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

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2025

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE TRANSITION PERIOD FROM TO**

Commission File Number 001-39103

CABALETTA BIO, INC.

(Exact name of Registrant as specified in its Charter)

Delaware	**82-1685768**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
2929 Arch Street, Suite 600 Philadelphia, PA	**19104**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (267) 759-3100

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.00001 per share	CABA	The Nasdaq Global Select Market

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

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 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	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☐

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

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

As of June 30, 2025 (the last business day of the registrant's most recently completed second fiscal quarter), the aggregate market value of the registrant's common stock held by non-affiliates was approximately $137 million based on the last reported sale price of the registrant's common stock on the Nasdaq Global Select Market on June 30, 2025.

The number of shares of registrant's Common Stock outstanding as of March 19, 2026 was 111,322,671.

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Summary of the Material and Other Risks Associated with Our Business

- We are a clinical-stage company with a limited operating history, have incurred significant losses since our inception, and anticipate that we will continue to incur significant losses for the foreseeable future.
- We are highly dependent on our relationships with Minaris Advanced Therapies, LLC, or Minaris (f/k/a WuXi Advanced Therapies, Inc) and/or Lonza Houston Inc., or Lonza, and/or Cellares Corporation, or Cellares, for our current manufacturing needs for our Phase 1/2 RESET, or Restoring Self-Tolerance, clinical trials for resecabtagene autoleucel, or rese-cel (formerly referred to as CABA-201), and if manufacturing capacity at any of these manufacturing partners is reduced or otherwise delayed or limited, including due to legislative action, or if we, Minaris, Lonza, Cellares or any third-party manufacturers encounter difficulties in manufacturing our product candidates, this could adversely impact the supply of product candidates for and enrollment in our trials.
- We are reliant on intellectual property licensed to us by Nanjing IASO Biotherapeutics Co., Ltd., or IASO, and termination of this license agreement would result in the loss of significant rights, which would have a material adverse effect on our business.
- If we are unable to obtain and maintain sufficient intellectual property protection for our current product candidates and technologies or any future product candidates, we may not be able to compete effectively in our markets.
- We will need to raise substantial additional funding before we can expect to complete development of any of our product candidates or generate any revenues from product sales.
- Our limited operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability.
- If we are unable to successfully develop our current programs into a portfolio of product candidates, or experience significant delays in doing so, we may not realize the full commercial potential of our current and future product candidates.
- If we encounter difficulties enrolling patients in our RESET™ clinical trials for rese-cel or future clinical trials, these clinical development activities could be delayed or otherwise adversely affected.
- If we are unable to advance our product candidates through clinical development, obtain regulatory approval and ultimately commercialize our product candidates, or experience significant delays in doing so, our business will be materially harmed.
- Results of earlier studies may not be predictive of future study or trial results, and we may fail to establish an adequate safety and efficacy profile to conduct clinical trials or obtain regulatory approval for our product candidates.
- If serious adverse events, undesirable side effects or unexpected characteristics are identified during the development of any of our product candidates, we may need to delay, abandon or limit our further clinical development of those product candidates.
- Manufacturing and administering our product candidates is complex and we may encounter difficulties in technology transfer to a contract manufacturing organization.
- We may be unable to reach agreement with the FDA or comparable foreign regulatory authorities on the methodologies for, and assessment of, comparability of different versions of a product candidate used in non-pivotal studies, pivotal studies and for intended commercial use or may be unable to establish such comparability.
- We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.
- We may establish our own manufacturing facility and infrastructure in addition to or in lieu of relying on third parties for the manufacture of our product candidates, which will be costly and time-consuming, and which may not be successful.

- Our future success depends in part upon our ability to retain our key employees, consultants and advisors and to attract, retain and motivate other qualified personnel.
- We have identified conditions that raise substantial doubt about our ability to continue as a going concern. If we are unable to secure additional funding beyond our current cash position that enables our operations into the fourth quarter of 2026, we may be forced to delay, reduce or discontinue our product development programs efforts or other operations.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K, including the sections entitled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations," contains express or implied forward-looking statements that are based on our management's belief and assumptions and on information currently available to our management. Although we believe that the expectations reflected in these forward-looking statements are reasonable, these statements relate to future events or our future operational or financial performance, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Forward-looking statements in this Annual Report on Form 10-K include, but are not limited to, statements about:

- the success, cost and timing and conduct of our clinical trial programs, including our Phase 1/2 RESET™ clinical trials for rese-cel, and any other product candidates, including statements regarding the timing of initiation, enrollment and completion of the clinical trials and the period during which the results of the clinical trials will become available;
- the expected timing and significance around the announcement of safety, biologic activity and/or any additional clinical data from our RESET™ clinical trials for rese-cel;
- the timing of and our ability to obtain and maintain regulatory approval of our product candidates, including rese-cel, and any other product candidates, in any of the indications for which we plan to develop them, and any related restrictions, limitations, and/or warnings in the label of an approved product candidate;
- our expectations for the tolerability and clinical activity of rese-cel and ability to advance this product candidate through our license agreement with IASO;
- the potential benefits of our Orphan Drug, Rare Pediatric Disease and Fast Track designations;
- our expected use of proceeds from sales of our common stock in "at-the-market" offerings and other offerings, and the period over which such proceeds, together with existing cash, will be sufficient to extend our current cash runway beyond our current expectations into the fourth quarter of 2026 and meet our operating needs, including our ability to continue as a going concern;
- our plans to pursue research and development of other product candidates;
- the potential advantages of our proprietary Cabaletta Approach for B cell Ablation platform, called our CABA® platform, and our product candidates;
- the extent to which our scientific approach and CABA® platform may potentially address a broad range of diseases;
- the potential benefits and success of our arrangements with IASO, Oxford, Minaris, Lonza and Cellares;
- our ability to successfully leverage our research and translational insights;
- our expectations regarding the results observed with the similarly-designed construct employed in recent academic publications, including the dosing regimen, and the implications on rese-cel;
- our ability to successfully commercialize our product candidates, including rese-cel and any other product candidates;
- the potential receipt of revenue from future sales of rese-cel and any other product candidates, if approved;
- the rate and degree of market acceptance and clinical utility of rese-cel and any other product candidates;
- our estimates regarding the potential market opportunity for rese-cel and any other product candidates, and our ability to serve those markets;
- our sales, marketing and distribution capabilities and strategy, whether alone or with potential future collaborators;

- our ability to establish and maintain arrangements or a facility for manufacture of rese-cel and any other product candidates;
- our ability to obtain funding for our operations, including funding necessary to initiate and complete our RESET™ clinical trials of rese-cel and any ongoing preclinical studies of other product candidates;
- our expectations for the efficiency of the trial design for our RESET™ clinical trials for rese-cel and the potential success and therapeutic benefits of rese-cel, including our belief that rese-cel may enable an "immune system reset" and provide deep and durable responses in patients across an increasing number of autoimmune diseases;
- the potential achievement of milestones and receipt of payments under our collaborations;
- our ability to enter into additional collaborations with existing collaborators or other third parties;
- our expectations regarding our ability to obtain and maintain intellectual property protection for our product candidates and our ability to operate our business without infringing on the intellectual property rights of others;
- our expectations regarding international expansion and results of our efforts to do so;
- the success of competing therapies that are or become available, and our competitive position;
- the accuracy of our estimates regarding expenses, future revenues, capital requirements and needs for additional financing;
- the impact of government laws and regulations in the United States and foreign countries, including any newly introduced legislation;
- the effect of any geopolitical conflicts or new or increased international tariffs, including mitigation efforts and economic effects, on any of the foregoing or other aspects of our business operations, including but not limited to any preclinical studies or research and development efforts, ongoing clinical trials and future clinical trials; and
- our ability to attract and retain key scientific or management personnel.

These factors should not be construed as exhaustive and should be read in conjunction with the other cautionary statements that are included in this Annual Report on Form 10-K. The forward-looking statements contained in this Annual Report on Form 10-K are made as of the date of this Annual Report on Form 10-K, and we undertake no obligations to publicly update or review any forward-looking statement, whether as a result of new information, future developments or otherwise. Therefore, you should not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this Annual Report on Form 10-K.

PART I

Item 1. Business.

Overview

We are a late clinical-stage biotechnology company focused on the discovery and development of innovative engineered T cell therapies that have the potential to provide deep and durable, perhaps curative, responses with one-time administration for patients with autoimmune diseases. Our proprietary CABA®, or Cabaletta Approach to B cell Ablation platform, focuses on the CARTA approach. CARTA refers to Chimeric Antigen Receptor T cells for Autoimmunity and is designed to potentially reset the immune system. Based on clinical data reported to date, we believe our CABA® platform has the potential to safely enable complete and durable responses for a broad range of autoimmune diseases and that it has potential applicability across dozens of autoimmune diseases that we have identified, evaluated and prioritized.

Resecabtagene autoleucel, or rese-cel (formerly referred to as CABA-201), is a 4-1BB co-stimulatory domain-containing fully human CD19-CAR T construct designed to treat patients with a broad range of autoimmune diseases and our lead product candidate within the CARTA strategy. Rese-cel is designed to achieve transient and deep depletion of all B cells following a single, weight-based infusion of T cells that are engineered to express an antibody fragment that recognizes a B cell receptor expressed on the surface of all B cells. The construct is designed to allow for the deep elimination of all B cells, including all B cells that contribute to disease, with subsequent repopulation by healthy transitional, naïve B cells. This approach has demonstrated the potential to reset the immune system and result in meaningful clinical responses without chronic therapy requirements in patients. The efficacy and safety of rese-cel was recently reviewed along with all other commercial and academic constructs in development in a February 2026 *Nature Biotechnology* publication.

In December 2025, we initiated a registrational trial with rese-cel for patients with dermatomyositis or anti-synthetase syndrome. In addition, we have ongoing Phase 1/2 trials evaluating rese-cel with a standard preconditioning regimen, fludarabine and cyclophosphamide, in systemic lupus erythematosus, or SLE, in patients with active lupus nephritis, or LN, or active SLE without renal involvement, systemic sclerosis, or SSc, and generalized myasthenia gravis, or gMG. In addition to our core development program across multiple indications using standard preconditioning regimens and standard manufacturing processes with partnered Contract and Development Manufacturing Organizations, or CDMOs, based on early data from a phase 1/2 trial evaluating rese-cel without preconditioning in pemphigus vulgaris patients, we are evaluating rese-cel without preconditioning in non-renal SLE and LN patients.

In addition, in January 2026 we announced INDa clearance for rese-cel to be manufactured using an automated manufacturing platform – the Cell Shuttle™ from Cellares - offering the potential for scalability to produce rese-cel for thousands of patients per year with minimal capital investment by the Company. The first clinical experience from these patients is expected to be presented in the first half of 2026.

Durability data from the no preconditioning SLE, LN and PV patients as well as the patients treated with rese-cel manufactured by the Cellares Cell Shuttle™ is expected to be presented in the second half of 2026.

RESET-Myositis®

The three adult myositis subtypes, dermatomyositis, or DM, anti-synthetase syndrome, or ASyS, and immune-mediated necrotizing myopathy, or IMNM, being evaluated in the RESET-Myositis® Phase 1/2 clinical trial of rese-cel affect approximately 80,000 patients in the U.S. Myositis typically affects middle-aged individuals, particularly women, and disease is often refractory, despite existing therapies. In the United States, we believe approximately 20% to 25% of the prevalent population, or 16,000 to 20,000 people, would be potentially eligible patients for rese-cel.

The RESET-Myositis® Phase 1/2 clinical trial is designed to treat at least six patients with DM, or ASyS, at least six patients with IMNM, as well as at least six patients with juvenile idiopathic inflammatory myopathy, or JIIM, all in separate parallel cohorts, with a single weight-based dose of 1.0×10^6 cells/kg. We announced the FDA granted Fast Track Designation for rese-cel for the treatment of patients with dermatomyositis and Orphan Drug Designation for rese-cel for the treatment of myositis in January and February 2024, respectively. In March 2024, we announced the FDA granted Rare Pediatric Disease designation for rese-cel for juvenile dermatomyositis. In May 2025, we

announced the FDA granted Regenerative Medicine Advanced Therapy, or RMAT, designation to rese-cel for the treatment of myositis.

Based on clinical data presented in October 2025 at the American College of Rheumatology, or the ACR, Convergence 2025, we have initiated a DM/ASyS registrational cohort within the RESET-Myositis® trial. There are approximately 60,000 patients with DM in the U.S. who have IVIg as their only FDA-approved treatment option and approximately 15,000 patients with ASyS in the U.S. who have no FDA-approved treatment options. Our registrational trial design includes a 16-week primary endpoint of moderate or major TIS response while off immunomodulators and on no or low-dose steroids. Based on the safety data from the phase 1/2 cohort, the protocol permits outpatient administration. In addition, we are planning for a pediatric submission in juvenile idiopathic inflammatory myopathy, or JIIM, based on data available at the time of adult submission from the ongoing Ph 1/2 cohort to support a pediatric label claim.

The planned size of 17 patients for the registrational cohort is based on the assumed treatment effect of rese-cel in DM/ASyS patients and an estimated background rate. The estimated background rate will be determined from a retrospective analysis of an external myositis patient registry and will include patients with similar inclusion criteria as those in the registrational DM/ASyS cohort. Based on comprehensive literature review to estimate the background rate, we estimate the likelihood of an active, refractory myositis patient achieving moderate or major TIS response within 16 weeks and concurrently discontinuing all immunomodulators to be less than 10%. Changes in the assumed background rate would result in a change in the number of rese-cel treated patients who would need to achieve the primary endpoint in the 17-patient registrational cohort.

The registrational cohorts will evaluate the same single, weight-based infusion of rese-cel at 1 x 10^6 cells/kg as used in the Phase 1/2 myositis cohorts with similar enrollment criteria. As presented at ACR Convergence 2025, all myositis patients in the Phase 1/2 DM/ASyS cohort with sufficient follow-up who met key registrational inclusion criteria exceeded the registrational primary endpoint, demonstrating major TIS responses with no immunomodulators. Based on discussions with the FDA, we plan to use pooled rese-cel safety data from across the entire RESET™ clinical trial program to supplement myositis specific safety data for the Biologics License Application, or BLA, submission in myositis, and the required safety database is expected to be approximately 100 autoimmune disease patients treated with the same single weight-based dose. We initiated enrollment in the registrational DM/ASyS cohort in December 2025 and anticipate BLA submission in 2027.

RESET-SLE™

SLE is a chronic, potentially severe, autoimmune disease, most commonly impacting young women between the ages of 15 and 40 with higher frequency and more severity in people of color, where the immune system attacks healthy tissue throughout the body. SLE affects an estimated up to 320,000 patients in the U.S., with LN as the most common end-organ manifestation, affecting approximately 30-40% of SLE patients.

The RESET-SLE™ Phase 1/2 clinical trial is designed to treat six SLE patients with active LN, and in a separate parallel cohort, six patients with active SLE without renal involvement, with a single weight-based dose of 1.0 x 10^6 cells/kg. In May 2023, we announced the FDA granted Fast Track Designation for rese-cel in patients with SLE and LN. In November 2025, we announced the FDA granted RMAT designation to rese-cel for treatment of SLE and LN. In January 2026, Cabaletta announced registrational cohort designs in RESET-SLE™ to evaluate the current rese-cel weight-based dose of 1 million cells/kg in a single infusion with preconditioning, including two independent, single-arm cohorts, one consisting of patients with non-renal SLE and one consisting of patients with LN each evaluating approximately 25 patients with unique endpoints in each cohort. Complete Phase 1/2 data from both cohorts is anticipated in the first half of 2026. Cabaletta will provide an update on next steps for these cohorts in 2026, subject to dose-ranging data evaluating rese-cel without preconditioning in lupus patients.

RESET-SSc™

SSc is a rare and potentially fatal chronic autoimmune disease characterized by progressive skin and internal organ fibrosis that can be life-threatening, including interstitial lung disease, pulmonary hypertension, and scleroderma renal crisis. SSc affects approximately 90,000 patients in the U.S., typically middle-aged individuals, particularly women.

The RESET-SSc™ Phase 1/2 clinical trial of rese-cel is designed to treat six patients with severe skin manifestations and six patients with severe organ involvement associated with SSc, each in separate parallel cohorts, with a single weight-based dose of 1.0 x 10^6 cells/kg. We announced the FDA granted Fast Track Designation for

rese-cel for the treatment of patients with SSc to improve associated organ dysfunction and Orphan Drug Designation for rese-cel for the treatment of SSc in January and March 2024, respectively. In January 2026, Cabaletta announced the FDA granted RMAT designation to rese-cel for treatment of SSc. Complete Phase 1/2 data from both cohorts is anticipated in the first half of 2026, and we anticipate announcing the registrational cohort design for SSc in the first half of 2026.

RESET-MG™

MG is a rare autoimmune disease characterized by autoantibodies that interfere with signaling at the neuromuscular junction, leading to potentially life-threatening muscle weakness. The majority of patients with MG have autoantibodies known to be pathogenic based on their interference with proteins in the NMJ, of which the majority target AChR. gMG affects approximately 100,000 patients in the U.S. Symptoms of gMG include profound muscle weakness throughout the body, disabling fatigue, and potential shortness of breath due to respiratory muscle weakness, with risk for episodes of respiratory failure.

The RESET-MG™ Phase 1/2 clinical trial of rese-cel is designed to treat six patients with AChR-positive gMG and six patients with AChR-negative gMG, each in separate parallel cohorts, with a single weight-based dose of 1.0×10^6 cells/kg.

In October 2025, we announced that rese-cel was generally well tolerated across two AChR-positive and two AChR-negative patients (both seronegative; no anti-MuSK or anti-LRP4 antibodies). No CRS (cytokine release syndrome) occurred in three of four patients, and grade 2 CRS occurred in AChR-pos-2 that resolved with no sequelae. As of the September 11, 2025 data cut-off, two evaluable patients (AChR-neg-1 and AChR-neg-2) remained off immunomodulatory medication and achieved significant improvements in MG-ADL (with AChR-neg-1 achieving Minimal Symptom Expression). AChR-pos-1 is not evaluable due to use of a prohibited cytotoxic medication that may have inhibited CAR T activity and AChR-pos-2 has insufficient follow-up.

Both cohorts have been fully enrolled. Complete Phase 1/2 data from both cohorts is anticipated in the first half of 2026, and we anticipate announcing the registrational cohort design for studies in MG in mid-2026.

RESET-PV®

Pemphigus vulgaris, or PV, is an autoimmune disease that occurs when the immune system produces antibodies that attack a protein called desmoglein, or DSG. DSG normally enables skin cells and the cells lining the inside of your mouth, nose, throat, eyelids, etc. to bind tightly together. Disruption by the antibodies directed to DSG causes the painful blisters and erosions characteristic of PV. Approximately 15,000 patients in the U.S. are affected by PV.

The ongoing RESET-PV® trial is designed to evaluate rese-cel as a monotherapy without preconditioning in patients with mucosal pemphigus vulgaris, or mPV, and mucocutaneous pemphigus vulgaris, or mcPV.

In October 2025, we announced that rese-cel exhibited similar CAR T cell expansion and contraction kinetics relative to translational data reported from other RESET™ trials with preconditioning. All three patients experienced substantial depletion of B cells within the first month post-infusion, with patients 2 and 3 achieving complete peripheral B cell depletion. In these two patients, rapid reduction in autoantibodies to desmoglein was observed and the increase in peak B cell activating factor, or BAFF, was at the low end of the range of patients dosed with rese-cel plus preconditioning from pre-infusion through the latest follow-up, suggestive of potential deep B cell depletion in the tissue. Additional follow up will be required to determine if the initial clinical effects are durable and to determine if the findings can be replicated in other autoimmune diseases. Rese-cel was generally well tolerated with no immune effector cell-associated neurotoxicity syndrome, or ICANS, reported as of the data cutoff. After infusion, patient 1 experienced transient fever (grade 1 cytokine release syndrome). Patient 2 required a course of steroids for a disease flare in the first two weeks following infusion after discontinuing immunomodulators.

PDAI activity scores have formed the basis for recent regulatory approvals in PV, and total PDAI scores in these patients were also reported to be consistent with the PDAI activity scores in the late breaking clinical trial session.

PDAI improvements were most significant in the two patients who seemed to experience complete peripheral B cell depletion.

Our History and Team

Our scientific co-founders, Aimee Payne, M.D., Ph.D., and Michael Milone, M.D., Ph.D., began partnering at Penn in 2013 to combine Dr. Payne's expertise in B cell-mediated autoimmune diseases with Dr. Milone's deep and experienced insights into the design and implementation of CAR T products. Dr. Payne is a worldwide leader in characterizing B cell-mediated autoantibody repertoires in PV and other autoimmune diseases. Dr. Milone is a renowned scientist in CAR T therapy and was a co-inventor of and a key driver in the preclinical discovery and development efforts that yielded Kymriah®, the first FDA-approved CAR T therapy for the treatment of B cell cancers. Their research attracted the attention of a colleague Steven Nichtberger, M.D., a professor of practice in the Vagelos LSM program and adjunct professor at the Wharton School at the University of Pennsylvania, and in 2017, based on over a year of interaction and discussions regarding the optimal strategy to advance the scientific opportunity into a commercially developed product portfolio that could offer potentially curative treatment options to patients, Drs. Payne, Milone and Nichtberger decided to launch Cabaletta Bio. The longstanding and highly productive partnership between our co-founders has been complemented by additional management experience that brings a successful history of translating academic cellular therapy research from Penn and elsewhere into commercially sponsored clinical trials and the establishment of a GMP manufacturing facility and organization.

Gwendolyn Binder, Ph.D., our President, Science and Technology, was an early member of the Translational Research Program Operations team at Penn for over five years and participated in the submission and acceptance of multiple INDs for novel engineered T cell therapy products. As part of the cell therapy organization at Penn, Dr. Binder partnered with Dr. Milone and others to drive the IND-enabling translational studies that facilitated the initial CAR T clinical trial in B cell cancers at Penn. Dr. Binder also built and led a clinical stage biotechnology company's manufacturing operations and quality teams, including creation of a fully functioning commercial grade GMP facility. Dr. Binder also built the translational research program and ultimately led the company's research organization.

Our Chief Medical Officer, David Chang, M.D. was the late-stage clinical development leader of the only two drugs approved for SLE in the United States in over 60 years, belimumab, or Benlysta, and anifrolumab, or Saphnelo, through his roles at GlaxoSmithKline plc and AstraZeneca Pharmaceuticals LP prior to joining the team at Cabaletta Bio. Dr. Chang completed his fellowship in Rheumatology and was a faculty member in the Division of Rheumatology at the Perelman School of Medicine at the University of Pennsylvania prior to his transition to the biopharmaceutical industry.

Our Chief Commercial Officer, Steve Gavel, joined Cabaletta in October 2025 and was previously Senior Vice President, Global Cell Therapy Commercial Development at Legend Biotech from 2018 to 2025, reporting to the CEO, where he created and scaled its commercial organization and implementation of all CAR T logistics and management of the leading CAR T centers in the U.S., in partnership with Johnson & Johnson, to successfully launch and grow Carvykti®, a treatment for patients with multiple myeloma. Earlier, Mr. Gavel led U.S. commercial strategy at Celgene.

Cabaletta was founded with the purpose of developing targeted, potential curative engineered cell therapies for patients with autoimmune disease. After three years developing a legacy form of cell therapy, we were encouraged by results from an initial case report published in the *New England Journal of Medicine* in August 2021 and a follow-up academic clinical study published in *Nature Medicine* in September 2022, showing the potential for CD19-CAR T cell therapy to transform the course of SLE. In five patients with SLE, one-time treatment with a 4-1BB-containing CD19-CAR T cell therapy induced deep and durable clinical responses in all five patients within three months after treatment, with favorable tolerability. Healthy B cells repopulated in all patients within five months of treatment, and responses remained durable off SLE-associated medications for up to 4 years of follow-up, as of September 2025. These findings demonstrate the potential for CD19-CAR T cell therapy to "reset the immune system," eliminating the cause of autoimmune disease with restoration of the healthy immune system.

Building on these results, we announced in October 2022 the development of rese-cel, a 4-1BB-containing CD19-CAR T investigational therapy, for the treatment of severe autoimmune diseases. Prompted by the initial case report in the *New England Journal of Medicine*, we conducted a global search to identify the optimally designed product candidate for patients with autoimmune diseases to be highly similar to the construct used by Dr. Georg Schett in the *Nature Medicine* paper. We are employing a clinically-evaluated fully human CD19 binder that has high

similarity, including identical epitopes and similar binding activity, to the construct employed in the academic reports. Our exclusive translational research partnership with Dr. Schett involves our robust translational research laboratory combined with confidential sharing of his unpublished clinical data to generate early and actionable insights from his trials that are informing our clinical development strategy and plans. As a result of the collaboration, in September 2023, Cabaletta scientists published "Cytokine and reactivity profiles in SLE patients following anti-CD19 CART therapy" in *Molecular Therapy: Methods and Clinical Development*, highlighting studies performed on serum samples from the first six SLE patients treated with CD19-CAR T cell therapy by Dr. Schett's team. The publication reports that in the three months following infusion, cytokine markers of systemic inflammation resolved, autoantibody titers declined, and humoral immunity was maintained.

Since announcing rese-cel in October 2022, Cabaletta has had five IND applications cleared within the routine 30-day period for the RESET™ Phase 1/2 clinical trials in SLE, myositis, SSc, gMG and MS, in addition to the RESET-PV® trial that is evaluating rese-cel without preconditioning. Accelerated by the emerging clinical data with rese-cel, our team's deep expertise in cell therapy in autoimmunity, demonstrated track record of strong clinical execution, positive regulatory interaction since 2018, and our successful cell therapy manufacturing, we are uniquely positioned to advance CD19-targeting cell therapy candidates to further our mission to develop therapies that deliver deep, durable and potentially curative responses for patients in a broad range of autoimmune diseases.

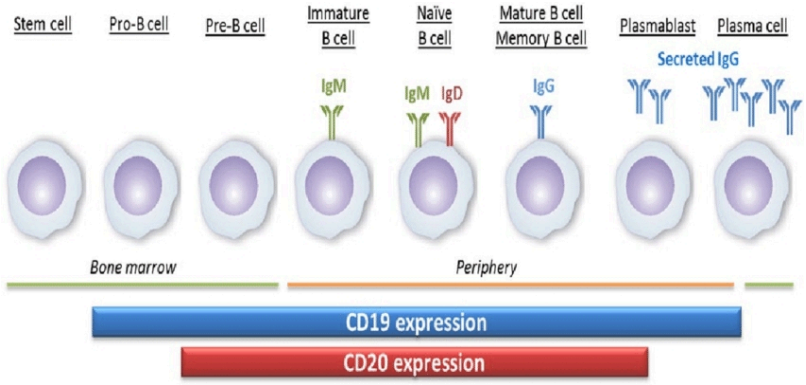
Our Strategy

Our goal is to build upon our deep expertise in engineered T cell therapies for autoimmune diseases to accelerate the discovery, development and commercialization of our product candidates. We believe achieving this goal could result in potentially curative therapies for patients with unmet medical needs who suffer from a broad range of autoimmune diseases with B cell involvement. To achieve this goal, key elements of our strategy include:

- ***Achieving compelling clinical responses and a favorable safety profile for our lead product candidate, rese-cel, and demonstrating its ability to be administered in the outpatient setting.*** In October 2025, we announced that all 4 DM/ASyS patients who met the key inclusion criteria for the myositis registrational cohort with sufficient follow-up achieved immunomodulatory-free TIS responses of moderate or major improvement at week 16, which formed the foundation to initiate the registrational cohort in DM and ASyS. In December 2025, we initiated enrollment in the DM/ASyS registrational trial and we announced that in the first 40 patients dosed with rese-cel with preconditioning across 4 RESET™ trials, 95% of patients had either no CRS or Grade 1 CRS (transient fever) and 95% of patients experienced no ICANS. Outpatient administration of rese-cel is permitted within the myositis registrational trial, and, if ultimately approved, for outpatient administration. If successful, we believe outpatient administration can reduce hospital resource utilization and improve the reimbursement framework for the 30% of autoimmune patients who are Medicare-insured.
- ***Leveraging our cellular therapy knowledge and manufacturing experience to manufacture rese-cel with the ability to achieve scalability to meet commercial demand with minimal capital investment.*** Our team has a successful track record of manufacturing novel cell therapy product candidates with academic and industry partners. We plan to launch utilizing multiple suppliers to ensure supply capacity and redundancy, while eliminating capital expenditure associated with a manufacturing facility. In addition, since 2023, we have partnered with Cellares Corporation, or Cellares, to incorporate automated manufacturing for rese-cel, which can enable scalability to produce rese-cel for thousands of patients per year with minimal capital investment, provide scheduling flexibility for rese-cel after commercialization and permit rapid expansion to support global expansion. Cellares is currently a manufacturer of rese-cel for the RESET™ clinical program and we anticipate initial clinical experience with Cellares in the first half of 2026 with full clinical and durability data in the second half of 2026.
- ***Develop differentiated innovations for rese-cel, including rese-cel without preconditioning, which could enable market expansion, improve patient and provider experience and accelerate outpatient adoption in the commercial setting.*** In October 2025, we announced initial clinical and translational data from the initial dose cohort in the RESET-PV® trial evaluating rese-cel without preconditioning. All three patients experienced substantial depletion of B cells within the first month post-infusion, with patients 2 and 3 achieving complete peripheral B cell depletion. Meaningful early clinical responses were observed in all three patients starting in the first month post-infusion based on Pemphigus Disease Area Index, or PDAI, score for skin, scalp and mucosal surfaces. Based on the safety and early efficacy data, multiple patients have now been enrolled at a higher dose cohort within the RESET-PV® study, and the no preconditioning approach was expanded in the RESET-SLE™ trial. We believe this innovation can potentially provide a simpler and more patient-focused alternative for lupus patients, many of whom are women of child-bearing potential, who may desire rese-cel without preconditioning. Based on evaluation of clinical durability data, the no-preconditioning strategy may be incorporated into each of our clinical trials.
- ***Advancing the RESET™ Phase 1/2 clinical trials to address significant unmet patient need while continuing to commit to optimize the patient experience.*** We are focused on developing the first potentially curative targeted cellular therapies for patients with autoimmune diseases. We plan to continue development of rese-cel across a broad range of autoimmune diseases where the biologic opportunity for cure or treatment may be possible, addressing significant unmet patient need across multiple indications for rese-cel, with the goal of realizing the potential of rese-cel. While potentially serving a broad range of patients, we are committed to advancing to optimize the patient experience through minimizing the requirement for inpatient stay, optimizing the preconditioning regimen, reducing the burden of apheresis, and/or innovating manufacturing to address scale in autoimmune disease.

B Cells in Autoimmune Diseases: Overview and Current Treatment Paradigm

The body's immune system, which is designed to protect the body from infection and cancer, includes B cells and T cells. In addition to producing antibodies against antigens that the body perceives as foreign, B cells are responsible for producing inflammatory cytokines, co-stimulating other immune cells, and presenting antigen to T cells to enable cell-mediated immunity. Autoimmune disease occurs when the immune response becomes mistakenly targeted to healthy tissues and cells, and B cells can contribute to the incitement and/or maintenance of these processes through their varied immune mechanisms. In the case of many autoimmune diseases, B cells are responsible for driving disease through production of autoantibodies, or antibodies against the 'self,' that lead to disease, as well as through costimulation of T cells and through cytokine production.



Thomas G. Forsthuber, et al. "B cell-based therapies in CNS autoimmunity: differentiating CD19 and CD20 as therapeutic targets." Therapeutic Advances in Neurological Disorders (2018): Vol 11: 1-13

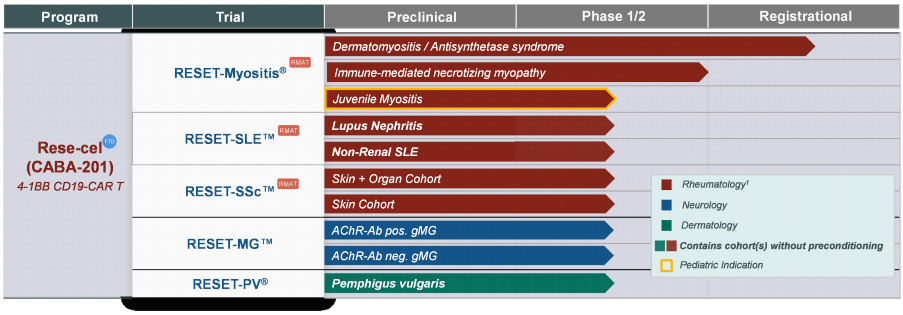
Key markers of B cell lineage. *CD19 serves as a B cell marker from the pro B cell phase until differentiation to plasma cells, while CD20 is a surface marker expressed in a narrower range of the B cell maturation process. Resecel is directed to the CD19 B cell marker. CAAR T product candidates are designed to eliminate antigen specific B cells in each targeted disease, preventing their further development to antibody secreting plasma cells. IgM: immunoglobulin M; IgD: immunoglobulin D; IgA: immunoglobulin A; sIg: surface immunoglobulin, representing the autoantibody on the B cell surface.*

There is currently no cure for autoimmune diseases. Current treatment options for autoimmune diseases involve generalized immune suppression, achieved through corticosteroids, immunosuppressive medications and biologics. Most commonly, corticosteroids are used on both a chronic and acute basis to control disease and act via a variety of mechanisms to control or downregulate multiple inflammatory pathways. In many cases, systemic immunosuppressive medications often used in chemotherapy such as mycophenolate, azathioprine and methotrexate, are added in an effort to minimize symptoms and manage the expected recurrences in patients. Biologic therapies have emerged as a new class of therapies and have a variety of targets including cytokines, B cells, and co-stimulation molecules. All of these current treatment options impair or destroy healthy B cells and/or other immune cells as well as pathogenic ones, weakening the patient's overall immune function, potentially putting them at risk for infection and impairing their response to vaccines. In general, these drugs require chronic administration and may have life-threatening side effects. We believe the ideal therapy in autoimmune diseases with B cell involvement would completely and specifically eliminate the pathogenic B cells with restoration of the normal immune system, enabling an "immune reset," restoring the body's immune system to its normal function of fighting foreign invaders, not healthy tissues.

Our Pipeline and Product Candidates

We are a clinical-stage biotechnology company focused on the discovery and development of engineered T cell therapies that have the potential to provide a deep and durable, perhaps curative, treatment for patients with

autoimmune diseases. Our CABA® platform focuses on the CARTA approach. Our current product candidate pipeline is illustrated below.



1. *Myositis patients can also be treated by neurologists or dermatologists; lupus nephritis patients can also be treated by nephrologists.*

RESET™ – REstoring SElf-Tolerance; Ab – Antibody; AChR – Acetylcholine receptor; gMG – Generalized myasthenia gravis; PV – Pemphigus vulgaris; SLE – Systemic lupus erythematosus; SSc – Systemic sclerosis. FDA Fast Track Designation received in dermatomyositis, SLE and lupus nephritis, systemic sclerosis, generalized myasthenia gravis and multiple sclerosis. FDA RMAT received in myositis, SLE, LN and systemic sclerosis.

Rese-cel for multiple autoimmune indications

Rese-cel is designed to achieve transient but deep depletion of all B cells following a single infusion, allowing for the elimination disease-causing B cells with subsequent repopulation by translational naïve healthy B cells. This strategy may be able to reset the immune system, providing potentially meaningful clinical responses to patients off immunosuppressive therapies. Cabaletta is advancing five RESET™ Phase 1/2 clinical trials in SLE, myositis, SSc, gMG and PV, with potential application in a broad range of other autoimmune diseases.

Rese-cel is comprised of a fully human anti-CD19 binder, which is the extracellular targeting domain. In addition, it contains a 4-1BB costimulatory domain and a CD3-zeta signaling domain, as shown in the figure below:

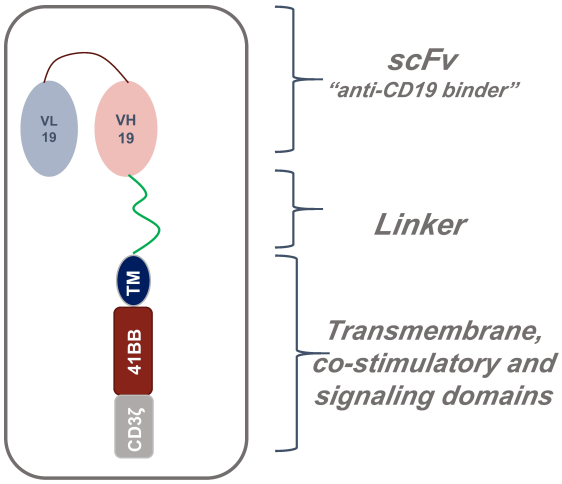


Image showing the design of rese-cel, with a fully human anti-CD19 binder, the 4-1BB costimulatory domain and the CD3-Zeta signaling domain. The costimulatory and signaling domain are identical to the construct used in the academic clinical studies published in Nature Medicine *and* Lancet Rheumatology *that were evaluated in SLE and myositis, respectively.*

Our exclusively licensed fully human CD19 binder has been clinically evaluated in a dual-CD19xCD22 CAR T candidate under development for B cell leukemia and lymphoma in an investigator-initiated trial in China in approximately 20 patients, where IASO has reported a tolerability profile that we believe is favorable for development in autoimmune diseases. Compared to FMC63-CART, rese-cel exhibits comparable biologic activity in vitro and in vivo (Peng, et al).

Based on the clinical and translational data that we have presented to date and given rese-cel's structural and functional similarity to the CD19-CAR T construct employed in the academic clinical study published in *Nature Medicine*, including incorporation of a 4-1BB co-stimulatory domain, we believe rese-cel may have the potential to reset the immune system and transform treatment of a broad range of autoimmune diseases with high unmet need.

Disease Backgrounds

Systemic lupus erythematosus is a chronic autoimmune disease, most common in young women between the ages of 15 and 40, with higher frequency and greater severity in people of color. In SLE, the immune system attacks healthy tissue throughout the body. It is results in a range of clinical manifestations, including end organ damage and an increased risk of death. SLE affects an estimated up to 320,000 patients in the U.S. Lupus nephritis is the most common end-organ manifestation of SLE, affecting approximately 30-40% of SLE patients. Among these patients, the risk of end-stage renal disease is approximately 17% and the risk of death is approximately 12%, each within 10 years of diagnosis.

Myositis refers to a group of autoimmune diseases characterized by severe inflammation and muscle weakness. It commonly impacts women of middle age, and in some cases, myositis may also affect other organs and systems in the body, such as the lungs, heart, or skin. Myositis is classified into several subtypes based on the underlying immune mechanisms and clinical characteristics. Although the pathogenesis of myositis is not well understood, there are several subtypes thought to be driven by B cells, including DM, ASyS and IMNM. All three subtypes can lead to severe functional impairment and may be life-threatening. Including juvenile myositis, or JIIM, patients, approximately 80,000 patients are affected by these subtypes in the U.S. Current standard of care typically involves medications to suppress the immune system and/or chronic intensive therapies such as intravenous immunoglobulin, or IVIg. Despite these therapies, many myositis patients have disease that remains refractory to existing medications.

Systemic sclerosis is a rare and potentially fatal chronic autoimmune disease characterized by progressive fibrosis and scarring of the skin and internal organs that can lead to life-threatening conditions, including interstitial lung disease, pulmonary hypertension, and scleroderma renal crisis. Although the etiology of SSc is not well understood, the pathogenic role of autoantibodies and B cells in SSc provides a rationale for studying CAR T therapy in this population. Approximately 90,000 patients in the U.S. are affected by SSc, commonly middle-aged women. Current treatments, which have modest effects, include generalized immunosuppression or drugs targeted to specific symptomatic manifestations. In some cases, autologous hematopoietic stem cell transplant may provide some benefits in organ involvement, but is associated with significant risks, including mortality, infertility, and secondary autoimmune disease, limiting its potential to be applied broadly. The risk of mortality in SSc remains high due to the lack of adequate treatments, with an average survival of approximately 12 years following initial diagnosis.

Myasthenia gravis is a rare autoimmune disease characterized by autoantibodies that interfere with signaling at the neuromuscular junction, or NMJ, leading to potentially life-threatening muscle weakness. The majority of patients with MG have autoantibodies known to be pathogenic based on their interference with proteins in the NMJ, of which the majority target AChR. Generalized MG affects approximately 100,000 patients in the U.S. Symptoms of gMG include profound muscle weakness throughout the body, disabling fatigue, shortness of breath due to respiratory muscle weakness and risk for episodes of respiratory failure. Standard of care therapies include cholinesterase inhibitors, steroids, immunomodulators, and biologics, which often require chronic administration, increasing the risk of serious long-term side effects.

Pemphigus vulgaris is an autoimmune disease that occurs when the immune system produces antibodies that attack a protein called DSG. DSG normally enables skin cells and the cells lining the inside of your mouth, nose, throat, and eyelids to bind tightly together. Disruption by the antibodies directed to DSG can cause extensive, painful blistering and life-threatening wounds characteristic of PV. Approximately 15,000 patients in the U.S. and approximately 20,000 patients in Europe are affected by PV. Current therapies do not adequately control the underlying autoimmune process, and PV management often involves long-term immunosuppression, with high-dose steroids used in initial treatment and for relapses. The risk of mortality among patients with PV has been reported to be 2- to 3-fold higher than in the general population.

Clinical Development Plan

Cabaletta is advancing RESET™ Phase 1/2 clinical trials in SLE, myositis, SSc, gMG and PV, with potential application in a broad range of other autoimmune diseases. These five RESET™ Phase 1/2 clinical trials are comprised of independent cohorts with specific objectively defined disease sub-types, which can enroll and dose patients in parallel, and each cohort is expected to be comprised of 6 patients. The trials are initiating at a weight-based dose, which is equivalent to the dose of the 4-1BB CD19-CAR T used in the academic publications (1.0×10^6 cells/kg) with the same preconditioning regimen of fludarabine and cyclophosphamide, with the exception of the RESET-PV® and RESET-SLE™ trials, which contain cohorts that are evaluating rese-cel without preconditioning. Our clinical strategy enables broad investigation of rese-cel across cohorts with well-defined patient populations in our Phase 1/2 clinical trials with the same dose and similar design. We have also received FDA Fast Track Designation for rese-cel in SLE, lupus nephritis, dermatomyositis, systemic sclerosis and multiple sclerosis.

Manufacturing

Manufacturing Strategy

Manufacturing supply is comprised of three primary components: plasmid (for lentiviral vector production), lentiviral vector (for gene transfer in the cellular product) and cellular product (the final drug product). Our

manufacturing strategy utilizes proven external suppliers, with a philosophy of maintaining redundant supply capability for cellular products while leveraging inventory build for plasmid and lentiviral vector, to mitigate potential supply interruption risk.

We established and implemented a phase-appropriate manufacturing supply strategy that optimized financial resources and speed for early clinical phase, or the Process A, and which was designed to enable a transition to a partially automated and commercially scalable process prior to the initiation of our first pivotal study in 2026, or the Process B. In addition, we are pursuing an automated version of Process B, or the Process C, capable of providing flexible and cost efficient supply at a scale that is estimated to be greater than what is achievable with the same footprint with Process B at existing CDMOs.

To support this manufacturing lifecycle plan, we designed and implemented a comparability strategy, which in alignment with our discussions with the FDA, supports the use of clinical safety data across Process A, B and C. Accordingly, Process A is undergoing a planned obsolescence in 2026. Process B is intended for initial commercial launch and is undergoing process validation activities in 2026 and 2027 to support BLA submission. Initial clinical manufacturing data using Process C is expected in 2026. If supportive, the process will be further refined and then put through process validation activities to support commercial application post BLA approval, in time to meet expanded commercial demand.

