,250
Total fair value of assets	$ 37,250	$ -	$ -	$ 37,250
Financial liabilities				
Common stock warrant liability	$ 150	$ -	$ -	$ 150
Earnout liability	-	-	18	18
Total fair value of financial liabilities	$ 150	$ -	$ 18	$ 168

	December 31, 2021			
	Level 1	**Level 2**	**Level 3**	**Total**
Financial assets				
Money market funds	$ 83,701	$ —	$ —	$ 83,701
Total fair value of assets	$ 83,701	$ —	$ —	$ 83,701
Financial liabilities				
Common stock warrant liability	$ 7,350	$ —	$ —	$ 7,350
Earnout liability	—	—	5,743	5,743
Total fair value of financial liabilities	$ 7,350	$ —	$ 5,743	$ 13,093

The following table sets forth a summary of the changes in the fair value of the Company's Level 3 financial liabilities (in thousands):

	Derivative tranche liability	Earnout Liability
Fair Value as of January 1, 2021	$ 8,158	$ —
Initial fair value of earnout liability	—	15,020
Change in the fair value included in other expense (income)	3,501	(9,277)
Settlement of obligation	(11,659)	—
Fair Value as of December 31, 2021	—	5,743
Fair Value as of January 1, 2022	$ —	$ 5,743
Change in the fair value included in other income	—	(5,725)
Fair Value as of December 31, 2022	$ —	$ 18

The derivative tranche liability was measured using the option pricing method by estimating the value using the Black-Scholes model. The significant inputs used in the Black-Scholes model include the fair value of the redeemable convertible preferred stock, the risk-free interest rate, the expected volatility and the expected term when each tranche will be settled. The fair value of the derivative tranche liability equaled its intrinsic value, a difference between the issued redeemable convertible preferred stock shares' fair value and the price paid by investors, at the date of settlement in February 2021. The Company recorded a $3.5 million loss from the remeasurement of the derivative tranche liability in its consolidated statements of operations and comprehensive loss during the year ended December 31, 2021. As of December 31, 2022 and 2021, the derivative tranche liability was fully settled. The following assumptions were used to determine the fair value of the derivative tranche liability as of settlement date:

Series A-1 redeemable convertible preferred stock value	$ 1.57
Purchase price	$ 0.75
Expected term (in years)	—
Expected volatility	0.00%
Risk-free interest rate	0.00%

The estimated fair value of the earnout liability is determined using a Monte Carlo simulation model, which uses a distribution of potential outcomes on a monthly basis over the earnout period prioritizing the most reliable information available. The assumptions utilized in the calculation are based on the achievement of certain stock price milestones, including the current Company's common stock price, expected volatility, risk-free rate and expected term. 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 following table presents quantitative information about the inputs and valuation methodologies used for the Company's fair value measurements classified in Level 3 of the fair value hierarchy at December 31, 2022:

	Fair value (in thousands)	Valuation methodology	Significant unobservable input	
Earnout liability	$ 18	Monte Carlo Simulation	Common stock price	$ 0.48
			Expected term (in years)	1.73
			Expected volatility	105.0%
			Risk-free interest rate	4.40%

The following table presents quantitative information about the inputs and valuation methodologies used for the Company's fair value measurements classified in Level 3 of the fair value hierarchy at December 31, 2021:

	Fair value (in thousands)	Valuation methodology	Significant unobservable input	
Earnout liability	$ 5,743	Monte Carlo Simulation	Common stock price	$ 7.85
			Expected term (in years)	2.73
			Expected volatility	74.00%
			Risk-free interest rate	0.90%

NOTE 5. 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,	
	2022	2021
Prepaid insurance	$ 1,362	$ 2,074
Research and development prepaid expenses	842	139
Payroll tax credit receivable	250	548
Other prepaid expenses and current assets	246	219
Other	118	150
Total	$ 2,818	$ 3,130

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,	
	2022	2021
Leasehold improvements	$ 2,477	$ 2,056
Lab equipment	1,706	1,569
Office furniture & fixtures	502	208
Computer equipment	145	140
Capitalized software	90	90
Property and equipment, gross	4,920	4,063
Less: accumulated depreciation and amortization	(1,352)	(377)
Property and equipment, net	$ 3,568	$ 3,686

Depreciation and amortization expense for the years ended December 31, 2022 and 2021 was $1.0 million and $0.4 million, respectively

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,	
	2022	2021
Research and development accrued expenses	$ 2,651	$ 1,660
Accrued employee and related compensation expenses	1,587	1,151
License option liability, current	—	200
Other	194	585
Total	$ 4,432	$ 3,596

Other non-current liabilities

The following table summarizes the details of other non-current liabilities as of the dates set forth below (in thousands):

	December 31,	
	2022	2021
CIRM grant liability	$ 2,264	$ 600
Accrued tax liability	—	24
Restricted stock liability	9	19
Other non-current liabilities	80	—
Total	$ 2,353	$ 643

NOTE 6. 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 over the next three years that are primarily based on patients' enrollment to the Company's clinical trials. CIRM may 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 product candidates or CIRM-funded technology 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 US 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 received an aggregate of $0.6 million from CIRM in January and March 2021 for milestones that were met in 2020, and such amounts were included in other receivables and in other long-term liabilities. As of December 31, 2021, the Company recorded $0.6 million in other long-term liabilities related to this grant. In October 2022, the Company met the second milestone and received $1.0 million in December 2022 related to this milestone, which was also recorded in other long-term liabilities. In December 2022, the third milestone was mutually amended by the parties and achieved by the Company. As of December 31, 2022, the Company recorded $0.7 million in other receivables and in other long-term liabilities related to the third milestone. As of December 31, 2022 approximately $50,000 is available for future distribution to the Company under the grant upon achievement of a future milestone.