Contract and Development Manufacturing Organizations (CDMOs)

In December 2021, we entered into the License and Supply agreement, or the LSA, with Oxford Biomedica (UK) Limited, or Oxford, to supply lentiviral vector for the clinical and commercial development of a legacy product candidate. In May 2023, we amended the LSA with Oxford to expand the license to include our rese-cel program. In August 2023, we entered into a vector supply agreement with Oxford, and a related second amendment to the LSA, for rese-cel. In February 2024, we and Oxford entered into a third amendment to the LSA to update the patent schedule. In June 2024, we and Oxford entered into a fourth amendment to the LSA eliminating royalties on net sales of products that incorporate the Oxford technology if Oxford manufactures the vector. Starting in December 2024, we and Oxford entered into work orders for certain process validation activities as part of commercial readiness activities.

For early phase cellular product supply, in January 2021 and as amended in August 2022, we entered into an agreement with Minaris to serve as a cell processing manufacturing partner for a legacy program and have since completed enabling engineering and patient production runs. In August 2023, as amended in August 2024, we entered into an agreement with Minaris to serve as our manufacturing partner for the global clinical development of rese-cel in multiple indications using Process A. Minaris serves as a second CMDO for Process A, in addition to the Cell and Vaccine Production Facility, or CVPF, at the University of Pennsylvania, which has been phased out of clinical production supply as of 2026.

In order to expand our clinical supply to address the increasing pace of enrollment in our clinical trials, as well as to implement Process B and prepare for registrational trial(s) across the RESET™ clinical development program, we entered into a clinical supply agreement with Lonza to serve as a clinical supplier of rese-cel using Process B. This clinical supply agreement supports the global clinical development of rese-cel, including potential late-stage clinical trials and preparations for commercial readiness. Our manufacturing process at Lonza will be used for registrational trial enrollment and plans are underway for commercial launch and supply.

In conjunction with our efforts to expand scalable commercial supply for rese-cel through full automation of production, in November 2023, we partnered with Cellares to evaluate Cellares' automated manufacturing platform, the Cell Shuttle™, through Cellares' Technology Adoption Program. As part of the collaboration, we and Cellares agreed on a proof-of-concept technology transfer process for the manufacture of rese-cel. In March 2025, we and Cellares announced the successful conclusion of the Technology Adoption Program on Cellares' automated cell therapy manufacturing Cell Shuttle™. In June 2025 and January 2026, we expanded our partnership with Cellares to introduce the Cellares manufacturing platform to support the RESET™ clinical program. In January 2026, we and Cellares entered into a clinical supply agreement with Cellares to service as a clinical supplier of rese-cel using Process C. This clinical supply agreement supports the clinical development of rese-cel. Engineering runs in Cellares' GMP facility were completed, and our IND amendment has been cleared. Initial clinical runs are ongoing in 2026 providing additional manufacturing and drug product quality data. Based on the outcome of clinical manufacturing performance and comparability data, the Cell Shuttle™ may be integrated into our future commercial manufacturing strategy for rese-cel.

Commercialization

Our aim is to become a fully integrated cellular therapy company focused on improving the lives of patients with autoimmune diseases. The product candidates from our CABA® platform are designed to address autoimmune indications where there is a compelling opportunity to improve clinical outcomes in comparison with the current standard of care.

Rese-cel is under development for autoimmune diseases with serious unmet medical need. Based on the differentiated expertise of Cabaletta's team members and our years of experience in conducting cell therapy clinical trials in autoimmunity, we are focused on launching an autologous CAR T product for patients with autoimmune diseases, while continuing to innovate on next-generation approaches and differentiation strategies to deliver an optimal product candidate profile.

We aim to launch rese-cel through expanding our CDMO relationships, including advancing a fully automated approach, offering the potential for scalability to produce rese-cel for thousands of patients per year with minimal capital investment. Our development and commercialization efforts will focus initially on the United States, with expansion to the European Union and Asia-Pacific geographies, potentially with the support of strategic partners.

Competition

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong focus on intellectual property. We face competition from many different players, including large and specialty pharmaceutical and biotechnology companies, academic research organizations and governmental agencies. Any therapeutic candidates we successfully develop and commercialize will compete with the existing standard of care as well as any novel therapies that may gain regulatory approval in the future.

There are multiple companies with marketed CAR T therapies for the treatment of hematologic cancers, including Novartis Pharmaceuticals Corporation, Gilead Sciences, Inc., Bristol Myers Squibb, Johnson and Johnson, Inc., Legend Biotech Corporation and Autolus. A subset of these companies along with other biopharmaceutical companies have announced CD19-targeting therapies and other methods of engineering T cells in development for the treatment of autoimmune diseases with B cell involvement, including SLE, myositis, SSc and MG, among others. There are also a number of companies with leading autoimmune franchises but without disclosed cell therapy platforms who may become competitors.

Within the CAR T field, we recognize that a subset of companies with an investment and expertise in CAR T cell development for oncology indications have announced they intend to leverage their technology in autoimmune disease-affected populations. We are aware of other pharmaceutical and biotechnology companies that are exploring CD19-CAR T as well as other methods of engineering T cells, natural killer, or NK, cells or bispecific antibodies for the treatment of autoimmune conditions.

Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals, and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industry may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Intellectual Property and Barriers to Entry

We strive to protect the proprietary technologies that we believe are important to our business, including pursuing and maintaining patent protection intended to cover our product candidates and their use, as well as other inventions that are important to our business. In addition to patent protection, we also rely on know-how, confidentiality agreements, invention assignment agreements and trade secrets to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection, to develop and maintain our

proprietary position. The confidentiality agreements are designed to protect our proprietary information and the invention assignment agreements are designed to grant us ownership of technologies that are developed for us by our employees, consultants or certain other third parties. We seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in our agreements and security measures, either may be breached, and we may not have adequate remedies. In addition, our trade secrets may otherwise become known or independently discovered by competitors.

Our commercial success depends in part upon our ability to obtain and maintain patent and other proprietary protection for commercially important technologies, inventions and trade secrets related to our business, defend and enforce our intellectual property rights, particularly our patent rights, preserve the confidentiality of our trade secrets and operate without infringing valid and enforceable intellectual property rights of others.

The patent positions for biotechnology companies like us are generally uncertain and can involve complex legal, scientific and factual issues. In addition, the coverage claimed in a patent application can be significantly reduced before a patent is issued, and its scope can be reinterpreted and even challenged after issuance. As a result, we cannot guarantee that any of our product candidates will be protectable or remain protected by enforceable patents. We cannot predict whether the patent applications we are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient proprietary protection from competitors. Any patents that we hold may be challenged, circumvented or invalidated by third parties.

As of March 1, 2026, our in-licensed patent estate included eight granted U.S. patents, ten granted foreign patents, six pending U.S. patent applications, and 28 pending foreign patent applications. See "Our Material Agreements - IASO Agreement" and "Our Material Agreements - Amended and Restated License Agreement with the Trustees of the University of Pennsylvania and the Children's Hospital of Philadelphia." As of March 1, 2026, our Cabaletta-owned patent estate included three pending international patent applications, two pending U.S. patent applications, and nine pending foreign applications.

With regard to our rese-cel product candidate, under the IASO Agreement, we have in-licensed one patent family which is directed to a CD19-specific chimeric antigen receptor and a CD19-specific antibody and contains granted patents in the United States, China, Japan, and Canada, which are scheduled to expire in 2040, without taking patent term adjustment or patent term extension into account. The family also contains one pending U.S. patent application and counterpart patent applications pending in Australia, China, Europe, and Hong Kong, which, if issued, would be expected to expire in 2040. This patent family is owned by IASO and is exclusively licensed to us in the field of the license. We also own two patent families containing two pending U.S. patent applications and nine pending foreign patent applications drawn to methods of treating autoimmune diseases with a chimeric antigen receptor, including a CD19-specific chimeric antigen receptor, including certain treatment methods that have different preconditioning regimens. Any granted patents in these two families would be expected to expire in 2044. We also own one international patent application drawn to other dosing regimens for treating autoimmune diseases with a chimeric antigen receptor, including a CD19-specific chimeric antigen receptor; one international patent application drawn to CD19-binding antibodies and CD19-specific chimeric antigen receptors; and one international patent application drawn to methods of manufacturing cell-therapy compositions. Any granted patents claiming priority to these applications would be expected to expire in 2045.

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file, the patent term is 20 years from the earliest date of filing a non-provisional patent application. In the United States, the term of a patent covering an FDA-approved drug may be eligible for a patent term extension under the Hatch-Waxman Act as compensation for the loss of patent term during the FDA regulatory review process. The period of extension may be up to five years beyond the expiration of the patent but cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval. Only one patent among those eligible for an extension may be extended, and a given patent may only be extended once. Similar provisions are available in Europe and in certain other jurisdictions to extend the term of a patent that covers an approved drug. It is possible that issued U.S. patents covering each of our product candidates may be entitled to patent term extensions. If our product candidates receive FDA approval, we intend to apply for patent term extensions, if available, to extend the term of patents that cover the approved product candidates. We also intend to seek patent term extensions in any jurisdictions where they are available, however, there is no guarantee that the applicable authorities, including the FDA, will agree with our assessment of whether such extensions should be granted, and even if granted, the length of such extensions.

In addition to patent protection, we also rely on know-how and trade secret protection for our proprietary information that is not amenable to, or that we do not consider appropriate for, patent protection, to develop and maintain our proprietary position. However, trade secrets can be difficult to protect. Although we take steps to protect our proprietary information, including restricting access to our premises and our confidential information, as well as entering into agreements with our employees, consultants, advisors and potential collaborators, third parties may independently develop the same or similar proprietary information or may otherwise gain access to our proprietary information. As a result, we may be unable to meaningfully protect our know-how, trade secrets, and other proprietary information. In addition, we plan to rely on regulatory protection based on orphan drug exclusivities, data exclusivities, and market exclusivities. See “Government Regulation” for additional information.

Our Material Agreements

IASO Agreement

On October 7, 2022, we entered into an Exclusive License Agreement, or the IASO Agreement, with IASO. Pursuant to the IASO Agreement, we received an exclusive, worldwide license under certain IASO intellectual property to use a novel clinical-stage anti-CD19 binder to develop, manufacture, commercialize and otherwise exploit T cell products directed to CD19 for the purpose of diagnosis, prevention or treatment of any autoimmune or alloimmune indications in humans. IASO has the right of first negotiation if we desire to grant a third party an exclusive license to develop, manufacture, commercialize or otherwise exploit the licensed products in the Greater China region. Pursuant to the IASO Agreement, we and IASO have agreed, subject to certain exceptions, to refrain from engaging in certain competitive activities with respect to certain programs. As partial consideration for the exclusive license, IASO received an upfront payment of $2.5 million. IASO is also eligible to receive up to mid double digit millions in milestone payments based upon the achievement of specified pre-clinical, development and regulatory milestones, and up to an additional low triple digit millions in milestone payments based upon achievement of specified sales milestones, for a total consideration, inclusive of the upfront payment, of up to $162 million, along with tiered mid-single digit royalties on future net sales for licensed products that may result from the IASO Agreement. We also may sublicense through multiple tiers the rights granted to it by IASO under the IASO Agreement at any time, however, we must pay IASO a low double-digit percentage of any revenue obtained from sublicenses or options to third parties, subject to certain customary exclusions. The IASO Agreement will continue on a country-by-country, licensed product-by-licensed product basis until the expiration of the royalty term as identified in the IASO Agreement, unless earlier terminated. We and IASO may terminate the IASO Agreement for a material, uncured breach or insolvency of the other party. We may also terminate the IASO Agreement at will upon advance written notice and in the event IASO rejects the IASO Agreement due to bankruptcy-related matters. IASO may also terminate the IASO Agreement if we fail to achieve certain specified diligence milestones in a timely manner and/or if we commence any patent challenges with respect to the patents and patent applications relating to the licensed sequence, in each case upon advance written notice. A milestone payment of $1.5 million was paid to IASO in the first quarter of 2024 after the first patient in a rese-cel trial was dosed.

Oxford Biomedica

In December 2021, we entered into the LSA with Oxford wherein the LSA grants us a non-exclusive license to Oxford’s LentiVector® platform for its application in our DSG3-CAART program and puts in place a multi-year vector supply agreement. Under the terms of the agreement, we were required to pay Oxford an upfront fee, as well as costs associated with initial vector manufacturing activities. Oxford, is eligible to receive regulatory and sales milestones in the low tens of millions and royalties in the low single digits on net sales of products that incorporate the Oxford technology. We can terminate the agreement at will upon advance written notice and subject to certain manufacturing slot cancellation fees. In May 2023, we amended the LSA with Oxford to expand the license to include our rese-cel program for an upfront fee of $0.5 million and in August 2023, we entered into a vector supply agreement with Oxford, and a related second amendment to the LSA, for rese-cel with a total cost of up to approximately $5.0 million under the vector supply agreement. In February 2024, we and Oxford entered into a third amendment to the LSA to update the patent schedule. In June 2024, we and Oxford entered into a fourth amendment to the LSA eliminating royalties on net sales of products that incorporate the Oxford technology if Oxford manufactures the vector. Starting in December 2024, we and Oxford entered into work orders for certain process characterization and process performance qualification activities as part of commercial readiness activities. We can terminate the LSA or any work order under the LSA at will upon advance written notice and subject to certain cancellation fees.

Minaris Manufacturing Agreement

In January 2021, we entered into a Development and Manufacturing Services Agreement, or the Minaris Agreement, with Minaris to serve as an additional cell processing manufacturing partner for the MuSK-CAART Phase 1 clinical trial, or MusCAARTes™ trial. The Minaris Agreement is scheduled to expire upon completion of Minaris' services related to MuSK-CAART and rese-cel. In August 2023, as amended in August 2024, we entered into an agreement with Minaris to serve as one of our manufacturing partners for the global clinical development of rese-cel in multiple indications, including potential late-stage clinical trials and commercial readiness activities for rese-cel. Under the August 2023 work orders, Minaris converted our non-dedicated suite to a dedicated suite for GMP

manufacturing for our rese-cel and MuSK-CAART programs, or the Dedicated Suite, for an initial term of 18 months with two 18 month extensions at our sole option on six months' notice prior to the end of the term. In August 2024, we notified Minaris that we would extend the initial term by 18 months through August 2026. In addition, we agreed to certain monthly minimum runs. In August 2024, the 2023 work order related to GMP manufacturing was amended to reduce the minimum monthly runs through the end of 2024. In lieu of the original $1.5 million termination fee under the terms of the Minaris Agreement, we would incur up to a $1.08 million termination fee if we terminate both the rese-cel and MuSK-CAART work orders for any reason. We may terminate for convenience the Minaris Agreement or any work order with six months' prior written notice, however, we may not terminate the Dedicated Suite without terminating both the MuSK-CAART and rese-cel GMP run work orders. Minaris may terminate the Minaris Agreement or any work order for convenience on 18 months' prior written notice, but such notice may not be effective prior to February 2028. In February 2026, we notified Minaris that we intend to permit the term to expire in August 2026.

Lonza Manufacturing Agreement

In December 2024, we entered into a Development and Manufacturing Services Agreement, or the Lonza Agreement, with Lonza to serve as one of our manufacturing partners for the global clinical development of rese-cel in multiple indications, including potential late-stage clinical trials and preparations for commercial readiness. The Lonza Agreement has a term of five years and can be extended for an additional three year term upon notice to Lonza at least 18 months prior to the expiration of the Lonza Agreement. We can terminate the Lonza Agreement at will upon nine months advance written notice to Lonza subject to the terms of the Lonza Agreement. Lonza can terminate the Lonza Agreement at will upon 24 months advance written notice to us subject to the terms of the Lonza Agreement. Under the initial work order, Lonza will perform cell therapy manufacturing activities for our CAR-T cell therapy product, rese-cel, for an initial term of 12 months with the ability to extend the manufacturing period on a rolling basis subject to the terms of the Lonza Agreement.

Cellares Agreement

In January 2026, we entered into a Development and Clinical Manufacturing Services Agreement, or the Cellares Agreement, with Cellares to serve as one of our manufacturing partners for the clinical development of rese-cel in multiple indications, including potential late-stage clinical trials and preparations for commercial readiness. The Cellares Agreement has a term of five years. We can terminate the Cellares Agreement at will by providing a certain advance written notice to Cellares subject to the terms of the Cellares Agreement. Cellares can terminate the Cellares Agreement at will by providing a certain advance written notice to us subject to the terms of the Cellares Agreement. Under the initial work order, Cellares will perform clinical cell therapy manufacturing activities for our CAR-T cell therapy product, rese-cel.

Amended and Restated License Agreement with the Trustees of the University of Pennsylvania and the Children's Hospital of Philadelphia

In August 2018, we entered into a license agreement with Penn, which was amended and restated in July 2019 to include CHOP, collectively, the Institutions, and collectively with such amendment, as amended in May 2020 and October 2021, the License Agreement, pursuant to which we obtained (a) a non-exclusive, non-sublicensable, worldwide research license to make, have made and use products in two subfields of use, (b) effective as of October 2018, an exclusive, worldwide, royalty-bearing license, with the right to sublicense, under certain of the Institutions' intellectual property to make, use, sell, offer for sale and import products in the same two subfields of use, and (c) effective as of October 2018, a non-exclusive, worldwide, royalty-bearing license, with limited rights to sublicense, under certain of Penn's know-how to make, have made, use, sell, offer for sale, import and have imported products in the same two subfields of use. Our rights are subject to the rights of the U.S. government and certain rights retained by the Institutions.

Unless earlier terminated, the License Agreement expires on the expiration or abandonment or other termination of the last valid claim in Penn's intellectual property licensed by us. We may terminate the License Agreement at any time for convenience upon 60 days' written notice. In the event of an uncured, material breach, Penn may terminate the License Agreement upon 60 days' written notice.

Government Regulation

U.S. Regulation

As a biopharmaceutical company that operates in the United States, we are subject to extensive regulation. Our cell products will be regulated as biologics. With this classification, commercial production of our products will need to occur in registered facilities in compliance with cGMP for biologics. The FDA categorizes human cell- or tissue-based products as either minimally manipulated or more than minimally manipulated and has determined that more than minimally manipulated products require clinical trials to demonstrate product safety and efficacy and the submission of a BLA for marketing authorization. Our products are considered more than minimally manipulated and will require evaluation in clinical trials and the submission and approval of a BLA before we can market them.

Government authorities in the United States (at the federal, state and local level) and in other countries extensively regulate, among other things, the research, development, testing, manufacturing, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of biopharmaceutical products such as those we are developing. Our product candidates must be approved by the FDA before they may be legally marketed in the United States and by the appropriate foreign regulatory agency before they may be legally marketed in foreign countries. Generally, our activities in other countries will be subject to regulation that is similar in nature and scope as that imposed in the United States, although there can be important differences. Additionally, some significant aspects of regulation in Europe are addressed in a centralized way, but country-specific regulation remains essential in many respects. The process for obtaining regulatory marketing approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources.

U.S. Biological Product Development

In the United States, the FDA regulates biologics under the Federal Food, Drug, and Cosmetic Act, or FDCA, and the Public Health Service Act, or PHSA, and their implementing regulations. Biologics are also subject to other federal, state and local statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may result in delays to the conduct of a study, regulatory review and approval or subject an applicant to administrative or judicial sanctions. These sanctions could include, among other actions, the FDA's refusal to approve pending applications, withdrawal of an approval, license suspension or revocation, refusal to allow an applicant to proceed with clinical trials, imposition of a clinical hold, issuance of untitled or warning letters, product recalls or withdrawals from the market, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement of profits, or civil or criminal investigations or penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

Our drug product candidates must be approved by the FDA through the BLA process before they may be legally marketed in the United States. The process required by the FDA before a biologic may be marketed in the United States generally involves the following:

- completion of extensive nonclinical, sometimes referred to as preclinical, laboratory tests, animal studies and formulation studies in accordance with applicable regulations, including the FDA's Good Laboratory Practice, or GLP, regulations and standards;
- submission to the FDA of an IND which must become effective before human clinical trials may begin;
- approval by an independent institutional review board, or IRB, representing each clinical site before each clinical trial may be initiated;

- performance of adequate and well-controlled human clinical trials in accordance with applicable IND regulations, good clinical practices, or GCPs, and other clinical trial-related regulations to establish the safety and efficacy of the proposed drug product candidate for its proposed indication;
- submission to the FDA of a BLA, which includes not only the results of the clinical trials, but also, detailed information on the chemistry, manufacture and quality controls for the product candidate and proposed labeling;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities where the product is produced to assess compliance with the FDA's current good manufacturing practice, or cGMP, requirements to assure that the facilities, methods and controls are adequate to preserve the product's identity, strength, quality, purity and potency;
- potential FDA audit of the preclinical trial sites and/or clinical trial sites that generated the data in support of the BLA; and
- FDA review and approval of the BLA prior to any commercial marketing or sale of the product in the United States.

The data required to support a BLA is generated in two distinct development stages: preclinical and clinical. The preclinical development stage generally involves laboratory evaluations of drug chemistry, formulation and stability, as well as studies to evaluate toxicity in animals, which support subsequent clinical testing. The conduct of the preclinical studies must comply with federal regulations, including GLPs. The sponsor must submit the results of the preclinical studies, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, as well as other information, to the FDA as part of the IND. An IND is a request for authorization from the FDA to administer an investigational drug product to humans. The central focus of an IND submission is on the general investigational plan and the protocol(s) for human trials. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions regarding the proposed clinical trials and places the IND on clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. The FDA may also impose clinical holds on a drug product candidate at any time before or during clinical trials due to safety concerns, non-compliance, or other issues affecting the integrity of the trial. Accordingly, we cannot be sure that submission of an IND will result in the FDA allowing clinical trials to begin, or that, once begun, issues will not arise that could cause the trial to be suspended or terminated.

In addition to the submission of an IND to the FDA before initiation of a clinical trial in the United States, certain human clinical trials involving recombinant or synthetic nucleic acid molecules are subject to oversight of institutional biosafety committees, or IBCs, as set forth in the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, or NIH Guidelines. Under the NIH Guidelines, recombinant and synthetic nucleic acids are defined as: (i) molecules that are constructed by joining nucleic acid molecules and that can replicate in a living cell (i.e., recombinant nucleic acids); (ii) nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules (i.e., synthetic nucleic acids); or (iii) molecules that result from the replication of those described in (i) or (ii). Specifically, under the NIH Guidelines, supervision of human gene transfer trials includes evaluation and assessment by an IBC, a local institutional committee that reviews and oversees research utilizing recombinant or synthetic nucleic acid molecules at that institution. The IBC assesses the safety of the research and identifies any potential risk to public health or the environment, and such review may result in some delay before initiation of a clinical trial. 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.

The clinical stage of development involves the administration of the drug product candidate to healthy volunteers and patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control, in accordance with GCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor subject safety and assess efficacy. Each protocol, and any subsequent amendments to the protocol, must be submitted to the FDA as part of the IND. Further, each clinical trial must be reviewed and approved by an IRB at or servicing each institution at which the clinical trial will be conducted. An IRB is charged with protecting the welfare and rights of trial participants and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the informed consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed.

There are also requirements governing the reporting of ongoing clinical trials and completed clinical trial results to public registries. Sponsors of certain clinical trials of FDA-regulated products, including biologics, are required to register and disclose certain clinical trial information, which is publicly available at www.clinicaltrials.gov.

Clinical trials are generally conducted in three sequential phases, known as Phase 1, Phase 2 and Phase 3, and may overlap. Phase 1 clinical trials generally involve a small number of healthy volunteers who are initially exposed to a single dose and then multiple doses of the drug product candidate. The primary purpose of these clinical trials is to assess the metabolism, pharmacologic action tolerability, adverse effects, and safety of the drug product candidate and, if possible, to gain early evidence on effectiveness. Phase 2 clinical trials typically involve studies in disease-affected patients to determine the dose required to produce the desired benefits. At the same time, safety and further pharmacokinetic and pharmacodynamic information is collected, as well as identification of possible adverse effects and safety risks and preliminary evaluation of efficacy. Phase 3 clinical trials generally involve large numbers of patients at multiple sites, in multiple countries, and are designed to provide the data necessary to demonstrate the efficacy of the product for its intended use, its safety in use, and to establish the overall benefit/risk relationship of the product and provide an adequate basis for product approval. Phase 3 clinical trials may include comparisons with placebo and/or other comparator treatments. The duration of treatment is often extended to mimic the actual use of a product during marketing. Generally, two adequate and well-controlled Phase 3 clinical trials have been required by the FDA for approval of a BLA, although there are known exceptions, particularly for rare diseases. FDA leadership announced in February 2026 that the FDA will, going forward, adopt the default position that one adequate and well-controlled trial, combined with confirmatory evidence, can serve as the basis of approval for novel products. In certain instances, FDA may condition approval of a BLA on the sponsor's agreement to conduct additional clinical trials to further assess the biologic's safety and effectiveness after BLA approval. Such post-approval trials are sometimes referred to as Phase 4 clinical trials. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication and further document clinical benefit in the case of drugs approved under Accelerated Approval regulations. Failure to exhibit due diligence with regard to conducting Phase 4 clinical trials could result in withdrawal of approval for products.

Progress reports detailing the results of the clinical trials, among other information, must be submitted at least annually to the FDA, and written IND safety reports must be submitted to the FDA and the investigators for serious and unexpected suspected adverse events, findings from other studies suggesting a significant risk to humans exposed to the biologic, findings from animal or in vitro testing that suggest a significant risk for human subjects, and any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, if at all. The FDA, the IRB, or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. 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 or committee. This group provides authorization for whether or not a trial may move forward at designated intervals based on access to certain data from the trial and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as interim data suggesting a lack of efficacy. We may also suspend or terminate a clinical trial based on evolving business objectives and/or competitive climate. Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the

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

BLA and FDA Review Process

Following trial completion, trial data are analyzed to assess safety and efficacy. The results of preclinical studies and clinical trials are then submitted to the FDA as part of a BLA, along with proposed labeling for the product and information about the manufacturing process and facilities that will be used to ensure product quality, results of analytical testing conducted on the chemistry of the drug product candidate, and other relevant information. The BLA is a request for approval to market the biologic for one or more specified indications and must contain proof of safety, purity, potency and efficacy, which is demonstrated by extensive preclinical and clinical testing. The application may include both negative or ambiguous results of preclinical and clinical trials as well as positive findings. Data may come from company-sponsored clinical trials intended to test the safety and efficacy of a use of a product, or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and efficacy of the investigational product to the satisfaction of the FDA. FDA approval of a BLA must be obtained before a biologic may be marketed in the United States.

Under the Prescription Drug User Fee Act, or PDUFA, as amended, each BLA must be accompanied by a significant user fee, which is adjusted on an annual basis. PDUFA also imposes an annual prescription drug product program fee. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business.

Once a BLA has been accepted for filing, which occurs, if at all, sixty days after the BLA's submission, the FDA's goal is to review BLAs within 10 months of the filing date for standard review or six months of the filing date for priority review, if the application is for a product intended for a serious or life-threatening condition and the product, if approved, would provide a significant improvement in safety or effectiveness. The FDA has substantial discretion in the approval process and may refuse to accept any application or decide that the data is insufficient for approval, and may require additional preclinical, clinical or other studies before it accepts the filing. Additionally, the review process is often significantly extended by FDA requests for additional information or clarification.

After the BLA submission is accepted for filing, the FDA reviews the BLA to determine, among other things, whether the proposed drug product candidate is safe and effective for its intended use, and whether the drug product candidate is being manufactured in accordance with cGMP to assure and preserve the drug product candidate's identity, strength, quality, purity and potency. The FDA may refer applications for novel drug product candidates or drug product candidates which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and 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. The FDA will likely re-analyze the clinical trial data, which could result in extensive discussions between the FDA and us during the review process. The review and evaluation of a BLA by the FDA is extensive and time consuming and may take longer than originally planned to complete, and we may not receive a timely approval, if at all.

Before approving a BLA, the FDA will conduct a pre-approval inspection of the manufacturing facilities for the new product to determine whether the facilities comply with cGMPs. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. In addition, before approving a BLA, the FDA may also audit data from clinical trials to ensure compliance with GCP requirements. After the FDA evaluates the application, manufacturing process and manufacturing facilities, it may issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete and the application will not be approved in its present form. A Complete Response Letter usually describes all of the specific deficiencies in the BLA identified by the FDA. The Complete Response Letter may require additional clinical data and/or an additional pivotal Phase 3 clinical trial(s), and/or other significant and time-consuming requirements related to clinical trials, preclinical studies or manufacturing. If a Complete Response Letter

is issued, the applicant may either resubmit the BLA, addressing all of the deficiencies identified in the letter, withdraw the application or request a hearing. Even if such data and information is submitted, the FDA may ultimately decide that the BLA does not satisfy the criteria for approval. Data obtained from clinical trials are not always conclusive, and the FDA may interpret data differently than we interpret the same data.

There is no assurance that the FDA will ultimately approve a product for marketing in the United States, and we may encounter significant difficulties or costs during the review process. If a product receives marketing approval, the approval may be significantly limited to specific populations, severities of allergies, and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling or may condition the approval of the BLA on other changes to the proposed labeling, development of adequate controls and specifications, or a commitment to conduct post-market testing or clinical trials and surveillance to monitor the effects of approved products. For example, the FDA may require Phase 4 testing which involves clinical trials designed to further assess the product's safety and effectiveness and may require testing and surveillance programs to monitor the safety of approved products that have been commercialized. The FDA may also place other conditions on approvals including the requirement for a Risk Evaluation and Mitigation Strategy, or REMS, to assure the safe use of the product. If the FDA concludes a REMS is needed, the sponsor of the BLA must submit a proposed REMS. The FDA will not approve the BLA without an approved REMS, if required. a REMS could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of products. Product approvals may be withdrawn for non-compliance with regulatory standards or based on the results of post-market studies or surveillance programs. Additionally, post-approval, many types of changes to the approved product, such as adding new indications, changing manufacturing processes and adding labeling claims, are subject to further testing requirements and FDA review and approval. Such post-approval requirements can be costly and time-consuming and can affect the potential market and profitability of the product.

Orphan Designation and Exclusivity

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biological product intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making the product available in the United States for this type of disease or condition will be recovered from sales of the product.

Orphan drug designation must be requested before submitting an NDA or BLA. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product that has orphan drug designation subsequently receives the first FDA approval for the use or indication for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications to market the same drug or biologic for the same indication for seven years from the date of such approval, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity on the basis of greater effectiveness or safety or providing a major contribution to patient care or in instances of drug supply issues. Competitors, however, may receive approval of either a different product for the same indication or the same product for a different indication but that could be used off-label in the orphan indication. Orphan drug exclusivity also could block the approval of one of our products for seven years if a competitor obtains approval before we do for the same product, as defined by the FDA, for the same indication we are seeking approval, or if our product is determined to be contained within the scope of the competitor's product for the same indication or disease. If we pursue marketing approval for an indication broader than the orphan drug designation we have received, we may not be entitled to orphan drug exclusivity. Orphan drug status in the European Union has similar, but not identical, requirements and benefits.

Expedited Development and Review Programs

The FDA has a Fast Track program that is intended to expedite or facilitate the process for reviewing new drugs and biological products that meet certain criteria. Specifically, new drugs and biological products are eligible for Fast Track Designation if they are intended to treat a serious or life-threatening condition and nonclinical or clinical data

demonstrate the potential to address unmet medical needs for the condition. Fast Track Designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a new drug or biologic may request the FDA to designate the drug or biologic as a Fast Track product concurrently with, or at any time after, submission of an IND, and the FDA must determine if the product qualifies for Fast Track Designation within 60 days of receipt of the sponsor's request. Under the Fast Track Designation, the FDA may consider for review sections of the marketing application on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the application, the FDA agrees to accept sections of the application and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the application.

Any product 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 priority review and accelerated approval. Any product is eligible for priority review, or review within a six-month timeframe from the date a complete BLA is accepted for filing, if it has the potential to provide a significant improvement in safety and effectiveness compared to available therapies. The FDA will attempt to direct additional resources to the evaluation of an application for a new drug or biological product designated for priority review in an effort to facilitate the review.

Additionally, a product may be eligible for accelerated approval. An investigational drug may obtain accelerated approval if it treats a serious or life-threatening condition and generally provides a meaningful advantage over available therapies and demonstrates an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, or IMM, that is reasonably likely to predict an effect on IMM or other clinical benefit. As a condition of approval, the FDA may require that a sponsor of a drug or biological product receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials and, under the Food and Drug Omnibus Reform Act of 2022, or FDORA, the FDA is now permitted to require, as appropriate, that such trials be underway prior to approval or within a specific time period after the date of approval for a product granted accelerated approval. Under FDORA, the FDA has increased authority for expedited procedures to withdraw approval of a drug or indication approved under accelerated approval if, for example, the confirmatory trial fails to verify the predicted clinical benefit of the product. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product. Fast Track Designation, priority review and accelerated approval do not change the standards for approval but may expedite the development or approval process.

Breakthrough Designation

A product can be designated as a breakthrough therapy if it is intended to treat a serious or life-threatening condition and preliminary clinical evidence indicates that it may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. A sponsor may request that a drug product candidate be designated as a breakthrough therapy concurrently with, or at any time after, the submission of an IND, and the FDA must determine if the drug product candidate qualifies for breakthrough therapy designation within 60 days of receipt of the sponsor's request. If so designated, the FDA shall act to expedite the development and review of the product's marketing application, including by meeting with the sponsor throughout the product's development, providing timely advice to the sponsor to ensure that the development program to gather preclinical and clinical data is as efficient as practicable, involving senior managers and experienced review staff in a cross-disciplinary review, assigning a cross-disciplinary project lead for the FDA review team to facilitate an efficient review of the development program and to serve as a scientific liaison between the review team and the sponsor, and taking steps to ensure that the design of the clinical trials is as efficient as practicable.

Accelerated Approval for Regenerative Medicine Advanced Therapies

FDA's regenerative medicine advanced therapy, or RMAT, program is intended to facilitate efficient development and expedite review of regenerative medicine advanced therapies, which are intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition. A drug sponsor may request that FDA designate a drug as an RMAT concurrently with or at any time after submission of an IND. FDA has 60 calendar days to determine whether the drug meets the criteria, including whether there is preliminary clinical evidence indicating that the drug has the potential to address unmet medical needs for a serious or life-threatening disease or condition. A BLA for an RMAT may be eligible for priority review or accelerated approval through (1) surrogate or intermediate endpoints reasonably likely to predict long-term clinical benefit or (2) reliance upon data obtained from a meaningful number of sites. Benefits of such designation also include early interactions with FDA to discuss any potential surrogate or intermediate endpoint to be used to support accelerated approval. An RMAT that is granted accelerated approval and

is subject to post approval requirements may fulfill such requirements through the submission of clinical evidence, clinical studies, 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.

Pediatric Trials

Under the Pediatric Research Equity Act, or PREA, a BLA or supplement to a BLA must contain data to assess the safety and efficacy of the product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDCA requires that a sponsor who is planning to submit a marketing application for a drug or biological product that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration submit an initial Pediatric Study Plan, or PSP, within sixty days of an end-of-Phase 2 meeting or as may be agreed between the sponsor and FDA. The initial PSP must include an outline of the pediatric study or studies that the sponsor plans to conduct, including study objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting information. The FDA and the sponsor must reach agreement on the PSP. A sponsor can submit amendments to an agreed-upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from nonclinical studies, early phase clinical trials, and/or other clinical development programs. The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of data or full or partial waivers.

Post-Marketing Requirements

Following approval of a new product, a manufacturer and the approved product are subject to continuing regulation by the FDA, including, among other things, monitoring and recordkeeping activities, reporting to the applicable regulatory authorities of adverse experiences with the product, providing the regulatory authorities with updated safety and efficacy information, product sampling, distribution, and tracking and tracing requirements, and complying with promotion and advertising requirements, which include, among others, standards for direct-to-consumer advertising, restrictions on promoting products for uses or in patient populations that are not described in the product's approved labeling (known as "off-label use"), limitations on industry-sponsored scientific and educational activities, and requirements for promotional activities involving the internet. Although physicians may prescribe legally available drugs and biologics for off-label uses, manufacturers may not market or promote such off-label uses.

Modifications or enhancements to the product or its labeling or changes of the site of manufacture are often subject to the approval of the FDA and other regulators, which may or may not be received or may result in a lengthy review process. Prescription drug promotional materials must be submitted to the FDA in conjunction with their first use.

In the United States, once a product is approved, its manufacture is subject to comprehensive and continuing regulation by the FDA. The FDA regulations require that products be manufactured in specific approved facilities and in accordance with cGMPs. We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our products in accordance with cGMP regulations. cGMP regulations require, among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. Manufacturers and other entities involved in the manufacture and distribution of approved products 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 cGMP and other laws. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. These regulations also impose certain organizational, procedural and documentation requirements with respect to manufacturing and quality assurance activities. BLA holders using contract manufacturers, laboratories or packagers are responsible for the selection and monitoring of qualified firms, and, in certain circumstances, qualified suppliers to these firms. These firms and, where applicable, their suppliers are subject to inspections by the FDA at any time, and the discovery of violative conditions, including failure to conform to cGMP, could result in enforcement actions that interrupt the operation of any such facilities or the ability to distribute products manufactured, processed or tested by them. Discovery of problems with a product after approval may result in restrictions on a product, manufacturer, or holder of an approved BLA, including, among other things, recall or withdrawal of the product from the market.

The FDA also may require post-approval testing, sometimes referred to as Phase 4 testing, REMS and post-marketing surveillance to monitor the effects of an approved product or place conditions on an approval that could restrict the distribution or use of the product. Discovery of previously unknown problems with a product or the failure to comply with applicable FDA requirements can have negative consequences, including adverse publicity, judicial or administrative enforcement, untitled or warning letters from the FDA, mandated corrective advertising or communications with doctors, and civil or criminal penalties, among others. Newly discovered or developed safety or effectiveness data may require changes to a product's approved labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures. Also, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of our products under development.

Other Regulatory Matters

Manufacturing, sales, promotion and other activities following product approval are also subject to regulation by numerous regulatory authorities in addition to the FDA, including, in the United States, the Centers for Medicare & Medicaid Services, or CMS, other divisions of the Department of Health and Human Services, or HHS (e.g., the Office of Inspector General, or OIG, and Office for Civil Rights), the Drug Enforcement Administration, the Consumer Product Safety Commission, the Federal Trade Commission, the Occupational Safety & Health Administration, the Environmental Protection Agency and state and local governments. In the United States, sales, marketing and scientific/educational programs must also comply with federal and state fraud and abuse laws, data privacy and security laws, transparency laws, and pricing and reimbursement requirements in connection with governmental payor programs, among others. The handling of any controlled substances must comply with the U.S. Controlled Substances Act and Controlled Substances Import and Export Act. Products must meet applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act. Manufacturing, sales, promotion and other activities are also potentially subject to federal and state consumer protection and unfair competition laws.

The distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products.

The failure to comply with regulatory requirements subjects firms to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in criminal prosecution, fines or other penalties, injunctions, recall or seizure of products, total or partial suspension of production, denial or withdrawal of product approvals, or refusal to allow a firm to enter into supply contracts, including government contracts. In addition, even if a firm complies with FDA and other requirements, new information regarding the safety or efficacy of a product could lead the FDA to modify or withdraw product approval. Prohibitions or restrictions on sales or withdrawal of future products marketed by us could materially affect our business in an adverse way.

From time to time, legislation is drafted, introduced, passed in Congress and signed into law that could significantly change the statutory provisions governing the approval, manufacturing, and marketing of products regulated by the FDA. In addition to new legislation, FDA regulations, guidances, and policies are often revised or reinterpreted by the agency in ways that may significantly affect the manner in which pharmaceutical products are regulated and marketed. Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the recall or discontinuation of our products; or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

U.S. Patent Term Restoration and Marketing Exclusivity

Depending upon the timing, duration and specifics of the FDA approval of our drug product candidates, some 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, commonly referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of a BLA plus the time between the submission date of a BLA and the approval of that application, except that the review period is reduced by any time during which the applicant failed to exercise due diligence. Only one patent applicable to an approved drug is eligible for the extension and the application for the extension must be submitted prior to the expiration of the

patent. The U.S. PTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we may apply for restoration of patent term for our currently owned or licensed patents to add patent life beyond its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant BLA.

An abbreviated approval pathway for biological products shown to be biosimilar to, or interchangeable with, an FDA-licensed reference biological product was created by the Biologics Price Competition and Innovation Act of 2009, or BPCI Act, which was part of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the ACA. This amendment to the PHSA attempts to minimize duplicative testing. Biosimilarity, which requires that the biological product be highly similar to the reference product notwithstanding minor differences in clinically inactive components and that there be no clinically meaningful differences between the product and the reference product in terms of safety, purity, and potency, can be shown through analytical studies, animal studies, and a clinical trial or trials. Interchangeability requires that a biological product be biosimilar to the reference product and that the product can be expected to produce the same clinical results as the reference product in any given patient and, for products administered multiple times, that the product and the reference product may be switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biological product. However, complexities associated with the larger, and often more complex, structure of biological products as compared to small molecule drugs, as well as the processes by which such products are manufactured, pose significant hurdles to implementation that are still being worked out by the FDA.

A reference biological product is granted twelve years of exclusivity from the time of first licensure of the product, and the FDA will not accept an application for a biosimilar or interchangeable product based on the reference biological product until four years after first licensure. “First licensure” typically means the initial date the particular product at issue was licensed in the United States. This does not include a supplement for the biological product or a subsequent application by the same sponsor or manufacturer of the biological product (or licensor, predecessor in interest, or other related entity) for a change that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device, or strength, unless that change is a modification to the structure of the biological product and such modification changes its safety, purity, or potency. Whether a subsequent application, if approved, warrants exclusivity as the “first licensure” of a biological product is determined on a case-by-case basis with data submitted by the sponsor.

Pediatric exclusivity is another type of regulatory market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods. This six-month exclusivity, which attaches to the twelve-year exclusivity period for reference biologics, may be granted based on the voluntary completion of a pediatric trial in accordance with an FDA-issued “Written Request” for such a trial, provided that at the time pediatric exclusivity is granted there is not less than nine months of term remaining.

Pricing and Reimbursement

United States

Sales of our products will depend, in part, on the extent to which our products, once approved, will be covered and reimbursed by third-party payors, such as government health programs, commercial insurance and managed healthcare organizations. These third-party payors are increasingly reducing reimbursements for medical products and services. The process for determining whether a third-party payor will provide coverage for a drug product, including a biologic, typically is separate from the process for setting the price of a drug product or for establishing the reimbursement rate that a payor will pay for the drug product once coverage is approved. Third-party payors may limit coverage to specific drug products on an approved list, also known as a formulary, which might not include all of the approved drugs for a particular indication.

In order to secure coverage and reimbursement for any drug product candidate that might be approved for sale, we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the drug product candidate, in addition to the costs required to obtain FDA or other comparable regulatory approvals. Whether or not we conduct such studies, our drug product candidates may not be considered medically necessary or cost-effective. A third-party payor’s decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Third party reimbursement may not be sufficient to enable us to maintain price levels high enough to realize an appropriate return on our investment in product

development. In the United States, the principal decisions about reimbursement for new drug products are typically made by CMS, an agency within HHS. CMS decides whether and to what extent a new drug product will be covered and reimbursed under Medicare, and private payors tend to follow CMS to a substantial degree. However, no uniform policy of coverage and reimbursement for drug products exists among third-party payors and coverage and reimbursement levels for drug products can differ significantly from payor to payor. Additionally, one third-party payor's decision to cover a particular product or service does not ensure that other payors will also provide coverage for the product or service, and the level of coverage and reimbursement can differ significantly from payor to payor. As a result, the coverage determination process will often require us to provide scientific and clinical support for the use of our products to each payor separately and can be a time-consuming process, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Factors payors consider in determining reimbursement are based on whether the product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

The containment of healthcare costs has become a priority of federal and state governments, and the prices of drugs, including biologics, have been a focus in this effort. The U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. In many countries, the prices of drug products are subject to varying price control mechanisms as part of national health systems. In general, the prices of drug products under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for drug products but monitor and control company profits. Accordingly, in markets outside the United States, the reimbursement for drug products may be reduced compared with the United States. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our net revenue and results. Decreases in third-party reimbursement for our drug product candidate or a decision by a third-party payor to not cover our drug product candidate could reduce physician usage of the drug product candidate and have a material adverse effect on our sales, results of operations and financial condition.