NOTE 7. SIGNIFICANT AGREEMENTS

Amgen License Agreement

On November 21, 2019, the Company entered into a license agreement with Amgen (the "Amgen License Agreement"), pursuant to which the Company obtained an exclusive, sublicensable license for certain patents, data, and non-data know-how related to Amgen's proprietary monoclonal antibody known as AMG-191, as renamed to JSP191 and then briquilimab. Concurrently with the execution of the license agreement, Amgen assigned to the Company its rights and obligations under the Investigator Sponsored Research Agreement (the "ISRA") previously entered into in June 2013 between Amgen and The Board of Trustees of the Leland Stanford Junior University ("Stanford") related to the study of briquilimab.

Under the ISRA, the Company was provided 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"). There are no other fees due under the ISRA. The Company exercised the Option in June 2020, and the definitive license with Stanford (the "Stanford License Agreement") was executed in March 2021. Upon exercise of the Option, the $1.0 million option exercise fee was recognized as research and development cost. In June 2020, the Company and Stanford agreed that the Investigational New Drug Application ("IND") and control of the study related to the ISRA would be transferred to the Company. As a result, the Company has worldwide exclusive rights to develop and commercialize briquilimab. The Company paid $0.2 million related to the option exercise fee in each of June and November 2020. The Company paid $0.2 million and $0.4 million related to this option exercise fee in 2022 and 2021 respectively. An amount of zero and $0.2 million is included in accrued expenses and other current liabilities as of December 31, 2022 and December 31, 2021, respectively.

The Amgen License Agreement terminates on a country-by-country basis on the 10th anniversary of the date on which the exploitation of the licensed products is no longer covered by a valid claim under a licensed patent in such country. On a country-by-country basis, upon the expiration of the term in each country with respect to the licensed products, the licenses to the Company by Amgen become fully paid and non-exclusive. The Company and Amgen have the right to terminate the agreement for a material breach as specified in the agreement.

Stanford License Agreement

In March 2021, the Company entered into the Stanford License Agreement, following the exercise of the Option in June 2020. 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 will use commercially reasonable efforts to develop, manufacture, and sell licensed product and to develop markets for a licensed product. In addition, the Company will use commercially reasonable efforts to meet the milestones as specified in the agreement over the six years from execution of the Stanford License Agreement and must notify Stanford in writing as each milestone is met.

The Company will 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 milestones 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 a $25,000 license maintenance fee in March 2022, which was recognized as research and development expense in the statements of operations and comprehensive loss for the year ended December 31, 2022.

The 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 agreement or any payment, missing a milestone or for a material breach, unless the Company remediates the problem in that 90-day period.

NOTE 8. DERIVATIVE FINANCIAL INSTRUMENTS

Common Stock Warrants

The Common Stock Warrants are traded on the Nasdaq Capital Market and may only be exercised for a whole number of shares. The Common Stock Warrants became exercisable on October 24, 2021 and expire on September 24, 2026, unless early redeemed or if the Company extends the exercise period. The fair value of $7.9 million of Common Stock Warrants was recognized as a liability on September 24, 2021, the Closing Date, based on the closing market price. 130 Common Stock Warrants have been exercised from the Closing Date through December 31, 2022.

The Company recognized a gain of $7.2 million and $0.5 million for the years ended December 31 2022, and 2021, respectively classified within change in fair value of common stock warrant liability in the consolidated statements of operations and comprehensive loss. The Common Stock Warrants' fair value was $0.2 million and $7.4 million as of December 31, 2022 and 2021, respectively.

Contingent Earnout Liability

Upon the closing of the Business Combination and pursuant to the Sponsor Support Agreement, the Sponsor agreed to place the Earnout Shares into escrow, which will be released as follows: (a) 250,000 Earnout Shares will be released if, during the period from and after September 24, 2021 until September 24, 2024 (the "Earnout Period"), over any twenty trading days within any thirty-day consecutive trading day period, the volume-weighted average price of the Company's common stock (the "Applicable VWAP") is greater than or equal to $11.50, (b) 500,000 Earnout Shares will be released if, during the Earnout Period, the Applicable VWAP is greater than or equal to $15.00, and (c) 300,000 Earnout Shares will be released if, during the Earnout Period, the Applicable VWAP is greater than or equal to $18.00 (the "triggering events").

The Earnout Shares placed in escrow are legally issued and outstanding shares that participate in voting and dividends. The Earnout Shares (along with related escrowed dividends, if any) will be forfeited and not released from escrow at the end of the Earnout Period unless the triggering events described above are achieved during the Earnout Period. Upon the closing of the Business Combination, the contingent obligation to release the Earnout Shares was accounted for as a liability classified financial instrument upon their initial recognition because the triggering events that determine the number of shares required to be released from escrow include events that were not solely indexed to the common stock of the Company. The earnout liability is remeasured each reporting period with changes in fair value recognized in earnings.

At December 31, 2022 and 2021, the estimated fair value of the earnout liability was less than $0.1 million and $5.7 million based on a Monte Carlo simulation model. Assumptions used in the valuations as of December 31, 2022 and 2021 are described in Note 4. No triggering event occurred as of December 31, 2022. The Company recognized a gain of $5.7 million and $9.3 million for the years ended December 31, 2022 and 2021, respectively, classified within change in fair value of earnout liability in the consolidated statements of operations and comprehensive loss.

NOTE 9. COMMITMENTS AND CONTINGENCIES

Operating Leases

In August 2020, the Company leased 7,781 rentable square feet and in January 2022, the Company leased an additional 5,611 square feet of laboratory and office space in Redwood City, California. The Company's operating lease will expire in August 2026. In March 2022, the Company entered into an agreement for 5,144 square feet of temporary office space in Redwood City, California, for use while the extra space leased in January 2022 was under construction. The Company paid a total of $0.1 million of rent expense during the year ended December 31, 2022 for the temporary office space rent.

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 will pay its share of operating expenses and taxes.