Outside of the United States, the pricing of pharmaceutical products is subject to governmental control in many countries. For example, 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 approved. Some countries may require the completion of additional studies that compare the cost effectiveness of a particular therapy to currently available therapies or so-called health technology assessments, in order to obtain reimbursement or pricing approval. Other countries may allow companies to fix their own prices for products but monitor and control product volumes and issue guidance to physicians to limit prescriptions. Efforts to control prices and utilization of pharmaceutical products will likely continue as countries attempt to manage healthcare expenditures. Historically, products launched in the European Union do not follow price structures of the United States and generally prices tend to be significantly lower.

Other Healthcare Laws and Compliance Requirements

Healthcare providers, physicians, and third-party payors will play a primary role in the recommendation and prescription of any products for which we obtain marketing approval. Our business operations in the United States and our current and future arrangements with clinical investigators, healthcare providers, consultants, third-party payors and patients may expose us to broadly applicable federal and state fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute any drugs for which we obtain marketing approval. In the United States, these laws include: the federal Anti-Kickback Statute, the False Claims Act, and HIPAA.

The Anti-Kickback Statute makes it illegal for any person, including a prescription drug manufacturer (or a party acting on its behalf), to knowingly and willfully solicit, receive, offer or pay any remuneration, directly or indirectly, in cash or in kind, that is intended to induce or reward referrals, including the purchase, recommendation, order or prescription of a particular drug, for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. Violations of this law are punishable by imprisonment, criminal fines, administrative civil money penalties and exclusion from participation in federal healthcare programs. In addition, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it. Moreover, the ACA provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers, and formulary managers on the other. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution.

Although we would not submit claims directly to payors, drug manufacturers can be held liable under the federal civil False Claims Act, which imposes civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities (including manufacturers) for, among other things, knowingly presenting, or causing to be presented to federal programs (including Medicare and Medicaid) claims for items or services, including drugs, that are false or fraudulent, claims for items or services not provided as claimed, or claims for medically unnecessary items or services. Penalties for a False Claims Act violation include three times the actual damages sustained by the government, plus mandatory civil penalties for each separate false claim, the potential for exclusion from participation in federal healthcare programs and, although the federal False Claims Act is a civil statute, conduct that results in a False Claims Act violation may also implicate various federal criminal statutes. The government may deem manufacturers to have "caused" the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off- label. Claims which include items or services resulting from a violation of the federal Anti-Kickback Statute are false or fraudulent claims for purposes of the False Claims Act. The federal False Claims Act also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the federal False Claims Act and to share in any monetary recovery. Our future marketing and activities relating to the reporting of wholesaler or estimated retail prices for our products, if approved, the reporting of prices used to calculate Medicaid rebate information and other information affecting federal, state and third-party reimbursement for our products, and the sale and marketing of our product candidates, are subject to scrutiny under this law.

The civil monetary penalties statute imposes penalties against any person or entity that, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent.

Additionally, we may be subject to data privacy and security regulations by both the federal government and states in which we conduct our business. For example, HIPAA created new federal criminal statutes that prohibit among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud or to obtain, by means of false or fraudulent pretenses, representations or promises, any money or property owned by, or under the control or custody of, any healthcare benefit program, including private third party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up by trick, scheme or device, a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Like 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.

HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or the HITECH, and its implementing regulations, mandates, among other things, the adoption of uniform standards for the electronic exchange of information in common healthcare transactions, as well as standards relating to the privacy and security of individually identifiable health information, which require the adoption of administrative, physical and technical safeguards to protect such information. Among other things, HITECH makes HIPAA's security standards directly applicable to business associates, defined as independent contractors or agents of covered entities, which include certain health care providers, health plans, and healthcare clearinghouses, that create, receive or obtain protected health information in connection with providing a service for or on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities and business associates and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions. In addition, certain state laws govern the privacy and security of health information and other personal data in certain circumstances, some of which are more stringent or otherwise different than HIPAA and many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and criminal penalties.

Further, the federal Physician Payments Sunshine Act, or the Sunshine Act, within the ACA, and its implementing regulations, require that certain manufacturers of drugs, devices, biological and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) report annually to CMS information related to certain payments or other transfers of value made or distributed to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other licensed health care practitioners and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members. In addition, many states also govern the reporting of payments or other transfers of value, many of which differ from each other in significant ways, are often not pre-empted, and may have a more prohibitive effect than the Sunshine Act, thus further complicating compliance efforts.

We may become subject to federal government price reporting laws, which would require us to calculate and report complex pricing metrics in an accurate and timely manner to government programs, as well as federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers.

Similar federal, state and foreign fraud and abuse laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services. Such laws are generally broad and are enforced by various state agencies and private actions. Also, many states have similar fraud and abuse statutes or regulations that may be broader in scope and may apply regardless of payor, in addition to items and services reimbursed under Medicaid and other state programs. Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant federal government compliance guidance, and require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures.

In order to distribute products commercially, we must comply with state laws that require the registration of manufacturers and wholesale distributors of drug and biological products in a state, including, in certain states, manufacturers and distributors who ship products into the state even if such manufacturers or distributors have no place of business within the state. Some states also impose requirements on manufacturers and distributors to establish the pedigree of product in the chain of distribution, including some states that require manufacturers and others to adopt new technology capable of tracking and tracing product as it moves through the distribution chain. Several states have enacted legislation requiring pharmaceutical and biotechnology companies to establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, clinical trials and other activities, and/or register their sales representatives, as well as to prohibit pharmacies and other healthcare entities from providing certain physician prescribing data to pharmaceutical and biotechnology companies for use in sales and marketing, and to prohibit certain other sales and marketing practices. All of our activities are potentially subject to federal and state consumer protection and unfair competition laws.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, contractual damages, reputational harm, diminished profits and future earnings, individual imprisonment, exclusion of drugs from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our financial results. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. Ensuring business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time- and resource- consuming and can divert a company's attention from the business.

Current and Future Legislation

In the United States and some foreign jurisdictions, there have been, and likely will continue to be, a number of legislative and regulatory changes and proposed changes regarding the healthcare system directed at broadening the availability of healthcare, improving the quality of healthcare, and containing or lowering the cost of healthcare.

For example, in 2010, the ACA was enacted in the United States. The ACA includes measures that have significantly changed, and are expected to continue to significantly change, the way healthcare is financed by both governmental and private insurers. Among the provisions of the ACA of greatest importance to the pharmaceutical industry are that the ACA:

- made several changes to the Medicaid Drug Rebate Program, including increasing pharmaceutical manufacturers' rebate liability by raising the minimum basic Medicaid rebate on average manufacturer price, or AMP, on most branded prescription drugs and adding a new rebate calculation for "line extensions" (i.e., new formulations, such as extended release formulations) of solid oral dosage forms of branded products, as well as potentially impacting their rebate liability by modifying the statutory definition of AMP;
- imposed a requirement on manufacturers of branded drugs to provide a 70% point-of-sale discount as a condition for a manufacturer's outpatient drugs being covered under Medicare Part D;
- extended a manufacturer's Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expanded the entities eligible for discounts under the 340B Drug Discount Program;
- imposed an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs, apportioned among these entities according to their market share in certain government healthcare programs, and
- established a Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research. The research conducted by the Patient-Centered Outcomes Research Institute may affect the market for certain pharmaceutical products. The ACA established the Center for Medicare and Medicaid Innovation within CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted:

- The Budget Control Act of 2011 and subsequence legislation, among other things, created measures for spending reductions by Congress that include aggregate reductions of Medicare payments to providers of 2% per fiscal year, which remain in effect through 2031. Due to the Statutory Pay-As-You-Go Act of 2010, estimated budget deficit increases resulting from the American Rescue Plan Act of 2021, and subsequent legislation, Medicare payments to providers were further reduced starting on January 1, 2025; however, legislation has been introduced in the U.S. Congress that would, if enacted, reverse these payment reductions. In addition to provider payment cuts under Medicare, the American Rescue Plan Act of 2021 also eliminated the statutory Medicaid drug rebate cap, previously set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, effective January 1, 2024. These laws and regulations may result in additional reductions in Medicare and other healthcare funding available for healthcare providers and may otherwise affect the prices we may obtain for any of our product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used.
- The American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors, which may adversely affect our future profitability.
- On May 30, 2018, the Right to Try Act was signed into law. The law, among other things, provides a federal framework for certain patients to request access to certain IND products that have completed a Phase I clinical trial and that are undergoing investigation for FDA approval. There is no obligation for a pharmaceutical manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.
- On April 13, 2017, CMS published a final rule that gives states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces.
- On May 23, 2019, CMS published a final rule to allow Medicare Advantage Plans the option of using step therapy for Part B drugs beginning January 1, 2020.

In addition, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient assistance programs, and reform government program reimbursement methodologies for drugs. At a federal level, President Trump reversed some of President Biden's executive orders including rescinding Executive Order 14087 entitled "Lowering Prescription Drug Costs for Americans." President Trump may issue new executive orders designed to impact drug pricing. A number of these and other proposed measures may require authorization through additional legislation to become effective. Congress and the Trump administration have indicated that they will continue to seek new legislative measures to control drug costs.

The Inflation Reduction Act of 2022, or IRA includes several provisions that may impact our business to varying degrees, including provisions that reduce the out-of-pocket spending cap for Medicare Part D beneficiaries from $7,050 to $2,000 which became effective in 2025, thereby effectively eliminating the coverage gap; impose new manufacturer financial liability on certain drugs under Medicare Part D, allow the U.S. government to negotiate Medicare Part B and Part D price caps for certain high-cost drugs and biologics without generic or biosimilar competition; require companies to pay rebates to Medicare for certain drug prices that increase faster than inflation; and delay until January 1, 2032 the implementation of the HSS rebate rule that would have limited the fees that pharmacy benefit managers can charge. Further, under the IRA, orphan drugs are exempted from the Medicare drug price negotiation program, but only if they have one orphan designation and for which the only approved indication is for that disease or condition. Under the One Big Beautiful Bill Act of 2025, or OBBBA, this restriction was eliminated; and effective for the 2028 initial price applicability year, all orphan drugs, regardless of the number of orphan drug designations or indications, are exempt from the Medicare drug price negotiation program. The

implementation of the IRA is currently subject to ongoing litigation challenging the constitutionality of the IRA's Medicare drug price negotiation program. The effects of the IRA on our business and the healthcare industry in general is not yet known.

Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain drug access and marketing cost disclosure and transparency measures, and designed to encourage importation from other countries and bulk purchasing. Certain states are also pursuing cost containment efforts through Prescription Drug Affordability Boards, or PDABs, and similar entities. While many PDABs have been granted authority to promote drug price transparency and reporting, some states have granted PDABs more expansive authority, including to set Upper Payment Limits, or UPLs, on select, high price drugs. The adoption and implementation of UPLs may put downward pressure on drug prices and impact our company's future revenues. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, financial condition, results of operations and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our drugs or put pressure on our drug pricing, which could negatively affect our business, financial condition, results of operations and prospects.

We cannot predict what healthcare reform initiatives may be adopted in the future. Further federal, state and foreign legislative and regulatory developments are likely, and we expect ongoing initiatives to increase pressure on drug pricing. Such reforms could have an adverse effect on anticipated revenues from product candidates and may affect our overall financial condition and ability to develop product candidates.

The Foreign Corrupt Practices Act

The FCPA prohibits any U.S. individual or business from paying, offering, or 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 accounting provisions requiring the company 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.

Additional Regulation

In addition to the foregoing, state and federal laws regarding environmental protection and hazardous substances, including the Occupational Safety and Health Act, the Resource Conservancy and Recovery Act and the Toxic Substances Control Act, affect our business. These and other laws govern our use, handling and disposal of various biological, chemical and radioactive substances used in, and wastes generated by, our operations. If our operations result in contamination of the environment or expose individuals to hazardous substances, we could be liable for damages and governmental fines. We believe that we are in material compliance with applicable environmental laws and that continued compliance therewith will not have a material adverse effect on our business. We cannot predict, however, how changes in these laws may affect our future operations.

Europe / Rest of World Government Regulation

In addition to regulations in the United States, we may be subject to a variety of regulations in other jurisdictions that we may in the future select governing, among other things, clinical trials and any commercial sales and distribution of our products. Whether or not we obtain FDA approval of a product, we would need to obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. Certain countries outside of the United States have a similar process that requires the submission of a clinical trial authorization application much like the IND prior to the commencement of human clinical trials. In the EU, for example, a clinical trial application must be submitted through the centralized EU platform (CTIS) for coordinated assessment by the competent authorities of the concerned Member States together with review by an ethics committee in accordance with national law, much like the FDA and IRB, respectively. Once the clinical trial authorization application is approved in accordance with the applicable Member State requirements under the EU Clinical Trials Regulation, the clinical trial may proceed in the relevant Member State(s).

The requirements and process governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, the clinical trials must be conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

To obtain regulatory approval of a medicinal product in the EU, we must submit a marketing authorization application, or MAA. The application used to file the BLA in the United States is similar to that required in the EU, with the exception of, among other things, country-specific document requirements.

The criteria for designating an "orphan medicinal product" in the EU are similar in principle to those in the United States. A medicinal product can be designated as an orphan if its sponsor can establish that: (1) the product is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition, (2) either (i) such condition affects no more than five in ten thousand persons in the EU when the application is made, or (ii) without the benefits derived from orphan status, it is unlikely that the marketing of the product in the EU would generate sufficient return to justify the necessary investment in its development; (3) there exists no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorized in the EU or, if such method exists, the product would be of significant benefit to those affected by that condition.

An orphan designation provides a number of benefits, including fee reductions, regulatory assistance and the possibility to apply for a centralized EU marketing authorization. Upon grant of a marketing authorization, orphan medicinal products are entitled to a ten-year period of market exclusivity, which means that the EMA and the competent authorities of the EU member states cannot accept another MAA, or grant a marketing authorization, or accept an application to extend a marketing authorization for a similar medicinal product for the same indication for a period of ten years. A "similar medicinal product" is defined as a medicinal product containing a similar active substance or substances as contained in an authorized orphan medicinal product, and which is intended for the same therapeutic indication. The period of market exclusivity is extended by two years for orphan medicinal products that have also complied with an agreed pediatric investigation plan. No extension to any supplementary protection certificate can be granted on the basis of pediatric studies for orphan indications. Orphan designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

The orphan exclusivity period may be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for which it received orphan destination, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity or where the prevalence of the condition has increased above the threshold. Additionally, a marketing authorization may be granted to a similar medicinal product for the same indication as an authorized orphan product at any time if (i) a second applicant can

establish that its product, although similar to the authorized orphan product, is safer, more effective or otherwise clinically superior; (ii) the marketing authorization holder for the authorized orphan product consents to a second medicinal product application; or (iii) the marketing authorization holder for the authorized product cannot supply enough orphan medicinal product.

The PRIority MEdicines ("PRIME"), scheme is intended to encourage product development in areas of unmet medical need. Eligible products must target conditions for which there is an unmet medical need (there is no satisfactory method of diagnosis, prevention or treatment in the EU or, if there is, the new medicine will bring a major therapeutic advantage) and they must demonstrate the potential to address the unmet medical need by introducing new methods of therapy or improving existing ones. Products from small- and medium-sized enterprises may qualify for earlier entry into the PRIME scheme than larger companies. Many benefits accrue to sponsors of therapeutic candidates with PRIME designation, including but not limited to early and proactive regulatory dialogue with the EMA, frequent discussions on clinical trial designs and other development program elements, and potentially accelerated MAA assessment once a dossier has been submitted. Importantly, a dedicated EMA contact and rapporteur from the Committee for Medicinal Products for Human Use are appointed early in the PRIME scheme facilitating increased understanding of the product at the EMA's Committee level. A kick-off meeting initiates these relationships and includes a team of multidisciplinary experts at the EMA to provide guidance on the overall development and regulatory strategies. Where, during the course of development, a medicine no longer meets the eligibility criteria, support under the PRIME scheme may be withdrawn.

The EU pharmaceutical legislation is currently undergoing a complete review process, in the context of the Pharmaceutical Strategy for Europe initiative, launched by the European Commission in November 2020. The European Commission introduced legislative proposals in April 2023 that, if implemented, will replace the current regulatory framework in the European Union for all medicines (including those for rare diseases and for children). In April 2024, the European Parliament adopted its position on the legislative proposals and, in June 2025, the Council of the European Union adopted its position. A common position on the text was agreed upon on December 11, 2025, in the context of subsequent inter-institutional trilogue negotiations. The proposed revisions remain to be adopted into EU law, and are not expected to become applicable before 2028.

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

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

European Union General Data Protection Regulation

In addition to EU regulations related to the approval and commercialization of our products, we may be subject to the EU's General Data Protection Regulation, or GDPR. The GDPR imposes stringent requirements for controllers and processors of personal data of persons in the EU, including, for example, ensuring an appropriate legal basis or condition applies to the processing of personal data, more robust disclosures to individuals and a strengthened individual data rights regime, shortened timelines for data breach notifications, limitations on retention of information, increased requirements pertaining to special categories of data, such as health data, and additional obligations when we contract with third-party processors in connection with the processing of the personal data. The GDPR also imposes strict rules on the transfer of personal data out of the European Union to the United States and other third countries. In addition, the GDPR provides that EU member states may make their own further laws and regulations limiting the processing of personal data, including genetic, biometric or health data.

In addition, further to the UK's exit from the EU, the GDPR ceased to apply in the UK at the end of the transition period on December 31, 2020. However, as of January 1, 2021, the UK's European Union (Withdrawal) Act 2018 incorporated the GDPR (as it existed on December 31, 2020 but subject to certain UK specific amendments) into UK law, referred to as the UK GDPR. The UK GDPR and the UK Data Protection Act 2018 set out the UK's data protection regime, which is independent from but aligned to the EU's data protection regime.

The GDPR and UK GDPR apply extraterritorially, and we may be subject to the GDPR and UK GDPR because of our data processing activities that involve the personal data of individuals located in the European Union or United Kingdom, such as in connection with our EU and UK clinical trials. Failure to comply with the requirements of the

GDPR or UK GDPR and the applicable national data protection laws of the EU member states and UK may result in fines of up to €20,000,000 (or £17.5 million for the UK) or up to 4% of the total worldwide annual turnover of the preceding financial year, whichever is higher, and other administrative penalties. GDPR and UK GDPR regulations may impose additional responsibility and liability in relation to the personal data that we process and we may be required to put in place additional mechanisms to ensure compliance with the new data protection rules.

Human Capital Resources

As of December 31, 2025, we had 156 employees, 154 of whom were full-time and 2 whom were part-time. Of those, 139 were engaged in research and development activities. Two full-time employees are located in Switzerland and two full-time employees are located in Germany. We do not have any employees that are represented by a labor union or covered under a collective bargaining agreement. We consider our relationship with our employees to be good.

Our future success depends on our ability to attract, develop and retain key personnel, maintain our culture, and ensure diversity and inclusion in our board, management and broader workforce. Our human 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. As these areas directly impact our ability to compete and innovate, they are key focus areas for our board of directors and senior executives. A testament to our strong culture is the strong results from our annual employee survey.

Corporate History and Trademarks

We were incorporated under the laws of the State of Delaware in April 2017 under the name Tycho Therapeutics, Inc. In August 2018, our corporate name was changed to Cabaletta Bio, Inc. We have two subsidiaries, Cabaletta Bio GmbH, incorporated in Switzerland and Cabaletta Bio (Germany) GmbH, incorporated in Germany. Our principal executive offices are located at 2929 Arch Street, Suite 600, Philadelphia, PA 19104, and we have limited corporate and research operations in Germany and Switzerland. Our telephone number is (267) 759-3100, and our website address is www.cabalettabio.com. We do not incorporate the information on or accessible through our website into this Annual Report on Form 10-K, and you should not consider any information on, or that can be accessed through, our website to be part of this Annual Report on Form 10-K. We have included our website address in this Annual Report on Form 10-K solely as an inactive textual reference.

We view our operations and measure our business as one reportable segment. All of the Company's tangible assets are held in the United States. Refer to Note 8, Segment Information, to our consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K for additional information.

We own or have rights to various trademarks, service marks and trade names that we use in connection with the operation of our business. This Annual Report on Form 10-K may also contain trademarks, service marks and trade names of third parties, which are the property of their respective owners. Our use or display of third parties' trademarks, service marks, trade names or products in this Annual Report on Form 10-K is not intended to, and does not imply a relationship with, or endorsement or sponsorship by us. Solely for convenience, the trademarks, service marks and trade names referred to in this Annual Report on Form 10-K may appear without the ®, ™ or SM symbols, but the omission of such references is not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the right of the applicable owner of these trademarks, service marks and trade names.

Available Information

Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, including exhibits, and any amendments to these reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, are available free of charge on our website located at www.cabalettabio.com as soon as reasonably practicable after they are filed with or furnished to the SEC. These reports are also available at the SEC's Internet website at www.sec.gov.

Investors and others should note that we announce material information to our investors using our investor relations website (https:// https://www.cabalettabio.com/investors), SEC filings, press releases, public conference calls and webcasts. We use these channels as well as social media, including LinkedIn and X (formerly Twitter) (@CabalettaBio), to communicate with the public about our company, our business, our product candidates and other matters. It is possible that the information we post on social media could be deemed to be material information. Therefore, we encourage investors, the media, and others interested in our company to review the information we post on the social media channels listed on our investor relations website. Information that is

contained in and can be accessed through our website or our social media posts are not incorporated into, and does not form a part of, this Annual Report on Form 10-K.

A copy of our Corporate Governance Guidelines, Code of Conduct and Business Ethics and the charters of the Audit Committee, Compensation Committee and Nominating and Corporate Governance Committee are posted on our website, www.cabalettabio.com, under the heading "Investors & Media."

Item 1A. Risk Factors.

Our business involves material and other risks, some of which are summarized and described below. You should carefully consider the risks and uncertainties described below, together with all of the other information contained in this Annual Report on Form 10-K, including "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the consolidated financial statements and the related notes. If any of the following risks actually occur, it could harm our business, prospects, operating results and financial condition and future prospects. In such event, the market price of our common stock could decline and you could lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations. This Annual Report on Form 10-K also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of factors that are described below and elsewhere in this Annual Report.

Risks Related to Our Business, Technology and Industry

Risks Related to Clinical Development

We are early in our development efforts. If we are unable to advance our product candidates through clinical development, obtain regulatory approval and ultimately commercialize our product candidates, or experience significant delays in doing so, our business will be materially harmed.

We are early in our development efforts and we have not yet completed any clinical trials. Our ability to generate product revenues, which we do not expect will occur for many years, if ever, will depend heavily on the successful development and eventual commercialization of one or more of our product candidates. Even if we are able to develop and commercialize a marketable product, we may face challenges generating revenue from product sales. The success of our product candidates will depend on several factors, including the following:

- successful completion of preclinical studies resulting in data that is supportive of advancing to an investigational new drug, or IND, or clinical trial application, or CTA submission;
- successful submission and acceptance of INDs, CTAs or comparable applications;
- successful initiation of clinical trials;
- demonstration of adequate safety to progress to a therapeutic dose level;
- successful patient enrollment in and completion of clinical trials;
- receipt and related terms of regulatory and marketing approvals and licensures from applicable regulatory authorities;
- establishing commercial manufacturing capabilities or making arrangements with third-party manufacturers for clinical supply and commercial manufacturing of our product candidates;
- making arrangements with various medical divisions across hospitals for administration of our product candidates, including with cancer treatment centers to conduct leukapheresis and with the relevant hospital divisions to perform infusion;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our product candidates;
- establishing sales, marketing and distribution and patient administration capabilities and launching commercial sales of our products, if and when licensed, whether alone or in collaboration with others;
- acceptance of our products, if and when licensed, by patients, the medical community and third-party payors;
- effectively competing with established and emerging therapies targeting the same indications as our product candidates;
- obtaining and maintaining third-party coverage and adequate reimbursement; and

- maintaining a continued acceptable safety profile of our products following licensure.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or be unable to successfully commercialize our product candidates, which would materially harm our business. If we do not receive regulatory approvals for our product candidates, we may not be able to continue our operations.

Cellular therapies, including our engineered chimeric antigen receptor T cell, or CAR T, chimeric autoantibody receptor T cell, or CAAR T, product candidates, represent a novel approach to the treatment of autoimmune diseases, which creates significant challenges for us. Negative perception or increased regulatory scrutiny of any product candidates that we develop could adversely affect our ability to conduct our business or obtain regulatory approvals for such product candidates.

Cellular therapies are a novel approach to the treatment of autoimmune diseases, and negative perception or increased regulatory scrutiny of any product candidates that we develop could adversely affect our ability to conduct our business or obtain regulatory approvals for such product candidates. There are no cellular immunotherapies licensed to date in the United States or the European Union to treat autoimmune diseases or alloimmune responses. CAR T or CAAR T cell therapies for autoimmune or alloimmune diseases may not gain the acceptance of the public or the medical community. For example, CAR Ts and other cellular therapies have in some cases caused severe side effects, including death, and their broader use may therefore be limited. In the future, in the event such severe side effects are observed with other CAR T therapies (including those with a CD19 binder), it may increase negative perception of, and regulatory scrutiny on, our product candidates. For example, in November 2023, the FDA announced that it would be conducting an investigation into reports of T cell malignancies following treatment with BCMA-directed or CD19-directed autologous CAR T cell immunotherapies. The FDA also stated that patients and clinical trial participants receiving treatment with such approved products should be monitored life-long for new malignancies. In January 2024, the FDA determined that new safety information related to T cell malignancies should be included in the labeling with boxed warning language on these malignancies for all BCMA- and CD19-directed genetically modified autologous T cell immunotherapies. Public perception may be influenced by claims that gene therapy, including the insertion of a transgene, is unsafe, and products incorporating gene therapy may not gain the acceptance of the public or the medical community. The patient populations targeted by our product candidates are also typically not at risk of near-term death, even if they may suffer life-threatening symptoms, so patients will need to deem the benefits of cell therapy to be worth the risk of unknown potential adverse side effects. Our success will depend upon physicians who specialize in the treatment of autoimmune diseases targeted by our product candidates prescribing treatments that involve the use of our product candidates in lieu of, or in addition to, existing treatments with which they are more familiar and for which greater clinical data may be available. Adverse events in clinical trials of our product candidates, in clinical trials of others developing similar products or in the post-approval setting and the resulting publicity, as well as any other adverse events in the field of cellular therapies, could result in a decrease in demand for any product that we may develop.

We are developing a pipeline of CAR T and CAAR T product candidates that are intended for use in treating individuals with autoimmune diseases. Advancing these novel product candidates creates significant challenges for us, including:

- manufacturing our product candidates to our specifications and in a timely manner to support our clinical trials, and, if licensed, commercialization;
- sourcing clinical and, if licensed, commercial supplies for the materials used to manufacture our product candidates;
- understanding and addressing variability in the quality and quantity of a subject's T cells, which could ultimately affect our ability to manufacture clinical supply and, if licensed, commercial supply of our product candidates in a reliable and consistent manner;
- educating medical personnel regarding the potential side effect profile of our product candidates, if licensed, such as the potential adverse side effects related to worsening of systemic lupus erythematosus, or SLE, idiopathic inflammatory myopathy (IIM), or myositis, systemic sclerosis, or SSc, muscle-specific kinase myasthenia gravis, or MuSK MG, generalized myasthenia gravis, or gMG, pemphigus vulgaris, or PV, multiple sclerosis, or MS, adverse effects related to infusion of activated T cells or medication taper, including cytokine release syndrome, or CRS, immune effector cell-associated neurotoxicity syndrome,

or ICANS, or other unexpected adverse effects of therapy with our product candidates or potential class-wide side effects, such as those related to CD19-directed autologous CAR T cell immunotherapies;

- facilitating patient access to the limited number of facilities able to administer our product candidates, if licensed;
- using medicines to manage adverse side effects of our product candidates that may not adequately control the side effects and/or may have a detrimental impact on the efficacy of the treatment;
- utilizing preconditioning agents in patients to enhance engraftment in advance of administering our product candidates, which may increase the risk of adverse side effects and potentially reduce the population eligible for therapy;
- obtaining and maintaining regulatory approval for our product candidates, as the FDA and other regulatory authorities have limited or no experience with development of engineered T cell therapies for the treatment of autoimmune diseases where B cells may play a role in initiating or maintaining disease;
- establishing sales and marketing capabilities upon obtaining any regulatory approval to gain market acceptance of a novel therapy; and
- managing costs of inputs and other supplies while scaling production.

In addition, preclinical murine and other animal models may not exist or be adequate for some or all of the autoimmune diseases where B cells may play a role in initiating or maintaining disease we choose to pursue in our programs, and because we are early in the clinical development process, we are unable to predict whether there may be short-term or long-term effects from treatment with any product candidates that we develop. In developing our product candidates, we have not exhaustively explored different options in the method for manufacturing CAR T or CAAR T cells. We may find our existing manufacturing process may be substantially improved with future design or process changes, necessitating further clinical testing, delaying commercial launch of our first products, and causing us to incur additional expenses. For example, while we have used a lentiviral vector in our manufacturing process, we may in the future find that another viral vector or non-viral vector-based process offers advantages. Switching from one lentiviral vector to another or switching from lentiviral to another delivery system would necessitate additional process development and clinical testing, and this may delay the development of existing product candidates.

In addition, for certain RESET™ trials, we do not know the doses to be evaluated in pivotal trials or, if licensed, commercially. Finding a suitable dose may delay our anticipated clinical development timelines, and we may elect to pause clinical trials to find a suitable dose or make assessments ahead of continuing a trial. Our expectations with regard to our scalability and costs of manufacturing may vary significantly as we develop our product candidates and understand these critical factors. We may experience delays in developing a sustainable, reproducible and scalable manufacturing process or transferring that process to commercial partners, which may prevent us from completing our clinical studies or commercializing our product candidates on a timely or profitable basis, if at all.

Moreover, our product candidates may not perform successfully in clinical trials or may be associated with adverse events that distinguish them from the CAR T therapies that have previously been licensed. For instance, subjects in our CAAR T clinical trials have been infused with our proposed therapies, and may possess strongly activating soluble antibodies, which are not present in oncology patients, and when they interact with our infused product candidates, could result in potential adverse side effects, such as CRS or ICANS, which have been observed in our clinical trials. Additionally, adverse side effects caused by even one of our CAR T or CAAR T product candidates could negatively affect our ability to develop future product candidates based on our CABA® platform. Unexpected side effects or clinical outcomes from any of our products candidates would significantly impact our business.

Further, the clinical study requirements of the FDA, the European Medicines Agency, or EMA, and other regulatory agencies and the criteria they use to determine the safety, potency and purity of a product candidate are determined 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 ours is less clear, and can be more complex and consequently have higher development risk, be more expensive and take longer than for other, better known or extensively studied pharmaceutical or other product candidates. Approvals by the FDA for existing cell therapies treating B cell-mediated diseases, such as Kymriah (Novartis Pharmaceuticals Corporation) and Yescarta® (Gilead Sciences, Inc.) in oncology indications, may not be indicative of what the FDA may require for approval of our therapies in autoimmune indications. Approvals by any regulatory agency may not be indicative of what any other

regulatory agency may require for approval or what such regulatory agencies may require for approval in connection with new product candidates. As we advance our product candidates, we will be required to consult with these regulatory agencies and comply with applicable requirements and guidelines. If we fail to do so, we may be required to delay or discontinue development of such product candidates. These additional processes may result in a review and approval process that is longer than we otherwise would have expected. More restrictive statutory regimes, government regulations or negative public opinion would have an adverse effect on our business, financial condition, results of operations and prospects and may delay or impair the development and commercialization of our product candidates or demand for any products we may develop.

In addition, responses by agencies at the federal and state level to negative public perception or ethical concerns may result in new legislation or regulations that could limit our ability to develop or commercialize any product candidates, obtain or maintain regulatory approval or otherwise achieve profitability. The FDA has expressed interest in further regulating biotechnology products, such as cellular therapies. Agencies at both the federal and state level in the United States, as well as the U.S. Congressional committees and other government entities or governing agencies have also expressed interest in further regulating the biotechnology industry. Such action may delay or prevent commercialization of some or all of our product candidates. Adverse developments in clinical trials of cellular therapy products conducted by others or in the post-approval setting may cause the FDA or other oversight bodies to change the requirements for approval of any of our product candidates. These regulatory review agencies and committees and the new requirements or 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 our product candidates or lead to significant post-approval limitations or restrictions.

Patients receiving T cell-based immunotherapies, such as our product candidates, have in the past and may in the future experience serious adverse events, including ICANS, CRS and killing of cells other than the intended B cells that express the autoantibodies. If our product candidates are revealed to have high and unacceptable severity and/or prevalence of side effects or unexpected characteristics, their clinical development, regulatory approval, and commercial potential will be negatively impacted, which will significantly harm our business, financial condition and prospects.

Our product candidates are CAR T or CAAR T cell-based immunotherapies. In our clinical trials and clinical trials of other similarly designed cellular immunotherapies to treat cancer, there have been life threatening events related to ICANS and/or CRS requiring intense medical intervention, such as intubation or medications to support blood pressure, and in several cases in clinical trials of other similarly situated clinical trials and of other similarly designed immunotherapies to treat cancer resulted in death. We have observed events of CRS and ICANS in our ongoing rese-cel REstoring SElf-Tolerance, or RESET, trial. ICANS is a condition that is currently defined clinically by cerebral edema, confusion, drowsiness, speech impairment, tremors, seizures or other central nervous system side effects, when such side effects are serious enough to lead to intensive care. CRS is a condition that is currently defined clinically by certain symptoms related to the release of cytokines, which can include fever, chills and low blood pressure, when such side effects are serious enough to lead to intensive care with mechanical ventilation or significant medications to support blood pressure. There is a possibility that our product candidates could have similarly life threatening serious adverse side effects, such as ICANS and CRS.

Our product candidates may have serious and potentially fatal consequences due to the targeting of cells within the body due to unexpected protein interactions with the CAR or CAAR. Although we have completed multiple preclinical studies designed to screen for toxicity caused by unintended off-target recognition by the cell binding domain of the DSG3 CAAR, MuSK CAAR and rese-cel and intend to screen future CAR candidates not yet tested in patients through preclinical studies, our product candidates may still recognize and react with one or more proteins unrelated to the intended surface immunoglobin target protein to which it is designed to link. If unexpected binding occurs in normal tissue, our product candidates may target and kill the normal tissue in a patient, leading to serious and potentially fatal adverse events, undesirable side effects, toxicities or unexpected characteristics. Detection of any unexpected targeting may halt or delay any ongoing clinical trials for our product candidates and prevent or delay regulatory approval. While we have developed a preclinical screening process to identify cross-reactivity of our product candidates, we cannot be certain that this process will identify all potential tissue that our product candidates may target. For example, a membrane protein array with DSG3-CAART yielded one weak signal against a protein that is designed to bind to glycoproteins and which was detected in both the test and control conditions. Further analysis of this protein in confirmatory cell-based assays repeatedly demonstrated that DSG3-CAART does not

recognize nor activate against this protein. We performed similar preclinical studies for rese-cel and did not observe any confirmed off target activity for rese-cel. However, this further analysis may prove to be inaccurate. Any unexpected targeting that impacts patient safety could materially impact our ability to advance our product candidates into clinical trials or to proceed to marketing approval and commercialization. Furthermore, in the event subjects are re-treated, they may respond differently than other subjects given the same dose, and may not tolerate the dose or develop safety concerns.

Results of our studies could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. Undesirable side effects caused by our product candidates 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 other regulatory agencies. Our clinical trials of rese-cel represent the first evaluation of this product candidate in patients and rese-cel is directed against all B cells expressing CD19; therefore, there is a risk for prolonged B cell aplasia and/or hypogammaglobulinemia, which may predispose patients to infections. Given that the autoimmune and alloimmune diseases we are seeking to treat are, in some cases, less serious than the later stage cancers being treated with other immunotherapy products, we believe the FDA and other regulatory authorities likely will apply a different benefit-risk assessment thresholds such that even if our product candidate demonstrated a similar safety profile as current CAR T therapies, the FDA may ultimately determine that the harmful side effects outweigh the benefits and require us to cease clinical trials or deny approval of our product candidates. We believe tolerance for adverse events in the patient population being pursued with our CAAR T and CAR T cell therapies in autoimmune and alloimmune indications will be lower than it is in oncology, and the risks of negative impact from these toxicities may therefore be higher for us than for CAR T programs in oncology.

Furthermore, treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete the studies or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff, as toxicities resulting from T cell-based immunotherapies are not normally encountered in routine medical care. Medical personnel may need additional training regarding T cell-based immunotherapy product candidates to understand their side effects. Inadequate training in recognizing or failure to effectively manage the potential side effects of T cell-based immunotherapy product candidates could result in patient deaths. Any of these occurrences may harm our business, financial condition and prospects significantly. In addition to side effects caused by our product candidates, any preconditioning, administration process or related procedures, which we evaluate from time to time as part of our process improvement and optimization efforts, may also cause adverse side effects. For example, prolonged or persistent cytopenias and ICANS have been noted to be associated with the use of certain lymphodepleting regimens and CAR T therapies.

Preconditioning regimens, as currently implemented in several of our clinical trials, may increase the risk of adverse side effects and impact our ability to accurately assess the efficacy of our product candidates.

In oncology patients receiving CAR T cell therapy, a lymphodepleting preconditioning regimen is typically used to condition the patient prior to CAR T cell infusion in order to improve tumor immunogenicity and to promote the expansion of the infused CAR T cells. Together, these effects have been shown to enhance the clinical activity of CAR T cells in oncology patients. These regimens often include cyclophosphamide and fludarabine and are usually administered within the week prior to infusion of CAR T cells. We implemented a preconditioning regimen in the DesCAARTes™ trial where certain subjects were pre-treated with IVIg and cyclophosphamide, and other patients were pre-treated with IVIg, cyclophosphamide, and fludarabine prior to DSG3-CAART infusion, have included planned dosing cohorts in the MusCAARTes™ trial where subjects were pre-treated with fludarabine and cyclophosphamide prior to MuSK-CAART infusion, and we have incorporated a lymphodepleting preconditioning regimen of fludarabine and cyclophosphamide in our RESET™ clinical trials. We are evaluating rese-cel without preconditioning in our RESET-PV® trial in patients with mPV and mcPV, as well as in a subset of patients enrolled in our RESET-SLE™ trial. Serious adverse events have been observed in some patients following CAR T cell infusion, and these include infection, cytokine release syndrome and ICANS. The lymphodepleting and immunomodulatory preconditioning regimen may contribute to the occurrence and severity of these adverse events due to its role in inducing leukopenia, or low levels of white blood cells in the blood, including lymphopenia, or low levels of lymphocytes in the blood, and regulating the activation and effector functions of other immune cells and antibodies, and enhanced CAR T cell activity.

In addition, a lymphodepleting regimen may eliminate pathogenic B cells targeted by our CAAR T cell product candidates. As a result, any lymphodepleting regimen for preconditioning that we use may delay or otherwise

adversely affect our ability to use DSG3 or MuSK autoantibody titers, a standard clinical assay, to assess the activity of DSG3-CAART and MuSK-CAART, respectively. An inability to use DSG3 or MuSK autoantibody levels to demonstrate the specific activity of our CAAR T cell product candidates may require us to rely on the subjective measurement of blister formation in patients in the DesCAARTes™ trial or muscle weakness in the MusCAARTes™ trial, which can be a less sensitive and accurate measurement of CAAR T cell activity. This therefore could delay a signal of potential biologic activity attributable to CAAR and therefore may slow clinical development. We are not actively enrolling patients in the MusCAARTes™ trial at this time.

In addition to lymphodepleting preconditioning, other preconditioning regimens with immunomodulatory effects may be considered to prepare the body for CAR T or CAAR T infusion. For example, if autoantibody is found to reduce or inhibit function of CAAR T in the body, then pretreatment of patients with antibody reducing therapies, such as FcRN inhibitors, IVIg, plasmapheresis, or treatment of post rituximab patients may be considered. Some of these types of preconditioning are standard of care for this autoimmune population and therefore are already considered to have a beneficial risk profile in this patient population. These other preconditioning regimens may cause serious adverse events, including hypotension, thromboembolism, and opportunistic infections.

Subjects in our RESET™ trials, except for our RESET-PV® trial and a subset of patients enrolled in our RESET-SLE™ trial, will be treated with a standard preconditioning regimen consisting of fludarabine and cyclophosphamide prior to rese-cel infusion. In addition, the lymphodepleting regimen may eliminate some of the pathogenic B cells targeted by rese-cel. As a result, the lymphodepleting regimen may contribute to the initial clinical response that may be observed after rese-cel, which may make interpretation of early efficacy difficult to assess and may also delay our ability to characterize the activity of rese-cel independent of the effects of fludarabine and cyclophosphamide. We intend to evaluate this potential impact of preconditioning in our CAAR and rese-cel studies, through the comparison to non-lymphodepletion arms.

Our clinical patients may experience increased or more severe adverse effects specifically related to the preconditioning regimens, such as severe allergic reactions, difficulty breathing, severe headaches, fevers and chills, serious infections, low blood counts, inflammation of the colon with bleeding, bladder irritation, blood clots, development of certain cancers, damage to the heart, lung or kidneys, and even death. These undesirable side effects, whether associated with the preconditioning regimen alone or in combination with our CAR T cell product candidates or CAAR T cell product candidates, could cause delays in patient enrollment in our clinical trials, could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a change to our clinical trial design, a more restrictive label or the delay or denial of regulatory approval by the FDA. Any of the foregoing may increase the duration and expense of the clinical development of our product candidates or limit market acceptance of such product candidates, if approved, any of which could have a material adverse effect on our business and financial condition.

Our business is highly dependent on the success of our initial product candidates targeting autoimmune diseases where B cells may play a role in initiating or maintaining disease. All of our product candidates will require significant additional preclinical and/or clinical development before we can seek regulatory approval for and launch a product commercially.

Our business and future success depend on our ability to obtain regulatory approval of, and then successfully launch and commercialize our initial product candidates targeting autoimmune diseases where B cells may play a role in initiating or maintaining disease. There is no guarantee that we will be able to advance our product candidates through clinical development or obtain marketing approval for any of our product candidates. The process for obtaining marketing approval for any product candidate is very long and risky and there will be significant challenges for us to address in order to obtain marketing approval as planned, if at all.

The initial clinical results we have observed may not be predictive of results of subsequent cohorts in this clinical trial, or of any future clinical trials. Because rese-cel is the first CAR T product candidate that we are testing in the clinic, we may experience preliminary complications surrounding trial design, protocol establishment and execution, establishing trial protocols, patient recruitment and enrollment, quality and supply of clinical doses, or safety issues.

Additionally, a failure of our rese-cel RESET™ clinical trial could influence physicians' and regulators' opinions with regard to the viability of our CABA® platform more broadly, particularly if treatment-related side effects are observed. The occurrence of any of these risks could significantly harm our development plans and business

prospects. If treatment-related side effects are observed with the administration of rese-cel, or if they are viewed as less safe, potent or pure than other therapies, our ability to develop other CAR T cell therapies may be significantly harmed.

We have never successfully completed any clinical trials, and we may be unable to do so for any product candidates we develop.