To complete certain leasehold improvements, the lessor agreed to provide the Company a tenant improvement allowance of $1.5 million as well as an option to take an additional allowance of $0.4 million to be repaid over the lease term at an interest rate of 9% per annum, which the Company exercised. The Company recognized $0.3 million and $1.6 million in leasehold improvements covered by these allowances as of December 31, 2022 and 2021, respectively. In accordance with the lease agreement, the lessor managed and supervised the construction of the improvements. In exchange for these services, the Company paid the lessor a fee equal to 5% of total construction costs. The leasehold improvements constructed are presented under property and equipment on the Company's consolidated balance sheets and will be depreciated on a straight-line basis over the remaining lease term.

In addition to the construction management and supervision fee noted above, the Company 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,	
	2022	2021
Lease cost		
Operating lease cost	$ 622	$ 479
Short-term lease cost	129	326
Total lease cost	$ 751	$ 805

Supplemental information related to the Company's operating leases is as follows:

	Year ended December 31,	
	2022	2021
Cash paid for amounts included in the measurement of lease liabilities (in thousands)	$ 870	$ 301
Weighted average remaining lease term (years)	3.6	4.6
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, 2022 (in thousands):

	Amount
Year ending December 31,	
2023	$ 1,119
2024	1,153
2025	1,187
2026	740
Total undiscounted lease payments	4,199
Less imputed interest	(548)
Total discounted lease payments	3,651
Less current portion of lease liability	(865)
Noncurrent portion of lease liability	$ 2,786

Stanford Sponsored Research Agreement

In September 2020, the Company entered into a sponsored research agreement with Stanford for a research program related to the treatment of Fanconi Anemia patients in Bone Marrow Failure requiring allogeneic transplant with non-sibling donors at Stanford Lucile Packard Children's Hospital (the "Research Project") using briquilimab. Stanford will perform the Research Project and is fully responsible for costs and operations related to the Research Project. In addition, Stanford owns the entire right, title, and interest, in and to all technology developed using Stanford facilities and by Stanford personnel through the performance of the Research Project under this agreement (the "Fanconi Anemia Research Project IP"). Under this agreement, Stanford granted the Company an exclusive option to license Stanford's rights in the Fanconi Anemia Research Project IP (the "Fanconi Anemia Option") in the field of commercialization of briquilimab. There is no license granted or other intellectual property transferred under this agreement until the Fanconi Anemia Option is exercised. As of December 31, 2022, the Company has not yet exercised the Fanconi Anemia Option.

As consideration for the services performed by Stanford under this sponsored research agreement, the Company agreed to pay Stanford a total of $0.9 million over approximately 3 years upon the achievement of development and clinical milestones, including FDA filings and patients' enrollment. The first milestone in the amount of $0.3 million was achieved in 2020. The second milestone in the amount of $0.3 million was achieved in February 2022 and recognized as a research and development expense in the consolidated statements of operations and comprehensive loss for the year ended December 31, 2022. The third milestone is based on the progress of the clinical trials and will be recognized if and when achieved.

License Agreements

In March 2021, the Company entered into the Stanford License Agreement (Note 7), pursuant to which the Company is 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. The Company is also obligated to pay late-stage clinical development milestones 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. All products were in development as of December 31, 2022 and 2021, and no such royalties were due as of such dates. The Company paid a $25,000 license maintenance fee in March 2022 and recognized this as a research and development expense in the consolidated statements of operations and comprehensive loss for the year ended December 31, 2022.

Legal Proceedings

The Company, from time to time, may be party to litigation arising in the ordinary course of business. The Company was not subject to any material legal proceedings during the years ended December 31, 2022 and 2021, and, to the best of its knowledge, no material legal proceedings are currently pending.

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, 2022 and 2021, the Company does not have any material indemnification claims that were probable or reasonably possible and consequently has not recorded related liabilities.

NOTE 10. 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 37,134,655 and 36,559,092 shares of voting common stock, 911,022 and 1,296,022 shares of non-voting common stock and no shares of preferred stock issued and outstanding as of December 31, 2022 and 2021, respectively.

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. On January 31, 2023, 911,022 shares of the Company's non-voting common stock were fully converted into 911,022 shares of the voting common stock per the holder's request, and no shares of non-voting common stock remained outstanding after such conversion.

As of December 31, 2022 and 2021, the Company had common stock reserved for future issuance as follows:

	December 31,	
	2022	**2021**
Outstanding and issued common stock options	6,169,180	2,660,383
Common stock warrants	4,999,863	4,999,883
Outstanding restricted stock units	2,617,445	—
Shares available for grant under 2021 Equity Incentive Plan	1,383,661	4,422,480
Shares available for grant under 2022 Inducement Equity Incentive Plan	1,295,672	—
Shares available for grant under 2021 Employee Stock Purchase Plan	869,117	550,000
Total shares of common stock reserved	17,334,938	12,632,746

Shelf Registration Statement

On October 7, 2022, the Company filed a shelf registration statement on Form S-3 ("Shelf Registration Statement") with the U.S. Securities and Exchange Commission ("SEC"). The Shelf Registration Statement allows us to sell from time to time up to $150.0 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. The SEC declared the Shelf Registration Statement effective on October 18, 2022. 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.

ATM Offering

On November 10, 2022, the Company also entered into a Controlled Equity Offering^{SM} Sales Agreement with Cantor Fitzgerald & Co. (the "Agent") pursuant to which we may offer and sell through or to the Agent, as sales agent or principal, shares of the Company's common stock from time to time (the "ATM Offering"). On November 10, 2022, the Company filed under the Shelf Registration Statement a prospectus supplement with the SEC in connection with the ATM Offering (the "ATM Prospectus Supplement"), pursuant to which the Company may offer pursuant to the ATM Offering shares of its common stock having an aggregate offering price of up to $15.5 million. As of December 31, 2022, there have been no sales under the ATM Offering and, as of December 31, 2022, the full capacity remained available for issuance. In January 2023, the Company issued and sold an aggregate of 2,337,496 shares of its common stock pursuant to the ATM Prospectus Supplement for total estimated net proceeds of $4.5 million.