We have not yet demonstrated our ability to successfully complete any clinical trials, including large-scale, pivotal clinical trials, obtain regulatory approvals, manufacture a commercial scale product, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful commercialization. Although our key employees have significant experience in leading clinical development programs, our experience conducting clinical trials with our product candidates is limited. We may not be able to file INDs or CTAs for any of our other product candidates on the timelines we expect, if at all. For example, we cannot be certain that the IND-enabling or CTA-enabling studies for our future product candidates will be completed in a timely manner or be successful or that the manufacturing process will be validated in a timely manner. Even if we submit an IND or CTA for a future product candidate, the FDA, the EMA, or other foreign regulatory authorities may not clear the IND or CTA and allow us to begin clinical trials in a timely manner or at all. The timing of submissions on future product candidates will be dependent on further preclinical and manufacturing success. Moreover, we cannot be sure that submission of an IND or a CTA will result in the FDA or other foreign regulatory authorities allowing further clinical trials to begin, or that, once begun, issues will not arise that require us to suspend or terminate clinical trials. Commencing each of these clinical trials is subject to finalizing the trial design based on discussions with the FDA and other foreign regulatory authorities. Any guidance we receive from the FDA or other foreign regulatory authorities is subject to change. These regulatory authorities could change their position, including, on the acceptability of our trial designs or selection of comparator or clinical endpoints, which may require us to complete additional clinical trials or impose stricter approval conditions than we currently expect. If the FDA disagrees with, or subsequently revises or withdraws its prior feedback regarding our clinical endpoints or how to measure clinically meaningful significance, then even if we meet clinical endpoints we may be prevented or delayed in obtaining marketing approval for such product candidates.

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

- be delayed in obtaining marketing approval for our product candidates;
- not obtain marketing approval at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- be subject to post-marketing testing requirements; or
- have the product removed from the market after obtaining marketing approval.

Our registrational trials may rely on a single-arm design and an external control; if regulatory authorities determine that the external control is unsuitable, we may be unable to obtain approval on our anticipated timelines, or at all.

We plan to conduct registrational trials using an open-label, single-arm design with an external comparator(s) rather than a blinded, randomized controlled trial. As a result, data generated from these studies may be subject to heightened FDA scrutiny regarding potential bias, confounding variables, and the overall reliability of treatment-effect estimates. In externally controlled trials, outcomes for patients who receive the investigational therapy according to the trial protocol are compared with outcomes from individuals who did not receive the investigational therapy and who are external to the trial. External controls may be historical (from an earlier time period) or concurrent (collected during the same time period in a different setting), and may be derived from real-world data sources such as patient registries, electronic health records, or medical claims. For example, in our RESET-Myositis® program for rese-cel, we intend to conduct a single-arm registrational trial in patients with dermatomyositis or antisynthetase syndrome evaluating a 16-week primary endpoint—defined as achievement of a moderate or major Total Improvement Score

while off immunomodulators and on no or low-dose steroids—and we intend to rely on a retrospective analysis of a myositis patient registry to estimate control response rates.

Use of a registry dataset introduces risks, including whether the dataset is sufficiently comparable to our trial population and whether key clinical and demographic variables are assessed consistently. If the FDA disagrees with, or subsequently revises or withdraws its prior feedback regarding the suitability of our trial design, analytical methods, or the external control dataset, the FDA may require additional data, extended follow-up, alternative endpoints, or a randomized controlled trial. Any of these outcomes could substantially delay or prevent regulatory approval. The FDA has highlighted multiple risks associated with the use of external controls, including the potential for confounding and bias arising from, among other factors: temporal changes in standard of care; geographic differences in treatment practices or access to care; heterogeneity in diagnostic criteria; differences in prognostic indicators; variations in background therapies; differing clinical characteristics and responses to standard of care among patients with different disease subtypes; differing assessment schedules or endpoint definitions; missing data; and selection bias in the external dataset. The FDA also generally expects patient-level access to external datasets and robust, pre-specified statistical analysis plans. Even with such plans, as well as propensity methods and sensitivity analyses, these approaches may insufficiently mitigate confounding and bias in the view of the FDA.

If our external control dataset, its pre-specification, or our planned analyses are viewed as inadequate, the FDA may determine that our single-arm registrational trial does not constitute an "adequate and well-controlled" investigation under applicable regulations, and may make such determination even where we believe that we have previously aligned with the FDA on the design of the registrational trial. The FDA may also determine that any patient registry we use—including the myositis registry supporting our RESET-Myositis® cohort—is unsuitable as an external control. In March 2026, FDA noted that concerns with the use of a registry include potential differences between the enrolled study population and registry population for the RESET-Myositis® cohort (e.g. diagnosis classification and refractory definition) and missing data as well as other criteria established by FDA guidance for industry, and that such details are needed in order to assess suitability of the proposed registry as an external control. In addition, FDA has recently issued Complete Response Letters or changed its feedback to sponsors in pre-BLA meetings citing concerns with external controls such as potential bias and design flaws, including eligibility criteria, endpoints, and timing of assessments not being closely aligned between trial population and the external dataset. If the FDA reaches similar conclusions in our case, it could reject our comparative analyses, request confirmatory data, or require a randomized trial, resulting in significant delays, increased costs, or failure to obtain approval.

Even if our clinical data and statistical analyses comparing our data to an external control—such as a myositis registry—demonstrate favorable evidence of the investigational candidate's effectiveness, the FDA may still determine that such evidence is insufficient to support approval. This could occur for a variety of reasons, including unfavorable interpretation of comparative analyses, perceived differences between the clinical and external datasets, questions regarding the adequacy of our sensitivity analyses, or concerns about the absence of additional control sources.

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 as a result of the clinical testing of our product candidates and will face an even greater risk if we commercialize any products. 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 testing, 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 product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- inability to bring our product candidates to the market;
- decreased demand for our product candidates;
- injury to our reputation;
- withdrawal of clinical trial participants;

- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- exhaustion of any available insurance and our capital resources;
- the inability to commercialize any product candidate; and
- a decline in our share price.

Since we have not yet commenced marketing of any products, we do not yet hold product liability insurance for commercialization of our product candidates. Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop, alone or with corporate collaborators. Our insurance policies may also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. Assuming we obtained clinical trial insurance for our clinical trials, we may have to pay amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Even if our agreements with any future corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

Risks Related to the Industry

Our product candidates may cause undesirable side effects or have other properties that could halt their clinical development, prevent their regulatory approval, limit their commercial potential or result in significant negative consequences.

Undesirable or unacceptable side effects caused by our product candidates 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 other foreign regulatory authorities. Further, clinical trials by their nature utilize a sample of the potential patient population. With a limited number of subjects and limited duration of exposure, rare and severe side effects of our product candidates may only be uncovered with a significantly larger number of patients exposed to the drug. Undesirable side effects could also result in an expansion in the size of our clinical trials, increasing the expected costs and timeline of our clinical trials. Additionally, results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics.

Licensed CAR T cell therapies and those under development have shown frequent rates of CRS and ICANS, and adverse events have resulted in the death of patients. Similar adverse events have occurred and could occur during treatment with our current or future CAR T or CAAR T cell product candidates. For example, activation of CAAR T cells by patient autoantibodies or alloantibodies could stimulate CRS. When CAAR T cells are infused and the CAAR binds to soluble antibodies in the blood or tissues of treated patients, these soluble antibodies may cause the CAAR T cells to proliferate, resulting in an activation of the immune system that is too high, leading to CRS. Further, it is possible that patients will exhibit acute rejection of the CAAR T cells because of preexisting immunity to the antigen within the CAAR. This could render our product candidates ineffective.

If unacceptable toxicities or health risks, including risks inferred from other unrelated immunotherapy trials, arise in the development of our product candidates, we could suspend or terminate our trials or the FDA, the Safety Monitoring Boards for our trials (e.g. Data Safety Monitoring Board, or DSMB, or Independent Data Safety Monitoring Committee, or IDMC), or local regulatory authorities such as institutional review boards, or IRBs, or independent ethics commits, or IECs, as applicable, could recommend or order us to cease clinical trials. Regulatory authorities, such as the FDA, could also deny approval of our product candidates for any or all targeted indications. Treatment-related side effects could also affect patient recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff, as toxicities resulting from T cell therapy are not normally encountered in the general patient population and by medical personnel. We expect to have to train medical personnel using CAR T or CAAR T cell product candidates to understand the side effect profile of our product candidates for both our preclinical studies and clinical trials and upon any commercialization of any of our product candidates, if licensed. Inadequate training in recognizing or managing the potential side effects of our product candidates could result in patient deaths. Any of these occurrences may harm our business, financial condition and prospects significantly.

Our preclinical studies and clinical trials may fail to demonstrate the safety, potency and purity of any of our product candidates, which would prevent or delay regulatory approval and commercialization.

Before obtaining regulatory approvals for the commercial sale of any of our product candidates, we must demonstrate through lengthy, complex and expensive preclinical testing and clinical trials that our product candidates are safe, potent and pure for use in each target indication. Clinical trials are expensive and can take many years to complete, and their outcomes are inherently uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials, including in any post-approval studies of our product candidates. In addition, initial success in any clinical trials may not be indicative of results obtained when such trials are completed. There is typically an extremely high rate of attrition from the failure of product candidates proceeding through clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety, potency and purity profile despite having progressed through preclinical studies and initial clinical trials. Similarly, while we believe rese-cel has a similar overall design to the construct used for the patients in the *Nature Medicine, Lancet, Annals of Rheumatic Diseases, and Rheumatology* publications, those studies involved a small number of patients, and a different product candidate, and the initial clinical results observed in those studies may not be predictive of clinical trial results with rese-cel or any of our other product candidates. Additionally, because those studies are not our own, we may not have access to accurate follow-up information or peer-reviewed results.

A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of potency or efficacy, insufficient durability of potency or efficacy or unacceptable safety issues, notwithstanding promising results in earlier trials, and we cannot be certain that we will not face similar setbacks. These setbacks have been caused by, among other things, preclinical and other nonclinical findings made while clinical trials were underway, or safety or efficacy observations made in preclinical studies and clinical trials, including previously unreported adverse events. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials nonetheless failed to obtain FDA or European Commission approval. Most product candidates that commence clinical trials are never approved as products.

Any preclinical studies or clinical trials that we may conduct may not demonstrate the safety, potency and purity necessary to obtain regulatory approval to market our product candidates. If the results of our ongoing or future preclinical studies and clinical trials are inconclusive with respect to evaluations of efficacy, the safety, potency and purity of our product candidates, if we do not meet the clinical endpoints with statistical and clinically meaningful

significance, or if there are safety concerns associated with our product candidates, we may be prevented or delayed in obtaining marketing approval for such product candidates. In some instances, there can be significant variability in evaluations of efficacy, safety, potency or purity results between different preclinical studies and 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 clinical trial protocols and the rate of dropout among clinical trial participants. For example, because our CAAR T cell product candidates only target approximately 0.01% to 1% of the B cells in a patient, they may not engage enough of the target to achieve adequate engraftment necessary for elimination of all pathogenic B cells. Insufficient safety or potency in clinical trials may delay product development to enable time to modify the product candidate for next generation approaches or make manufacturing changes or may lead us to discontinue development of the product candidate.

Additionally, our ongoing clinical trials utilize, and our planned trials may utilize, an "open-label" trial design. An "open-label" clinical trial is one where both the patient and investigator know whether the patient is receiving the investigational product candidate or either an active drug or placebo. Most typically, open-label clinical trials test only the investigational product candidate and sometimes may do so at different dose levels. Open-label clinical trials are subject to various limitations that may exaggerate any therapeutic effect as patients in open-label clinical trials are aware when they are receiving treatment. Open-label clinical trials may be subject to a "patient bias" where patients perceive their symptoms to have improved merely due to their awareness of receiving an experimental treatment. In addition, open-label clinical trials may be subject to an "investigator bias" where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge. The results from an open-label trial may not be predictive of future clinical trial results with any of our product candidates for which we include an open-label clinical trial when studied in a controlled environment with a placebo or active control.

In addition, we cannot guarantee that the FDA or other foreign regulatory authorities will interpret the results of any of our ongoing or planned clinical trials as we do, and more trials could be required before we submit our product candidates for approval. To the extent that the results of the trials are not satisfactory to the FDA or other foreign regulatory authorities to support a marketing application, approval of our product candidates may be significantly delayed, or we may be required to expend significant additional resources, which may not be available to us, to conduct additional trials in support of potential approval of our product candidates.

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 products. Whether or not it obtains FDA approval for a product, an applicant must obtain the necessary approvals by the comparable foreign regulatory authorities before commencing clinical trials or marketing of the product in those countries or jurisdictions. For example, the process governing approval of medicinal products in the European Union generally follows the same lines as in the United States but can differ in significant ways. It entails the 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 of a marketing authorization application to the EMA (for products within the scope of the centralized marketing authorization procedure) and the granting of a marketing authorization by the European Commission before the product can be marketed and sold in the European Union.

Interim, topline or preliminary data from any preclinical studies or clinical trials that we conduct may change as more data become available and are subject to audit and verification procedures that could result in material changes in the final data.

Our RESET™ trials in SLE, myositis, SSc, gMG, MS and PV are designed as open-label trials. From time to time, we may publicly disclose interim, preliminary or topline data from our preclinical studies and clinical trials, including safety data and evaluations of efficacy, which will be based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following our receipt of additional data or a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data.

As a result, the topline results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated.

Topline data 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, topline data should be viewed with caution until the final data are available. From time to time, we may also disclose interim data from planned interim analyses in our clinical trials. Interim data 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. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects. Further, disclosure of interim data by us or our competitors, or by patients or caregivers who are aware that a patient is receiving investigational product, due to the open-label design of the trial, could result in volatility in the price of our common stock.

Regulatory agencies, including the FDA or other foreign regulatory authorities, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general.

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.

The increasing use of social media platforms presents new risks and challenges.

Social media is increasingly being used to communicate about our clinical development programs and the diseases our product candidates are being developed to treat. We intend to utilize appropriate social media in connection with communicating about our development programs. Social media practices in the biopharmaceutical industry continue to evolve and regulations relating to such use are not always clear. This evolution creates uncertainty and risk of noncompliance with regulations applicable to our business. For example, patients may use social media channels to report an alleged adverse event during a clinical trial, or public news outlets and opinion pieces relating to our industry or CAR T therapies more generally may be published and/or disseminated. When such disclosures occur, there is a risk that we fail to monitor and comply with applicable adverse event reporting obligations, or we may not be able to defend our business or the public's legitimate interests in the face of the political and market pressures generated by social media due to restrictions on what we may say about our investigational products and/or the industry in which we operate. There is also a risk of inappropriate disclosure of sensitive information or negative or inaccurate posts or comments about us on any social networking website, or a risk that a post on a social networking website by any of our employees may be construed as inappropriate promotion. If any of these events were to occur or we otherwise fail to comply with any applicable regulations, we could incur liability, face regulatory actions, or incur other harm to our business such as reputational damage.

We may encounter substantial delays in our clinical trials or may not be able to conduct our trials on the timelines we expect or at all.

Clinical testing is expensive, time consuming and subject to uncertainty. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. Even if these trials begin as planned, issues may arise that could suspend or terminate such clinical trials. A failure of one or more clinical trials can occur at any stage of testing, and our ongoing and future clinical trials may not be successful. Events that may prevent successful or timely completion of clinical development include:

- inability to generate sufficient preclinical, toxicology or other in vivo or in vitro data to support the initiation of clinical trials;
- delays in sufficiently developing, characterizing or controlling a manufacturing process suitable for clinical trials;
- delays in developing suitable assays for screening patients for eligibility for clinical trials with respect to certain product candidates;
- delays in reaching a consensus with the FDA and other regulatory agencies on trial design;

- delays in reaching agreement on acceptable terms with prospective CMOs, CROs and clinical study sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CMOs, CROs and clinical trial sites;
- delays in obtaining required institutional review board, or IRB, approval at each clinical trial site;
- imposition of a temporary or permanent clinical hold by regulatory agencies for a number of reasons, including after review of an IND submission or amendment, or equivalent application or amendment; as a result of a new safety finding that presents unreasonable risk to clinical trial participants; a negative finding from an inspection of our clinical study operations or study sites; developments on trials conducted by competitors for related technology or by those that rely on a similar construct, design and/or third-party research that raise FDA or other foreign regulatory authorities concerns about risk to patients of the technology or construct broadly, and/or negative public perception of the same; or if FDA or other foreign regulatory authorities find that the investigational protocol or plan is clearly deficient to meet its stated objectives;
- delays in recruiting eligible patients to participate in our clinical trials, including pediatric patients who need parental consent;
- delays in treating one or more patients, once enrolled, due to a patient's inability to accommodate parts of the complex study procedures schedule;
- difficulty collaborating with patient groups and investigators;
- failure by our CROs, other third parties or us to adhere to clinical trial requirements and the potential termination of ongoing agreements with our CROs;
- failure to perform in accordance with the FDA's Good Clinical Practice, or GCP, requirements or applicable regulatory guidelines in other countries;
- transfer of manufacturing processes to any new CMO or our own manufacturing facilities or any other development or commercialization partner for the manufacture of product candidates;
- delays in having patients complete participation in a trial or return for post-treatment follow-up;
- patients dropping out of a trial;
- occurrence of adverse events associated with the product candidate that are viewed to outweigh its potential benefits;
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols;
- changes in the standard of care on which a clinical development plan was based, which may require new or additional trials;
- the cost of clinical trials of our product candidates being greater than we anticipate;
- clinical trials of our product candidates producing negative or inconclusive results, which may result in our deciding, or regulators requiring us, to conduct additional clinical trials or abandon product development programs;
- delays or failure to secure supply agreements with suitable raw material suppliers, or any failures by suppliers to meet our quantity or quality requirements for necessary raw materials; and
- delays in manufacturing or inability to manufacture sufficient clinical supply (for example, due to capacity constraints, supply interruption, or the need to engineer the process to meet higher dose requirements), testing, releasing, validating or importing/exporting sufficient stable quantities of our product candidates for use in clinical trials or the inability to do any of the foregoing.

Any inability to successfully complete preclinical and clinical development could result in additional costs to us or impair our ability to generate revenue. If we make manufacturing or formulation changes to our product candidates, we may be required to, or we may elect to, conduct additional trials to bridge our modified product

candidates to earlier versions. Clinical trial delays could also shorten any periods during which our product candidates and products, if licensed, have patent protection and may allow our competitors to bring products to market before we do, which could impair our ability to successfully commercialize our product candidates and may harm our business and results of operations.

We could also encounter delays if a clinical trial is suspended or terminated by us, the FDA or other regulatory authority, or if the IRBs of the institutions in which such trials are being conducted suspend or terminate the participation of their clinical investigators and sites subject to their review. Such authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product candidate, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

Delays in the initiation, conduct or completion of any clinical trial of our product candidates will increase our costs, slow down our product candidate development and approval process and delay or potentially jeopardize our ability to commence product sales and generate revenue. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. In the event we identify any additional product candidates to pursue, we cannot be sure that submission of an IND or comparable foreign regulatory submission will result in the FDA or other foreign regulatory authorities allowing clinical trials to begin in a timely manner, if at all.

In addition, from time to time, we may publicly announce the expected timing of various scientific, clinical, regulatory, manufacturing and other product development milestones. These milestones may include the commencement, completion or development of data from our preclinical studies and clinical trials or the submission of regulatory filings, such as an IND or a CTA. All of these milestones are, and will be, based on a variety of assumptions. If any of the foregoing events impact our ability to meet the publicly announced timing of our milestones, we may experience adverse effects on our business, financial condition and prospects and the price of our common stock could decline.

Monitoring safety of patients receiving our product candidates will be challenging, which could adversely affect our ability to obtain regulatory approval and commercialize our product candidates.

For our RESET™ and other planned clinical trials, we expect to continue to contract with academic medical centers and hospitals experienced in the assessment and management of toxicities arising during clinical trials. In the future, we may also contract with non-academic medical centers and hospitals with similar capabilities. Nonetheless, these centers and hospitals may have difficulty observing patients, including due to failure by patients to comply with post-clinical trial follow-up programs, and treating toxicities, which may be more challenging due to personnel changes, inexperience, inadequate institutional safety procedures, shift changes, house staff coverage or related issues. This could lead to more severe or prolonged toxicities or even patient deaths, which could result in us or the FDA delaying, suspending or terminating one or more of our clinical trials, and which could jeopardize regulatory approval. We also expect the centers using rese-cel and our other product candidates, if licensed, on a commercial basis could have similar difficulty in managing adverse events. Medicines used at centers to help manage adverse side effects of rese-cel, DSG3-CAART, MuSK-CAART and our other product candidates may not adequately control the side effects and/or may have a detrimental impact on the efficacy of the treatment.

If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the trial until its conclusion. The enrollment of patients depends on many factors, including:

- the size and nature of the patient population;
- the patient eligibility criteria defined in the protocol;

- the size of the patient population required for analysis of the trial's primary endpoints;
- recruiting an adequate number of suitable patients to participate in a clinical trial;
- reaching agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;
- obtaining IRB and other required reviewing body approval at each clinical trial site;
- the proximity of patients to trial sites;
- the design of the trial and whether the FDA or other foreign regulatory authorities agree to the design and implementation of the trial;
- our ability to identify clinical trial sites and recruit clinical trial investigators with the appropriate capabilities, competencies and experience;
- clinicians', patients' and parents' (for juvenile patients) perceptions as to the potential advantages and risks of the product candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating, or with CAR T cell therapies broadly following the FDA's investigation into reports of T cell malignancies for approved BCMA- and CD19-directed CAR T cell immunotherapies;
- the occurrence of dose-limiting toxicity in the clinical trial;
- the efforts to facilitate timely enrollment in clinical trials;
- the patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment;
- our ability to obtain and maintain patient consents;
- the risk that patients enrolled in clinical trials will drop out of the trials before the infusion of our product candidates or trial completion; and
- the ability of patients to meet the complex follow-up requirements of the clinical trial.

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 might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Since the number of qualified clinical investigators is limited, some of our clinical trial sites may also be used by some of our competitors, which may reduce the number of patients who are available for our clinical trials in that clinical trial site.

Moreover, because our product candidates represent a departure from more commonly used methods for autoimmune diseases where B cells may play a role in initiating or maintaining disease treatment, potential patients and their doctors may be inclined to use conventional therapies, such as corticosteroids or systemic immunosuppressive medications, rather than enroll patients in our clinical trial. Delays in patient enrollment may result in increased costs or may affect the timing or outcome of our ongoing and planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our product candidates.

Our RESET™ trials in SLE, myositis, SSc, gMG, PV and MS and any additional expected clinical trials for each of our product candidates will enroll a limited number of patients. The activity and toxicity data from these clinical trials of our product candidates may differ from future results of subsequent clinical trials that enroll a larger number of patients. Since the number of patients that we plan to dose in our RESET™ trials in SLE, myositis, SSc, gMG, PV and MS is small, and the number of patients in clinical trials for any future product candidates may be small, the results from such clinical trials, once completed, may be less reliable than results achieved in larger clinical trials, which may hinder our efforts to obtain regulatory approval for our product candidates. In a subset of our RESET-SLE™ trial, our RESET-PV® trial and our RESET-MS™ trial, we plan to evaluate the toxicity profile of our product candidates and establish the recommended dose for the next clinical trial. The preliminary results of clinical trials with smaller sample sizes, such as our RESET™ trials, as well as any clinical trials for future product candidates, can be disproportionately influenced by various biases associated with the conduct of small clinical trials, such as the potential failure of the smaller sample size to accurately depict the features of the broader patient population, which limits the ability to generalize the results across a broader community, thus making the clinical trial results less reliable than clinical trials with a larger number of patients. As a result, there may be less certainty that such product candidates would achieve a statistically significant effect in any future clinical trials. If we conduct any future clinical trials of rese-cel, we may not achieve a statistically significant result or the same level of statistical significance, if any, that we might have anticipated based on the results observed in our RESET™ trials.

Risks Related to Sales, Marketing and Competition

The market opportunities for our product candidates may be limited to those patients who are ineligible for or have failed prior treatments and may be small.

Our projections of both the number of people who have autoimmune diseases where B cells may play a role in initiating or maintaining disease we are targeting, as well as the subset of people with these diseases in a position to receive second or later lines of therapy and who have the potential to benefit from treatment with our product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations, or market research and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these autoimmune diseases where B cells may play a role in initiating or maintaining disease. The number of patients may turn out to be lower than expected. Additionally, the potentially addressable patient population for our product candidates may be limited or may not be amenable to treatment with our product candidates.

We face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively.

The biopharmaceutical and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong focus on intellectual property. We face competition from many different players, including large and specialty pharmaceutical and biotechnology companies, academic research organizations and governmental agencies. Any therapeutic candidates we successfully develop and commercialize will compete with the existing standard of care as well as novel therapies that may gain regulatory approval in the future. Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff and experienced marketing and manufacturing organizations and well-established sales forces. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. We are one of several companies developing CAR T drug candidates for the treatment of autoimmune diseases where B cells may play a role in initiating or maintaining disease. Additionally, despite the significant differences in discovery, development and target

populations between oncology and autoimmune targets, we recognize that companies with an investment and expertise in CAR T cell development for oncology indications could also attempt to leverage their expertise into autoimmune diseases where B cells may play a role in initiating or maintaining disease affected populations. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors, either alone or with collaborative partners, may succeed in developing, acquiring or licensing on an exclusive basis drug or biologic products that are more effective, safer, more easily commercialized or less costly than our product candidates or may develop proprietary technologies or secure patent protection that we may need for the development of our technologies and products.

We are aware of several other biopharmaceutical companies developing therapies for SLE, myositis, SSc, gMG and PV. Some product candidates may be directly competitive to our product candidates, such that even if we obtain regulatory approval of our product candidates, the availability and price of these other products, whether directly competitive or not, could limit the demand and the price we are able to charge for our product candidates. We may not be able to implement our business plan if the acceptance of our product candidates is inhibited by price competition or the reluctance of physicians to switch from existing methods of treatment to our product candidates, or if physicians switch to other new drug or biologic products or choose to reserve our product candidates for use in limited circumstances.

Even if we obtain regulatory approval of our product candidates, the products may not gain the market acceptance among physicians, patients, hospitals, treatment centers and others in the medical community necessary for commercial success.

The use of engineered T cells as a potential treatment for B cell-mediated autoimmune diseases is a recent development and may not become broadly accepted by physicians, patients, hospitals, treatment centers and others in the medical community. We expect physicians to be particularly influential and we may not be able to convince them to use our product candidates for many reasons. Additional factors will influence whether our product candidates are accepted in the market, including:

- the clinical indications for which our product candidates are licensed;
- physicians, hospitals, treatment centers and patients considering our product candidates as a safe and effective treatment;
- the potential and perceived advantages of our product candidates over alternative treatments;
- the prevalence and severity of any side effects;
- product labeling or product insert requirements of the FDA or other regulatory authorities;
- limitations or warnings contained in the labeling approved by the FDA or other regulatory authorities;
- the timing of market introduction of our product candidates as well as competitive products;
- the cost of treatment in relation to alternative treatments;
- the availability of coverage and adequate reimbursement and pricing by third-party payors and government authorities;
- the willingness of patients to pay out-of-pocket in the absence of coverage and adequate reimbursement by third-party payors and government authorities;
- relative convenience and ease of administration, including as compared to alternative treatments and competitive therapies; and
- the effectiveness of our sales and marketing efforts.

The product candidates we plan to develop and commercialize are premised on offering a potential cure for autoimmune diseases where B cells may play a role in initiating or maintaining disease, which may result in a high degree of uncertainty related to pricing and long-term demand for our product. Our target patient populations are relatively small. Because of this pricing and demand for our product candidates, if licensed, may not be adequate to support an extended period of commercial viability, which could adversely affect our continued ability to successfully produce and market our product or any follow-on products.

In addition, if our product candidates are licensed but fail to achieve market acceptance among physicians, patients, hospitals, treatment centers or others in the medical community, we will not be able to generate significant revenue. Even if our products achieve market acceptance, we may not be able to maintain that market acceptance over time if new products or technologies are introduced that are more favorably received than our products, are more cost effective or render our products obsolete.

Risks Related to Business Development

We may not be successful in our efforts to identify additional product candidates. Due to our limited resources and access to capital, we must prioritize development of certain product candidates, which may prove to be wrong and may adversely affect our business.

Although we intend to explore other therapeutic opportunities, in addition to the product candidates that we are currently developing, we may fail to identify viable new product candidates for clinical development for a number of reasons. If we fail to identify additional potential product candidates, our business could be materially harmed.

Research programs to pursue the development of our existing and planned product candidates for additional indications and to identify new product candidates and disease targets require substantial technical, financial and human resources whether or not they are ultimately successful. Our research programs may initially show promise in identifying potential indications and/or product candidates, yet fail to yield results for clinical development for a number of reasons, including:

- the research methodology used may not be successful in identifying potential indications and/or product candidates;
- potential product candidates may be identified but may not be able to be expressed on T cells in a manner that enables product activity;
- potential product candidates may, after further study, be shown to have harmful adverse effects or other characteristics that indicate they are unlikely to be effective drugs; or
- it may take greater human and financial resources than we will possess to identify additional therapeutic opportunities for our product candidates or to develop suitable potential product candidates through internal research programs, thereby limiting our ability to develop, diversify and expand our product portfolio.

Because we have limited financial and human resources, we intend to initially focus on research programs and product candidates for a limited set of indications. 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 or a greater likelihood of success. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities.

Accordingly, there can be no assurance that we will ever be able to identify additional therapeutic opportunities for our product candidates or to develop suitable potential product candidates through internal research programs, which could materially adversely affect our future growth and prospects. We may focus our efforts and resources on potential product candidates or other potential programs that ultimately prove to be unsuccessful.

If we fail to develop additional product candidates, our commercial opportunity will be limited.

One of our core strategies is to pursue clinical development of additional product candidates beyond rese-cel. Developing, obtaining regulatory approval and commercializing additional product candidates will require substantial additional funding and is prone to the risks of failure inherent in medical product development. We cannot provide you any assurance that we will be able to successfully advance any of these additional product candidates through the development process.

Even if we receive FDA or other foreign regulatory authority approval to market additional product candidates for the treatment of autoimmune diseases where B cells may play a role in initiating or maintaining disease, we cannot assure you that any such product candidates will be successfully commercialized, widely accepted in the marketplace or more effective than other commercially available alternatives. If we are unable to successfully develop and

commercialize additional product candidates, our commercial opportunity will be limited. Moreover, a failure in obtaining regulatory approval of additional product candidates may have a negative effect on the approval process of any other, or result in losing approval of any approved, product candidate.

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

Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our management, scientific, and medical personnel, including our Chief Executive Officer and President, our Scientific Advisory Board members, our President, Science and Technology, our Chief Medical Officer, our Chief Financial Officer and our Chief Commercial Officer. The loss of the services of any of our executive officers, other key employees, and other scientific and medical advisors, and our inability to find suitable replacements could result in delays in product development and harm our business.

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. 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. Although we have employment agreements with our key employees, these employment 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 person" 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 expect to grow the size of our organization, and we may experience difficulties in managing this growth.

As of December 31, 2025, we had 154 full-time employees and two part-time employees. As our development and commercialization plans and strategies develop, and as we continue to broaden our operational capabilities, we expect to expand our employee base and continue to add managerial, operational, sales, research and development, marketing, financial and other personnel. Current and future growth imposes significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, retaining and motivating additional employees in an increasingly competitive, inflationary market;
- managing our internal development efforts effectively, including the clinical and FDA or other regulatory authority 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 our growth, and our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial 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 certain research and development as well as general and administrative support, pursuant to agreements which expire after a certain period of time. There can be no assurance 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. There can be no assurance

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 raise sufficient funds in the future to support our hiring efforts beyond our research and development personnel, we may not be able to successfully implement the tasks necessary to further develop and commercialize our product candidates and, accordingly, may not achieve our research, development and commercialization goals.

Business disruptions, including due to natural disasters, global conflicts or political unrest, could seriously impact our operations, research and trials and harm our future revenue and financial condition.

Our operations, Minaris Advanced Therapies, LLC, or Minaris', operations, Lonza Houston Inc., or Lonza's, operations, Cellares Corporation, or Cellares, and those of any CMOs, CROs and other contractors and consultants that we may engage could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or man-made disasters or business interruptions, for which we are predominantly self-insured. Further, global conflicts or political unrest, such as the ongoing military conflict between Russia and Ukraine, the Israel-Hamas war, and the conflict in the Middle East may disrupt our global clinical trials and increase the likelihood of supply interruptions. Additionally, the effect of global financial and economic conditions and geopolitical events, including the consequences of the current administration in the United States, events or changes related thereto, including reductions in force at administrative agencies and tariffs, or political unrest or otherwise, or similar events, may have an impact on our business. Sanctions imposed by the U.S. and other countries in response to geopolitical events and conflicts may also adversely impact the financial markets and the global economy, and any economic countermeasures by the affected countries or others could exacerbate market and economic instability. The occurrence of any of these business disruptions could seriously harm our research, clinical trials, operations and financial condition and increase our costs and expenses. Our ability to obtain clinical supplies of our product candidates could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption.

There are also geopolitical tensions with China. For example, in December, 2025, the National Defense Authorization Act for Fiscal Year 2026, or the NDAA, was enacted, which includes Section 851, commonly referred to as the "BIOSECURE Act." The BIOSECURE Act restricts U.S. government agencies from procuring biotechnology equipment or services from, or entering into contracts with, entities that use biotechnology equipment or services from, designated "biotechnology companies of concern", or BCCs, and from expending federal loan or grant funds for such equipment or services. If our current or future vendors with which we work are designated as BCCs in the future, or if our collaborators, customers, investors, or future commercial partners become subject to BIOSECURE-related restrictions as a result of their relationships with such vendors, we could be required to terminate or restructure existing arrangements, transition manufacturing or other services to alternative suppliers, or delay or suspend development activities, subject to a grace period of 5 years during which time a company could continue to work with such restricted vendor. Any such transition could involve significant cost, operational complexity, regulatory risk, and delays, and alternative suppliers may not be available on acceptable terms or at all.

In addition, the increased prevalence of personnel working from home may negatively impact productivity, or disrupt, delay, or otherwise adversely impact our business operations. Further, this could increase our cyber security risk, create data accessibility concerns, and make us more susceptible to communication disruptions, any of which could adversely impact our business operations or delay necessary interactions with local and federal regulators, ethics committees, manufacturing sites, research or clinical trial sites and other important agencies and contractors.

Risks Related to Our Financial Condition and Capital Requirements

Risks Related to Past Financial Condition

We have incurred net losses in every period since our inception and anticipate that we will incur substantial net losses over the next several years, and may never achieve or maintain profitability.

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 licensed for commercial sale, and we will continue to incur significant research and development and other expenses related to our ongoing operations. Our net losses may fluctuate significantly from quarter to quarter and year to year. We have to date financed our operations primarily through private placements of our preferred stock, the sale of common stock in our initial and secondary public offerings and sales of our common stock from time to time in "at-the-market" offerings.

As a result, we are not profitable and have incurred net losses in each period since our inception. For the years ended December 31, 2025 and 2024, we recorded net losses of $167.9 million and $115.9 million, respectively. As of December 31, 2025, we had an accumulated deficit of $517.0 million. We expect to incur significant losses for the foreseeable future, and we expect these losses to increase substantially if, and as, we:

- continue our research and development efforts and submit additional INDs and/or CTAs for our product candidates;
- conduct preclinical studies and clinical trials for our current and future product candidates;
- further develop our product candidate platform;
- continue to discover and develop additional product candidates;
- maintain, expand and protect our intellectual property portfolio;
- hire additional clinical, scientific manufacturing and commercial personnel;
- establish a commercial manufacturing source and secure supply chain capacity sufficient to provide commercial quantities of any product candidates for which we may obtain regulatory approval, whether through a CMO or through a manufacturing facility that we establish;
- acquire or in-license other product candidates and technologies, including advanced manufacturing and translational capabilities that we will need for the further development and possible commercialization of our product candidates;
- seek marketing approvals for any product candidates that successfully complete clinical trials;
- establish a sales, marketing and distribution infrastructure to support the sales and marketing of any product candidates for which we may obtain marketing approvals; and
- add operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts, as well as to support our operations as a public company.

To become and remain profitable, we must succeed in developing, and eventually commercializing, a product or products that generate significant revenue. The ability to achieve this success will require us to be effective in a range of challenging activities, including completing preclinical testing and clinical trials of our product candidates, discovering additional product candidates, obtaining regulatory approval for these product candidates and manufacturing, marketing and selling any products for which we may obtain regulatory approval. We are only in the preliminary stages of most of these activities and have not yet demonstrated our ability to successfully develop any product candidate, obtain regulatory approvals, manufacture a commercial scale product or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. We may never be able to develop, manufacture or commercialize a marketable product.

Even if we are able to succeed in these activities, we may never generate revenues that are significant enough to achieve profitability. Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. Our expenses will increase if, among other things:

- there are any delays in completing our clinical trials or the development of any of our product candidates;
- we are required by the FDA or other regulatory authorities to perform trials or studies in addition to, or different than, those expected; or
- there are any third-party challenges to our intellectual property or we need to defend against any intellectual property-related claim.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses we will incur or when, if ever, we will be able to achieve profitability. Even if we succeed in commercializing one or more of our product candidates, we will continue to incur substantial research and development and other expenditures to develop, seek regulatory approval for and market additional product candidates. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital.

We have a limited operating history, which may make it difficult to evaluate the success of our business to date and to assess our future viability, and we may face significant challenges and expense as we test our product candidates and build our capabilities.

We were incorporated in 2017 and initially acquired rights to license certain patent rights from Penn in August 2018, and acquired rights to license certain patent rights from Nanjing IASO Biotherapeutics Co., Ltd., or IASO, in October 2022. All of our product candidates are still in the preclinical development or clinical stage. We have not yet demonstrated our ability to successfully complete any clinical trials, including large-scale, pivotal clinical trials, obtain marketing approvals, manufacture clinical and commercial scale therapeutics, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful commercialization. Our ability to generate product revenue or profits, which we do not expect will occur for many years, if ever, will depend heavily on the successful development and eventual commercialization of our product candidates, which may never occur. We may never be able to develop or commercialize a marketable product.

Our limited operating history, particularly in light of the rapidly evolving cell therapy field, may make it difficult to evaluate our current business and predict our future performance. Our relatively short history as an operating company makes any assessment of our future success or viability subject to significant uncertainty. We will encounter risks and difficulties frequently experienced by clinical-stage companies in rapidly evolving fields. If we do not address these risks successfully, our business will suffer. Similarly, we expect that our financial condition and operating results will continue to fluctuate from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. As a result, our shareholders should not rely upon the results of any quarterly or annual period as an indicator of future operating performance.

We currently do not have in-house resources sufficient to enable the development of our product candidates, including our CAR T and CAAR T cell platforms. We are reliant on Minaris manufacturing services for rese-cel in multiple indications through a Development, Manufacturing and Testing Services Agreement, or the Minaris Agreement. Our ability to rely on services from Minaris is limited to a specified period of time, to specific capabilities, and is subject to Minaris' right to terminate these services with or without cause. We are also reliant on Lonza manufacturing services for rese-cel in multiple indications through a Development and Manufacturing Services Agreement, or the Lonza Agreement. Our ability to rely on services from Lonza is limited to a specified period of time, to specific capabilities, and is subject to Lonza's right to terminate these services with or without cause. If we are unable to establish necessary relationships with third party partners and/or build our own capabilities, our operating and financial results could differ materially from our expectations, and our business could suffer. As we build our own capabilities, and enter into agreements with third parties, we expect to encounter risks and uncertainties frequently experienced by growing companies in new and rapidly evolving fields, including the risks and uncertainties described herein.

All of our programs require additional preclinical research and development, clinical development, regulatory approval in multiple jurisdictions, obtaining manufacturing supply, capacity and expertise, building of a commercial organization, substantial investment and significant marketing efforts before we generate any revenue from product sales. Other programs of ours require additional discovery research and then preclinical and clinical development. In addition, our product candidates must be licensed for marketing by the FDA or other foreign regulatory authorities before we may commercialize any product.

We have not generated any revenue from our product candidates and our ability to generate revenue from product sales and become profitable depends significantly on our success in a number of areas.

To become and remain profitable, we or any potential future collaborator must develop and eventually commercialize products with significant market potential at an adequate profit margin after cost of goods sold and other expenses. All of our product candidates are in the early stages of development and we will require additional preclinical studies, clinical development, regulatory review and approval, substantial investment, access to sufficient commercial manufacturing capacity and significant marketing efforts before we can generate any revenue from product sales. Our ability to generate revenue depends on a number of factors, including, but not limited to:

- timely completion of our preclinical studies and clinical trials, which may be significantly slower or cost more than we currently anticipate and will depend substantially upon the performance of third-party academic and commercial contractors;
- our ability to complete IND-enabling studies and successfully submit INDs or comparable applications;
- whether we are required by the FDA or other foreign regulatory authorities to conduct additional clinical trials or other studies beyond those planned to support the licensure and commercialization of our product candidates or any future product candidates;
- our ability to demonstrate to the satisfaction of the FDA or other foreign regulatory authorities, the safety, potency, purity and acceptable risk to benefit profile of our product candidates or any future product candidates;
- the prevalence, duration and severity of potential side effects or other safety issues experienced with our product candidates or future product candidates, if any;
- the cost of manufacturing and processing our product candidates being greater than we anticipate;
- the timely receipt of necessary marketing approvals from the FDA or other foreign regulatory authorities;
- the willingness of physicians, operators of clinics and patients to utilize or adopt any of our product candidates or future product candidates to treat autoimmune diseases where B cells may play a role in initiating or maintaining disease;
- our ability and the ability of third parties with whom we contract to manufacture adequate clinical and commercial supplies of our product candidates or any future product candidates, remain in good standing with regulatory authorities and develop, validate and maintain commercially viable manufacturing processes that are compliant with FDA's current Good Manufacturing Practices, or cGMP;
- our ability to successfully develop a commercial and competitive strategy and thereafter commercialize our product candidates or any future product candidates in the United States or other countries, if licensed for marketing, reimbursement, sale and distribution, whether alone or in collaboration with others;
- patient demand for our product candidates and any future product candidates, if licensed; and
- our ability to establish and enforce intellectual property rights in and to our product candidates or any future product candidates.

Many of the factors listed above are beyond our control and could cause us to experience significant delays or prevent us from obtaining regulatory approvals or commercialize our product candidates. Even if we are able to commercialize our product candidates, we may not achieve profitability soon after generating product sales, if ever. If we are unable to generate sufficient revenue through the sale of our product candidates or any future product candidates, we may be unable to continue operations without continued funding.

If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Additionally, even if we succeed in commercializing one or more of our product candidates, we will continue to incur substantial research and development and other expenditures to research, develop and market additional product candidates. 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 also could cause you to lose all or part of your investment.

We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital.

Risks Related to Future Financial Condition

We will require substantial additional financing to develop and commercialize our product candidates and implement our operating plans. We have also identified conditions that raise substantial doubt about our ability to continue as a going concern. If we fail to obtain additional financing or cannot obtain financing at the levels we require, we may be forced to delay, reduce or discontinue our plans and operations or unable to complete the development and commercialization of our product candidates.

Our operations have consumed substantial amounts of cash since inception. We expect to continue to spend substantial amounts to continue the preclinical and clinical development of our product candidates, including our RESET™ trials, and our research and development, preclinical studies and clinical trials for any future product candidates, to seek regulatory approvals for our product candidates, to enable commercial production of our products, if licensed, and to initiate and complete registration trials for multiple products. As of December 31, 2025, we had $133.6 million of cash, cash equivalents and investments. Since our initial public offering and through December 31, 2025, we have generated cash from public offerings of our common stock and pre-funded warrants to purchase our common stock resulting in aggregate net proceeds of approximately $384.0 million. While we currently expect our existing cash, cash equivalents and investments to be sufficient to fund our operations into the fourth quarter of 2026, which includes our plans to complete the Phase 1/2 RESET-SLE™, RESET-Myositis®, RESET-SSc™ and RESET-MG™ trials and generate clinical data from the RESET-PV® dose escalation trial and RESET-SLE™ without preconditioning, we expect to require significant additional financing to complete these clinical trials and any future clinical trials of these and our other product candidates. Further, if marketing approval is received, we will require significant additional amounts of cash to launch and commercialize our product candidates. However, we have based this estimate on assumptions that may prove to be wrong. Additionally, changing circumstances may cause us to consume capital significantly faster than we currently anticipate, and we may need to spend more money than currently expected because of circumstances beyond our control. We may require substantial additional capital for the further development and commercialization of our product candidates, including funding our internal manufacturing capabilities, and may need to raise additional funds sooner if we choose to expand more rapidly than we presently anticipate. Because the length of time and activities associated with development of our product candidates is highly uncertain, we are unable to estimate the actual funds we will require for development and any approved marketing and commercialization activities. Our future funding requirements, both near- and long-term, will depend on many factors, including, but not limited to:

- the initiation, progress, timing, costs and results of preclinical studies and clinical trials for our product candidates;
- the clinical development plans we establish for these product candidates;
- the number and characteristics of product candidates that we may develop or in-license;

- the terms of any collaboration agreements we may choose to conclude;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA or other foreign regulatory authorities;
- the cost of filing, prosecuting, defending and enforcing our patent claims and other intellectual property rights;
- the cost of defending intellectual property disputes, including patent infringement actions brought by third parties against us or our product candidates;
- the effect of competing technological and market developments;
- the costs of establishing and maintaining a supply chain for the development and manufacture of our product candidates;
- the cost and timing of establishing, expanding and scaling manufacturing capabilities;
- the cost of maintaining the amount patient data for which we would be responsible following commercialization of one or more of our product candidates; and
- 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.

We cannot be certain that additional funding will be available on acceptable terms, or at all. As widely reported, global credit and financial markets have experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, inflation, increases in unemployment rates and uncertainty about economic stability. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Until we are able to generate sufficient revenue to finance our cash requirements, we will need to finance our future cash needs through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing or distribution arrangements. 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 our research and development initiatives and clinical development plans. We could be required to seek collaborators for our 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 our product candidates in markets where we otherwise would seek to pursue development or commercialization ourselves.

Based on our current operating plan, we believe there is substantial doubt about our ability to continue as a going concern for at least twelve months following the filing of this Annual Report on Form 10-K, and we will need to obtain additional funding. We may be forced to delay or reduce the scope of our product development programs, reduce our research and development costs and/or limit or cease our operations if we are unable to obtain additional funding to support our current operating plan. Our cash forecast contains estimates and assumptions based on the success of our ongoing clinical trials, and management cannot predict the amount or timing of all expenditures with certainty. Nevertheless, our financial statements do not include any adjustments that might result from the outcome of this uncertainty. We will need to raise additional capital to fund our future operations and remain as a going concern. However, we cannot guarantee that we will be able to obtain any or sufficient additional funding or that such funding, if available, will be obtainable on terms satisfactory to us.

Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

We expect that significant additional capital may be needed in the future to continue our planned operations, including conducting clinical trials, commercialization efforts, expanded research and development activities and costs associated with operating a public company. To raise capital, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell 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.

Subsequently, we issued (i) 39,200,000 shares of our common stock and accompanying warrants to purchase an aggregate of 39,200,000 shares of common stock (or pre-funded warrants in lieu thereof) and (ii) in lieu of common stock, to certain investors, pre-funded warrants to purchase an aggregate of up to 10,800,000 shares of our common stock and accompanying warrants to purchase an aggregate of 10,800,000 shares of common stock (or pre-funded warrants in lieu thereof), at an exercise price of $0.00001 per pre-funded warrant, or the 2025 Offering. The combined offering price of each share of common stock and accompanying common stock warrant was $2.00. The combined offering price of each pre-funded warrant and accompanying common stock warrant was $1.99999. The accompanying warrant has an exercise price of $2.50 per share, is immediately exercisable from the date of issuance and will expire on September 12, 2026, fifteen months from the date of issuance. Aggregate net proceeds were $93.6 million after deducting underwriting discounts and commissions and offering expenses. As a result of this offering, our stockholders experienced significant dilution. Sales of common stock, debt securities or other equity securities by us may represent a significant percentage of our common stock currently outstanding. If we sell, or the market perceives that we intend to sell, substantial number of additional shares of our common stock under the 2025 Registration Statement or otherwise, the market price of our common stock could decline significantly.

On August 7, 2025, we filed the 2025 Registration Statement (File No. 333-289339) with SEC, which was declared effective on August 15, 2025, in relation to the registration of common stock, preferred stock, debt securities, warrants and/or units of any combination thereof for the purposes of selling, from time to time, our common stock, debt securities or other equity securities in one or more offerings. We also simultaneously entered into the 2025 Sales Agreement with TD Cowen to provide for the offering, issuance and sale of up to an aggregate amount of $150.0 million of our common stock from time to time in "at-the-market" offerings, or 2025 ATM Program, under the 2025 Shelf Registration Statement and subject to the limitations thereof. During the year ended December 31, 2025, we sold 4,160,176 shares pursuant to the 2025 ATM Program for net proceeds of $10.2 million. Subsequent to December 31, 2025, we sold 8,055,260 shares of common stock pursuant to the 2025 ATM Program for net proceeds of $22.6 million.

In addition, as of December 31, 2025, we had outstanding 53,090,190 common stock warrants and pre-funded warrants to purchase 6,000,000 shares of our common stock. If some or all of these warrants are exercised, our stockholders could experience substantial dilution and may cause the market price of our stock to decline.

We have also filed registration statements on Form S-8 to register shares issued or reserved for issuance under our equity compensation plans and will file additional registration statements on Form S-8 to register additional shares pursuant to the "evergreen" provisions under our equity compensation plans, the Plan Amendment and any subsequent amendments to our equity compensation plans. Shares registered under these registration statements on Form S-8 can be freely sold in the public market upon issuance and once vested, subject to volume limitations applicable to affiliates and the lock-up agreements described above. If any of these additional shares are sold, or if it is perceived that they will be sold, in the public market, the market price of our common stock could decline.

Pursuant to our equity incentive plans, our management is authorized to grant stock options to our employees, directors and consultants. Additionally, the number of shares of our common stock reserved for issuance under the 2019 Stock Option and Incentive Plan, or the 2019 Plan, automatically increased on January 1, 2026 and will automatically increase each January 1 thereafter through and including January 1, 2029, by 4% of the total number of shares of our capital stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares determined by our board of directors. Unless our board of directors elects not to increase the number of shares available for future grant each year, our stockholders may experience additional dilution, which could cause our stock price to fall. In addition, on April 7, 2023, our board of directors adopted, and at our 2023 annual meeting our stockholders approved, an amendment to the 2019 Plan, or the Plan Amendment, to increase the aggregate number of shares authorized for issuance under the 2019 Plan by 3,000,000 shares, subject to adjustment.

In addition, certain of our employees, executive officers, and directors may enter into Rule 10b5-1 trading plans providing for sales of shares of our common stock from time to time. Under a Rule 10b5-1 trading plan, a broker executes trades pursuant to parameters established by the employee, director, or officer when entering into the plan, without further direction from the employee, officer, or director. A Rule 10b5-1 trading plan may be amended or terminated in some circumstances. Our employees, executive officers, and directors also may buy or sell additional shares outside of a Rule 10b5-1 trading plan when they are not in possession of material, nonpublic information.

Future issuances of our common stock or other equity securities, or the perception that sales of this nature may occur, could adversely affect the trading price of our common stock, and impair our ability to raise capital through future offerings of shares or equity securities. No prediction can be made as to the effect, if any, that future sales of common stock or the availability of common stock for future sales will have on the trading price of our common stock.

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.

Our outstanding common stock warrants may not be exercised, and we may not receive any additional funds upon the exercise of such warrants.

As of December 31, 2025, we had outstanding 53,090,190 common stock warrants. If all common stock warrants were exercised for cash, we would receive approximately an additional $132 million in gross proceeds from the 2025 Offering. However, the warrant holders are not obligated to exercise these warrants, so we may receive little to no additional proceeds. Our common stock warrants have an exercise price of $2.50 per share and are exercisable at any time after the date of issuance. The common stock warrants expire on September 12, 2026, fifteen months from the date of issuance. Warrant holders are unlikely to exercise their warrants voluntarily unless our stock price is above the exercise price. We cannot provide any assurance that our stock price will meaningfully exceed the exercise price before the warrants expire. If our stock price remains at or below the exercise price, the warrants will likely expire unexercised, and we will not receive any additional funds from these warrants to support our clinical trials and operations.

In addition, the common stock warrants may be exercised on a cashless basis if there is no effective registration statement registering the shares underlying such warrants, in which case we would not receive any additional proceeds. Though we intend to maintain an effective registration statement for the underlying shares, we may not be able to do so. If the common stock warrants are not exercised for cash, or only a portion of the common stock warrants are exercised for cash, we would not receive anticipated warrant exercise proceeds which could materially and adversely affect our financial condition and ability to execute our business strategy.

We will not receive any meaningful amount of additional funds upon the exercise of the pre-funded warrants; however, any exercise would increase the number of shares of our common stock eligible for future resale in the public market and result in dilution to our stockholders.

In the 2025 Offering, we issued and sold pre-funded warrants to purchase up to 10,800,000 shares of our common stock. As of December 31, 2025, 4,800,000 pre-funded warrants had been exercised and 6,000,000 remain outstanding. Each pre-funded warrant is exercisable until it is fully exercised and by means of payment of the nominal cash purchase price upon exercise or by means of a "cashless exercise" according to a formula set forth in the pre-funded warrant. Accordingly, we will not receive any meaningful additional funds upon the exercise of the pre-funded warrants. To the extent such pre-funded warrants are exercised, additional shares of common stock will be issued for nominal or no additional consideration, which will result in dilution to the then existing holders of our common stock and will increase the number of shares eligible for resale in the public market.

Risks Related to Our Intellectual Property

We rely heavily on certain in-licensed patent and other intellectual property rights in connection with our development of our product candidate and, if we fail to comply with our obligations under our existing and any future intellectual property licenses with third parties, we could lose license rights that are important to our business.

Our ability to develop and commercialize our product candidate is heavily dependent on in-licenses to patent rights and other intellectual property granted to us by third parties. For example, we depend on our Exclusive License Agreement with IASO, which was entered into in October 2022, pursuant to which we obtained a worldwide, exclusive license under certain intellectual property to develop, manufacture, commercialize and otherwise exploit T cell products directed to CD19 for the purpose of diagnosis, prevention or treatment of an autoimmune or alloimmune indication in humans, or the IASO Agreement. We may enter into additional license agreements in the future. Our license agreement with IASO imposes, and we expect that future license agreements will impose, various diligence, milestone payment, royalty, insurance and other obligations on us. If we fail to comply with our obligations under these licenses, our licensors, including IASO may have the right to terminate these license agreements, in which event we might not be able to market our product candidate. Termination of any of our license agreements or reduction or elimination of our licensed rights may also result in our having to negotiate new or reinstated licenses with less favorable terms.

We may need to obtain additional licenses from third parties to advance our research or allow commercialization of our product candidate, and we have done so from time to time. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we may be required to expend significant time and resources to develop or license replacement technology. If we are unable to do so, we may be unable to develop or commercialize the affected product candidate, which could harm our business significantly. We cannot provide any assurances that third-party patents do not exist which might be enforced against our current product candidate or future products, resulting in either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties.

Furthermore, in many cases, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we in-license from third parties. For example, pursuant to our IASO Agreement, IASO controls such activities for the patent rights licensed to us under such agreement. Therefore, although we provide input to IASO on these activities, we cannot be certain that these patents will be prosecuted, maintained and enforced in a manner consistent with the best interests of our business. If our current or future licensors or collaboration partners fail to obtain, maintain or protect any patents or patent applications licensed to us, our rights to such patents and patent applications may be reduced or eliminated and our right to develop and commercialize any of our product candidate that are the subject of such licensed rights could be adversely affected.

Disputes may arise between us and our current and future licensors regarding intellectual property subject to a license agreement, including those related to:

- the scope of rights granted under the IASO Agreement and other interpretation-related issues;
- whether we have breached the IASO Agreement and whether any such breach is subject to a cure period;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense patent and other rights to third parties under collaborative development relationships;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidate, and what activities satisfy those diligence obligations; and
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners.

Furthermore, disputes may arise between us and our current or future licensors regarding the ownership of intellectual property developed by us, such that we may be required to assign or otherwise transfer such intellectual property to such licensor. In the event that the assigned or transferred intellectual property is covered by an existing license agreement with such licensor we may be required to make additional royalty or milestone payments, or both,

to such licensor. If the assigned or transferred intellectual property is not covered by an existing license agreement, then we may be required to enter into an additional license agreement to advance our research or allow commercialization of our product candidate, which may not be available on commercially reasonable terms or at all.

If disputes over intellectual property that we have licensed, or license in the future, prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidate.

If our efforts to protect the proprietary nature of the intellectual property related to our current and any future product candidates are not adequate, we may not be able to compete effectively in our market.

Our success depends in large part on our ability to obtain and maintain intellectual property protection in the United States and other countries with respect to our product candidates. If we do not adequately protect or enforce our intellectual property rights, competitors may be able to erode or negate any competitive advantage we may have, which could harm our business and ability to achieve profitability. To protect our proprietary position, we have filed and in-licensed patent rights in the United States and abroad relating to the product candidates that are important to our business. The patent application and approval process is expensive, complex and time-consuming. We or our licensors 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 position of biotechnology and pharmaceutical companies generally is highly uncertain. No consistent policy regarding the breadth of claims allowed in biotechnology and pharmaceutical patents has emerged to date in the United States or in many foreign jurisdictions. In addition, the determination of patent rights with respect to biological and pharmaceutical products commonly involves complex legal and factual questions, which has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. 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 to file a patent application is generally entitled to the patent. However, prior to March 16, 2013, in the United States, the first 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 typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we or our licensors were the first to make the inventions claimed in the patents or pending patent applications, or that we and our licensors were the first to file for patent protection of such inventions.

Moreover, because the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, the patents or pending patent applications that we own or in-license may be challenged in the courts or patent offices in the United States and abroad. For example, we may be subject to a third party preissuance submission of prior art to the U.S. Patent and Trademark Office, or USPTO, or become involved in post-grant review procedures, derivation proceedings, reexaminations, or *inter partes* review in the United States, or oppositions and other comparable proceedings in foreign jurisdictions, challenging our patent rights or the patent rights of others. An adverse determination in any such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, 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 product candidates. 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.

Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of the patents we in-license 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, European patent law is more restrictive than U.S. patent law in connection with the patentability of methods of treatment of the human body and Chinese bankruptcy law may not provide a licensee the same protections as U.S. bankruptcy law. This could impact our in-license under the IASO Agreement with IASO, a China-based company, if IASO declared bankruptcy, and could have a material adverse effect on the development of rese-cel.

A European Unified Patent Court, or the UPC, came into force during 2023. The UPC is a common patent court to hear patent infringement and revocation proceedings effective for member states of the European Union. This could enable third parties to seek revocation of our European patents in a single proceeding at the UPC rather than through multiple proceedings in each of the jurisdictions in which the European patent is validated. Any such revocation and loss of patent protection could have a material adverse impact on our business and our ability to commercialize or license our technology and products. Moreover, the controlling laws and regulations of the UPC will develop over time, and may adversely affect our ability to enforce or defend the validity of our European patents. Although we have decided, and may continue to decide, to opt out certain of our European patents and patent applications from the UPC, if certain formalities and requirements are not met, then our European patents and patent applications could be challenged for non-compliance and brought under the jurisdiction of the UPC. Thus, we cannot be certain that our European patents and patent applications will avoid falling under the jurisdiction of the UPC.

We cannot predict whether the patent applications that we own or in-license will issue as patents, whether the claims of any patent that has or may issue will provide us with a competitive advantage or prevent competitors from designing around the claims to develop competing technologies in a non-infringing manner, or whether we or our licensors will be able to successfully pursue patent applications in the future relating to our current product candidates or future products and product candidates. Moreover, the patent application and approval process is expensive and time-consuming. We or our licensors may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. Furthermore, we, or any future partners, collaborators, or licensees, may fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Therefore, we may miss potential opportunities to seek additional patent protection.

It is possible that defects of form in the preparation or filing of 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 fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If there are material defects in the form, preparation, prosecution or enforcement of the patents or patent applications we in-license, 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.

Even if the patent applications we own or in-license issue as patents, they may not issue in a form that will 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 patent rights 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 product candidates. Alternatively, our competitors may seek to market generic versions of any approved products by submitting abbreviated BLAs to the FDA during which process they may claim that our owned or in-licensed patents are invalid, unenforceable or not infringed. In these circumstances, we may need to defend or assert our intellectual property rights, 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 the patents we own or in-license invalid or unenforceable, or that our competitors are competing in a non-infringing manner. Thus, even if we own or in-license 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 competitive position, business, financial conditions, results of operations, and prospects.

In the future, we likely will need to expand our patent portfolio to pursue patent coverage for new product candidates that we wish to develop. The patent prosecution process is competitive, and other companies, some which may have greater resources than we do in this area, may also be pursuing intellectual property rights that we may consider necessary or attractive in order to develop and commercialize future product candidates.

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 could be less extensive than those in the United States. Although our IASO Agreement grants us worldwide rights, there can be no assurance that we will obtain or maintain patent rights in or outside the United States under any future license agreements. 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 even in jurisdictions where we and our licensors pursue patent protection. Consequently, we and our licensors may not be able to prevent third parties from practicing our inventions in all countries outside the United States, even in jurisdictions where we and our licensors pursue patent protection, 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 and our licensors have not pursued and obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we and our licensors have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our product candidates and the patents we in-license 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 certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of the patents we in-license or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights, even if obtained, in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put the patents we in-license at risk of being invalidated or interpreted narrowly and the patent applications we own or in-license 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. 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.

We or our licensors may be subject to claims challenging the inventorship or ownership of the patents and other intellectual property that we own or license.

We or our licensors may be subject to claims that former employees, collaborators or other third parties have an ownership interest in the patents and intellectual property that we own or in-license or that we may own or in-license in the future. While it is our policy to require our employees and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own or such assignments may not be self-executing or may be breached. Our licensors may face similar obstacles. We or our licensors could be subject to ownership disputes arising, for example, from conflicting obligations of employees, consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against any claims challenging inventorship or ownership. If we or our licensors fail in defending any such claims, we may have to pay monetary damages and may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property, which could adversely impact our business, results of operations and financial condition.

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

Certain of the intellectual property rights we have licensed were generated through the use of U.S. government funding and may therefore be subject to certain federal laws and regulations. As a result, the U.S. government has certain rights to intellectual property embodied in our DSG3-CAART product candidate and may have rights in future product candidates pursuant to the Bayh-Dole Act of 1980. 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 has the right to require us to grant exclusive, partially exclusive, or non-exclusive licenses to any of these inventions to a third party if it determines that: (i) adequate steps have not been taken to commercialize the invention; (ii) government action is necessary to meet public health or safety needs; or (iii) 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 these inventions 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. In addition, the U.S. government requires that 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 product candidates covered by such intellectual property.

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

Competitors may infringe, misappropriate or otherwise violate patents, trademarks, copyrights or other intellectual property that we own or in-license. To counter infringement, misappropriation or other unauthorized use, we may be required to file 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 violators could provoke these parties to assert counterclaims against us alleging that we infringe, misappropriate or otherwise violate their intellectual property, in addition to counterclaims asserting that the patents we in-license are invalid or unenforceable, or both. In any patent infringement proceeding, there is a risk that a court will decide that a patent we own or in-license 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. In the U.S., grounds for a validity challenge in a court proceeding could be an alleged failure to meet one or more statutory requirements for patentability, including, for example, lack of novelty, obviousness, lack of written description or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Additionally, third parties are able to challenge the validity of issued patents through administrative proceedings in the patent offices of certain countries, including the USPTO and the European Patent Office.

Even if the validity of a patent is upheld during a court proceeding, there is a risk that 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 the patent claims do not cover the invention. An adverse outcome in a litigation or proceeding involving the patents we own or in-license could limit our ability to assert the patent 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.

Even if we establish infringement, misappropriation or another violation of our intellectual property rights, the court may decide not to grant an injunction against the offender 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 our shares. Moreover, there can be no assurance that we will have sufficient financial or other resources to file and pursue such 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.

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

Changes in either the patent laws or the interpretation of the patent laws in the United States or other jurisdictions could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. When implemented, the Leahy-Smith Act included several significant changes to U.S. patent law that impacted how patent rights could be prosecuted, enforced and defended. In particular, the Leahy-Smith Act also

included provisions that switched the United States from a "first-to-invent" system to a "first-to-file" system, allowed third-party submission of prior art to the USPTO during patent prosecution and set forth additional procedures to attack the validity of a patent by the USPTO administered post grant proceedings. Under a first-to-file system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to the patent on an invention regardless of whether another inventor had made the invention earlier. The USPTO developed new regulations and procedures governing the administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, became effective on March 16, 2013. It remains unclear what impact, if any, the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of the patent applications we in-license and the enforcement or defense of the issued patents we in-license, all of which could have a material adverse effect on our business.

The patent positions of companies engaged in the development and commercialization of biologics are particularly uncertain. For example, the Supreme Court of the United States issued its decision in Association for Molecular Pathology v. Myriad Genetics, Inc., or Myriad, a case involving patent claims held by Myriad Genetics, Inc. relating to the breast cancer susceptibility genes BRCA1 and BRCA2. Myriad held that an isolated segment of naturally occurring DNA, such as the DNA constituting the BRCA1 and BRCA2 genes, is not patent-eligible subject matter, but that complementary DNA, which is an artificial construct that may be created from RNA transcripts of genes, may be patent-eligible. Thereafter, the USPTO issued a guidance memorandum instructing USPTO examiners on the ramifications of the Prometheus and Myriad rulings and apply the Myriad ruling to natural products and principles including all naturally occurring nucleic acids. Certain claims of our owned and in-licensed patent applications contain, and any future patents we may obtain may contain, claims that relate to specific recombinant DNA sequences that are naturally occurring at least in part and, therefore, could be the subject of future challenges made by third parties.

We cannot assure you that our efforts to seek patent protection for one or more of our product candidates will not be negatively impacted by this Supreme Court decision, rulings in other cases or changes in guidance or procedures issued by the USPTO. We cannot fully predict what impact the Supreme Court's decisions in Myriad may have on the ability of life science companies to obtain or enforce patents relating to their products in the future. These decisions, the guidance issued by the USPTO and rulings in other cases or changes in USPTO guidance or procedures could have a material adverse effect on our existing patent rights and our ability to protect and enforce our intellectual property in the future.

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

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect certain proprietary know-how that is not patentable or that we elect not to patent, processes for which patents are difficult to enforce, and any other elements of our product candidate discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. However, trade secrets can be difficult to protect and some courts inside and outside the United States are less willing or unwilling to protect trade secrets. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with our employees, consultants, scientific advisors, and contractors. We cannot guarantee that we have entered into such agreements with each party that may have or has had access to our trade secrets or proprietary technology and processes. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach.

In addition, our trade secrets may otherwise become known or be independently discovered by competitors. Competitors and other third parties could infringe, misappropriate or otherwise violate 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.

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

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. In the United States, the Drug Price Competition and Patent Term Restoration Act of 1984 permits a patent term extension of up to five years beyond the normal expiration of the patent, which is limited to the approved indication (or any additional indications approved during the period of extension). However, a patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of the product's approval by the FDA, only one patent applicable to an approved drug is eligible for the extension, and only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended. In the future, if and when our product candidates receive FDA approval, we plan to apply for patent term extensions on patents covering those product candidates in any jurisdiction where these are available. However, the applicable authorities, including the FDA and the USPTO in the United States, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to the patents we own or in-license, or may grant more limited extensions than we request. Moreover, we may not receive an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. If this occurs, our competitors may be able to take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case.

We may be subject to claims asserting that our employees, consultants or advisors have wrongfully used or disclosed alleged trade secrets of their current or former employers or claims asserting ownership of what we regard as our own intellectual property.

Certain of our employees, consultants or advisors are currently, or were previously, employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that these individuals or we have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer. 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. Our licensors may face similar risks, which could have an adverse impact on intellectual property that is licensed to us.

We may become subject to claims that we are infringing certain third-party patents or other third-party intellectual property rights, any of which may prevent or delay our development and commercialization efforts and have a material adverse effect on our business.

Our commercial success depends in part on avoiding infringing, misappropriating and otherwise violating the patents and other intellectual property and proprietary rights of third parties. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, and administrative proceedings such as interferences, *inter partes* review and post grant review proceedings before the USPTO and opposition proceedings before foreign patent offices. Numerous U.S. and foreign issued patents and pending patent applications, which are owned or controlled by third parties, including our competitors, exist in the fields in which we are pursuing product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties.

Third parties may assert that we or our licensors are employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims to materials, methods of manufacture or methods for treatment relating to our product candidates and, because patent applications can take many years to issue, there may be currently pending third party patent applications which may later result in issued

patents, in each case that our product candidates, their manufacture or use may infringe or be alleged to infringe. We may fail to identify potentially relevant patents or patent applications, incorrectly conclude that a patent is invalid or does not cover our activities, or incorrectly conclude that a patent application is unlikely to issue in a form of relevance to our activities.

Parties making patent infringement claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates. Defense of these claims, including demonstrating non-infringement, invalidity or unenforceability of the respective patent rights in question, regardless of their merit, is time-consuming, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. For example, in order to successfully challenge the validity of any U.S. patent in federal court, we would need to overcome a presumption of validity. This is a high burden requiring us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, and we can provide no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent. We may not have sufficient resources to bring these actions to a successful conclusion. 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 our shares.

In the event that a holder of any such patents seeks to enforce its patent rights against us with respect to one or more of our product candidates, and our defenses against the infringement of such patent rights are unsuccessful, we may be precluded from commercializing our product candidates, even if approved, without first obtaining a license to some or all of these patents, which may not be available on commercially reasonable terms or at all. Moreover, we may be required to pay significant fees and royalties to secure a license to the applicable patents. Such a license may only be non-exclusive, in which case our ability to stop others from using or commercializing technology and products similar or identical to ours may be limited. Furthermore, we could be liable for damages to the holder of these patents, which may be significant and could include treble damages if we are found to have willfully infringed such patents. In the event that a challenge to these patents were to be unsuccessful or we were to become subject to litigation or unable to obtain a license on commercially reasonable terms with respect to these patents, it could harm our business, financial condition, results of operations and prospects.

We are aware of third-party U.S. patents relating to the lentiviral vectors which may be used in the manufacture or use of our product candidates. We are also aware of a patent family that includes granted U.S. and European patent rights directed to methods using, and compositions containing, genetically engineered T cells that may be relevant to our rese-cel product candidate. If these patent rights were enforced against us, we believe that we have defenses against any such action, including that these patents would not be infringed by our product candidates and/or that these patents are not valid. However, if these patents were enforced against us and defenses to such enforcement were unsuccessful, unless we obtain a license to these patents, which may not be available on commercially reasonable terms, or at all, we could be liable for damages and precluded from commercializing any product candidates that were ultimately held to infringe these patents, which could have a material adverse effect on our business, financial condition, results of operations and prospects. Furthermore, even if our arguments are successful, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted in pursuing these proceedings, which could significantly harm our business and operating results.

Even in the absence of a finding of infringement, we may need or may choose to obtain licenses from third parties to advance our research or allow commercialization of our product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, or at all. In that event, we would be unable to further develop and commercialize our product candidates. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business. Any of the foregoing could materially adversely affect our business, results of operations and financial condition.

Intellectual property rights do not necessarily address all potential threats.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to make products that are similar to our product candidates or utilize similar cell therapy technology but that are not covered by the claims of our current or future patent portfolio;
- we, or our current or future licensors or collaborators, might not have been the first to make the inventions covered by the issued patents or pending patent applications that we own or license now or that we may own in the future;
- we, or our current or future licensors or collaborators, might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our owned or licensed intellectual property rights;
- it is possible that our current or future owned or licensed patent applications will not lead to issued patents;
- issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors or other third parties;
- our competitors or other third parties might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may harm our business;
- we may choose not to file a patent application in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent application covering such intellectual property; and
- third-party patents may issue with claims covering our activities; we may have infringement liability exposure arising from such patents.

Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations and prospects.

Risks Related to Our Reliance on Third Parties

We currently, and will likely continue to, rely on third parties to conduct our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval of or commercialize our product candidates.

We depend and will continue to depend upon third parties, including independent investigators and collaborators, such as universities, medical institutions, CROs and strategic partners, to conduct our preclinical studies and clinical trials under agreements with us. Specifically, we depend on clinical trial sites to enroll patients and conduct the RESET™ trials in a timely and appropriate manner. If our clinical trial sites do not conduct the trials on the timeline we expect or otherwise fail to support the trials, our clinical trial results could be significantly delayed, thereby adversely impacting our leadership position in the autoimmune cell therapy space and our ability to progress additional product candidates. As we open additional clinical trial sites, we expect to have to negotiate budgets and contracts with CROs and study sites, which may result in delays to our development timelines and increased costs.

We will rely heavily on these third parties to conduct our manufacturing, and as a result, will have limited control over pace at which these activities are carried out. Nevertheless, we are responsible for ensuring that each of our trials is conducted in accordance with applicable protocol, legal, regulatory and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. We and these third parties are required to comply with FDA's GCPs which are regulations and guidelines enforced by the FDA for product candidates in

clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of these third parties fail to comply with applicable GCP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA may require us to perform additional clinical trials before approving our marketing applications. We cannot provide assurance that, upon inspection, such regulatory authorities will not determine that some or all of our clinical trials do not fully comply with the GCP requirements. For any violations of laws and regulations during the conduct of our clinical trials, we could be subject to untitled and warning letters or enforcement action that may include civil penalties up to and including criminal prosecution. In addition, our clinical trials must be conducted with biologic product produced under cGMPs and will require a large number of test patients. We also are required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

As widely reported, global credit and financial markets have experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. Regional or single-source dependencies may in some cases accentuate these risks. For example, the pharmaceutical industry in general, and in some instances we or our collaborators or other third parties on which we or they rely, depend on China-based suppliers or service providers for certain raw materials, products and services, or other activities, Our ability or the ability of our collaborators or such other third parties to continue to engage these China-based suppliers or service providers for certain preclinical research programs and clinical development programs could be restricted due to geopolitical developments between the United Sates and China.

There have been, and may continue to be, significant changes to U.S. trade policies, sanctions, legislation, treaties and tariffs, including, but not limited to, trade policies and tariffs affecting products from outside of the U.S. The extent and duration of increased tariffs and the resulting impact on general economic conditions and on our business are uncertain and depend on various factors, such as negotiations between the U.S. and affected countries, the responses of other countries or regions, exemptions or exclusions that may be granted, availability and cost of alternative sources of supply and demand in affected markets. Supply chain disruptions and delays as a result of any new tariff policies or trade restrictions could negatively impact our cost of materials processes. If we or our current or future service providers, manufacturers and other partners are unable to obtain materials in sufficient quantity and in a timely manner due to disruptions in the global supply chain caused by macroeconomic events and conditions, the development, testing and our clinical trials and any future product candidates may be delayed or infeasible, and regulatory approval or commercial launch of any resulting product may be delayed or not obtained, which could significantly harm our business.

Further, in the event that one or more of our current or future service providers, manufacturers and other partners do not successfully carry out their contractual duties, meet expected deadlines, or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, due to the economic downturn, the enactment of legislative proposals or for any other reasons, then we may not be able to obtain, or may be delayed in obtaining, marketing approvals for any product candidates we may develop and will not be able to, or may be delayed in our efforts to, successfully commercialize our medicines. Our failure or the failure of these third parties to comply with applicable regulatory requirements or our stated protocols could also subject us to enforcement action. Moreover, our business may be implicated if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

Any third parties conducting our clinical trials will not be our employees and, except for remedies available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our ongoing preclinical and clinical programs. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical studies or other drug development activities, which could affect their performance on our behalf. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to complete development of, obtain regulatory approval of or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.

If any of our relationships with trial sites, or any CRO that we may use in the future, terminates, we may not be able to enter into arrangements with alternative trial sites or CROs or do so on commercially reasonable terms. Switching or adding third parties to conduct our clinical trials involves substantial cost and requires extensive management time and focus. In addition, there is often a natural transition period when a new third party commences work. As a result, delays may occur, which can materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

We also expect to rely on other third parties to store and distribute drug supplies for our clinical trials. Any performance failure on the part of our distributors could delay clinical development or marketing approval of any product candidates we may develop or commercialization of our medicines, producing additional losses and depriving us of potential product revenue.

We intend to rely on third parties to manufacture our clinical product supplies, and we may have to rely on third parties to produce and process our product candidates, if licensed.

Although we may eventually secure our own clinical manufacturing facility for any late phase clinical development that we undertake, we currently rely on third parties to manufacture our product candidates, and we intend in the future to continue to rely on CMOs. In the case of any manufacturing performed for us by third parties, the services performed for us risk being delayed because of the competing priorities that such parties have for utilization of their manufacturing resources and any capacity issues that thereby arise.

We do not yet have sufficient information to reliably estimate the cost of the manufacturing and processing of our product candidates in clinical quantity or commercial quantity, and the actual cost to manufacture and process our product candidates could ultimately materially and adversely affect the commercial viability of our product candidates. As a result, we may never be able to develop a commercially viable product.

In addition, our anticipated reliance on a limited number of third-party manufacturers exposes us to the following risks:

- We may be unable to identify manufacturers on acceptable terms or at all because the number of potential manufacturers is limited and the FDA may have questions regarding any replacement contractor. This may require new testing and regulatory interactions. In addition, a new manufacturer would have to be educated in, or develop substantially equivalent processes for, production of our products after receipt of FDA questions, if any.
- Our third-party manufacturers might be unable to timely formulate and manufacture our product or produce the quantity and quality required to meet our clinical and commercial needs, if any.
- Contract manufacturers may not be able to execute our manufacturing procedures appropriately.
- Any contract manufacturers that we engage may not perform as agreed or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store and distribute our product candidates.
- Manufacturers are subject to ongoing periodic unannounced inspection by the FDA and corresponding state agencies to ensure strict compliance with cGMP and other government regulations. We do not have control over third-party manufacturers' compliance with these regulations and standards.
- We may not own, or may have to share, the intellectual property rights to any improvements made by our third-party manufacturers in the manufacturing process for our product candidates.
- Our third-party manufacturers could breach or terminate their agreement with us.

Furthermore, all of our contract manufacturers are engaged with other companies to supply and/or manufacture materials or products for such companies, which exposes our manufacturers to regulatory risks related to the production of such materials and products. As a result, failure to meet the regulatory requirements for the production of those materials and products may affect the regulatory clearance of our contract manufacturers' facilities generally. If the FDA does not approve these facilities for the manufacture of our product candidates or if any agency withdraws

its approval in the future, we may need to find alternative manufacturing facilities, which would negatively impact our ability to develop, obtain regulatory approval for or market our product candidates, if licensed.

Our contract manufacturers would also be subject to the same risks we face in developing our own manufacturing capabilities, as described above. Each of these risks could delay our clinical trials, the approval, if any of our product candidates by the FDA or the commercialization of our product candidates or result in higher costs or deprive us of potential product revenue. In addition, we will rely on third parties to perform release tests on our product candidates prior to delivery to patients. If these tests are not appropriately done and test data are not reliable, patients could be put at risk of serious harm.

For more information, see "Risk Factors—Risks Related to Manufacturing and Supply".

We may form or seek strategic alliances or enter into additional licensing arrangements in the future, and we may not realize the benefits of such alliances or licensing arrangements.

We may form or seek strategic alliances, create joint ventures or collaborations or enter into additional licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our product candidates and any future product candidates that we may develop. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business. In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view our product candidates as having the requisite potential to demonstrate safety, potency and purity. Any delays in entering into new strategic partnership agreements related to our product candidates could delay the development and commercialization of our product candidates in certain geographies for certain indications, which would harm our business prospects, financial condition and results of operations.

If we license products or businesses, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture. We cannot be certain that, following a strategic transaction or license, we will achieve the results, revenue or specific net income that justifies such transaction.

We may not realize the benefits of acquired assets or other strategic transactions, including any transactions whereby we acquire or license manufacturing and other advanced technologies.

In October 2022, we entered into the IASO Agreement, pursuant to which we were granted worldwide license under certain intellectual property to develop, manufacture, commercialize and otherwise exploit T cell products directed to CD19 for the purpose of diagnosis, prevention or treatment of an autoimmune or alloimmune indication in humans.

We actively evaluate various strategic transactions on an ongoing basis. We may acquire other businesses, products or technologies as well as pursue joint ventures or investments in complementary businesses. The success of our strategic transactions, including the License Agreement, and any future strategic transactions depends on the risks and uncertainties involved including:

- unanticipated liabilities related to acquired companies or joint ventures;
- difficulties integrating acquired personnel, technologies and operations into our existing business;
- retention of key employees;
- diversion of management time and focus from operating our business to management of strategic alliances or joint ventures or acquisition integration challenges;
- increases in our expenses and reductions in our cash available for operations and other uses;
- disruption in our relationships with collaborators or suppliers as a result of such a transaction; and
- possible write-offs or impairment charges relating to acquired businesses or joint ventures.

If any of these risks or uncertainties occur, we may not realize the anticipated benefit of any acquisition or strategic transaction. Additionally, foreign acquisitions and joint ventures are subject to additional risks, including those related to integration of operations across different cultures and languages, currency risks, potentially adverse tax consequences of overseas operations and the particular economic, political, legal and regulatory risks associated with specific countries. For example, IASO is based in China and we may not receive the same protections under Chinese law, including with respect to applicable bankruptcy, insolvency, liquidation, arrangement, moratorium or similar laws relating to or affecting our rights.

Future acquisitions or dispositions could result in potentially dilutive issuances of our equity securities, the incurrence of debt, contingent liabilities or amortization expenses or write-offs of goodwill, any of which could harm our financial condition.

Risks Related to Manufacturing and Supply

We are reliant on Minaris and Lonza for our current manufacturing activities and termination would disrupt normal business operations, and we intend to continue to rely on other third parties for our future manufacturing needs prior to establishing our own manufacturing facility.

We are reliant on Minaris and Lonza for our current manufacturing activities for our preclinical and clinical research. If Minaris were to fail to perform their obligations in accordance with the terms of the Minaris Agreement or terminate the Minaris Agreement, or if Lonza were to fail to perform their obligations in accordance with the terms of the Lonza Agreement or terminate the Lonza Agreement, we may have difficulty continuing our normal business operations and our business prospects, financial condition and results of operations could be harmed. We continue to expand our agreements for manufacturing operations within the industry, including Cellares.

There are also current geopolitical tensions with China. These tensions and the related risks are described in the Risk Factor in this Report titled, “Risks Related to Business Development – Business disruptions, including due to natural disasters, global conflicts or political unrest, could seriously impact our operations, research and trials and harm our future revenue and financial condition.”

The CARTA Services Agreement is scheduled to expire on the later of February 9, 2026 or completion of all research and development projects, and unless the CARTA Services Agreement is amended, Penn will not be obligated to provide any further services under the CARTA Services Agreement after that time. In addition, Penn has the right to terminate the CARTA Services Agreement in whole at any time with 180 days’ notice. From time to time, we may enter into further addenda to the CARTA Services Agreement that provide Penn with the right to terminate such addenda with limited notice periods. If we do not have adequate personnel and capabilities at the time that we assume responsibilities for such services, we may not be successful in effectively or efficiently transitioning these services from Penn, which could disrupt our business and have a material adverse effect on our financial condition and results of operations. Even if we are able to successfully transition these services, they may be more expensive or less efficient than the services we are receiving from Penn during the transition period.

The Minaris Agreement is scheduled to expire upon completion of Minaris' services related to MuSK-CAART and rese-cel. In August 2023, as amended in August 2024, we entered into new work orders under the Minaris Agreement for Minaris to serve as one of our cell processing manufacturing partners for the planned global clinical development of rese-cel in multiple indications, including potential late-stage clinical trials and commercial readiness activities for rese-cel. Under the August 2023 work orders, Minaris converted our non-dedicated suite to a dedicated suite for GMP manufacturing for our rese-cel and MuSK-CAART programs, or the Dedicated Suite, for an initial term of 18 months with two 18 month extensions at our sole option on six months notice prior to the end of the term. In August 2024, we notified Minaris that we would extend the initial term by 18 months through August 2026. We may terminate for convenience with six months prior written notice, however, we may not terminate the Dedicated Suite without terminating both the MuSK-CAART and rese-cel GMP run work orders. In lieu of the existing 18 month termination right for convenience under the Minaris Agreement, Minaris may not terminate prior to February 2028. If Minaris were to fail to perform their obligations in accordance with the terms of the Minaris Agreement or terminate the Minaris Agreement, our clinical trials and commercial readiness may be adversely impacted which could in turn materially and adversely affect our business, results of operations and prospects.

The Lonza Agreement has an initial five year term with the ability to extend subject to the terms. Under the Lonza Agreement, Lonza will serve as one of our manufacturing partners for the global clinical development of

rese-cel in multiple indications, including potential late-stage clinical trials and preparations for commercial readiness. Lonza has the right to terminate the Lonza Agreement in whole at any time with written notice including a three month ramp down period. If Lonza were to fail to perform their obligations in accordance with the terms of the Lonza Agreement or terminate the Lonza Agreement, our clinical trials and commercial readiness may be adversely impacted which could in turn materially and adversely affect our business, results of operations and prospects.

Further, we may not be able to achieve clinical manufacturing and cell processing through our CMOs or on our own on a timely basis. While our current manufacturing process is similar to the well-established process developed at Penn for CD19 CAR-T, or CART19, which was later commercialized, we have limited experience as an organization in managing the CAR-T engineering process at commercial scale. Finally, because clinical manufacturing and cell processing is highly complex and patient donor material is inherently variable, we cannot yet be sure that our manufacturing process, will consistently result in product that meets specifications for release. Success in manufacturing in smaller early phase clinical trials may not predict the frequency of success at larger late phase clinical trials, or success at the commercial phase production until process qualification and validation is completed and submitted for BLA filing.

Changes in manufacturers or manufacturing processes for rese-cel, including process optimization and scale-up for commercial production, present significant risks. If we cannot establish comparability, validate our processes and methods (including for critical materials such as lentiviral vector), and/or if our CMO(s) fails pre-approval inspection, the initiation or completion of pivotal studies, regulatory approval and commercialization could be delayed or prevented.

Cell therapy products like rese-cel are complex and sensitive to changes in materials, equipment, sites, and processes. The physical and chemical properties of cell therapies such rese-cel generally cannot be fully characterized, and regulators expect robust process controls and phase-appropriate but maturing analytical methods to assure identity, quality, purity, and strength. As a result, assays of the finished product may not be sufficient to ensure that the product will perform in the intended manner. Accordingly, we employ multiple steps to control our manufacturing process to assure that the product candidate is made strictly and consistently in compliance with the applicable quality standards. We may encounter problems achieving adequate quantities and quality of clinical materials that meet FDA, or other applicable foreign standards or specifications. Manufacturing deviations or seemingly minor process changes can alter critical quality attributes, leading to lot failures, supply interruptions, or additional investigations, any of which can delay clinical timelines or regulatory submissions.

Challenges complying with cGMP requirements and other quality issues could arise during efforts to increase manufacturing capacity, optimize manufacturing and scale up production. In addition, in order to obtain regulatory approval of our product candidates (and in order to release our products for commercial use), our manufacturing processes and analytical methods, including with respect to certain raw materials used in the manufacturing of our product candidates, such as lentiviral vector, must be validated in accordance with regulatory guidelines. Failure to successfully validate, or maintain validated state of our manufacturing processes and analytical methods for the product candidates or certain raw materials used in the manufacturing of our product candidates, such as lentiviral vector, in a timely or cost-effective manner, or at all, may undermine our clinical development timelines or delay, or prevent, our ability to obtain regulatory approval of our product candidates. Any process performance qualification (PPQ) campaign for rese-cel must show that the commercial process can consistently produce product meeting predefined specifications under normal variability, including variability of critical materials such as lentiviral vector (LVV). Regulators may question PPQ approaches that rely on limited or single lots of critical inputs to establish consistency, and may expect a risk assessment, process characterization, and evidence that input material specifications are representative of intended commercial supply. If our PPQ design or results are deemed insufficient, we could be required to perform additional PPQ runs, repeat validation activities, adjust specifications, or conduct further studies, which could be costly and delay our BLA or other regulatory approval.