Public Offering

In January 2023, the Company entered into an underwriting agreement (the "Underwriting Agreement") with Credit Suisse Securities (USA) LLC, William Blair & Company, L.L.C. and Oppenheimer & Co. Inc., as the representatives of the several underwriters named therein (the "Underwriters"), relating to an underwritten public offering (the "Offering") under the Shelf Registration Statement of 69,000,000 shares of Common Stock, which included the exercise in full by the Underwriters of their option to purchase 9,000,000 additional shares of Common Stock. The public offering price was $1.50 per share and the Underwriters agreed to purchase the Common Stock pursuant to the Underwriting Agreement at a price of $1.41 per share. The total estimated net proceeds of the Offering were $96.9 million.

NOTE 11. STOCK-BASED COMPENSATION

On September 23, 2021, the 2021 Equity Incentive Plan ("2021 Plan") and the 2021 Employee Stock Purchase Plan ("ESPP") became effective upon the prior approval of Old Jasper's board of directors and stockholders. The 2021 Plan and ESPP provide for annual automatic increases in the number of shares reserved under each plan, beginning on January 1, 2022. The number of shares available for issuance under the 2021 Plan will increase annually in an amount equal to the least of (i) 2,750,000 shares, (ii) a number of shares equal to 4% of the total number of shares of all classes of common stock of the Company outstanding on the last day of the immediately preceding fiscal year, or (iii) such lesser number of shares determined by the Company's Board of Directors (the "Board") no later than the last day of the immediately preceding fiscal year. The number of shares of common stock available for issuance under the ESPP will increase annually in an amount equal to the least of (i) 550,000 shares of common stock, (ii) a number of shares of common stock equal to 1% of the total number of shares of all classes of common stock of the Company on the last day of the immediately preceding fiscal year, or (iii) such number of shares determined by the Board. As of December 31, 2022, 5,904,271 shares were reserved for issuance under the 2021 Plan, of which 1,383,661 shares were available for future grant and 4,520,610 shares were subject to outstanding options and restricted stock units ("RSUs"), including performance-based awards. As of December 31, 2022, 59,434 shares have been issued under the ESPP and 869,117 shares were reserved and available for future issuance.

Under the 2021 Plan, the Company can grant incentive stock options ("ISOs"), nonstatutory stock options, restricted stock awards, stock appreciation rights, RSUs, performance awards and other awards to employees, directors and consultants. Under the 2022 Inducement Plan, the Company can 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. Under the ESPP, the Company can grant purchase rights to employees to purchase shares of common stock at a purchase price which 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 adopted the 2022 Inducement Equity Incentive Plan (the "2022 Inducement Plan"), pursuant to which the Company may grant equity awards to new employees. The only persons eligible to receive grants under the 2022 Inducement Plan are individuals who satisfy the standards for inducement grants under Nasdaq guidance. As of December 31, 2022, 3,000,000 shares were reserved for issuance under the 2022 Inducement Plan, of which 1,295,672 shares were available for future grant and 1,704,328 shares were subject to an outstanding stock option. In February 2023, the Company granted a stock option under the 2022 Inducement Plan to purchase 1,093,831 shares of the Company's common stock.

Stock options under the 2021 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 ISO (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.

Stock Option Activity

The following table summarizes the stock option activities, including performance-based stock options, under the 2021 Plan, the 2022 Inducement Plan and the 2019 Plan for the year ended December 31, 2022:

	Options Outstanding	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value
Balance, January 1, 2022	2,660,383	$ 0.81	8.54	$ 18,731,908
Options granted	3,997,553	$ 3.32		
Options exercised	(37,387)	$ 0.71		
Options cancelled/forfeited	(451,369)	$ 3.32		
Balance, December 31, 2022	6,169,180	$ 2.25	7.80	$ -
Vested and expected to vest, December 31, 2022	6,169,180	$ 2.25	7.80	$ -
Exercisable	2,438,614	$ 1.27	6.75	$ -

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. Aggregate intrinsic value as of December 31, 2022 is zero since the fair market value of the common stock as of such date was less than the exercise price of the outstanding stock options. The total intrinsic value of the options exercised during the years ended December 31, 2022 and 2021 was $0.1 million and $2.1 million, respectively.

The total fair value of options that vested during the years ended December 31, 2022 and 2021 was $1.8 million and $1.4 million, respectively. The weighted-average grant date fair value of options granted during the years ended December 31, 2022 and 2021 was $2.38 and $2.66 per share, respectively.

Future stock-based compensation for unvested options as of December 31, 2022 was $6.6 million, which is expected to be recognized over a weighted-average period of 2.7 years, including $0.1 million related to performance-based stock options, which is expected to be recognized over a weighted-average period of 0.3 years.

Performance-based stock options

The following table summarizes the performance-based stock options activity under the 2021 Plan and the 2019 Plan for the year ended December 31, 2022:

	Options Outstanding	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value
Balance, January 1, 2022	306,459	$ 0.71	8.41	$ 2,188,645
Options granted	157,500	$ 2.80		
Balance, December 31, 2022	463,959	$ 1.42	8.06	$ -
Vested and expected to vest, December 31, 2022	463,959	$ 1.42	8.06	$ -
Exercisable	308,959	$ 0.73	7.43	$ -

Restricted Stock Units (RSUs)

The following table provides a summary of RSUs activity under the 2021 Plan during the year ended December 31, 2022:

	Number of Shares	Weighted Average Grant date Fair Value
Unvested restricted stock units at January 1, 2022	-	$ -
Granted	2,865,350	$ 0.88
Vested	(93,722)	$ 3.54
Cancelled	(154,183)	$ 0.79
Unvested restricted stock units at December 31, 2022	2,617,445	$ 0.79
Vested and unreleased	-	$ -
Outstanding restricted stock units at December 31, 2022	2,617,445	$ 0.79

The total fair value of RSUs that vested during the year ended December 31, 2022 was $0.3 million. Unamortized stock-based compensation for restricted stock units as of December 31, 2022 was $1.6 million, which is expected to be recognized over a weighted-average period of 0.8 years.