Lentiviral vector, or LVV, is a critical manufacturing input for CAR T-cell products. FDA guidance highlights expectations for vector manufacturing and testing, including identity, purity, functional (e.g., potency-related) characteristics, and safety testing. Regulators also emphasize having an appropriately qualified potency strategy in place as development progresses, and they may expect potency-relevant assays for critical components used to support pivotal study supplies, or, if not available at the time of manufacture, a risk-based justification with follow-up testing. Challenges in qualifying or validating vector-related assays, securing vector supply, or meeting evolving specifications could delay batch release, clinical milestones, or approval.

Transferring processes, methods, and know-how to a new manufacturers or manufacturing site is complex and time-consuming, may necessitate method bridging/transfer, and can introduce site-specific changes in equipment, raw materials, or procedures. As is customary, we have been, and may continue, optimizing and scaling manufacturing for later-stage development and potential commercialization, and we have transferred, and may in the future transfer, manufacturing to one or more contract manufacturers or additional manufacturing sites. Regulators expect sponsors to demonstrate comparability—analytically, and when needed via nonclinical or clinical bridging—between products made before and after process changes and across manufacturing sites. If our manufacturers fail to demonstrate adequate comparability on the expected timelines and at the required quality, and/or if FDA or other applicable foreign regulators do not agree with our proposed plans for demonstrating the comparability of the two processes, it may require us to incur additional costs or delay initiation or completion of clinical trials, complete additional pre-clinical studies and/or clinical trials, develop additional assays, or modify release specifications, and/or could delay or prohibit regulatory approval, including regulatory approval of certain manufacturing sites or processes.

Reliance on third parties for manufacture of our product candidates and raw materials utilized in manufacturing our product candidates entails certain risks, including reliance on the third party for regulatory compliance and quality assurance, the possibility that the third-party manufacturer does not maintain the financial, personnel or other resources to meet its obligations, the possibility that the third party fails to manufacture such components, or our product candidates or any products we may eventually commercialize, in accordance with our specifications, misappropriation of our proprietary information, including our trade secrets and know-how, and the possibility of termination of our manufacturing relationship by the third party, based on its own business priorities, at a time that is costly or damaging to us. In addition, the FDA and other regulatory authorities require that our product candidates and any products that we may eventually commercialize be manufactured according to cGMP and similar jurisdictional standards. These requirements include, among other things, quality control, quality assurance and the maintenance of records and documentation. The FDA or similar foreign regulatory agencies may also implement new standards at any time, or change their interpretations and enforcement of existing standards for manufacture, packaging or testing of products. We have little control over our manufacturers' compliance with these regulations and standards.

In some cases, the technical skills required to manufacture our product candidates may be unique or proprietary to a particular CMO, and we may have difficulty, or there may be contractual restrictions prohibiting us from transferring such skills to a back-up or alternate supplier if needed, or we may be unable to transfer such skills at all.

Our product candidates are uniquely manufactured. If we or any of our third-party manufacturers encounter difficulties in manufacturing our product candidates, our ability to provide supply of our product candidates for clinical trials or, if licensed, for commercial sale, could be delayed or stopped, or we may be unable to maintain a commercially viable cost structure.

The manufacturing process used to produce our product candidates is complex and novel, and it has not yet been validated for commercial production. The manufacture of our product candidates includes harvesting white blood cells from each patient, stimulating certain T cells from the white blood cells and thereby causing them to activate and proliferate, combining patient T cells with lentiviral delivery vector through a process known as transduction, expanding the transduced T cells to obtain the desired dose, formulating and freezing the cell product, and ultimately infusing the modified T cells back into the patient's body. Because of the bespoke nature of this product for patients, the cost to manufacture our product candidates is higher than traditional small molecule chemical compounds and monoclonal antibodies. Furthermore, our manufacturing process development and scale-up is at an early stage, and evaluation of cost at large scale has not yet been finalized. The actual cost to manufacture and process our product candidates could be greater than we expect and could materially and adversely affect the commercial viability of our product candidates.

Our manufacturing process may be susceptible to technical and logistics delays or failures due to the fact that each patient is an independent manufacturing lot, and also due to unique supply chain requirements. These include the collection of white blood cells from patients' blood, variability in the quality of white blood cells collected from patients' blood, cryopreservation of the white blood cells collected, packaging and shipment of frozen white blood cells to the manufacturing site in order to enable multi-site studies, procurement of lentiviral vectors that meet potency and purity requirements and shipment to the product candidate manufacturing site, shipment of the final product to clinical centers, manufacturing issues associated with interruptions in the manufacturing process, scheduling constraints for cell manufacturing slots, process contamination, equipment or reagent failure or supply shortage(s)/interruption(s), improper installation or operation of equipment, vendor or operator error, and

inconsistency in cell growth. Even minor deviations from normal manufacturing processes could result in reduced production yields, lot failures, product defects, product recalls, product liability claims and other supply disruptions. If microbial, viral, or other contaminations are discovered in our product candidates or in the manufacturing facilities in which our product candidates are made, production at such manufacturing facilities may be interrupted for an extended period of time to investigate and remedy the contamination. Further, as product candidates are developed through preclinical studies to late-stage clinical trials toward approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods, are altered along the way in an effort to optimize processes and results. Such changes may result in the need to enroll additional patients or to conduct additional clinical studies to evaluate the impact of changes on product safety and efficacy. Penn has informed us that it will be unable provide clinical supply for any late-phase or non-U.S. clinical trials of our product candidates that we may conduct. Therefore, we will need maintain and/or add new agreements with additional CMOs to produce clinical supply of our product candidates for late-phase clinical trials and at the necessary scale. We cannot guarantee that we will be able to enter into such agreements on commercially acceptable terms, if at all. Such changes carry the risk that they will not achieve these intended objectives, and any of these changes could cause our product candidates to perform differently and affect the results of ongoing and planned clinical trials or other future clinical trials.

Although we continue to optimize our manufacturing process for our product candidates, doing so is a difficult and uncertain task, and there are risks associated with scaling to the level required for advanced clinical trials or commercialization, including, among others, cost overruns, potential problems with process scale-up, process reproducibility, stability issues, lot consistency and timely availability of reagents and/or raw materials. If we are unable to adequately scale-up the manufacturing process for our product candidates with Minaris and Lonza, we may need to transfer to another manufacturer and/or our own facility, which can be lengthy. If we are able to adequately establish and scale-up the manufacturing process for our product candidates with an alternative manufacturer, we will still need to negotiate with such manufacturer an agreement for commercial supply and it is not certain we will be able to come to agreement on terms acceptable to us. This may impact our cost of goods and thus commercial viability and/or competitiveness.

In addition, many of the components which are required to support our cell manufacturing process, such as equipment, media, growth factors and disposables, are highly specialized and it is possible that the supply chain for these materials may be interrupted. If we are unable to promptly remedy such interruption, then there may be delays to our clinical development efforts.

The manufacturing process for any products that we may develop is subject to the FDA approval process, and we will need to contract with manufacturers who can meet all applicable FDA requirements on an ongoing basis.

The manufacturing process for any products that we may develop is subject to the FDA approval process, and we will need to contract with manufacturers who can meet all applicable FDA requirements on an ongoing basis. If we or our CMOs are unable to reliably produce products to specifications acceptable to the FDA, we may not obtain or maintain the approvals we need to commercialize such products. Even if we obtain regulatory approval for any of our product candidates, there is no assurance that either we or our CMOs will be able to manufacture the approved product in accordance with requirements from the FDA, to produce it in sufficient quantities to meet the requirements for the potential launch of the product, or to meet potential future demand. Any of these challenges could delay completion of clinical trials, require bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, suspension of production or recalls of the product candidates or marketed biologics, operating restriction and criminal prosecutions, delay approval of our product candidates, impair commercialization efforts, increase our cost of goods, and have an adverse effect on our business, financial condition, results of operations and growth prospects. Our future success depends on our ability to manufacture our products, if licensed, on a timely basis with acceptable manufacturing costs, while at the same time maintaining good quality control and complying with applicable regulatory requirements, and an inability to do so could have a material adverse effect on our business, financial condition, and results of operations. In addition, we could incur higher manufacturing costs if manufacturing processes or standards change, and we could need to replace, modify, design, or build and install equipment, all of which would require additional capital expenditures. Specifically, because our product candidates may have a higher cost of goods than conventional therapies, the risk that coverage and reimbursement rates may be inadequate for us to achieve profitability may be greater.

The manufacture of viral vectors is complex and variable, and there are a limited number of manufacturers able to supply us with viral vectors.

Our rese-cel product candidates utilize a lentiviral delivery vector and some or all of our other product candidates may require a lentiviral delivery vector, a key drug substance that delivers the CAR to the target T cells. We do not have the capability to manufacture lentiviral vector and plan to obtain the vector we require from third parties. The manufacturing process for lentiviral vector is variable and still evolving. It is not uncommon for manufacturing runs to fail, whether due to contamination, supplier error, or equipment failure, or to be delayed. To the extent our product candidates use a lentiviral delivery vector, a lack of vector supply will cause us to be unable to manufacture our CAR T cells as well as a delay in patient enrollment, which may have a negative impact on our ability to successfully develop our product candidates.

Further, there are a limited number of manufacturers capable of producing lentiviral vectors. It can be challenging to secure a relationship with any of these manufacturers, and the manufacturing and release process can take a significant amount of time. We have secured a supply of lentiviral vector from CAROT and Oxford for the patients we plan to enroll in our RESET™ clinical trials. In December 2021, as amended in May 2023, February 2024 and May 2024, we secured a license and supply agreement with Oxford to establish a process and supply lentiviral vector for the clinical and commercial development of our rese-cel candidate. There is no assurance that we will be able to continue to secure adequate and timely supply of lentiviral vector. Moreover, we cannot be certain that our CAR T cell product candidates produced with lentiviral vector from different manufacturers will be comparable or that results of clinical trials will be consistent if conducted with lentiviral vector from different manufacturers.

Vector production also requires the production of high-quality DNA plasmids, for which there is also a limited number of suppliers. Although we have established relationships with suppliers for lentiviral vector and plasmids, we do not yet have our own clinical-scale manufacturing facility established, and are therefore highly dependent on the ability of these suppliers to manufacture necessary materials and to deliver these materials to us on a timely and reliable basis.

If we are to operate our own manufacturing facility, significant resources will be required and we may fail to successfully operate our facility, which could adversely affect our clinical trials and the commercial viability of our product candidates.

If we establish our own manufacturing facility, our operations will be subject to review and oversight by the FDA and the FDA could object to our use of our manufacturing facility. We must first receive approval from the FDA prior to licensure to manufacture our product candidates, which we may never obtain. Even if licensed, we would be subject to ongoing periodic unannounced inspection by the FDA and corresponding state agencies to ensure strict compliance with cGMPs and other government regulations. Our license to manufacture product candidates will be subject to continued regulatory review. Our cost of goods development is at an early stage. The actual cost to manufacture and process our product candidates at a manufacturing facility of our own could be greater than we expect and could materially and adversely affect the commercial viability of our product candidates.

The manufacture of biopharmaceutical products is complex and requires significant expertise, and can be impacted by resource constraints, labor disputes and workforce limitations.

The manufacture of biopharmaceutical products is complex and requires significant expertise, including the development of advanced manufacturing techniques and process controls. Manufacturers of cell therapy products often encounter difficulties in production, particularly in scaling out and validating initial production and ensuring the absence of contamination. These problems include difficulties with production costs and yields, quality control, including stability of the product, quality assurance testing, operator error, shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. Furthermore, if contaminants are discovered in our supply of product candidates or in the manufacturing facilities upon which we currently or will rely, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. We cannot assure you that any stability or other issues relating to the manufacture of our product candidates, whether by Minaris, Lonza, or other third-party CMOs, or at any manufacturing facility that we may establish, will not occur in the future.

Minaris, Lonza, or other third-party CMOs that we engage, or we may fail to manage the logistics of storing and shipping our product candidates. Storage failures and shipment delays and problems caused by us, our vendors or other factors not in our control, such as weather, could result in loss of usable product or prevent or delay the delivery of product candidates to patients.

Minaris, Lonza, or other third-party CMOs that we engage, or we may also experience manufacturing difficulties due to resource constraints, labor disputes or workforce limitations arising from the expanding need for manufacturing in the cell therapy field and the limited number of training programs for technical staff. If we were to encounter any of these difficulties, our ability to provide our product candidates to patients would be jeopardized.

We are dependent upon the availability of specialty raw materials and the production capabilities of small manufacturers to source the components of our product candidates.

Our product candidates require many specialty raw materials, some of which are manufactured by small companies with limited resources and experience to support a commercial product, and the suppliers may not be able to deliver raw materials to our specifications. In addition, those suppliers generally do not have the capacity to support commercial products manufactured under cGMP by biopharmaceutical firms. The suppliers may be ill-equipped to support our needs, especially in non-routine circumstances like an FDA inspection or medical crisis, such as widespread contamination. We also do not have contracts with many of these suppliers, and we may not be able to contract with them on acceptable terms or at all. Accordingly, we may experience delays in receiving key raw materials to support clinical or commercial manufacturing.

In addition, some raw materials are currently available from a single supplier, or a small number of suppliers. We cannot be sure that these suppliers will remain in business or that they will not be purchased by one of our competitors or another company that is not interested in continuing to produce these materials for our intended purpose. In addition, the lead time needed to establish a relationship with a new supplier can be lengthy, and we may experience delays in meeting demand in the event we must switch to a new supplier. The time and effort to qualify a new supplier could result in additional costs, diversion of resources or reduced manufacturing yields, any of which would negatively impact our operating results. Further, we may be unable to enter into agreements with a new supplier

on commercially reasonable terms, which could have a material adverse impact on our business. We are also unable to predict how changing global economic conditions or global health concerns will affect our third-party suppliers and manufacturers. Regional or single-source dependencies may in some cases accentuate these risks. For example, the pharmaceutical industry generally, and in some instances our Company or our collaborators or other third parties on which we rely, depend on China-based suppliers or service providers for certain raw materials, products and services, or other activities. Our ability or the ability of our collaborators or such other third parties to continue to engage these China-based suppliers or service providers for certain preclinical research programs and clinical development programs could be restricted due to geopolitical developments between the United States and China, including as a result of the escalation of tariffs or other trade restrictions or due to the enactment of the NDAA, which includes Section 851, commonly referred to as the "BIOSECURE Act.". Any negative impact of such matters on our third-party suppliers and manufacturers may also have an adverse impact on our results of operations or financial condition.

We may encounter difficulties in production, particularly with respect to process development or scaling up of our manufacturing capabilities. If we encounter such difficulties, our ability to provide supply of our CAR T cells for clinical trials or for commercial purposes could be delayed or stopped.

Establishing clinical and commercial manufacturing and supply is a difficult and uncertain task, and there are risks associated with scaling to the level required for advanced clinical trials or commercialization, including, among others, increased costs, potential problems with process scale-out, process reproducibility, stability issues, lot consistency, and timely availability of reagents or raw materials. For example, we may find it difficult to establish a manufacturing process that is consistent. If this occurs, we may need to complete more than one manufacturing run for each treated patient, which would impact the availability of adequate coverage and reimbursement from third-party payors. Competitors that have developed CAR T cell therapies have had difficulty reliably producing engineered T cell therapies in the commercial setting. If we experience similar challenges manufacturing product candidates to approved specifications, this may limit our product candidates' utilization and our ability to receive payment for these product candidates once licensed. Alternatively, these challenges may require changes to our manufacturing processes, which could require us to perform additional clinical studies, incurring significant expense. We may ultimately be unable to reduce the expenses associated with our product candidates to levels that will allow us to achieve a profitable return on investment.

If we or our third-party suppliers use hazardous, non-hazardous, biological or other materials in a manner that causes injury or violates applicable law, we may be liable for damages.

Our research and development activities involve the controlled use of potentially hazardous substances, including chemical and biological materials. We and our suppliers are subject to federal, state and local laws and regulations in the United States governing the use, manufacture, storage, handling and disposal of medical and hazardous materials. Although we believe that we and our suppliers' procedures for using, handling, storing and disposing of these materials comply with legally prescribed standards, we and our suppliers cannot completely eliminate the risk of contamination or injury resulting from medical or hazardous materials. As a result of any such contamination or injury, we may incur liability or local, city, state or federal authorities may curtail the use of these materials and interrupt our business operations. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. We do not have any insurance for liabilities arising from medical or hazardous materials. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development and production efforts, which could harm our business, prospects, financial condition or results of operations.

Changes in product candidate manufacturing or formulation may result in additional costs or delay, which could adversely affect our business, results of operations and financial condition.

As product candidates are developed through preclinical studies to later-stage clinical trials towards approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods or formulation, are altered along the way in an effort to optimize processes and results. Any of these changes could cause our product candidates to perform differently and affect the results of ongoing and planned clinical trials or other future clinical trials conducted with the altered materials or with materials made with the altered methods. Such changes may also require additional testing, or notification to, or approval by the FDA or other regulatory authorities. This could delay completion of clinical trials, require the conduct of bridging clinical trials or studies, require the

repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and/or jeopardize our ability to commence product sales and generate revenue.

Risks Related to Government Regulation

The regulatory approval process is lengthy and time-consuming, and we may experience significant delays in the clinical development and regulatory approval of our product candidates.

The research, testing, manufacturing, labeling, approval, selling, import, export, marketing and distribution of drug products, including biologics, are subject to extensive regulation by the FDA and other regulatory authorities in the United States and comparable authorities in other jurisdictions, such as the EMA in Europe. We are not permitted to market any biological drug product in the United States until we receive approval of a Biologics License Application, or BLA, from the FDA. We have not previously submitted a BLA to the FDA, or similar licensure filings to comparable foreign authorities. A BLA must include extensive preclinical and clinical data and supporting information to establish the product candidate's safety, potency and purity for each desired indication. The BLA must also include significant information regarding the chemistry, manufacturing and controls for the product, including with respect to chain of identity and chain of custody of the product.

We expect the novel nature of our product candidates to create further challenges in obtaining regulatory approval. For example, to our knowledge, the FDA has not previously reviewed regulatory applications for marketing authorization of CAR T cells for treatment of autoimmune disease or CAAR T cells for treatment of pemphigus, and there is no cell therapy currently approved by the FDA for the treatment of mPV, MuSK myasthenia gravis, SLE, myositis, SSc, gMG or MS. Because of this, we have little guidance as to which endpoints will be accepted, how many clinical trials we may expect to conduct, and whether open-label clinical trials will be deemed acceptable, among other things. We may also request regulatory approval of future CAR T or CAAR T cell-based product candidates by target, regardless of disease type or origin, which the FDA may have difficulty accepting if our clinical trials only involved diseases of certain origins. The FDA may also require a panel of experts, referred to as an Advisory Committee, to deliberate on the adequacy of the safety, potency and purity data to support licensure. The opinion of the Advisory Committee, although not binding, may have a significant impact on our ability to obtain licensure of the product candidates based on the completed clinical trials, as the FDA often adheres to the Advisory Committee's recommendations. Further, given the rapidly evolving landscape of cell therapy, we could encounter a significant change in the regulatory environment for our product candidates once we have already begun one or more lengthy and expensive clinical trials for our product candidates. For example, the U.S. Supreme Court's July 2024 decision to overturn prior established case law giving deference to regulatory agencies' interpretations of ambiguous statutory language has introduced uncertainty regarding the extent to which FDA's regulations, policies, and decisions may become subject to increasing legal challenges, delays, and/or changes. Moreover, the incoming U.S. administration may propose policy changes that create additional uncertainty for our business and may result in increased regulatory uncertainty, judicial interpretations overturing precedent and other impacts to the agency rulemaking process. Accordingly, the regulatory approval pathway for our product candidates may be uncertain, complex, expensive and lengthy, and approval may not be obtained.

We may also experience delays in completing ongoing and planned clinical trials for a variety of reasons, including delays related to:

- obtaining regulatory authorization to begin a trial, if applicable;
- the availability of financial resources to commence and complete the planned trials;
- reaching agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining approval at each clinical trial site by an independent IRB;
- recruiting suitable patients to participate in a trial;
- having patients complete a trial, including having patients enrolled in clinical trials dropping out of the trial before the product candidate is manufactured and returned to the site, or return for post-treatment follow-up;
- clinical trial sites deviating from trial protocol or dropping out of a trial;

- addressing any patient safety concerns that arise during a trial;
- adding new clinical trial sites; or
- manufacturing sufficient quantities of qualified materials under cGMPs and applying them on a patient by patient basis for use in clinical trials.

We could also encounter delays if physicians encounter unresolved ethical issues associated with enrolling patients in clinical trials of our product candidates in lieu of prescribing existing treatments that have established safety and efficacy profiles. If we experience delays in the completion of, any future clinical trial of our product candidates, the commercial prospects for our product candidates will be harmed, and our ability to generate product revenue will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product development and approval process and jeopardize our ability to commence product sales and generate revenue. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may ultimately lead to the denial of regulatory approval of our product candidates.

We expect the product candidates we develop will be regulated as biological products, or biologics, and therefore they may be subject to competition.

The Biologics Price Competition and Innovation Act of 2009, or BPCIA, was enacted as part of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively the ACA, to establish an abbreviated pathway for the approval of biosimilar and interchangeable biological products. The regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as "interchangeable" based on its similarity to a licensed biologic. Under the BPCIA, an application for a biosimilar product cannot be licensed by the FDA until 12 years after the reference product was licensed under a BLA. The law is complex and is still being interpreted and implemented by the FDA.

We believe that any of the product candidates we develop that is licensed in the United States as a biological product under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider the subject product candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Moreover, the extent to which a biosimilar, once licensed, will be substituted for any one of the reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

In the European Union, there is a special regime for biosimilars, or biological medicinal products that are similar to a reference medicinal product but that do not meet the definition of a generic medicinal product. For such products, the results of appropriate preclinical or clinical trials must be provided in support of an application for market authorization. Guidelines from the EMA detail the type and quantity of supplementary data to be provided for different types of biological product.

The regulatory landscape that will govern our product candidates is uncertain; regulations relating to more established cell therapies and other therapies for autoimmune diseases where B cells may play a role in initiating or maintaining disease 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.

Because we are developing novel CAR T and CAAR T cell product candidates that are unique biological entities, the regulatory requirements that we will be subject to are not entirely clear. Even with respect to more established products that fit into the categories of gene therapies or cell therapies, the regulatory landscape is still developing. For example, regulatory requirements governing gene therapy products and cell therapy products have changed frequently and may 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 established the Office of Tissues and Advanced Therapies, or OTAT, in 2016, within its Center for Biologics Evaluation and Research, or 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 September 2022, the FDA announced retitling of OTAT to the Office of Therapeutic Products, or OTP, and elevation of OTP to a "Super Office" to meet its growing cell and gene therapy workload. In addition, under guidelines

issued by the National Institutes of Health, or NIH, gene therapy clinical trials are also subject to review and oversight by an institutional biosafety committee, or IBC, a local institutional committee that reviews and oversees research utilizing recombinant or synthetic nucleic acid molecules at that institution. Before a clinical trial can begin at any institution, that institution's institutional review board, or IRB, and its IBC assesses the safety of the research and identifies 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. Although the FDA decides whether individual gene therapy protocols may proceed, review process and determinations of other reviewing bodies can impede or delay the initiation of a clinical study, even if the FDA has reviewed the study and approved its initiation. Conversely, the FDA can place an IND application on clinical hold even if such other entities have provided a favorable review. Furthermore, each clinical trial must be reviewed and approved by an independent IRB at or servicing each institution at which a clinical trial will be conducted. In addition, adverse developments in clinical trials of gene therapy products conducted by others or in the post-approval context may cause the FDA or other regulatory bodies to change the requirements for approval of any of our product candidates. For example, after the FDA's November 2023 announcement of its investigation into reports of T cell malignancies for BCMA- and CD19-directed CAR T cell immunotherapies, the FDA informed us that, based on those reports, patients receiving rese-cel in our clinical trials will require life-long monitoring for new malignancies.

Complex regulatory environments exist in other jurisdictions in which we might consider seeking regulatory approvals for our product candidates, further complicating the regulatory landscape. For example, in the European Union, a special committee called the Committee for Advanced Therapies was established within the EMA in accordance with Regulation (EC) No 1394/2007 on advanced-therapy medicinal products, or ATMPs, to assess and provide an opinion on the quality, safety and efficacy of ATMPs which are the subject of a marketing authorization application, and to follow scientific developments in the field. ATMPs include gene therapy products as well as somatic cell therapy products and tissue engineered products. These various regulatory review committees and advisory groups and new or revised guidelines that they promulgate from time to time may lengthen the regulatory review process, require us to perform additional studies, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of our product candidates or lead to significant post-approval limitations or restrictions. Because the regulatory landscape for our CAR T and CAAR T cell product candidates is new, we may face even more cumbersome and complex regulations than those emerging for gene therapy products and cell therapy products. Furthermore, even if our product candidates obtain required regulatory approvals, such approvals may later be withdrawn because of changes in regulations or the interpretation of regulations by applicable regulatory agencies. Delay or failure to obtain, or unexpected costs in obtaining, the regulatory approval necessary to bring a potential product to market could decrease our ability to generate sufficient product revenue to maintain our business.

If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals for our product candidates, we will not be able to commercialize, or will be delayed in commercializing, our product candidates, and our ability to generate revenue will be materially impaired.

Our product candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, distribution, import and export are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States. Before we can commercialize any of our product candidates, we must obtain marketing approval. We have not received approval to market any of our product candidates from regulatory authorities in any jurisdiction and it is possible that none of our product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval. We, as a company, have no experience in filing and supporting the applications necessary to gain regulatory approvals and expect to rely on third-party CROs and/or regulatory consultants to assist us in this process. Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the drug candidate's safety, potency and purity.

Securing regulatory approval also requires the submission of information about the drug manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Our product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use.

The process of obtaining regulatory approvals is expensive, may take many years if additional clinical trials are required, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted IND, BLA or comparable application types in other countries, may cause delays in the approval or rejection of an application. The FDA and foreign regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. Our product candidates could be delayed in receiving, or fail to receive, regulatory approval for many reasons, including the following:

- the FDA or other foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA that a drug candidate is safe, potent and pure for its proposed indication or a related companion diagnostic is suitable to identify appropriate patient populations;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or other foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or other foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of an BLA, or other submission or to obtain regulatory approval in the United States or elsewhere;
- the FDA or other foreign regulatory authorities may fail to approve the manufacturing processes, test procedures and specifications, or facilities that we may establish or of third-party manufacturers with which we may contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or other foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

Of the large number of drugs in development, only a small percentage successfully complete the FDA approval process and are commercialized. The lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market our product candidates, which would significantly harm our business, results of operations and prospects. Although we have discussed the designs of our trials for rese-cel with the FDA to align on the key aspects of the studies, the FDA may not ultimately agree that the data from such trials supports regulatory approval. For example, in March 2026, the FDA noted that details are needed in order for the FDA to assess suitability of the proposed registry as an external control, including information on potential baseline differences between the enrolled study population and registry population (e.g., diagnosis classification and refractory definition) and the risk of missing or unavailable data, as well as other criteria established by FDA guidance for industry.

We expect the novel nature of our product candidates to create further challenges in obtaining regulatory approval. As a result, our ability to develop product candidates and obtain regulatory approval may be significantly impacted. For example, the general approach for FDA approval of a new biologic or drug is for sponsors to seek licensure or approval based on dispositive data from well-controlled, Phase 3 clinical trials of the relevant product candidate in the relevant patient population. Phase 3 clinical trials typically involve hundreds of patients, have significant costs and take years to complete. We believe that we may be able to utilize the FDA's Regenerative Medicine Advanced Therapy designation for our product candidates given the limited alternatives for treatments for certain rare diseases and autoimmune diseases where B cells may play a role in initiating or maintaining disease, but the FDA may not agree with our plans.

Moreover, approval of genetic or biomarker diagnostic tests may be necessary to advance some of our product candidates to clinical trials or potential commercialization. In the future, regulatory agencies may require the development and approval of such tests. Accordingly, the regulatory approval pathway for such product candidates may be uncertain, complex, expensive and lengthy, and approval may not be obtained.

In addition, even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our products, if licensed, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

If we experience delays in obtaining approval or if we fail to obtain approval of our product candidates, the commercial prospects for our product candidates may be harmed and our ability to generate revenues will be materially impaired.

Even though we may apply for orphan drug designation for our product candidates, we may not be able to obtain orphan drug marketing exclusivity.

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition, defined as a disease or condition with a patient population of fewer than 200,000 in the United States, or a patient population of 200,000 or more in the United States when there is no reasonable expectation that the cost of developing and making available the drug or biologic in the United States will be recovered from sales in the United States for that drug or biologic. In order to obtain orphan drug designation, the request must be made before submitting a BLA. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages, and user-fee waivers. After the FDA grants orphan drug designation, the generic identity of the drug and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

If a product that has orphan drug designation subsequently receives the first FDA approval of that particular product for the use or indication for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications, including a BLA, to market the same biologic (meaning, a product with the same principal molecular structural features) for the same indication for seven years, except in limited circumstances such as a showing of clinical superiority to the product with orphan drug exclusivity or if FDA finds that the holder of the orphan drug exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug was designated. As a result, even if one of our product candidates receives orphan exclusivity, the FDA can still approve other biologics that do not have the same principal molecular structural features for use in the same indication or the same biologic for a different indication during the exclusivity period. Furthermore, the FDA can waive orphan exclusivity if we are unable to manufacture sufficient supply of our product or if a subsequent applicant demonstrates clinical superiority over our product.

We have obtained from the FDA orphan drug designation for DSG3-CAART for the treatment of pemphigus vulgaris, for MuSK-CAART for the treatment of MuSK MG and for rese-cel for the treatment of idiopathic inflammatory myopathies (IIM, or myositis) and systemic sclerosis. We may seek orphan drug designation for certain other of our product candidates, but may be unable to obtain orphan drug designation for some or all of our product candidates in specific orphan indications in which we believe there is a medically plausible basis for the use of these products. Even if we obtain orphan drug designation, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan designated indication and may be lost if the FDA later determines that the request for designation was materially defective or if we are unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition, or if a subsequent applicant demonstrates clinical superiority over our products, if licensed. Although we may seek orphan drug designation for other product candidates, we may never receive such designations. In addition, the FDA may further reevaluate the Orphan Drug Act and its regulations and policies. 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.

The FDA has granted rare pediatric disease designation to rese-cel for the treatment of juvenile dermatomyositis. However, a marketing application for rese-cel or any other product candidate, if approved, may not meet the eligibility criteria for a priority review voucher.

The FDA has granted rare pediatric disease designation to rese-cel for the treatment of juvenile dermatomyositis. Designation of a drug as a drug for a rare pediatric disease does not guarantee that an NDA or BLA for such drug will meet the eligibility criteria for a rare pediatric disease priority review voucher at the time the application is approved. Under the FDCA, we will need to request a rare pediatric disease priority review voucher in our original BLA for rese-cel. The FDA may determine that a BLA for rese-cel, if approved, does not meet the eligibility criteria for a priority review voucher, including for the following reasons:

- juvenile dermatomyositis no longer meets the definition of a rare pediatric disease;
- the BLA contains an active ingredient that has been previously approved by the FDA;
- the BLA does not rely on clinical data derived from studies examining a pediatric population and dosages of the drug intended for that population (that is, if the BLA does not contain sufficient clinical data to allow for adequate labeling for use by the full range of affected pediatric patients); or
- the BLA is approved for a different adult indication than the rare pediatric disease for which rese-cel is designated.

The FDA's rare pediatric disease priority voucher program began to sunset on December 20, 2024, on failure to pass a continuing resolution package that included its reauthorization. Under the amended statutory sunset provisions, after December 20, 2024, the FDA may award a priority review voucher for an approved rare pediatric disease product application only if the sponsor has rare pediatric disease designation for the drug and if that designation was granted by December 20, 2024. After September 30, 2026, the FDA may not award any rare pediatric disease priority review vouchers. Congress may vote to reauthorize this program, and legislative proposals to do so remain pending in Congress, but its future remains unknown at this time unless any such proposal is passed and enacted into law. Absent any such reauthorization, if a BLA for rese-cel is not approved prior to September 30, 2026 for any reason, regardless of whether it meets the criteria for a rare pediatric disease priority review voucher, it will not be eligible for a priority review voucher.

A fast track designation by the FDA, even if granted, may not lead to a faster development or regulatory review or approval process, and does not increase the likelihood that our current product candidate and any future product candidates will receive marketing approval.

If a drug is intended for the treatment of a serious or life-threatening condition and the drug demonstrates the potential to address unmet medical needs for this condition, the drug sponsor may apply for FDA fast track designation for a particular indication. Fast track is a process designed to facilitate the development, and expedite the review of drugs to treat serious or life-threatening conditions and address an unmet medical need. We have received fast track designation for DSG3-CAART for improving healing of mucosal blisters in patients with mPV, for MuSK-CAART for improving activities of daily living and muscle strength in patients with MuSK antibody-positive myasthenia gravis

and for rese-cel, designed to deplete CD19-positive B cells and improve disease activity in patients with SLE, LN and the myositis subtype of dermatomyositis, for the treatment of patients with systemic sclerosis to improve associated organ dysfunction and for the treatment of relapsing and progressive forms of MS. We may also apply for fast track designation for certain of our other product candidates, but there is no assurance that the FDA will grant this status to any of our other current or future product candidates. Marketing applications filed by sponsors of products in fast track development may qualify for priority review under the policies and procedures offered by the FDA, but the fast track designation does not assure any such qualification or ultimate marketing approval by the FDA. The FDA has broad discretion whether or not to grant fast track designation, so even if we believe a particular product candidate is eligible for this designation, there can be no assurance that the FDA would decide to grant it. Even though we have received fast track designation for certain of our product candidates, we may not experience a faster development process, regulatory review or approval for these product candidates as compared to conventional FDA procedures, and receiving a fast track designation does not provide assurance of ultimate FDA approval. In addition, the FDA may withdraw fast track designation if it believes that the designation is no longer supported by data from our clinical development program. In addition, the FDA may withdraw any fast track designation at any time.

Although we may pursue expedited regulatory approval pathways for a product candidate, it may not qualify for expedited development or, if it does qualify for expedited development, it may not actually lead to a faster development or regulatory review or approval process.

Although we believe there may be an opportunity to accelerate the development of certain of our product candidates through one or more of the FDA's expedited programs, such as fast track, breakthrough therapy, Regenerative Medicine Advanced Therapy, accelerated approval or priority review, we cannot be assured that any of our product candidates will qualify for such programs.

For example, we may seek a Regenerative Medicine Advanced Therapy, or RMAT, designation for some of our product candidates. We have received RMAT designation for our myositis and systemic sclerosis programs. An RMAT is defined as cell 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. A new drug application or a BLA for an RMAT may be eligible for priority review or accelerated approval through (1) surrogate or intermediate endpoints reasonably likely to predict long-term clinical benefit or (2) reliance upon data obtained from a meaningful number of sites. Benefits of such designation also include early interactions with FDA to discuss any potential surrogate or intermediate endpoint to be used to support accelerated approval. A Regenerative Medicine Therapy that is granted accelerated approval and is subject to post-approval requirements may fulfill such requirements through the submission of clinical evidence, clinical studies, 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. Although RMAT designation or access to any other expedited program may expedite the development or approval process, it does not change the standards for approval. If we apply for RMAT designation or any other expedited program for our product candidates, the FDA may determine that our proposed target indication or other aspects of our clinical development plans do not qualify for such expedited program. Even if we are successful in obtaining a RMAT designation or access to any other expedited program, we may not experience faster development timelines or achieve faster review or approval compared to conventional FDA procedures. Access to an expedited program may also be withdrawn by the FDA if it believes that the designation is no longer supported by data from our clinical development program. Additionally, qualification for any expedited review procedure does not ensure that we will ultimately obtain regulatory approval for such product candidate.

Disruptions at the FDA, the USPTO, the SEC and other government agencies, including from government shutdowns, or other disruptions to these agencies' operations, could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

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, ability to hire and retain key personnel and accept the payment of user fees,

substantial changes in leadership and shifting policy priorities as a result of changes in the presidential administration and its appointees tasked to oversee the agency, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA, patent offices in the United States and abroad and other agencies – including as a result of reductions in force, significant organizational changes, substantial leadership departures, and policy changes – may also slow the time necessary for new drugs or biologics to be reviewed or for patent applications to be examined and granted, which would adversely affect our business. Changes and cuts in FDA staffing have also been reported by some within the pharmaceutical industry as creating instances of in delays in the FDA's responsiveness or in its ability to review IND submissions or applications, issue regulations or guidance, or implement or enforce regulatory requirements in a timely fashion. In addition, over the past decade, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical employees and stop critical activities. Specifically, in October 2025, the U.S. federal government entered a shutdown suspending services deemed non-essential as a result of the failure by Congress to enact regular appropriations for the 2026 fiscal year. In addition, the U.S. government has issued certain policies and executive orders directed towards reducing the employee headcount and costs associated with U.S. administrative agencies, including the FDA, and it remains unclear the degree to which these efforts may limit or otherwise adversely affect the FDA's ability to conduct routine activities. If a prolonged government shutdown, such as the one that occurred in October 2025, or if funding shortages or staffing limitations hinder or prevent the FDA, the SEC or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, including formal and informal interactions with product developers, it could significantly affect the ability of the FDA or other such regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns or other substantial disruptions at other government agencies, such as the SEC, may also impact our business by delaying review of our public filings, which in turn could delay or frustrate our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Significant political, trade, regulatory developments, and other circumstances beyond our control, could have a material adverse effect on our financial condition or results of operations.

We operate beyond the United States and, if approved, we may sell our products in countries throughout the world. Significant political, trade, or regulatory developments in the jurisdictions in which we may sell our products, such as those stemming from the change in U.S. federal administration, are difficult to predict and may have a material adverse effect on us. Similarly, changes in U.S. federal policy that affect the geopolitical landscape could give rise to circumstances outside our control that could have negative impacts on our business operations. For example, certain governments (including the United States and other countries) have imposed or may impose tariffs on a wide range of products, raw materials, and intermediate goods. Additional tariffs, or retaliatory measures by other countries in response, may be implemented at any time. Historically, tariffs have led to increased trade and political tensions, between not only the U.S. and China, but also between the U.S. and other countries in the international community. In response to tariffs, other countries have implemented retaliatory tariffs on U.S. goods. Political tensions as a result of trade policies could reduce trade volume, investment, technological exchange and other economic activities between major international economies, resulting in a material adverse effect on global economic conditions and the stability of global financial markets. Any changes in political, trade, regulatory, and economic conditions, including U.S. trade policies, could have a material adverse effect on our financial condition or results of operations. Until we know what policy changes are made, whether those policy changes are challenged and subsequently upheld by the court system and how those changes impact our business and the business of our competitors over the long term, we will not know if, overall, we will benefit from them or be negatively affected by them.

Risks Related to Ongoing Regulatory Obligations

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

Any regulatory approvals that we receive for our product candidates will require surveillance to monitor the safety, potency and purity of the product candidate. We believe it is likely that the FDA will require a Risk Evaluation and Mitigation Strategy, or REMS, in order to approve our product candidates, which could entail requirements for a medication guide, physician communication plans or additional elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA approves our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our product candidates will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs and GCPs for any clinical trials that we conduct post-approval. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any BLA, other marketing application and previous responses to inspectional observations. Additionally, manufacturers and manufacturers' facilities are required to comply with extensive FDA, and comparable foreign regulatory authority requirements, including ensuring that quality control and manufacturing procedures conform to cGMP regulations and applicable product tracking and tracing requirements. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control. In addition, the FDA could require us to conduct another study to obtain additional safety or biomarker information. Additionally, under the Food and Drug Omnibus Reform Act of 2022, or FDORA, sponsors of approved drugs and biologics must provide six months' notice to the FDA of any changes in marketing status, such as the withdrawal of a drug, and failure to do so could result in a letter citing such failure to comply and public posting of such letter and redacted company response, which could damage the company's reputation.

Further, we will be required to comply with FDA promotion and advertising rules, which include, among others, standards for direct-to-consumer advertising, restrictions on promoting products for uses or in patient populations that are not described in the product's approved uses (known as "off-label use"), limitations on industry-sponsored scientific and educational activities and requirements for promotional activities involving the internet and social media. Later discovery of previously unknown problems with our product candidates through follow-up programs with our clinical trial patients, including adverse events of unanticipated severity or frequency, or with our third-party suppliers or manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information, imposition of post-market studies or clinical studies to assess new safety risks, or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of our product candidates, withdrawal of the product from the market or voluntary or mandatory product recalls;
- fines, warning letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of license approvals;
- product seizure or detention, or refusal to permit the import or export of our product candidates; and
- injunctions or the imposition of civil or criminal penalties.

The FDA's policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action. If these executive actions impose restrictions on FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, and we may not achieve or sustain profitability.

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

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our research and development activities involve the use of biological and hazardous materials and produce hazardous

waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials, which could cause an interruption of our commercialization efforts, research and development efforts and business operations, environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. Although we believe that the safety procedures utilized by our third-party manufacturers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources and state or federal or other applicable authorities may curtail our use of certain materials and/or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

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 or other work-related injuries, this insurance may not provide adequate coverage against potential liabilities. We do not carry specific biological waste or hazardous waste insurance coverage, workers compensation or property and casualty and general liability insurance policies that include coverage for damages and fines arising from biological or hazardous waste exposure or contamination.

Our employees, independent contractors, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk of employee fraud or other illegal activity by our employees, independent contractors, consultants, commercial partners and vendors. Misconduct by these parties could include intentional, reckless and/or negligent conduct that fails to comply with the laws of the FDA, provide true, complete and accurate information to the FDA, comply with manufacturing standards we have established, comply with healthcare fraud and abuse laws in the United States and similar foreign fraudulent misconduct laws, or report financial information or data accurately or to disclose unauthorized activities to us. If we obtain FDA approval of any of our product candidates and begin commercializing those products in the United States, our potential exposure under such laws will increase significantly, and our costs associated with compliance with such laws are also likely to increase. These laws may impact, among other things, our current activities with principal investigators and research patients, as well as proposed and future sales, marketing and education programs.

Risks Related to Healthcare

Coverage and reimbursement may be limited or unavailable in certain market segments for our product candidates, which could make it difficult for us to sell our product candidates, if licensed, profitably.

Successful commercialization of our product candidates, if licensed, will depend in part on the extent to which reimbursement for those drug products 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 drug products they will pay for and establish reimbursement levels. The availability and extent of reimbursement by governmental and private payors is essential for most patients to be able to afford a drug product. Sales of drug products depend substantially, both domestically and abroad, on the extent to which the costs of drugs products are paid for by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third-party payors. Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we obtain regulatory approval. Any product candidate for which we seek regulatory approval and reimbursement will need to meet or surpass our target product profile, or TPP, to be deemed a viable alternative to currently approved therapies. In addition, because our product candidates represent new approaches to the treatment of autoimmune diseases where B cells may play a role in initiating or maintaining disease, we cannot accurately estimate the potential revenue from our product candidates. For more information, see

the section titled "Business—Government regulation—Pricing and Reimbursement" included in this Annual Report on Form 10-K.

Obtaining coverage and reimbursement of a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide the payor with supporting scientific, clinical and cost-effectiveness data for the use of our products, if licensed. In the United States, the principal decisions about reimbursement for new drug products are typically made by the Centers for Medicare and Medicaid Services, or CMS, an agency within the U.S. Department of Health and Human Services, or HHS. CMS decides whether and to what extent a new drug product will be covered and reimbursed under Medicare, and private payors tend to follow CMS to a substantial degree. However, no uniform policy of coverage and reimbursement for drug products exists among third-party payors and coverage and reimbursement levels for drug products can differ significantly from payor to payor. Further, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage for the product. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

Even if we obtain coverage for a given product, if the resulting reimbursement rates are insufficient, hospitals may not approve our product for use in their facility or third-party payors may require co-payments that patients find unacceptably high. Patients are unlikely to use our product candidates unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our product candidates. Separate reimbursement for the product itself may or may not be available. Instead, the hospital or administering physician may be reimbursed only for providing the treatment or procedure in which our product is used. Further, from time to time, CMS revises the reimbursement systems used to reimburse health care providers, including the Medicare Physician Fee Schedule and Outpatient Prospective Payment System, which may result in reduced Medicare payments. In some cases, private third-party payors rely on all or portions of Medicare payment systems to determine payment rates. Changes to government healthcare programs that reduce payments under these programs may negatively impact payments from private third-party payors, and reduce the willingness of physicians to use our product candidates.

The marketability of any product candidates for which we receive regulatory approval for commercial sale may suffer if government and other third-party payors fail to provide coverage and adequate reimbursement. We expect downward pressure on pharmaceutical pricing to continue. Further, 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 we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Healthcare legislative measures aimed at reducing healthcare costs may have a material adverse effect on our business and results of operations.

In the United States, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay regulatory approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidates for which we obtain regulatory approval. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and in additional downward pressure on the price that we, or any collaborators, may receive for any approved products. For more information, see the section titled "Business—Government regulation—Current and Future Legislation" included in this annual report on Form 10-K.

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. For instance, multiple executive actions in the first half of 2025 signal the federal government's increasing focus on lowering prescription drug prices, adding to the uncertainty surrounding future drug pricing and reimbursement frameworks. For example:

- On May 12, 2025, President Trump signed the executive order titled "Delivering Most-Favored-Nation Prescription Drug Pricing," which directs the Secretary of Health and Human Services (HHS) to identify and communicate most-favored-nation (MFN) price targets for prescription drugs and to propose a rulemaking plan to impose such pricing if "significant progress" is not made. The order also directs the federal government to explore regulatory pathways that would facilitate direct-to-patient sales for manufacturers that meet these price targets. Additionally, it signals potential further action against manufacturers that fail to offer MFN pricing, including evaluating whether to modify or rescind marketing approvals or allow individual drug importation waivers. Notably, a similar rule promulgated during

President Trump's first term would have tied Medicare Part B reimbursement rates to the lowest price available for a drug in certain foreign countries. That rule was subject to litigation and ultimately rescinded by the Biden Administration in August 2021. In a related development, FDA Commissioner Makary announced in July 2025 that the agency is considering a new fast-track priority review voucher program for manufacturers that commit to pricing drugs in line with those in economically comparable countries. The implementation timeline and commercial implications of these proposals remain uncertain.

- On April 15, 2025, President Trump issued the executive order "Lowering Drug Prices by Once Again Putting Americans First," which contains a broad set of directives aimed at reducing drug costs. Among other actions, the order directs HHS to revise guidance under the Inflation Reduction Act (IRA) to eliminate the so-called "pill penalty," which currently subjects small molecule drugs to Medicare price negotiation four years earlier than biologics. The order also calls for a comprehensive evaluation of the role played by pharmacy benefit managers, or PBMs, in drug pricing and market access.

Further, the Medicare Drug Price Negotiation Program, administered by CMS as part of the Inflation Reduction Act of 2022, commonly referred to as the IRA, may apply to our products if they are selected for negotiation, which could materially reduce the amount of revenue we can generate from our products if they are approved. Prior to the enactment of the One Big Beautiful Bill Act of 2025, or the OBBBA, orphan drugs were exempt from Medicare price negotiation under the IRA only if they had received a single orphan designation and were approved solely for the corresponding rare disease or condition. The OBBBA amended this exemption to apply more broadly: now, any orphan-designated drug is exempt from price negotiation, regardless of the number of orphan designations it has received, provided the drug's approved indications are exclusively for those rare diseases. The OBBBA also included significant reforms to Medicaid, including an estimated $1 trillion in reduced federal Medicaid spending from 2025 through 2034, the imposition of work requirements for certain adult enrollees, more frequent eligibility redeterminations, and increased cost-sharing for beneficiaries. These changes are expected to reduce overall Medicaid enrollment and access to care. Although the effect on our future product candidates or business is unknown, any decrease in the number of insured patients or reimbursement levels for our products could adversely affect our potential for revenue and our commercial prospects.

On December 19, 2025, CMS released two proposed rules that would incorporate MFN pricing principles into federal reimbursement for prescription drugs. The first proposal, the Global Benchmark for Efficient Drug Pricing Model, or GLOBE, for Medicare Part B, would require manufacturers of specified single source drugs and sole source biologics to pay incremental rebates based on international benchmark prices, with participation triggered for products meeting CMS's spending and eligibility criteria. The second proposal, the Guarding U.S. Medicare Against Rising Drug Costs, or GUARD, model for Medicare Part D, would similarly mandate manufacturer rebates for qualifying sole source drugs where the Medicare net price exceeds an MFN benchmark derived from international reference pricing methodologies. As proposed, GLOBE would begin a five year performance period on October 1, 2026 and GUARD would begin its performance period in 2027. These proposals will likely be subject to legal challenges that could delay their implementation or modify their impact on manufacturer pricing and revenue. Additionally, in November 2025, CMS introduced the GENErating cost Reductions for U.S. Medicaid Model, or GENEROUS Model, a voluntary MFN framework for manufacturers participating in the Medicaid Drug Rebate Program. Although it is voluntary, the GENEROUS Model could also impact the drug pricing landscape for manufacturers.

We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

- the demand for our product candidates, if we obtain regulatory approval;
- our ability to set a price that we believe is fair for our products, if licensed;
- our ability to generate revenue and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

We expect that the healthcare reform measures that have been adopted and may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product and could seriously harm our future revenues. Any reduction in reimbursement from Medicare or

other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our products.

Our relationships with customers, healthcare providers, physicians, and third-party payors will be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, health information privacy and security laws, and other healthcare laws and regulations. If we or our employees, independent contractors, consultants, commercial partners and vendors violate these laws, we could face substantial penalties.

These laws may impact, among other things, our clinical research program, as well as our proposed and future sales, marketing and education programs. In particular, the promotion, sales and marketing of healthcare items and services is subject to extensive laws and regulations designed to prevent fraud, kickbacks, self-dealing and other abusive practices, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act, which may constrain the business or financial arrangements and relationships through which such companies sell, market and distribute pharmaceutical products. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive and other business arrangements. We may also be subject to federal, state and foreign laws governing the privacy and security of individual identifiable health information and other personally identifiable information. For more information, see the section titled "Business—Government regulation—Other Healthcare Laws and Compliance Requirements" included in this Annual Report on Form 10-K.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Ensuring business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time- and resource-consuming and can divert a company's attention from the business.

The failure to comply with any of these laws or regulatory requirements subjects entities to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, possible exclusion from participation in federal and state funded healthcare programs, contractual damages and the curtailment or restructuring of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws. Any action for violation of these laws, even if successfully defended, could cause a pharmaceutical manufacturer to incur significant legal expenses and divert management's attention from the operation of the business. Prohibitions or restrictions on sales or withdrawal of future marketed products could materially affect business in an adverse way.

Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available, it is possible that some of our business activities, or our arrangements with physicians, some of whom receive stock options as compensation, could be subject to challenge under one or more of such laws. If we or our employees, independent contractors, consultants, commercial partners and vendors violate these laws, we may be subject to investigations, enforcement actions and/or significant penalties. We have adopted a code of business conduct and ethics, but it is not always possible to identify and deter employee misconduct or business noncompliance, and the precautions we take to detect and prevent inappropriate conduct may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. Efforts to ensure that our business arrangements will comply with applicable healthcare laws may involve substantial costs. It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and 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, including the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements and/or oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Risks Related to Data Privacy and Security

Data collection is governed by restrictive regulations governing the use, processing, and cross-border transfer of personal information.

We are subject to stringent privacy and data protection requirements and these requirements may become more complex as we grow our business and begin to operate in other jurisdictions. For example, the collection, use, storage, disclosure, transfer, or other processing of personal data regarding individuals in the European Economic Area, or the EEA, including personal health data, is subject to the EU General Data Protection Regulation, or the EU GDPR, and similarly, processing of personal data regarding individuals in the UK is subject to the UK General Data Protection Regulation and the UK Data Protection Act 2018, or the UK GDPR, and together with the EU GDPR, or the GDPR. The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to having a legal basis or condition for processing personal data, stricter requirements relating to the processing of sensitive data (such as health data), where required by the GDPR 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, requiring data protection impact assessments for high risk processing and taking certain measures when engaging third-party processors. The GDPR also imposes strict rules on the transfer of personal data to countries outside the EEA/UK, including the United States, and permits data protection authorities to impose large penalties for violations of the GDPR, including potential fines of up to €20 million (£17.5 million under UK GDPR) or 4% of annual global revenues, whichever is greater. The GDPR 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 includes restrictions on cross-border data transfers of personal data to countries outside the EEA/UK that are not considered by the European Commission and UK government as providing "adequate" protection to personal data, or third countries, including the United States. The GDPR may increase our responsibility and liability in relation to personal data that we process where such processing is subject to the GDPR, and we may be required to put in place additional mechanisms to ensure compliance with the GDPR, including as implemented by individual countries. Compliance with the GDPR is rigorous and time-intensive process that may increase our cost of doing business or require us to change our business practices, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with our European activities.

To enable the transfer of personal data outside of the EEA or the UK, adequate safeguards (for example, the European Commission approved Standard Contractual Clauses, or SCCs and the UK International Data Transfer Agreement/Addendum, or UK IDTA) must be implemented in compliance with European and UK data protection laws. In addition, transfers made pursuant to the SCCs (and other similar appropriate transfer safeguards) need to be

assessed on a case-by-case basis taking into account the legal regime applicable in the destination country, in particular regarding applicable surveillance laws and relevant rights of individuals with respect to the transferred personal data, to ensure an "essentially equivalent" level of protection to that guaranteed in the EEA in the jurisdiction where the data importer is based, or the Transfer Impact Assessment. Further, the EU and United States have adopted its adequacy decision for the EU-U.S. Data Privacy Framework, or the Framework, which entered into force on July 11, 2023. This Framework provides that the protection of personal data transferred between the EU and the United States is comparable to that offered in the EU. This provides a further avenue to ensuring transfers to the United States are carried out in line with GDPR. There has been an extension to the Framework to cover UK transfers to the United States. The Framework could be challenged like its predecessor frameworks. We are required to implement these safeguards and carry out Transfer Impact Assessments when conducting restricted data transfers under the GDPR and doing so will require significant effort and cost, and may result in us needing to make strategic considerations around where EEA or UK personal data is stored and transferred, and which service providers we can utilize for the processing of EEA/UK personal data. Although the UK is regarded as a third country under the EU GDPR, the European Commission has issued a decision recognizing the UK as providing adequate protection under the EU GDPR, or the Adequacy Decision, and, therefore, transfers of personal data originating in the EEA to the UK remain unrestricted. The UK government has confirmed that personal data transfers from the UK to the EEA remain free flowing.

Despite Brexit, the UK and EEA data protection regimes remain largely aligned. However, going forward, there is increasing risk for divergence in application, interpretation and enforcement of the data protection laws as between the UK and EEA, creating additional regulatory uncertainty. For example, the UK Data (Use and Access) Act 2025 ("UK Act"), now in force, further differentiates the UK's data protection regime. In December 2025, the European Commission adopted a decision determining that the UK continues to provide a level of data protection that is "essentially equivalent" to the EU standards and extended the validity of the UK adequacy decision for six years, through December 2031. While this renewal reduces immediate adequacy concerns, uncertainty remains regarding how UK data protection laws will evolve in the medium to longer term. The lack of clarity on future UK laws and regulations and their interaction with EU laws and regulations may affect our efforts to maintain a harmonized approach to processing European personal data and expose us to two parallel regimes where the UK GDPR and EU GDPR both apply with differing interpretation and enforcement approaches. This could increase our legal risk, uncertainty, complexity and compliance cost associated with the handling of European personal data, and may require us to adapt our privacy and data security compliance programs to account for legal and regulatory divergence between the UK and EEA.

In the EEA, the NIS 2 Directive ("NIS 2") is replacing the cybersecurity legal framework under the current NIS framework, aiming to ensure a high level of cybersecurity in the region. NIS 2 brings new medium and large organisations providing services in the EEA within scope of the legal framework. It extends to additional sectors and expands the list of in-scope healthcare organisations, including to certain providers engaged in research and development of medicinal products. The new regime imposes direct obligations on management in respect of an in-scope organization's compliance with NIS 2, requires covered organisations to put in place certain cyber risk management measures, strengthens incident reporting requirements and provides supervisory authorities with a greater oversight. The majority of obligations will come into force when national legislation implementing NIS 2 becomes effective in the relevant EU Member State. EU Member States had until 17 October 2024 to transpose NIS 2 into national legislation, although many countries have still not completed the transposition. As such, the cybersecurity regulatory landscape in the EU is currently fragmented and uncertain. Although we are not currently subject to NIS 2, we have evaluated its requirements and have already implemented various cybersecurity measures that align with NIS 2 obligations. To the extent that we become subject to NIS 2 in the future, we will continue working closely with our Data Protection Officer to ensure that our compliance programs are fully aligned with NIS 2 and national implementing legislation where applicable. Under NIS 2 companies may be subject to administrative fines of up to the higher amount of €10 million or 2% of worldwide turnover.

In the United States, there has been a flurry of legislative activity related to privacy at the state level. In California, for example, the California Consumer Privacy Act, or CCPA, broadly defines personal information, creates comprehensive individual privacy rights and protections for California consumers (as defined in the law), places increased privacy and security obligations on entities handling personal data of consumers or households, and provides for civil penalties for violations and a private right of action for data breaches. The CCPA requires covered companies to provide certain disclosures to consumers about their data collection, use and sharing practices, and to provide affected California residents with ways to opt-out of certain sales or transfers of personal information. The California Privacy Rights Act, or CPRA, effective January 1, 2023, significantly modified the CCPA, including by expanding

consumers' rights with respect to certain sensitive personal information. The CPRA also created a state agency vested with authority to implement and enforce the CCPA. While there is an exception for protected health information that is subject to HIPAA and clinical trial regulations, the effects of the CCPA, as amended by the CPRA are potentially significant and may require us to modify our data collection or processing practices and policies and to incur substantial costs and expenses in an effort to comply and decrease our potential exposure to regulatory enforcement and/or litigation.

Numerous other states have enacted similarly comprehensive privacy laws, adding additional complexity, variation in requirements, restrictions and potential legal risk, requiring additional investment of resources in compliance programs. These laws impact our strategies, the availability of previously useful data and could result in increased compliance costs and/or changes to our business practices and policies. The existence of comprehensive privacy laws in different states in the country make our compliance obligations more complex and costly and may increase the likelihood that we may be subject to enforcement actions or otherwise incur liability for noncompliance. There are also states that are specifically regulating health information. For example, Washington state passed a health privacy law that regulates the collection and sharing of health information, and the law also has a private right of action, which further increases the relevant compliance risk. Connecticut and Nevada have also passed similar laws regulating consumer health data. In addition, other states have proposed and/or passed legislation that regulates the privacy and/or security of certain specific types of information. For example, a small number of states have passed laws that regulate genetic data and biometric data specifically. These various privacy and security laws may impact our business activities, including our identification of research subjects, relationships with business partners and ultimately the marketing and distribution of our products. State laws are changing rapidly and there is discussion in the U.S. Congress of comprehensive federal data privacy laws to which we may could become subject, if enacted.

At the federal level, failing to take appropriate steps to keep consumers' personal information secure constitutes unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act ("FTC Act"). The FTC's current guidance for appropriately securing consumers' personal information is similar to what is required by the HIPAA security regulations, but this guidance may change in the future, resulting in increased complexity and the need to expend additional resources to ensure we are complying with the FTC Act. Moreover, regulators and legislators are increasingly scrutinizing and restricting certain personal data transfers and transactions involving foreign countries. For example, the Department of Justice's January 8, 2025, rule on "Preventing Access to U.S. Sensitive Personal Data and Government-Related Data by Countries of Concern or Covered Persons," prohibits data brokerage transactions involving certain sensitive personal data categories, including health data, genetic data, and biospecimens, to countries of concern, including China. The regulations also restrict certain investment agreements, employment agreements and vendor agreements involving such data and countries of concern, absent specified cybersecurity controls. Similar state laws regulating health and genetic data and public procurement may also restrict transfers of data to, or partnerships with entities, outside the U.S. Actual or alleged violations of these regulations may be punishable by criminal and/or civil sanctions and may result in exclusion from participation in federal and state programs.

All of these evolving compliance and operational requirements impose significant costs, such as costs related to organizational changes, implementing additional protection technologies, training employees and engaging consultants and legal advisors, which are likely to increase over time. Further, various other jurisdictions around the world continue to propose new and/or amended laws that regulate the privacy and/or security of certain types of personal data. Complying with these laws, if enacted, would require significant resources and leave us vulnerable to possible fines and penalties if we are unable to comply. The regulatory framework governing the collection, processing, storage, use and sharing of certain information is rapidly evolving and is likely to continue to be subject to uncertainty and varying interpretations. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our existing data management practices or the features of our services and platform capabilities. Compliance with the above and any other applicable privacy and data security laws and regulations is a rigorous and time-intensive process, and we may be required to put in place additional mechanisms ensuring compliance with the new data protection rules, modify our data processing practices and policies, utilize management's time and/or divert resources from other initiatives and projects. Any failure or perceived failure by us, or any third parties with which we do business, to comply with our posted privacy policies, evolving laws, rules and regulations, industry standards, or contractual obligations to which we or such third parties are or may become subject, may result in actions or other claims against us by governmental entities or private actors, the expenditure of substantial costs, time and other resources or the incurrence of significant fines, penalties or other liabilities. In

addition, any such action, particularly to the extent we were found to be guilty of violations or otherwise liable for damages, would damage our reputation and adversely affect our business, financial condition and results of operations.

If our security measures or those of our contractors, consultants or other service providers are breached or unauthorized access to confidential and/or proprietary information or other sensitive information, including individually identifiable health information or other personally identifiable information, is otherwise obtained, our reputation may be harmed, and we may incur significant liabilities.

We and the third parties upon which we rely face a variety of evolving threats, which could cause cybersecurity incidents or data breaches, which, could result in unauthorized access to systems and data, loss of data, and compromise, misuse, or corruption of such data and information. The systems of any CMOs that we may engage now or in the future, and present and future CROs, contractors, consultants and other service providers also could experience breaches or cybersecurity incidents leading to the exposure of confidential and sensitive information. Despite the implementation of security measures, our internal computer systems and information technology systems and infrastructure and those of our third party CROs, vendors, and other contractors and consultants upon which our business relies are vulnerable to breakdown or damage or interruption from, among other things, natural disasters, terrorism, war, telecommunication and electrical failures, and sophisticated cyber attacks, including the theft, fraud, and subsequent misuse of employee credentials, wrongful conduct by insider employees or vendors, denial-of-service attacks, ransomware attacks, business email compromises, computer malware, malicious codes, viruses, breakdown, wrongful intrusions, data breaches, and social engineering (including phishing attacks). Such threats are prevalent and continue to rise, are increasingly difficult to detect, and come from a variety of sources. Because the techniques used by computer programmers who may attempt to penetrate and sabotage our information technology systems and infrastructure, network security or our website change frequently and may not be recognized until launched against a target, we may be unable to anticipate these techniques or to adequately prevent or address them. Attempts to disrupt or gain unauthorized access to our and our third-party vendors' information systems from malicious third parties or insider threats may be enhanced or facilitated by evolving technologies, including artificial intelligence.

It is also possible that unauthorized access to our confidential and/or proprietary information or other sensitive information, including customer or employee information, may be obtained through inadequate use of security controls by customers, suppliers or other vendors. We rely on such third parties to implement effective security measures and identify and correct for any failures, deficiencies, compromises or breaches.

In the event of a cybersecurity incident or data breach, our company could be required to provide legal notifications and disclosures, and could suffer loss of business, severe reputational damage adversely affecting investor confidence, regulatory inquiries, investigations and orders, litigation, indemnity obligations, damages for contract breach, penalties and fines for violation of applicable laws or regulations, significant costs for remediation and other liabilities. For example, the loss of preclinical study or clinical trial data from completed or future preclinical studies or clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security compromise or breach were to result in a loss or misappropriation of, or damage to, our data, systems, or applications, or inappropriate disclosure of confidential or proprietary information or other sensitive information, we could incur liability and the further development and commercialization of our product candidates could be delayed.

We have incurred and expect to incur significant expenses to prevent cybersecurity incidents and data breaches, including costs related to deploying additional personnel and protection technologies, training employees, and engaging third-party solution providers and consultants. Although we expend significant resources to create security protections that are designed to shield our confidential and/or proprietary information or other sensitive information, including customer data, against potential theft and security compromises or breaches, such measures cannot provide absolute security. Moreover, as we outsource more of our information systems to vendors and rely more on cloud-based information systems, the related security risks will increase, and we will need to expend additional resources to protect our technology and information systems.

Like other companies in our industry, we, and our third party vendors, have experienced and will continue to experience threats and cybersecurity incidents relating to our information technology systems and infrastructure. We remain at risk for future cybersecurity incidents and data breaches, including, without limitation, those that may occur as a result of third-party action, or wrongful conduct by insider employees or vendors or malfeasance and other causes. If, in the future, we experience a data breach or security incident, we could experience harm to our reputation, financial performance, and customer and vendor relationships. Further, we could experience possible legal notifications and

disclosures, as well as litigation or regulatory investigations or actions by state and federal governmental authorities and non-U.S. authorities, including fines, penalties, and other legal and financial exposure and liabilities. Additionally, actual, potential or anticipated attacks or compromises may cause us to incur increasing costs, including costs to deploy additional personnel and protection technologies, train employees, conduct security incident investigation or remediation and engage third-party experts and consultants.

Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our privacy and data security obligations. Further, although we maintain cyber liability insurance, this insurance may not provide adequate coverage against potential liabilities related to any experienced cybersecurity incident or breach.

Interruptions in the availability of server systems or communications with internet or cloud-based services, or failure to maintain the security, confidentiality, accessibility or integrity of data stored on such systems, could harm our business.

We rely upon a variety of internet service providers, third-party web hosting facilities and cloud computing platform providers to support our business. Failure to maintain the security, confidentiality, accessibility or integrity of data stored on or processed by such systems could result in interruptions in our operations, damage our reputation in the market, increase our service costs, cause us to incur substantial costs, subject us to liability for damages and/or fines, and divert our resources from other tasks, any one of which could materially adversely affect our business, financial condition, results of operations and prospects. If our security measures or those of our third-party data center hosting facilities, cloud computing platform providers, or third-party service partners, are breached, and unauthorized access is obtained to or there is misuse of our data or our information technology systems, we may incur significant legal and financial exposure and liabilities.

We also do not have control over the operations of the facilities of our cloud service providers and our third-party web hosting providers, and they also may be vulnerable to damage, security compromise or interruption from natural disasters, cybersecurity attacks, terrorist attacks, power outages and similar events or acts of misconduct. In addition, any changes in these providers' service levels may adversely affect our ability to meet our requirements and operate our business.

Our use of new and evolving technologies, such as artificial intelligence, may present risks and challenges that can impact our business, including by posing cybersecurity and other risks to our confidential and/or proprietary information, including personal information, and as a result we may be exposed to reputational harm and liability.

We may use and integrate artificial intelligence (AI) into our business processes both in our own development and implementation of AI and through the adoption of commercially available tools. Use of this technology could pose cybersecurity, data privacy, IT, intellectual property, regulatory, legal, operational, competitive, reputational and other risks and challenges that could affect our business. Specifically, risks related to accuracy, bias, AI hallucinations, discrimination, harmful content, misinformation, fraud, scams, targeted attacks (including model poisoning or data poisoning), surveillance, data leakage, inequality, environmental harms, and other harms may flow from our development, use, or deployment of AI technologies.

The rapid evolution of AI will require the application of significant resources to design, develop, test and maintain such systems to help ensure that AI is implemented in accordance with applicable law and regulation and in a socially responsible manner and to minimize any real or perceived unintended harmful impacts. If we enable or offer solutions that draw controversy due to perceived or actual negative societal impact, we may experience brand or reputational harm, competitive harm or legal liability. Additionally, the use of certain AI technology can give rise to intellectual property risks, including by disclosing or otherwise compromising our confidential or proprietary intellectual property and intellectual property infringement, or by undermining our ability to assert or defend ownership rights in intellectual property created with the assistance of AI tools.

Moreover, a growing number of legislators and regulators are adopting laws and regulations and have focused enforcement efforts on the adoption of AI and use of such technologies in compliance with ethical standards and societal expectations. These developments may increase our compliance burden and costs in connection with use of AI and lead to legal liability if we fail to meet evolving legal standards or if use of such technologies results in harms or other causes of action we did not predict. For example, the EU began implementing the Artificial Intelligence Act, or AI Act, on August 1, 2024, with a significant part of the law scheduled to come into effect in August 2026. As

currently enacted, the AI Act, which may be amended as part of the EU's Digital Omnibus, imposes significant obligations on providers and deployers of high-risk AI systems, and encourages providers and deployers of AI systems to account for EU ethical principles in their development and use of these systems. The scope of requirements depends on judicial interpretations and forthcoming legislative amendments, and non-compliance can lead to significant fines.

In the U.S., the AI regulatory environment is complex and uncertain. Over the past year, states have advanced, and in some cases passed, dozens of laws focusing on AI governance and regulation, including on deployment of AI in healthcare settings. At the federal level, the FDA has advanced guidance and proposed frameworks for regulating AI in drug discovery, marketing submissions, and medical device development. At the same time, the Trump Administration has endorsed a federal moratorium on the enforcement of state AI laws, including through a December 11, 2025, executive order on "Ensuring a National Policy Framework for Artificial Intelligence." So far, these efforts have not been successful at curtailing state action on AI regulation, contributing to a complicated legislative patchwork, which may be litigated in state and federal courts. If we develop or use AI systems that are governed by the these laws or regulations, we will need to meet higher standards of data quality, transparency, and human oversight, and we would need to adhere to specific and potentially burdensome and costly ethical, accountability, and administrative requirements. We may also be subject to significant enforcement or litigation in the event of any perceived non-compliance.

The rapid evolution of AI will require the application of significant resources to design, develop, test and maintain our products and services to help ensure that AI is implemented in accordance with applicable law and regulation and in a socially responsible manner and to minimize any real or perceived unintended harmful impacts. Our vendors may in turn incorporate AI tools into their offerings, and the providers of these AI tools may not meet existing or rapidly evolving regulatory or industry standards, including with respect to privacy and data security. Any of these effects could damage our reputation, result in the loss of valuable property and information, cause us to breach applicable laws and regulations, and adversely impact our business. Bad actors around the world also use increasingly sophisticated methods, including the use of AI, to engage in illegal activities involving the theft and misuse of personal information, confidential information and intellectual property. In addition, the use of generative AI models in our internal or third-party systems may create new attack surfaces or methods for adversaries, which could impact us and our vendors. Any of these effects could damage our reputation, result in the loss of valuable property and information, cause us to breach applicable laws and regulations, and adversely impact our business.

Risks Related to Ownership of Our Common Stock

Risks Related to Ownership Generally

Our principal stockholders and management own a large percentage of our stock and could be able to exert significant control over matters subject to stockholder approval.

As of December 31, 2025, our executive officers, directors, and 5% stockholders beneficially owned, in the aggregate, approximately 40% of our common stock. Accordingly, these stockholders could have the ability to influence us through this ownership position and may be able to determine the outcome of certain matters requiring stockholder approval. For example, these stockholders may be able to control the outcome of elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders.

If we fail to establish and maintain proper and effective internal control over financial reporting, our operating results and our ability to operate our business could be harmed.

As a public company, we are required to maintain internal control over financial reporting and to report any material weaknesses in such internal controls. The Sarbanes-Oxley Act requires that we evaluate and determine the effectiveness of our internal control over financial reporting and, beginning with our second annual report following our initial public offering, provide a management report on internal control over financial reporting. However, while we remain a smaller reporting company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm.

Ensuring that we have adequate internal financial and accounting controls and procedures in place so that we can produce accurate financial statements on a timely basis is a costly and time-consuming effort that needs to be re-evaluated frequently. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with generally accepted accounting principles. In compliance with Section 404 of the Sarbanes-Oxley Act, we will continue to dedicate internal resources, continue to engage outside consultants, and maintain a detailed work plan to assess and document the adequacy of internal control over financial reporting. Additionally, we will enhance control processes as needed, validate their effectiveness through testing, and implement a continuous monitoring and improvement process.

Implementing any appropriate changes to our internal controls may distract our officers and employees, entail substantial costs to modify our existing processes, and take significant time to complete. These changes may not, however, be effective in maintaining the adequacy of our internal controls, and any failure to maintain that adequacy, or consequent inability to produce accurate financial statements on a timely basis, could increase our operating costs and harm our business. In addition, investors' perceptions that our internal controls are inadequate or that we are unable to produce accurate financial statements on a timely basis may harm our stock price and make it more difficult for us to effectively market and sell our service to new and existing customers.

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

The dual class structure of our common stock may limit your ability to influence corporate matters. Holders of our common stock are entitled to one vote per share, while holders of our non-voting common stock are not entitled to any votes. Nonetheless, each share of our non-voting common stock may be converted at any time into one share of our common stock at the option of its holder by providing written notice to us, subject to the limitations provided for in our amended and restated certificate of incorporation. Additionally, stockholders who hold, in the aggregate, more than 10% of our common stock and non-voting common stock, but 10% or less of our common stock, and are not otherwise a company insider, may not be required to report changes in their ownership due to transactions in our non-voting common stock pursuant to Section 16(a) of the Exchange Act, and may not be subject to the short-swing profit provisions of Section 16(b) of the Exchange Act. No shares of non-voting common stock are currently outstanding.

Sales of a substantial number of shares of our common stock by our existing stockholders in the public market could cause our stock price to fall.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. Certain holders of our common stock have rights, subject to conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares held by affiliates, as defined in Rule 144 under the Securities Act. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock.

Risks Related to our Charter and Bylaws

Anti-takeover provisions under our charter documents and Delaware law could delay or prevent a change of control which could limit the market price of our common stock and may prevent or frustrate attempts by our stockholders to replace or remove our current management.

Our amended and restated certificate of incorporation and amended and restated bylaws, as amended, or the amended and restated bylaws, contain provisions that could delay or prevent a change of control of our company 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 the board 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 the board of directors, the chief executive officer, 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 the holders of not less than 75% of the votes that all our stockholders would be entitled to cast in an annual election of directors;
- a requirement of approval of not less than 75% of all outstanding shares of our voting stock to amend any bylaws by stockholder action or to amend specific provisions of our amended and restated certificate of incorporation; and
- the authority of the board of directors to issue preferred stock on terms determined by the board of directors without stockholder approval and which preferred stock may include rights superior to the rights of the holders of common stock.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporate Law, 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 amended and restated certificate of incorporation and amended and restated 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 the then-current board of directors and could also delay or impede a merger, tender offer or proxy contest involving our company. 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 amended and restated bylaws designate certain courts as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or employees.

Pursuant to our amended and restated bylaws, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware is the sole and exclusive forum for state law claims for: (i) any derivative action or proceeding brought on our behalf; (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers, or other employees to us or our stockholders; (iii) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law or our amended and restated certificate of incorporation or amended and restated bylaws (including the interpretation, application or validity thereof); or (iv) any action asserting a claim governed by the internal affairs doctrine (the Delaware Forum Provision). The Delaware Forum Provision will not apply to any causes of action arising under the Securities Act of 1933, as amended (the Securities Act) or the Securities Exchange Act of 1934. Our amended and restated bylaws further provide that, unless

we consent in writing to the selection of an alternative forum, the federal district courts of the United States of America are the sole and exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, or the rules and regulations promulgated thereunder, or the Federal Forum Provision. In addition, our amended and restated bylaws provide that any person or entity purchasing or otherwise acquiring any interest in shares of our common stock is deemed to have notice of and consented to the foregoing Delaware Forum Provision and Federal Forum Provision; provided, however, that stockholders cannot and will not be deemed to have waived our compliance with the U.S. federal securities laws and the rules and regulations thereunder.

The Delaware Forum Provision and the Federal Forum Provision may impose additional litigation costs on stockholders in pursuing any such claims. Additionally, these forum selection clauses may limit our stockholders' ability to bring a claim in a judicial forum that they find favorable for disputes with us or our directors, officers or employees, which may discourage the filing of lawsuits against us and our directors, officers and employees even though an action, if successful, might benefit our stockholders. In addition, 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. While the Delaware Supreme Court and other states have upheld the validity of federal forum selection provisions purporting to require claims under the Securities Act be brought in federal court, there is uncertainty as to whether other courts will enforce our Federal Forum Provision. If the Federal Forum Provision is found to be unenforceable, we may incur additional costs with resolving such matters. The Federal Forum Provision may also impose additional litigation costs on us and/or our stockholders who assert that the provision is invalid or unenforceable. The Court of Chancery of the State of Delaware or the federal district courts of the United States of America may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments may be more or less favorable to us than our stockholders.

Risks Related to Tax

Changes in tax laws could adversely affect our business and financial condition.

The rules dealing with U.S. federal, state, and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect us or holders of our common stock. For example, the OBBBA was signed into law on July 4, 2025 and made significant changes to U.S. federal tax law. In recent years, many such changes have been made and changes are likely to continue to occur in the future. Future changes in tax laws could have a material adverse effect on our business, cash flow, financial condition or results of operations. Prospective investors in our common stock should consult with their legal and tax advisors with respect to potential changes in tax laws and the tax consequences of investing in or holding our common stock.

As of December 31, 2025, we had U.S. federal, state and local net operating loss, or NOL, carryforwards of $319.9 million, $255.1 million and $257.6 million, respectively. $0.3 million of the federal amounts expire in 2037. The state NOLs begin to expire in 2037 and the local NOLs begin to expire in 2042. Approximately $319.6 million of the federal NOLs can be carried forward indefinitely. Certain NOL carryforwards could expire unused and be unavailable to offset future taxable income. In addition, in general, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, and corresponding provisions of state law, a corporation that undergoes an "ownership change" is subject to limitations on its ability to utilize its pre-change NOL carryforwards or tax credits to offset future taxable income or taxes. For these purposes, an ownership change generally occurs where the aggregate stock ownership of one or more stockholders who own at least 5% of a corporation's stock increases its ownership by more than 50 percentage points (by value) over its lowest ownership percentage within a specified testing period. Our existing NOLs or tax credits may be subject to limitations arising from previous ownership changes. In addition, future changes in our stock ownership, many of which are outside of our control, could result in an ownership change under Sections 382 and 383 of the Code and further limit our ability to utilize NOLs or tax credits. Our NOLs or tax credits may also be impaired under state law. Accordingly, we may not be able to utilize a material portion of our NOLs or tax credits. Furthermore, our ability to utilize our NOLs or tax credits is conditioned upon our attaining profitability and generating U.S. federal and state taxable income. As described above under "—Risks Related to Our Financial Condition and Capital Requirements", we have incurred significant net losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future; and therefore, we do not know whether or when we will generate the U.S. federal or state taxable income necessary to utilize our NOLs or tax credits. Under current law, U.S. federal NOL carryforwards generated in taxable years beginning after December 31, 2017 will not be subject

to expiration. However, any such NOL carryforwards may only offset 80% of our annual taxable income in taxable years beginning after December 31, 2020.

General Risk Factors

Adverse developments affecting the financial services industry could adversely affect our current and projected business operations and our financial condition and results of operations.

Adverse developments that affect financial institutions, such as events involving liquidity that are rumored or actual, have in the past and may in the future lead to market-wide liquidity problems. For example, on March 10, 2023, Silicon Valley Bank was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation as receiver. Although we assess our banking relationships as we believe necessary or appropriate, our access to funding sources and other credit arrangements in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that us, the financial institutions with which we have credit agreements or arrangements directly, or the financial services industry or economy in general. These factors could include, among others, events such as liquidity constraints or failures, the ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, disruptions or instability in the financial services industry or financial markets, or concerns or negative expectations about the prospects for companies in the financial services industry. While it is not possible at this time to predict the extent of the impact that high market volatility and instability of the financial services industry could have on economic activity and our business in particular, the failure of other banks and financial institutions and the measures taken by governments, businesses and other organizations in response to these events could adversely impact our business, financial condition and results of operations.

Public health crises, such as a pandemic, epidemic or outbreak of other highly infectious or contagious diseases, could seriously harm our research, development and potential future commercialization efforts, increase our costs and expenses and have a material adverse effect on our business, financial condition and results of operations.

Public health crises, such as a pandemic, epidemic or outbreak of other highly infectious or contagious diseases, could adversely impact our business, the business operations of third parties on whom we rely and our ongoing or planned research and development activities. Additionally, timely enrollment in our ongoing and planned clinical trials is dependent upon clinical trial sites which may be adversely affected by global health concerns. Public health crises could result in increased adverse events and deaths in our clinical trials. Some factors from public health crises that could delay or otherwise adversely affect enrollment in the clinical trials of our product candidates, as well as our business generally, include:

- the potential diversion of healthcare resources away from the conduct of clinical trials to focus on public health crises, including the attention of physicians serving as our clinical trial investigators, hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our prospective clinical trials and the need for drugs, such as tocilizumab, and other supplies that clinical trial sites must have on hand to conduct our clinical trials to be used to address such public health crises;
- limitations on travel that could interrupt key trial and business activities, such as clinical trial site initiations and monitoring, domestic and international travel by employees, contractors or patients to clinical trial sites, including any government-imposed travel restrictions or quarantines that will impact the ability or willingness of patients, employees or contractors to travel to our clinical trial sites or secure visas or entry permissions, a loss of face-to-face meetings and other interactions with potential partners, any of which could delay or adversely impact the conduct or progress of our prospective clinical trials;
- interruption in global shipping affecting the transport of clinical trial materials, such as patient samples, investigational drug product and conditioning drugs and other supplies used in our prospective clinical trials;
- interruptions in operations at our third-party manufacturers, which could result in delays or disruptions in the supply of our current product candidates and any future product candidates; and
- business disruptions caused by potential workplace, laboratory and office closures and an increased reliance on employees working from home, disruptions to or delays in ongoing laboratory experiments and operations, product manufacturing and supply, staffing shortages, travel limitations or mass transit

disruptions, any of which could adversely impact our business operations or delay necessary interactions with local regulators, ethics committees and other important agencies and contractors.

Any of these factors, and other factors related to any such disruptions that are unforeseen, could have a material adverse effect on our business and our results of operations and financial condition. Further, uncertainty around these and related issues could lead to adverse effects on the economy of the United States and other economies, which could impact our ability to raise the necessary capital needed to develop and commercialize our product candidates.

The price of our stock may be volatile, and you could lose all or part of your investment.

The trading price of our common stock has been, and is likely to be in the future, highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. In addition to the factors discussed in this "Risk Factors" section, these factors include:

- the commencement, enrollment or results of our planned preclinical studies or clinical trials of our product candidates or any preclinical studies or future clinical trials we may conduct, or changes in the development status of our product candidates;
- our decision to initiate a preclinical study or clinical trial, not to initiate a preclinical study or clinical trial or to terminate an existing preclinical study or clinical trial;
- adverse results or delays in preclinical studies or clinical trials of our product candidates;
- 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;
- our failure to commercialize our product candidates;
- adverse regulatory decisions, including failure to receive regulatory approval of our product candidates;
- changes in laws or regulations applicable to our product candidates, including, but not limited to, clinical trial requirements for approvals;
- adverse developments concerning our manufacturers or suppliers;
- our inability to obtain adequate product supply for any licensed product or inability to do so at acceptable prices;
- our inability to establish collaborations, if needed;
- additions or departures of key scientific or management personnel;
- unanticipated serious safety concerns related to the use of our product candidates;
- introduction of new products or services offered by us or our competitors;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- our ability to effectively manage our growth;
- the size and growth of our initial target markets;
- our ability to successfully treat additional types of autoimmune diseases where B cells may play a role in initiating or maintaining disease;
- actual or anticipated variations in annual or quarterly operating results;
- our cash position;
- our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public;

- publication of research reports about us or our industry or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- publication of news reports about us or our industry;
- inappropriate disclosure of sensitive information or negative or inaccurate posts or comments about us on any social networking website;
- changes in the market valuations of similar companies;
- overall performance of the equity markets;
- sales of our common stock by us or our stockholders in the future;
- trading volume of our common stock;
- changes in accounting practices;
- ineffectiveness of our internal controls;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- significant lawsuits, including patent or stockholder litigation;
- general political and economic conditions, including inflation and tariffs;
- global health concerns; and
- other events or factors, many of which are beyond our control.

In addition, the stock market in general, and The Nasdaq Global Select Market and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations in recent years that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. Securities class action litigation has often been instituted against companies, particularly in the biopharmaceutical and life sciences industries, following periods of volatility in the market price of a company's securities. We have been subject to such a securities class action lawsuit filed in February 2022 and voluntarily dismissed by the plaintiff in October 2022, against certain of our officers and certain of our current and former directors, and may become subject to additional securities class action lawsuits in the future. This type of litigation could result in substantial costs and a diversion of management's attention and resources, which would harm our business, operating results or financial condition.

Our business is affected by macroeconomic conditions, including rising inflation, interest rates and supply chain constraints.

Various macroeconomic factors could adversely affect our business and the results of our operations and financial condition, including changes in inflation, interest rates, the risk of economic slowdown or recession in the United States, instability in the banking system, and overall economic conditions and uncertainties such as those resulting from the current and future conditions in the global financial markets, including the presidential transition in the United States. Recent supply chain constraints have led to higher inflation, which if sustained could have a negative impact on our product development and operations. If inflation or other factors were to significantly increase our business costs, our ability to develop our current pipeline and new therapeutic products may be negatively affected. Interest rates, the liquidity of the credit markets and the volatility of the capital markets could also affect the operation of our business and our ability to raise capital on favorable terms, or at all, in order to fund our operations. Similarly, these macroeconomic factors could affect the ability of our third-party suppliers and manufacturers to manufacture clinical trial materials for our product candidates.

We do not intend to pay dividends on our common stock, so any returns will be limited to the value of our stock.

We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to stockholders will therefore be limited to the appreciation of their stock.

We are a "smaller reporting company," and we cannot be certain if the reduced reporting requirements applicable to smaller reporting companies will make our common stock less attractive to investors.

We are considered a "smaller reporting company" under Rule 12b-2 of the Exchange Act. We are therefore entitled to rely on certain reduced disclosure requirements, such as an exemption from providing selected financial data and executive compensation information. These exemptions and reduced disclosures in our SEC filings due to our status as a smaller reporting company also mean our auditors are not required to review our internal control over financial reporting and may make it harder for investors to analyze our results of operations and financial prospects. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our common stock prices may be more volatile. We will remain a smaller reporting company for as long as (i) the market value of our common stock held by non-affiliates is less than $250.0 million or (ii) our annual revenue is less than $100.0 million during the most recently completed fiscal year and the market value of our common stock held by non-affiliates is less than $700.0 million as of the prior June 30.

Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

We may seek additional capital through a combination of public and private equity offerings, debt financings, strategic partnerships and alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder. The incurrence of indebtedness would result in increased fixed payment obligations and could involve certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. If we raise additional funds through strategic partnerships and alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or product candidates or grant licenses on terms unfavorable to us.