Employee Stock Purchase Plan

The first offering period commenced in June 2022 and ended in December 2022. The second offering period commenced in December 2022 and will end in June 2023.

The Company issued 59,434 shares of common stock under the ESPP as of December 31, 2022 and recognized $0.1 million compensation expense related to the ESPP for the year ended December 31, 2022. Unamortized stock-based compensation for shares issuable under the ESPP as of December 31, 2022 was less than $0.1 million, which is expected to be recognized over a weighted-average period of 0.4 years. The Company recorded less than $0.1 million in accrued expenses and other current liabilities related to contributions withheld as of December 31, 2022.

Stock-Based Compensation Expense

The following table presents stock-based compensation expenses related to options and RSUs granted to employee and non-employees, ESPP awards and restricted common stock shares issued to founders (in thousands):

	Year Ended December 31,	
	2022	**2021**
Research and development	$ 1,423	$ 612
General and administrative	2,668	436
Total	$ 4,091	$ 1,048

The Company recognized $0.2 million and $0.1 million of stock-based compensation expense related to performance-based options and RSUs during the years ended December 31, 2022 and 2021, 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,	
	2022	**2021**
Expected term (in years)	1.00 – 6.08	5.29 – 6.08
Expected volatility	63.41% – 106.03%	75.27% – 75.79%
Risk-free interest rate	1.40% – 3.62%	0.65% – 0.80%
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 as the Company does not have any trading history for its common stock. 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 was estimated using a Black-Scholes option-pricing model with the following assumptions:

	Year Ended December 31, 2022
Expected term (in years)	0.50
Expected volatility	75.61% - 78.89%
Risk-free interest rate	1.81% - 4.72%
Expected dividend yield	—

NOTE 12. 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,	
	2022	2021
Numerator:		
Net loss attributable to common stockholders	$ (37,685)	$ (30,637)
Denominator:		
Weighted average common shares outstanding	37,935,117	12,363,677
Less: Weighted-average unvested restricted shares	(402,356)	(685,129)
Less: Shares subject to earnout	(1,050,000)	(284,795)
Weighted average shares used to compute basic and diluted net loss per share	36,482,761	11,393,753
Net loss per share attributable to common stockholders – basic and diluted	$ (1.03)	$ (2.69)

Earnout Shares are not included in the net loss per share as the triggering events are contingent upon the Company's common stock price exceeding specific thresholds and were not met as of each of December 31, 2021 and 2022.

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,	
	2022	2021
Common stock warrants	4,999,863	4,999,883
Outstanding and issued common stock options	6,169,180	2,660,383
Outstanding RSUs	2,617,445	—
Unvested restricted common stock	258,847	541,225
Total	**14,045,335**	**8,201,491**

NOTE 13. INCOME TAXES

During the years ended December 31, 2022 and 2021, the Company did not incur any tax expense or benefit as the Company operated with taxable losses and provided a full valuation allowance.

The provision for income taxes differs from the amount computed by applying the federal statutory income tax rate to loss before taxes as follows (in thousands):

	Year Ended December 31,	
	2022	2021
Federal tax benefit at statutory rate	$ (7,914)	$ (6,433)
State taxes	(4,518)	(1,729)
Change in fair value of derivative	—	735
Change in fair value of warrant liability	(1,512)	(105)
Change in fair value of earnout liability	(1,202)	(1,948)
Non-deductible expenses	(108)	633
Research and development credits	(1,835)	(1,095)
Change in valuation allowance	16,243	10,095
Other	846	(153)
Provision for income taxes	$ —	$ —

The Inflation Reduction Act 2022 (the "IRA"), which incorporates a Corporate Alternative Minimum Tax, was signed into law on August 16, 2022. The changes will affect the tax years beginning after December 31, 2022. The new tax will require companies to compute two separate calculations for federal income tax purposes and pay the greater of the new minimum tax or their regular tax liability. The Company does not expect the IRA to have a material impact on the Company's consolidated financial statements.

Significant components of the Company's net deferred tax assets (liabilities) as of December 31, 2022 and 2021 were as follows (in thousands):

	December 31,	
	2022	2021
Deferred tax assets:		
Accrued expenses and other	$ 1,281	$ 510
Intangibles	484	407
Net operating losses	20,669	14,683
Research and development credits	3,245	1,410
Stock based compensation	985	222
Lease liability	1,090	760
Section 195 start-up amortization	351	—
Fixed assets	99	—
Capitalized section 174	6,284	—
Unrealized gain/loss	—	13
Total deferred tax assets	34,488	18,005
Valuation allowance	(33,925)	(17,682)
Total net deferred tax assets	563	323
Deferred tax liabilities:		
Right-of-use asset	(563)	(302)
Fixed assets	—	(21)
Total deferred tax liabilities	(563)	(323)
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 $16.2 million and increased by $10.1 million for the years ended December 31, 2022 and 2021, respectively.

The following table sets forth the Company's federal and state net operating loss carryforwards as of December 31, 2022 (amounts in thousands):

	Amount	Expiration Years
Net operating losses, Federal	$ 68,798	Do not expire
Net operating losses, states primarily California	$ 120,035	2038-2042

As of December 31, 2022, the Company had research and development credit carryforwards of approximately $2.7 million and $2.2 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, 2021 and has appropriately reflected its net operating loss deferred tax assets. Any future ownership changes may result in further limitations.

Uncertain Tax Positions

A reconciliation of the beginning and ending balances of the unrecognized tax benefits during the periods ended December 31, 2022 and 2021 is as follows (in thousands):

	Year Ended December 31,	
	2022	**2021**
Balance at beginning of year	$ 828	$ 252
Additions based on tax positions related to current year	894	576
Balance at end of year	$ 1,722	$ 828

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 years 2022 and 2021. The Company does not expect its unrecognized tax benefit to change materially over the next twelve months.

The Company's federal returns for tax years 2019 through 2021 remain open to examination, and the Company's state returns remain subject to examination for tax years 2019 through 2021. Carryforward attributes that were generated in years where the statute of limitations is closed may still be adjusted upon examination by the Internal Revenue Service or other relevant tax authorities. No income tax returns are currently under examination by taxing authorities.

NOTE 14. 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. $0.1 million and zero contributions were made to the 401(k) Plan by the Company for the years ended December 31, 2022 and 2021, respectively.

NOTE 15. RELATED PARTIES

The Company entered into consulting agreements with two founders, who also received founders' common stock shares for services and assigned patents. The Company recorded $0.5 million for the founders' advisory and consulting services performed for each of the years ended December 31, 2022 and 2021. These expenses were recorded as research and development expenses in the consolidated statements of operations and comprehensive loss. Also, the Company's Licensed Technology from Stanford (see Note 7) was created in the Stanford laboratory of Professor Judith Shizuru, one of the Company's founders and a member of the Board.

In December 2020, the Company entered into a material transfer agreement with Zai Lab Limited where both companies collaborated on a research project and shared total expenses of up to $0.3 million equally. The Company recorded zero and $36,000 as a reduction to research and development expenses for expenses reimbursed by Zai Lab Limited for the years ended December 31, 2022 and 2021, respectively. The Company's chairman is a board member of Zai Lab Limited.

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, 2022 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, 2022.

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 due to an exemption established by the JOBS Act for "emerging growth companies."

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, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

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 2023 annual meeting of stockholders (the "2023 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 2023 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 2023 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 2023 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 2023 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 2023 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 2023 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 2023 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 2023 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 2023 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:

Exhibit Number	Description	Incorporated by Reference			
		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	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*	Description of Securities of Jasper Therapeutics, Inc.				
10.1	Form of Subscription Agreement, dated May 5, 2021.	8-K	001-39138	5/6/2021	10.1
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. 2021 Equity Incentive Plan.	8-K	001-39138	9/29/2021	10.3
10.4#	Jasper Therapeutics, Inc. 2021 Equity Incentive Plan Form of Stock Option Grant Notice and Stock Option Agreement.	8-K	001-39138	9/29/2021	10.4
10.5#	Jasper Therapeutics, Inc. 2021 Equity Incentive Plan Form of RSU Grant Notice and Award Agreement (RSU Award).	8-K	001-39138	9/29/2021	10.5
10.6#	Jasper Therapeutics, Inc. 2021 Employee Stock Purchase Plan.	8-K	001-39138	9/29/2021	10.6
10.7#	Jasper Therapeutics, Inc. 2022 Inducement Equity Incentive Plan.	8-K	001-39138	3/16/2022	10.1
10.8#	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
10.9#	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
10.10#	Jasper Therapeutics, Inc. 2019 Equity Incentive Plan.	S-4/A	333-256875	7/19/2021	10.12
10.11#	Employment Agreement, dated as of February 25, 2022, by and between Jasper Therapeutics, Inc. and Ronald Martell.	8-K	001-39138	2/28/2022	10.1
10.12#	Employment Agreement, dated as of September 24, 2021, by and between Jasper Therapeutics, Inc. and Jeet Mahal.	8-K	001-39138	9/29/2021	10.8
10.13#	Jasper Therapeutics, Inc. Employee Severance Plan for Vice Presidents and Executive Committee Members.	S-4/A	333-256875	7/19/2021	10.11
10.14#	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
10.15#	Service Agreement, dated March 7, 2022, by and between Jasper Therapeutics, Inc. and William Lis.	8-K	001-39138	3/11/2022	10.1
10.16#	Separation Agreement and General Release of All Claims, dated March 17, 2022, by and between the Registrant and Kevin N. Heller, M.D.	10-Q	001-39138	5/12/2022	10.6
10.17#*	Jasper Therapeutics, Inc. Non-Employee Director Compensation Policy.				
10.18#	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
10.19	Sponsor Support Agreement, dated as of May 5, 2021, by and among Amplitude Healthcare Acquisition Corporation, Amplitude Healthcare Holdings LLC and Jasper Therapeutics, Inc.	8-K	001-39138	5/6/2021	10.2
10.20	Amendment to Sponsor Support Agreement, dated as of September 24, 2021, by and among Amplitude Healthcare Acquisition Corporation, Amplitude Healthcare Holdings LLC and Jasper Therapeutics, Inc.	8-K	001-39138	9/29/2021	10.14
10.21^	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

10.22	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
10.23^	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
10.24^	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
10.25^	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
10.26^	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
10.27^	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
10.28^	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

10.29^	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
10.30^	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
10.31^	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
10.32	Controlled Equity Offering℠ Sales Agreement, dated as of November 10, 2022, by and between Jasper Therapeutics, Inc. and Cantor Fitzgerald & Co.	10-Q	001-39138	11/10/2022	10.1
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.				
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 8, 2023

JASPER THERAPEUTICS, INC.

By: /s/ Ronald Martell
Ronald Martell
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/ Ronald Martell Ronald Martell	President, Chief Executive Officer and Director (Principal Executive Officer)	March 8, 2023
/s/ Jeet Mahal Jeet Mahal	Chief Financial Officer and Chief Operating Officer (Principal Accounting and Financial Officer)	March 8, 2023
/s/ William Lis William Lis	Chairman of the Board	March 8, 2023
/s/ Anna French, D.Phil. Anna French, D.Phil.	Director	March 8, 2023
/s/ Vishal Kapoor Vishal Kapoor	Director	March 8, 2023
/s/ Lawrence Klein, Ph.D. Lawrence Klein, Ph.D.	Director	March 8, 2023
/s/ Christian W. Nolet Christian W. Nolet	Director	March 8, 2023
/s/ Judith Shizuru, M.D., Ph.D. Judith Shizuru, M.D., Ph.D.	Director	March 8, 2023
/s/ Kurt von Emster Kurt von Emster	Director	March 8, 2023

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 (the "Certificate of Incorporation"), the Company's Second 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.

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, except that the Class I directors as of September 24, 2021 shall serve an initial one-year term (and three-year terms subsequently) and the Class II directors as of September 24, 2021 shall serve an initial two-year term (and three-year terms subsequently). 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 December 31, 2022, 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 the three-year anniversary 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. 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 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.

Warrants

As of December 31, 2022, the Company had outstanding warrants to purchase 4,999,863 shares of Voting Common Stock with an exercise price of $11.50 per share (the "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 $0.01 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 $18.00 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 $18.00 redemption trigger price (as adjusted for stock splits, stock dividends, reorganizations, recapitalizations and the like) as well as the $11.50 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."

JASPER THERAPEUTICS, INC.

NON-EMPLOYEE DIRECTOR COMPENSATION POLICY

Each non-employee member of the board of directors (the "***Board***") of Jasper Therapeutics, Inc. (the "***Company***") shall be eligible to receive cash and equity compensation for his or her service on the Board as set forth in this Non-Employee Director Compensation Policy (this "***Policy***"). The cash and equity compensation described in this Policy shall be paid or be made, as applicable, automatically and without further action of the Board (or any committee thereof), to each member of the Board who is not an employee of the Company or any parent or subsidiary of the Company (each, a "***Non-Employee Director***") who is eligible to receive such cash or equity compensation, unless such Non-Employee Director declines the receipt of such cash or equity compensation by advance written notice to the Company. This Policy shall remain in effect until it is revised or rescinded by further action of the Board or the Compensation Committee of the Board (the "***Compensation Committee***"). This Policy and the compensation to be provided hereunder may be amended, modified or terminated by the Board or the Compensation Committee at any time in its sole discretion. The terms and conditions of this Policy shall supersede any prior cash and/or equity compensation arrangements between the Company and any of its Non-Employee Directors with respect to such Non-Employee Director's service on (or on behalf of) the Board or any committee thereof. No Non-Employee Director shall have any rights hereunder, except with respect to the cash compensation and stock options granted pursuant to this Policy. Non-Employee Directors may be eligible to receive discretionary awards granted outside this Policy.

1. Cash Compensation. The following are effective as of January 1, 2023:

(a) Annual Cash Retainers. Each Non-Employee Director shall be eligible to receive an annual cash retainer of $40,000 for service on the Board.

(b) Additional Annual Cash Retainers. In addition, a Non-Employee Director shall receive the following annual cash retainers, if applicable:

(i) Chairperson of the Board. A Non-Employee Director serving as Chairperson of the Board shall receive an additional annual cash retainer of $30,000 for such service.

(ii) Audit Committee. A Non-Employee Director serving as Chairperson of the Audit Committee of the Board (the "***Audit Committee***") shall receive an additional annual cash retainer of $15,000 for such service. A Non-Employee Director serving as a member of the Audit Committee (other than the Chairperson) shall receive an additional annual cash retainer of $7,500 for such service.

(iii) Compensation Committee. A Non-Employee Director serving as Chairperson of the Compensation Committee shall receive an additional annual cash retainer of $10,000 for such service. A Non-Employee Director serving as a member of the Compensation Committee (other than the Chairperson) shall receive an additional annual cash retainer of $5,000 for such service.

(iv) Nominating and Corporate Governance Committee. A Non-Employee Director serving as Chairperson of the Nominating and Corporate Governance Committee of the Board (the "***Nominating and Corporate Governance Committee***") shall receive an additional annual cash retainer of $8,000 for such service. A Non-Employee Director serving as a member of the Nominating and Corporate Governance Committee (other than the Chairperson) shall receive an additional annual cash retainer of $4,000 for such service.

(v) Research and Development Committee. A Non-Employee Director serving as Chairperson of the Research and Development Committee of the Board (the "***R&D Committee***") shall receive an additional annual cash retainer of $11,300 for such service. A Non-Employee Director serving as a member of the R&D Committee (other than the Chairperson) shall receive an additional annual cash retainer of $6,300 for such service.

(c) Payment of Retainers. The annual cash retainers described in Sections 1(a) and 1(b) shall be earned on a quarterly basis based on a calendar quarter and shall be paid by the Company in arrears not later than the 30th day following the end of each calendar quarter. In the event a Non-Employee Director does not serve as a Non-Employee Director, or in the applicable positions described in Section 1(b), for an entire calendar quarter, the retainer paid to such Non-Employee Director shall be prorated for the portion of such calendar quarter actually served as a Non-Employee Director, or in such position, as applicable. For avoidance of doubt, if a Non-Employee Director serves on the Board or a committee thereof for less than a full calendar quarter, the annual cash retainers described in Sections 1(a) and 1(b) shall be prorated for the portion of the calendar quarter in which the Non-Employee Director began serving on the Board or a committee thereof, as applicable, such that each Non-Employee Director shall receive annual cash retainers under this Policy only for the periods during which such Non-Employee Director actually serves on the Board or a committee thereof, as applicable. There are no per meeting attendance fees for attending meetings of the Board or any committee thereof.

(d) Revisions. Each of the Board and the Compensation Committee, in its discretion, may change and otherwise revise the terms of the cash compensation granted under this Policy, including, without limitation, the amount of cash compensation to be paid, on or after the date the Board or the Compensation Committee determines to make any such change or revision.

2. Equity Compensation. Non-Employee Directors shall be granted the equity awards described below. The awards described below shall be granted under and shall be subject to the terms and provisions of the Company's 2021 Equity Incentive Plan, as may be amended or restated from time to time, or any other applicable Company equity incentive plan then-maintained by the Company (the "***Equity Plan***"), and shall be granted subject to the execution and delivery of award agreements, including attached exhibits, in substantially the forms previously approved by the Board or the Compensation Committee, setting forth the vesting schedule applicable to such awards and such other terms as may be required by the Equity Plan (as may be amended or restated from time to time, collectively, the "***Additional Terms***"). All applicable terms of the Equity Plan apply to this Policy as if fully set forth herein, and all stock options granted pursuant to this Policy are subject in all respects to the terms of the Equity Plan and the Additional Terms.

(a) Appointment Awards for New Non-Employee Directors. Commencing March 3, 2023, upon the date an individual first becomes appointed or elected as a Non-Employee Director, such individual shall be automatically, and without further action of the Board or the Compensation Committee, granted a one-time non-statutory stock option to purchase 94,000 shares of voting Common Stock of the Company ("***Common Stock***") (subject to adjustment for recapitalizations, stock splits, stock dividends and similar transactions). The awards described in this Section 2(a) shall be referred to as "***Appointment Awards***."

(b) Annual Awards. Commencing March 3, 2023, on the date of each annual meeting of stockholders of the Company (each, an "***Annual Meeting***"), each individual who is a Non-Employee Director immediately prior to such Annual Meeting and who will continue to serve as a Non-Employee Director immediately following such Annual Meeting shall be automatically, and without further action of the Board or the Compensation Committee, granted a non-statutory stock option to purchase 47,000 shares of Common Stock (subject to adjustment for recapitalizations, stock splits, stock dividends and similar transactions). The awards described in this Section 2(b) shall be referred to as "***Annual Awards***." For the avoidance of doubt, a Non-Employee Director elected for the first time to the Board at an Annual Meeting shall only receive an Appointment Award in connection with such election, and shall not receive any Annual Award on the date of such Annual Meeting.

(c) Termination of Employment of Employee Directors. Members of the Board who are employees of the Company or any parent or subsidiary of the Company who subsequently terminate their employment with the Company and any parent or subsidiary of the Company and remain on the Board will not receive an Appointment Award grant pursuant to Section 2(a) above, but to the extent that they are otherwise eligible, will be eligible to receive, after termination from employment with the Company and any parent or subsidiary of the Company, Annual Awards as described in Section 2(b) above.

(d) Terms of Awards Granted to Non-Employee Directors.

(i) Purchase Price. The per share exercise price of each option granted to a Non-Employee Director shall equal the Fair Market Value (as defined in the Equity Plan) of a share of Common Stock on the date the option is granted.

(ii) Vesting. 25% of the shares subject to each Appointment Award shall vest and become exercisable on the one-year anniversary of the date of grant, with the remaining shares vesting on a monthly basis thereafter over the following 36 months, in each case subject to the Non-Employee Director continuing in service on the Board through and including such vesting date. Each Annual Award shall vest and become exercisable on the one-year anniversary of the date of grant, in each case subject to the Non-Employee Director continuing in service on the Board through and including such vesting date. No portion of an Appointment Award or Annual Award that is unvested or unexercisable at the time of a Non-Employee Director's termination of service on the Board shall become vested or exercisable thereafter. All Appointment Awards and Annual Awards held by a Non-Employee Director shall vest in full as of immediately prior to, and contingent upon, the occurrence of a Change in Control (as defined in the Equity Plan), subject to such Non-Employee Director's continuous service with the Company (or a parent or subsidiary of the Company) through immediately prior to such Change in Control.

(iii) Term. The term of each stock option granted to a Non-Employee Director shall be ten years from the date the option is granted. Upon a Non-Employee Director's termination of service on the Board for any reason, his or her then-vested stock options to purchase shares of Common Stock granted pursuant to this Policy shall remain exercisable for three months following the termination of his or her service on the Board (or such longer period as the Board may determine in its discretion on or after the date of grant of such stock options).

(iv) Option Award Agreements. Notwithstanding anything to the contrary in this Policy, each Appointment Award and Annual Award shall be subject to the terms and conditions of the Equity Plan and the Additional Terms.

(e) Revisions. Each of the Board and the Compensation Committee, in its discretion, may change and otherwise revise the terms of awards granted under this Policy, including, without limitation, the types of awards, the number of shares, the exercise prices, and vesting schedules, for awards granted on or after the date the Board or the Compensation Committee determines to make any such change or revision.

3. Expense Reimbursement. Upon presentation of documentation of such expenses reasonably satisfactory to the Company, each Non-Employee Director shall be reimbursed for his or her reasonable out-of-pocket business expenses incurred in connection with attending meetings of the Board and its committees or in connection with other business related to service on the Board or its committees. Each Non-Employee Director also shall be reimbursed for his or her reasonable out-of-pocket business expenses authorized by the Board or one of its committees that are incurred in connection with attendance at meetings with the Company's management. All reimbursements under this Section 3 shall be made in accordance with the Company's applicable expense reimbursement policies and procedures as in effect from time to time.

Adopted on October 25, 2021 and amended October 7, 2022 and March 3, 2023

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 (Nos. 333-260306 and 333-267777) and S-8 (Nos. 333-263773 and 333-263702) of Jasper Therapeutics, Inc. of our report dated March 8, 2023 relating to the financial statements, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP
San Jose, California
March 8, 2023

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, Ronald Martell, 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/ Ronald Martell
Ronald Martell
President, Chief Executive Officer, and Director
(Principal Executive Officer)

Dated: March 8, 2023

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, 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
Chief Financial and Business Officer and Corporate Secretary
(Principal Financial Officer)

Dated: March 8, 2023

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, 2022 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/ Ronald Martell
Ronald Martell

President and Chief Executive Officer
(Principal Executive Officer)
March 8, 2023

By: /s/ Jeet Mahal
Jeet Mahal

Chief Financial and Business Officer and Corporate Secretary
(Principal Financial Officer)
March 8, 2023

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.