We could be subject to significant legal proceedings which may adversely affect our results of operations or financial condition.

We are subject to the risk of litigation, derivative claims, securities class actions, regulatory and governmental investigations and other proceedings, including proceedings arising from investor dissatisfaction with us or our performance or claims brought by employees, government agencies or supplies. In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and pharmaceutical companies have experienced significant stock price volatility in recent years. In addition, if any individuals acting on our behalf fails to satisfy his or her relevant legal or contractual duties, we could have liability to third parties, including the government or investors. If any claims were brought against us and resulted in a finding of substantial legal liability, the finding could materially adversely affect our business, financial condition or results of operations or cause significant reputational harm to us, which could seriously adversely impact our business. Allegations of improper conduct by private litigants or regulators, regardless of veracity, also may harm our reputation and adversely impact our ability to grow our business. Even if the allegations against us in future legal matters are unfounded or we ultimately are not held liable, the costs to defend ourselves may be significant and the litigation may subject us to substantial settlements, fines, penalties or judgments against us and may consume management's bandwidth and attention, some or all of which may negatively impact our financial condition and results of operations. Litigation also may generate negative publicity, regardless of whether the allegations are valid, or we ultimately are liable, which could damage our reputation, and adversely impact our sales and our relationship with our employees, customers, and partners. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock depends in part on the research and reports that securities or industry analysts publish about us or our business. In the event that one or more of the analysts who covers us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price may decline. If one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

The U.S. Congress or the current administration may make substantial changes to fiscal, tax, and other federal policies that may adversely affect our business.

Since the start of the current administration in 2025, there have been significant changes to U.S. trade, healthcare, immigration and government regulatory policy and additional changes are likely. For example, the U.S. government has imposed substantial tariffs on most countries throughout the world and has further threatened to continue to broadly impose tariffs, which could lead to corresponding punitive actions by the countries with which the U.S. trades. Changes to U.S. policy implemented by the U.S. Congress, the current administration or any new future administration have impacted and may in the future impact, among other things, the U.S. and global economy, international trade relations, unemployment, immigration, healthcare, taxation, the U.S. regulatory environment, inflation and other areas. Although we cannot predict the impact, if any, of these changes to our business, they could adversely affect our business. Until we know what policy changes are made, whether those policy changes are challenged and subsequently upheld by the court system and how those changes impact our business and the business of our competitors over the long term, we will not know if, overall, we will benefit from them or be negatively affected by them.

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity.

Cyber Risk Management and Strategy

We, under the oversight of the audit committee of our board of directors, have implemented and maintain a cybersecurity risk management program that is designed to identify, assess, and mitigate risks from cybersecurity threats. Our risk management is supported by various tools and technologies, including third-party security solutions, monitoring, and alerting tools, designed to monitor, identify, and address risks from cybersecurity threats.

We engage with other third-party providers and consultants to support our cyber risk management efforts, including through periodic security testing and assessments. We have a process to assess certain major third-party vendors and service providers, including through a review of responses to compliance questionnaires and contractual requirements, as appropriate.

We, like other companies in our industry, face a number of risks from cybersecurity threats in connection with our business. Although such risks have not materially affected, and we do not believe they are reasonably likely to materially affect, us, including our business strategy, results of operations or financial condition, to date, we have, from time to time, experienced threats to and security incidents related to our data and systems. For more information about the risks from cybersecurity threats we face, please see Item 1A- Risk Factors.

Governance Related to Cybersecurity Risks

Our board of directors, as a whole and through its committees, has responsibility for the periodic review and oversight of information technology risks, including risks from cybersecurity threats.

The audit committee is responsible for oversight of our cyber risk management program. The day-to-day management of the cyber program is directed by the Director of IT under the direction of the Chief Financial Officer. Currently, the Director of IT reports to the Chief Financial Officer and provides periodic updates to the Chief Financial Officer on cyber matters.

The Director of IT meets with the Chief Financial Officer periodically to discuss and review our cybersecurity risk management processes and to address matters related to potential cybersecurity and information technology risks, with input from the Company's third-party technology providers, as appropriate. The Chief Financial Officer provides periodic reports on cybersecurity and information technology matters to the audit committee, which is responsible for reviewing and overseeing the Company's risk management process, including risks from cybersecurity threats, as set forth in the audit committee charter. The audit committee periodically reports on cybersecurity risk management to the full board of directors.

Item 2. Properties.

Our corporate headquarters are located in Philadelphia, PA, where we lease 7,672 square feet of office space subject to a lease agreement that is in effect through June 30, 2026. We also have a lease consisting of approximately 13,179 square feet of laboratory space in Philadelphia, PA subject to a lease agreement that is in effect through November 15, 2026. We believe our facilities are currently adequate for us to conduct our business.

Item 3. Legal Proceedings.

From time to time, we may be involved in lawsuits, claims, investigations and proceedings, consisting of intellectual property, commercial, employment and other matters which arise in the ordinary course of business. While the outcome of any such proceedings cannot be predicted with certainty, as of December 31, 2025, we were not party to any legal proceedings that we would expect to have a material adverse impact on our financial position, results of operations or cash flow.

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.

Our common stock trades on The Nasdaq Global Select Market under the symbol "CABA". Trading of our common stock commenced on October 25, 2019, in connection with our initial public offering, or IPO. Prior to that time, there was no established public trading market for our common stock.

Stockholders

As of March 19, 2026, we had approximately 86 holders of record of our common stock. The actual number of holders of our common stock is greater than this number of record holders and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers or held by other nominees. The number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Dividend Policy

We have never declared or paid any cash dividends on our common stock. We currently intend to retain all available funds and any future earnings, if any, to fund the development and growth of our business. We do not expect to pay any cash dividends in the foreseeable future. Any future determination to pay dividends will be made at the discretion of our board of directors and will depend on various factors, including applicable laws, our results of operations, financial condition, future prospects, then applicable contractual restrictions and any other factors deemed relevant by our board of directors. Investors should not purchase our common stock with the expectation of receiving cash dividends.

Equity Compensation Plan

The information required by Item 5 of Form 10-K regarding equity compensation plans is incorporated herein by reference to Item 12 of Part III of this Annual Report on Form 10-K.

Issuer Purchases of Equity Securities

We did not purchase any of our equity securities during the period covered by this Annual Report on Form 10-K.

Recent Sales of Unregistered Securities

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 related notes appearing elsewhere in this Annual Report on Form 10-K, or this Annual Report. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the section entitled "Risk Factors," our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis. You should carefully read the section entitled "Risk Factors" to gain an understanding of the important factors that could cause actual results to differ materially from our forward-looking statements. Please also see the section entitled "Special Note Regarding Forward-Looking Statements." We do not assume any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

Overview

We are a late clinical-stage biotechnology company focused on the discovery and development of innovative engineered T cell therapies that have the potential to provide deep and durable, perhaps curative, responses with one-time administration for patients with autoimmune diseases. Our proprietary CABA®, or Cabaletta Approach to B cell Ablation platform, focuses on the CARTA approach. CARTA refers to Chimeric Antigen Receptor T cells for Autoimmunity and is designed to potentially reset the immune system. Based on clinical data reported to date, we believe our CABA® platform has the potential to safely enable complete and durable responses for a broad range of autoimmune diseases and that it has potential applicability across dozens of autoimmune diseases that we have identified, evaluated and prioritized.

Resecabtagene autoleucel, or rese-cel (formerly referred to as CABA-201), is a 4-1BB co-stimulatory domain-containing fully human CD19-CAR T construct designed to treat patients with a broad range of autoimmune diseases and our lead product candidate within the CARTA strategy. Rese-cel is designed to achieve transient and deep depletion of all B cells following a single, weight-based infusion of T cells that are engineered to express an antibody fragment that recognizes a B cell receptor expressed on the surface of all B cells. The construct is designed to allow for the deep elimination of all B cells, including all B cells that contribute to disease, with subsequent repopulation by healthy transitional, naïve B cells. This approach has demonstrated the potential to reset the immune system and result in meaningful clinical responses without chronic therapy requirements in patients. The efficacy and safety of rese-cel was recently reviewed along with all other commercial and academic constructs in development in a February 2026 *Nature Biotechnology* publication.

In December 2025, we initiated a registrational trial with rese-cel for patients with dermatomyositis or anti-synthetase syndrome. In addition, we have ongoing Phase 1/2 trials evaluating rese-cel with a standard preconditioning regimen, fludarabine and cyclophosphamide, in systemic lupus erythematosus, or SLE, in patients with active lupus nephritis, or LN, or active SLE without renal involvement, systemic sclerosis, or SSc, and generalized myasthenia gravis, or gMG. In addition to our core development program across multiple indications using standard preconditioning regimens and standard manufacturing processes with partnered Contract and Development Manufacturing Organizations, or CDMOs, based on early data from a phase 1/2 trial evaluating rese-cel without preconditioning in pemphigus vulgaris patients, we are evaluating rese-cel without preconditioning in non-renal SLE and LN patients.

In addition, in January 2026 we announced INDa clearance for rese-cel to be manufactured using an automated manufacturing platform – the Cell Shuttle™ from Cellares - offering the potential for scalability to produce rese-cel

for thousands of patients per year with minimal capital investment by the Company. The first clinical experience from these patients is expected to be presented in the first half of 2026.

Durability data from the no-preconditioning SLE, LN and PV patients as well as the patients treated with rese-cel manufactured by the Cellares Cell Shuttle™ is expected to be presented in the second half of 2026.

RESET-Myositis®

The three adult myositis subtypes, dermatomyositis, or DM, anti-synthetase syndrome, or ASyS, and immune-mediated necrotizing myopathy, or IMNM, being evaluated in the RESET-Myositis® Phase 1/2 clinical trial of rese-cel affect approximately 80,000 patients in the U.S. Myositis typically affects middle-aged individuals, particularly women, and disease is often refractory, despite existing therapies. In the United States, we believe approximately 20% to 25% of the prevalent population, or 16,000 to 20,000 people, would be potentially eligible patients for rese-cel.

The RESET-Myositis® Phase 1/2 clinical trial is designed to treat at least six patients with DM, or ASyS, at least six patients with IMNM, as well as at least six patients with juvenile idiopathic inflammatory myopathy, or JIIM, all in separate parallel cohorts, with a single weight-based dose of 1.0 x 10^6 cells/kg. We announced the FDA granted Fast Track Designation for rese-cel for the treatment of patients with dermatomyositis and Orphan Drug Designation for rese-cel for the treatment of myositis in January and February 2024, respectively. In March 2024, we announced the FDA granted Rare Pediatric Disease designation for rese-cel for juvenile dermatomyositis. In May 2025, we announced the FDA granted Regenerative Medicine Advanced Therapy, or RMAT, designation to rese-cel for the treatment of myositis.

Based on clinical data presented in October 2025 at the American College of Rheumatology, or the ACR, Convergence 2025, we have initiated a DM/ASyS registrational cohort within the RESET-Myositis® trial. There are approximately 60,000 patients with DM in the U.S. who have IVIg as their only FDA-approved treatment option and approximately 15,000 patients with ASyS in the U.S. who have no FDA-approved treatment options. Our registrational trial design includes a 16-week primary endpoint of moderate or major TIS response while off immunomodulators and on no or low-dose steroids. Based on the safety data from the phase 1/2 cohort, the protocol permits outpatient administration. In addition, we are planning for a pediatric submission in juvenile idiopathic inflammatory myopathy, or JIIM, based on data available at the time of adult submission from the ongoing Ph 1/2 cohort to support a pediatric label claim.

The planned size of 17 patients for the registrational cohort is based on the assumed treatment effect of rese-cel in DM/ASyS patients and an estimated background rate. The estimated background rate will be determined from a retrospective analysis of an external myositis patient registry and will include patients with similar inclusion criteria as those in the registrational DM/ASyS cohort. Based on comprehensive literature review to estimate the background rate, we estimate the likelihood of an active, refractory myositis patient achieving moderate or major TIS response within 16 weeks and concurrently discontinuing all immunomodulators to be less than 10%. Changes in the assumed background rate would result in a change in the number of rese-cel treated patients who would need to achieve the primary endpoint in the 17-patient registrational cohort.

The registrational cohorts will evaluate the same single, weight-based infusion of rese-cel at 1 x 10^6 cells/kg as used in the Phase 1/2 myositis cohorts with similar enrollment criteria. As presented at ACR Convergence 2025, all myositis patients in the Phase 1/2 DM/ASyS cohort with sufficient follow-up who met key registrational inclusion criteria exceeded the registrational primary endpoint, demonstrating major TIS responses with no immunomodulators. Based on discussions with the FDA, we plan to use pooled rese-cel safety data from across the entire RESET™ clinical trial program to supplement myositis specific safety data for the Biologics License Application, or BLA, submission in myositis, and the required safety database is expected to be approximately 100 autoimmune disease patients treated with the same single weight-based dose. We initiated enrollment in the registrational DM/ASyS cohort in December 2025 and anticipate BLA submission in 2027.

RESET-SLE™

SLE is a chronic, potentially severe, autoimmune disease, most commonly impacting young women between the ages of 15 and 40 with higher frequency and more severity in people of color, where the immune system attacks healthy tissue throughout the body. SLE affects an estimated up to 320,000 patients in the U.S., with LN as the most common end-organ manifestation, affecting approximately 30-40% of SLE patients.

The RESET-SLE™ Phase 1/2 clinical trial is designed to treat six SLE patients with active LN, and in a separate parallel cohort, six patients with active SLE without renal involvement, with a single weight-based dose of 1.0 x

10^6 cells/kg. In May 2023, we announced the FDA granted Fast Track Designation for rese-cel in patients with SLE and LN. In November 2025, we announced the FDA granted RMAT designation to rese-cel for treatment of SLE and LN. In January 2026, Cabaletta announced registrational cohort designs in RESET-SLE™ to evaluate the current rese-cel weight-based dose of 1 million cells/kg in a single infusion with preconditioning, including two independent, single-arm cohorts, one consisting of patients with non-renal SLE and one consisting of patients with LN each evaluating approximately 25 patients with unique endpoints in each cohort. Complete Phase 1/2 data from both cohorts is anticipated in the first half of 2026. Cabaletta will provide an update on next steps for these cohorts in 2026, subject to dose-ranging data evaluating rese-cel without preconditioning in lupus patients.

RESET-SSc™

SSc is a rare and potentially fatal chronic autoimmune disease characterized by progressive skin and internal organ fibrosis that can be life-threatening, including interstitial lung disease, pulmonary hypertension, and scleroderma renal crisis. SSc affects approximately 90,000 patients in the U.S., typically middle-aged individuals, particularly women.

The RESET-SSc™ Phase 1/2 clinical trial of rese-cel is designed to treat six patients with severe skin manifestations and six patients with severe organ involvement associated with SSc, each in separate parallel cohorts, with a single weight-based dose of 1.0 x 10^6 cells/kg. We announced the FDA granted Fast Track Designation for rese-cel for the treatment of patients with SSc to improve associated organ dysfunction and Orphan Drug Designation for rese-cel for the treatment of SSc in January and March 2024, respectively. In January 2026, Cabaletta announced the FDA granted RMAT designation to rese-cel for treatment of SSc. Complete Phase 1/2 data from both cohorts is anticipated in the first half of 2026, and we anticipate announcing the registrational cohort design for SSc in the first half of 2026.

RESET-MG™

MG is a rare autoimmune disease characterized by autoantibodies that interfere with signaling at the neuromuscular junction, leading to potentially life-threatening muscle weakness. The majority of patients with MG have autoantibodies known to be pathogenic based on their interference with proteins in the NMJ, of which the majority target AChR. gMG affects approximately 100,000 patients in the U.S. Symptoms of gMG include profound muscle weakness throughout the body, disabling fatigue, and potential shortness of breath due to respiratory muscle weakness, with risk for episodes of respiratory failure.

The RESET-MG™ Phase 1/2 clinical trial of rese-cel is designed to treat six patients with AChR-positive gMG and six patients with AChR-negative gMG, each in separate parallel cohorts, with a single weight-based dose of 1.0 x 10^6 cells/kg.

In October 2025, we announced that rese-cel was generally well tolerated across two AChR-positive and two AChR-negative patients (both seronegative; no anti-MuSK or anti-LRP4 antibodies). No CRS (cytokine release syndrome) occurred in three of four patients, and grade 2 CRS occurred in AChR-pos-2 that resolved with no sequelae. As of the September 11, 2025 data cut-off, two evaluable patients (AChR-neg-1 and AChR-neg-2) remained off immunomodulatory medication and achieved significant improvements in MG-ADL (with AChR-neg-1 achieving Minimal Symptom Expression). AChR-pos-1 is not evaluable due to use of a prohibited cytotoxic medication that may have inhibited CAR T activity and AChR-pos-2 has insufficient follow-up.

Both cohorts have been fully enrolled. Complete Phase 1/2 data from both cohorts is anticipated in the first half of 2026, and we anticipate announcing the registrational cohort design for studies in MG in mid-2026.

RESET-PV®

Pemphigus vulgaris, or PV, is an autoimmune disease that occurs when the immune system produces antibodies that attack a protein called desmoglein, or DSG. DSG normally enables skin cells and the cells lining the inside of your mouth, nose, throat, eyelids, etc. to bind tightly together. Disruption by the antibodies directed to DSG causes the painful blisters and erosions characteristic of PV. Approximately 15,000 patients in the U.S. are affected by PV.

The ongoing RESET-PV® trial is designed to evaluate rese-cel as a monotherapy without preconditioning in patients with mucosal pemphigus vulgaris, or mPV, and mucocutaneous pemphigus vulgaris, or mcPV.

In October 2025, we announced that rese-cel exhibited similar CAR T cell expansion and contraction kinetics relative to translational data reported from other RESET™ trials with preconditioning. All three patients experienced substantial depletion of B cells within the first month post-infusion, with patients 2 and 3 achieving complete

peripheral B cell depletion. In these two patients, rapid reduction in autoantibodies to desmoglein was observed and the increase in peak B cell activating factor, or BAFF, was at the low end of the range of patients dosed with rese-cel plus preconditioning from pre-infusion through the latest follow-up, suggestive of potential deep B cell depletion in the tissue. Additional follow up will be required to determine if the initial clinical effects are durable and to determine if the findings can be replicated in other autoimmune diseases. Rese-cel was generally well tolerated with no immune effector cell-associated neurotoxicity syndrome, or ICANS, reported as of the data cutoff. After infusion, patient 1 experienced transient fever (grade 1 cytokine release syndrome). Patient 2 required a course of steroids for a disease flare in the first two weeks following infusion after discontinuing immunomodulators.

PDAI activity scores have formed the basis for recent regulatory approvals in PV, and total PDAI scores in these patients were also reported to be consistent with the PDAI activity scores in the late breaking clinical trial session. PDAI improvements were most significant in the two patients who seemed to experience complete peripheral B cell depletion.

We were incorporated in April 2017 and started principal operations in August 2018. Our operations to date have been financed primarily by proceeds from the sale of convertible notes and convertible preferred stock prior to our initial public offering, or IPO, and proceeds from the sale of our common stock in public equity offerings, including our IPO, “at-the-market” offerings and follow-on offerings of shares of our common stock and pre-funded warrants. As of December 31, 2025, we had $133.6 million in cash, cash equivalents and investments.

Material Agreements

Refer to section titled "Business – Our Material Agreements" included in this Annual Report on Form 10-K for a discussion of our material agreements.

Components of Operating Results

Revenue

To date, we have not generated any revenue from product sales and do not expect to generate any revenue from the sales of products for several years, if at all. If our development efforts for our current or future product candidates are successful and result in marketing approval, we may generate revenue in the future from product sales. We cannot predict if, when or to what extent we will generate revenue from the commercialization and sale of our product candidates. We may never succeed in obtaining regulatory approval for any of our product candidates.

We may also in the future enter into license or collaboration agreements for our product candidates or intellectual property, and we may generate revenue in the future from payments as a result of such license or collaboration agreements.

Operating Expenses

Research and Development

Our research and development expenses include:

- personnel costs, which include salaries, benefits and stock-based compensation expense;
- expenses incurred under agreements with consultants and third-party contract organizations that conduct research and development activities on our behalf;
- costs related to sponsored research service agreements;
- costs related to production of preclinical and clinical materials, including fees paid to contract manufacturers;
- licensing fees for intellectual property and know-how;
- laboratory and vendor expenses related to the execution of preclinical studies and ongoing and planned clinical trials; and
- laboratory supplies and equipment used for internal research and development activities and related depreciation expense.

We have not reported program costs since inception because historically we have not tracked or recorded our research and development expenses on a pre-clinical program-by-program basis. We use our personnel and infrastructure resources across the breadth of our research and development activities, which are directed toward identifying and developing product candidates.

We expense all research and development costs in the periods in which they are incurred. Costs for certain research and development activities are recognized based on an evaluation of the progress to completion of specific tasks using information and data provided to us by our vendors and third-party service providers.

We expect our research and development expenses to increase substantially for the foreseeable future as we continue to invest in research and development activities related to developing our product candidates, including investments in manufacturing, as our programs advance and we conduct clinical trials. The process of conducting the necessary clinical research to obtain regulatory approval is costly and time-consuming, and the successful development of our product candidates is highly uncertain. As a result, we are unable to determine the duration and completion costs of our research and development projects or when and to what extent we will generate revenue from the commercialization and sale of any of our product candidates.

Because of the numerous risks and uncertainties associated with product development, we cannot determine with certainty the duration and completion costs of the current or future preclinical studies and clinical trials or if, when, or to what extent we will generate revenues from the commercialization and sale of our product candidates. We may never succeed in achieving regulatory approval for our product candidates. The duration, costs and timing of preclinical studies and clinical trials and development of our product candidates will depend on a variety of factors, including:

- successful completion of preclinical studies and IND and/or CTA-enabling studies;
- development of chemistry, manufacturing and controls, or CMC, processes and procedures for purposes of IND and/or CTA applications;
- successful patient enrollment in, and the initiation and completion of, clinical trials;
- the impact of any business interruptions to our operations, including the timing and enrollment of patients in our ongoing and planned clinical trials, or to those of our clinical sites, manufacturers, suppliers, or other vendors resulting from public health crises;
- receipt of regulatory approvals from applicable regulatory authorities;
- establishing commercial manufacturing capabilities or arrangements with third-party manufacturers;
- obtaining and maintaining patent and trade secret protection and non-patent exclusivity;
- launching commercial sales of our product candidates, if and when approved, whether alone or in collaboration with others;
- acceptance of our product candidates, if and when approved, by patients, the medical community and third-party payors;
- effectively competing with other therapies and treatment options;
- a continued acceptable safety and efficacy profile following approval;
- enforcing and defending intellectual property and proprietary rights and claims; and
- achieving desirable medicinal properties for the intended indications.

We may never succeed in achieving regulatory approval for any of our product candidates. We may obtain unexpected results from our preclinical studies and clinical trials. We may elect to discontinue, delay or modify clinical trials of some product candidates or focus on others. A change in the outcome of any of these factors could mean a significant change in the costs and timing associated with the development of our current and future preclinical and clinical product candidates. For example, if the FDA or another regulatory authority, were to require us to conduct clinical trials beyond those that we currently anticipate will be required for the completion of clinical development, or if we experience significant delays in execution of or enrollment in any of our preclinical studies or clinical trials, we could be required to expend significant additional financial resources and time on the completion of preclinical and clinical development. We expect our research and development expenses to increase for the foreseeable future as we continue the development of product candidates.

General and Administrative Expenses

Our general and administrative expenses consist primarily of personnel costs, costs related to maintenance and filing of intellectual property, depreciation expense and other expenses for outside professional services, including legal, human resources, information technology, audit and accounting services. Personnel costs consist of salaries, benefits and stock-based compensation expense. We expect our general and administrative expenses to increase over the next several years to support our continued research and development activities, manufacturing activities, increased costs of operating as a public company and the potential commercialization of our product candidates. We anticipate our general and administrative costs will increase with respect to the hiring of additional personnel, developing commercial infrastructure, fees to outside consultants, lawyers and accountants, and increased costs associated with being a public company such as expenses related to services associated with maintaining compliance with Nasdaq listing rules and the Securities and Exchange Commission, or the SEC, requirements, insurance and investor relations costs.

Other Income

Other income consists of interest earned on our cash, cash equivalents and short-term investments and amortization of bond discount or premium.

Interest Expense

Interest expense consists primarily of interest expense associated with finance lease arrangements.

Other Income, net

Other income, net primarily consists of foreign currency gains and losses and proceeds received from the sale of our Pennsylvania research and development tax credits.

Results of Operations for the years ended December 31, 2025 and 2024

The following sets forth our results of operations:

	Year Ended December 31,		Change
	2025	2024	
	(in thousands)		
Statements of Operations Data:			
Operating expenses:			
Research and development	$ 142,674	$ 97,203	$ 45,471
General and administrative	29,567	27,938	1,629
Total operating expenses	172,241	125,141	47,100
Loss from operations	(172,241)	(125,141)	(47,100)
Other income (expense):			
Interest income	6,031	10,025	(3,994)
Interest expense	(2,004)	(748)	(1,256)
Other income, net	358	—	358
Net loss	$ (167,856)	$ (115,864)	$ (51,992)

Research and Development

Research and development expenses were $142.7 million for the year ended December 31, 2025 as compared to $97.2 million for the year ended December 31, 2024. The table below summarizes our research and development expenses:

	Year Ended December 31,		Change
	2025	2024	
	(in thousands)		
Clinical trials	$ 39,581	$ 22,286	$ 17,295
Manufacturing of preclinical and clinical supplies	38,240	15,523	22,717
Personnel	46,934	39,239	7,695
Development services	15,350	16,417	(1,067)
License of intellectual property	—	1,523	(1,523)
Other	2,569	2,215	354
	$ 142,674	$ 97,203	$ 45,471

Specific changes in our research and development expenses year over year include a:

- $22.7 million increase in manufacturing costs primarily due to expanded cell processing capabilities, increase in patient enrollment and related activities, including those for commercial readiness;
- $17.3 million increase in clinical trial costs primarily due to higher enrollment and clinical trial sites across multiple clinical studies for rese-cel;
- $7.7 million increase in personnel costs primarily driven by an increase in headcount to support overall growth related to our rese-cel program, including an increase of $1.3 million in stock-based compensation expense; partially offset by a
- $1.5 million decrease in license of intellectual property costs due to a $1.5 million milestone payment to IASO in the first quarter of 2024 for the first patient dosed in the rese-cel trial; and
- $1.1 million decrease in development services due to lower spend on laboratory consumables and external research activities.

General and Administrative Expenses

General and administrative expenses were $29.5 million for the year ended December 31, 2025 as compared to $27.9 million for the year ended December 31, 2024. The increase of $1.6 million in our general and administrative expenses year over year includes:

- $1.6 million increase in personnel costs, primarily driven by higher personnel-related expenses, including a $0.2 million increase in stock-based compensation expense.

Interest Income

Interest income decreased by $4.0 million for the year ended December 31, 2025 as compared to the year ended December 31, 2024, primarily due to lower cash, cash equivalents and investment balances earning interest during 2025 as prior financing proceeds were utilized to fund operating activities, as well as reductions in interest rates on government securities.

Interest Expense

Interest expense increased $1.3 million for the year ended December 31, 2025 as compared to the year ended December 31, 2024, primarily as a result of finance lease arrangements from embedded leases within our manufacturing agreements with Minaris and Lonza.

Liquidity, Capital Resources and Going Concern

From our inception in April 2017 to the time of our initial public offering, or IPO, our operations were financed by proceeds of $86.4 million from the sale of convertible notes and our convertible preferred stock and proceeds of $71.0 million from the sale of common stock in our IPO. Since our IPO and through December 31, 2025, we have generated cash from public offerings of our common stock and pre-funded warrants to purchase our common stock resulting in aggregate net proceeds of approximately $384.0 million. As of December 31, 2025, we had $133.6 million in cash and cash equivalents which should enable us to fund our operations and capital expenditures into the fourth quarter of 2026. Cash in excess of immediate requirements is invested in accordance with our investment policy, primarily with a view to liquidity and capital preservation.

We have incurred losses since our inception and, as of December 31, 2025, we had an accumulated deficit of $517.0 million. Our primary use of cash is to fund operating expenses, which consist primarily of research and development expenditures, and to a lesser extent, general and administrative expenditures. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our outstanding prepaid expenses and other current assets, accounts payable and accrued expenses.

Any product candidates we may develop may never achieve commercialization and we anticipate that we will continue to incur losses for the foreseeable future. We expect that our research and development expenses, general

and administrative expenses, and capital expenditures will continue to increase. As a result, until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity offerings, debt financings or other capital sources, including potentially collaborations, licenses and other similar arrangements. Our primary uses of capital are, and we expect will continue to be, compensation and related expenses, third-party clinical research, manufacturing and development services, costs relating to the build-out of our headquarters, laboratories and manufacturing facility, license payments or milestone obligations that may arise, laboratory and related supplies, clinical costs, manufacturing costs, legal and other regulatory expenses and general overhead costs.

We evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about our ability to continue as a going concern within one year after the date that the consolidated financial statements are issued. Based on our current operating plan, we believe there is substantial doubt about our ability to continue as a going concern for at least twelve months following the filing of this Annual Report on Form 10-K, and we will need to obtain additional funding. Our cash forecast contains estimates and assumptions based on success of ongoing clinical trials, and we cannot predict the amount or timing of all expenditures with certainty. We will continue to seek funds through equity offerings, debt financings or other capital sources, including potentially collaborations, licenses and other similar arrangements. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. If we do raise additional capital through public or private equity offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Any failure to raise capital as and when needed could have a negative impact on our financial condition and on our ability to pursue our business plans and strategies. If we are unable to raise capital, we will need to delay, reduce or terminate certain planned activities to reduce costs.

At-The-Market Offering Sales Agreement

On March 31, 2025, we converted the Form S-3ASR to a Form S-3 (File No. 333-278126) by post-effective amendments. This Form S-3 was declared effective on March 31, 2025. We had a Sales Agreement with TD Securities (USA) LLC, as successor to Cowen and Company, LLC, or TD Cowen, to provide for the offering, issuance and sale of up to an aggregate amount of $200.0 million of common stock from time to time in "at-the-market" offerings, or the 2024 ATM Program, pursuant to its S-3, and subject to the limitations thereof. On June 11, 2025, the 2024 ATM Program with TD Cowen was terminated. Prior to termination, we sold an aggregate of 2,609,865 shares pursuant to the 2024 ATM Program for total net proceeds of $7.7 million, consisting of $5.1 million in 2024 and $2.6 million in 2025.

On August 7, 2025, we filed a Registration Statement (File No. 333-289339) with the SEC, which was declared effective on August 15, 2025, or the 2025 Shelf Registration Statement, in relation to the registration of common stock, preferred stock, debt securities, warrants and/or units of any combination thereof for the purposes of selling, from time to time, our common stock, debt securities or other equity securities in one or more offerings. We also simultaneously entered into a Sales Agreement with TD Cowen to provide for the offering, issuance and sale of up to an aggregate amount of $150.0 million of our common stock from time to time in "at-the-market" offerings, or the 2025 ATM Program, under the 2025 Shelf Registration Statement and subject to the limitations thereof, or the 2025 Sales Agreement. During the year ended December 31, 2025, we sold 4,160,176 shares pursuant to the 2025 ATM Program for net proceeds of $10.2 million. Subsequent to December 31, 2025, we sold 8,055,260 shares of common stock pursuant to the 2025 ATM Program for net proceeds of $22.6 million.

June 2025 Financing

In June 2025, we issued (i) 39,200,000 shares of our common stock and accompanying warrants to purchase an aggregate of 39,200,000 shares of common stock (or pre-funded warrants in lieu thereof) and (ii) in lieu of common stock, to certain investors, pre-funded warrants to purchase an aggregate of up to 10,800,000 shares of our common stock and accompanying warrants to purchase an aggregate of 10,800,000 shares of common stock (or pre-funded warrants in lieu thereof), at an exercise price of $0.00001 per pre-funded warrant. The combined offering price of each share of common stock and accompanying common stock warrant was $2.00. The combined offering price of each pre-funded warrant and accompanying common stock warrant was $1.99999. The pre-funded warrants were

exercisable immediately. The common stock and pre-funded warrants were sold in combination with an accompanying common stock warrant to purchase one share of common stock (or a pre-funded warrant in lieu thereof) for each share of common stock or pre-funded warrant sold. Each common stock warrant has an exercise price per share of $2.50. The common stock warrants are immediately exercisable from the date of issuance and will expire on September 12, 2026, fifteen months from the date of issuance. Aggregate net proceeds were $93.6 million after deducting underwriting discounts and commissions and offering expenses. As of December 31, 2025, 4,800,000 pre-funded warrants had been exercised and 6,000,000 remain outstanding. As of December 31, 2025, no common stock warrants had been exercised and 53,090,190 remain outstanding. Subsequent to December 31, 2025, 2,775,100 common stock warrants were exercised for proceeds of $6.9 million.

Because of the numerous risks and uncertainties associated with research, development and commercialization of pharmaceutical products, we are unable to estimate the exact amount of our operating capital requirements. Our future funding requirements will depend on many factors, including, but not limited to:

- the scope, progress, results and costs of researching, developing and manufacturing our lead product candidates or any future product candidates, and conducting preclinical studies and clinical trials;
- the timing of, and the costs involved in, obtaining regulatory approvals or clearances for our lead product candidates or any future product candidates;
- the impact of any business interruptions to our operations or to those of our clinical sites, manufacturers, suppliers, or other vendors resulting from public health crises;
- the number and characteristics of any additional product candidates we develop or acquire;
- the timing of any cash milestone payments if we successfully achieve certain predetermined milestones;
- the cost of manufacturing our lead product candidate or any future product candidates and any products we successfully commercialize, including costs associated with building-out our manufacturing capabilities;
- our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of any such agreements that we may enter into;
- the expenses needed to attract and retain skilled personnel;
- the costs associated with being a public company; and
- the timing, receipt and amount of sales of any future approved or cleared products, if any.

Further, our operating plans may change, and we may need additional funds to meet operational needs and capital requirements for clinical trials and other research and development activities. We currently have no credit facility or committed sources of capital. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated product development programs.

Cash Flows

The following table summarizes our cash flows for the periods indicated:

	Year Ended December 31,	
	2025	2024
	(in thousands)	
Net cash provided by (used in):		
Operating activities	$ (131,080)	$ (88,222)
Investing activities	(50,266)	47,289
Financing activities	100,347	11,677
Effect of exchange rate changes on cash and cash equivalents	19	(20)
Net decrease in cash and cash equivalents	$ (80,980)	$ (29,276)

Operating Activities

During the year ended December 31, 2025, cash used in operating activities of $131.1 million was attributable to our net loss of $167.9 million, partially offset by non-cash charges of $37.2 million for stock-based compensation charges, amortization of finance lease, non-cash operating lease expense, depreciation, accretion of operating lease liabilities and foreign currency exchange rates and a net change of $0.4 million in our net operating assets and liabilities.

During the year ended December 31, 2024, cash used in operating activities of $88.2 million was attributable to our net loss of $115.9 million, partially offset by non-cash charges of $26.0 million for stock-based compensation charges, amortization of finance lease, non-cash operating lease expense, depreciation, amortization of premium on investments, accretion of operating lease liabilities and foreign currency exchange rates and a net change of $1.7 million in our net operating assets and liabilities.

Investing Activities

During the year ended December 31, 2025, cash used in investing activities of $50.2 million was attributable to $99.0 million of purchases of investments and $1.2 million of purchases of property and equipment partially offset by $50.0 million from the maturity of short-term investments.

During the year ended December 31, 2024, cash provided by investing activities of $47.3 million was attributable to $49.5 million from the maturity of short-term investments, partially offset by purchases of $2.2 million of property and equipment.

Financing Activities

During the year ended December 31, 2025, cash provided by financing activities of $100.3 million was attributable to $93.6 million in sales of common stock, warrants and pre-funded warrants to purchase common stock, net of issuance costs paid, $12.7 million in sales of common stock under our 2024 ATM Program and 2025 ATM Program, net of sales agent commission and fees and $0.3 million from the purchases of shares under our 2019 Employee Stock Purchase Plan, or 2019 ESPP, offset by $6.3 million in principal payments on finance leases.

During the year ended December 31, 2024, cash provided by financing activities of $11.7 million was from $10.9 million in sales of common stock under our 2024 ATM Program, net of issuance costs paid, $1.7 million from the exercise of employee stock and purchases of shares under our 2019 ESPP, offset by $0.9 million in principal payments on finance leases.

Contractual Obligations and Commitments

We lease our headquarters office space and laboratory space under non-cancelable operating lease agreements. The lease term of our office space commenced in May 2019 and was amended in October 2024 for an additional 12 months through June 30, 2026. The lease term for our laboratory space was amended in September 2024 through August 2026 and further extended in October 2025 through November 2026. We also have embedded manufacturing leases with Minaris and Lonza, our cell processing manufacturing partners. Minaris' lease term is through August 2026 and Lonza's is for an initial 12 months with the ability to extend the manufacturing period on a rolling basis. Total undiscounted aggregate future finance and operating lease obligations under all of our leases as of December 31, 2025 are $28.8 million. See Note 9 of the consolidated financial statements for additional detail on our leases.

We have no material contractual obligations not fully recorded on our balance sheets or fully disclosed in the notes to the consolidated financial statements. Our commitments include:

- *IASO Exclusive License Agreement.* As partial consideration for the exclusive license, IASO received an upfront payment of $2.5 million. IASO is also eligible to receive up to mid double digit millions in milestone payments based upon the achievement of specified pre-clinical, development and regulatory milestones, and up to an additional low triple digit millions in milestone payments based upon achievement of specified sales milestones, for a total consideration, inclusive of the upfront payment, of up to $162 million, along with tiered mid-single digit royalties on future net sales for licensed products

that may result from the IASO Agreement. We also may sublicense through multiple tiers the rights granted to it by IASO under the IASO Agreement at any time, however, we must pay IASO a low double-digit percentage of any revenue obtained from sublicenses or options to third parties, subject to certain customary exclusions. The IASO Agreement will continue on a country-by-country, licensed product-by-licensed product basis until the expiration of the royalty term as identified in the IASO Agreement, unless earlier terminated. A milestone payment of $1.5 million was paid to IASO in the first quarter of 2024 after the first patient in a rese-cel trial was dosed.

- *Oxford Licence and Supply Agreement.* Under the terms of the agreement, we were required to pay Oxford an upfront fee, as well as costs associated with initial vector manufacturing activities for our DSG3-CAART program. In May 2023, we amended the LSA with Oxford to expand the license to include our rese-cel program for an upfront fee of $0.5 million and in August 2023, we entered into a vector supply agreement with Oxford, and a related second amendment to the LSA, for rese-cel with a total cost of up to approximately $5.0 million under the vector supply agreement. In February 2024, we and Oxford entered into a third amendment to the LSA to update the patent schedule. In June 2024, we and Oxford entered into a fourth amendment to the LSA eliminating royalties on net sales of products that incorporate the Oxford technology if Oxford manufactures the vector. Starting in December 2024, we and Oxford entered into work orders for certain process characterization and process performance qualification activities as part of commercial readiness activities. We can terminate the LSA or any work order under the LSA at will upon advance written notice and subject to certain cancellation fees.
- *Autolus Option and License Agreement.* In January 2023, we entered into an Option and License Agreement, or the Autolus Agreement, with Autolus Holdings (UK) Limited (Autolus), wherein the Autolus Agreement grants us a non-exclusive license to access Autolus' RQR8 technology in our CD19-CAR T cell therapy program, and subject to additional nominal option exercise fees, up to four additional targets. In January 2025, the Company and Autolus agreed to novate the Autolus Agreement with both Autolus and Autolus Limited jointly assuming the rights, obligations and liabilities of Autolus under the Autolus Agreement. Under the terms of the Autolus Agreement, we were required to pay Autolus an upfront license fee of $1.2 million, of which $1.1 million was paid in 2023 and $0.1 million was paid in January 2024. Autolus is also eligible to receive regulatory milestones of up to $12 million for each licensed target, sales milestones of up to a total of $15 million and royalties in the low single digits on net sales of all products that incorporate the RQR8 technology. The Autolus Agreement will continue on a country-by-country, licensed product-by-licensed product basis until the expiration of the royalty term as identified in the Autolus Agreement, unless earlier terminated. We can terminate the Autolus Agreement at will upon advance written notice. Each of Autolus and us may terminate the Agreement for a material, uncured breach or insolvency of the other party.

- *The Penn License Agreement.* Under the License Agreement, we are required to make milestone payments upon successful completion of certain development, regulatory and sales milestones on a product-by-product and geographical basis. The payment obligations under the License Agreement are contingent upon future events such as our achievement of specified development, regulatory and commercial milestones and we will be required to make development milestone payments and royalty payments in connection with the sale of products developed under the License Agreement. As of December 31, 2025, we are unable to estimate the timing or likelihood of achieving the milestones or making future product sales.
    - Under the License Agreement, we must use commercially reasonable efforts to develop and commercialize a product in each subfield. During the term of the License Agreement until the first commercial sale of the first product, we are obligated to pay Penn a non-refundable, non-creditable annual license maintenance fee of $10,000. We are required to pay certain milestone payments upon the achievement of specified clinical and commercial milestones. Milestone payments are reduced by a certain percentage for the second product that achieves a milestone, by an additional percentage for the third product that achieves a milestone, and so on, for each subsequent product that achieves a milestone. In the event that we are able to successfully develop and launch multiple products under the License Agreement, total milestone payments could be approximately $21.0 million. Penn is also eligible to receive tiered royalties at percentage rates in the low single-digits, subject to an annual minimum royalty, on annual worldwide net sales of any products that are commercialized by us or our sublicensees that contain or incorporate, or are covered by, the intellectual property licensed by us. To the extent we sublicense our license rights under the License Agreement, Penn would be eligible to receive tiered sublicense income at percentage rates in the mid-single to low double-digits. We have also entered into a subscription and technology transfer agreement with Penn, pursuant to which we owed Penn an upfront subscription fee, which was paid in 2019, and a nominal non-refundable royalty on net sales of products, a portion of which will be credited toward milestone payments and royalties under this License Agreement. Technology transfer activities would be at our cost and subject to agreement as to the technology to be transferred.
- *Minaris Manufacturing agreement*. In January 2021, we entered into the Development and Manufacturing Services Agreement, or the Minaris Agreement, to serve as an additional cell processing manufacturing partner for the MusCAARTes™ trial. In August 2023, we entered into new work orders under the Minaris Agreement for Minaris to serve as one of our cell processing manufacturing partners for the global clinical development of rese-cel in multiple indications, including potential late-stage clinical trials and commercial readiness activities for rese-cel. Under the August 2023 work orders, Minaris will convert our non-dedicated suite to a dedicated suite for GMP manufacturing for our rese-cel and MuSK-CAART programs for an initial term of 18 months with two 18 month extensions at our sole option on six months' notice prior to the end of the term. In addition, we agreed to certain monthly minimum runs. We would incur up to a $1.08 million termination fee if we terminate both the rese-cel and MuSK-CAART work orders for any reason. We may terminate for convenience the Minaris Agreement or any work order with six months' prior written notice, however, we may not terminate the Dedicated Suite without terminating both the MuSK-CAART and rese-cel GMP run work orders. In February 2026, we notified Minaris that we intend to permit the term to expire in August 2026.

- *Lonza Manufacturing agreement*. In December 2024, we entered into a Development and Manufacturing Services Agreement, or the Lonza Agreement, with Lonza to serve as one of our manufacturing partners for the global clinical development of rese-cel in multiple indications, including potential late-stage clinical trials and preparations for commercial readiness. The Lonza Agreement has a term of five years and can be extended for an additional three year term upon notice to Lonza at least 18 months prior to the expiration of the Lonza Agreement. We can terminate the Lonza Agreement at will upon nine months advance written notice to Lonza subject to the terms of the Lonza Agreement. Lonza can terminate the Lonza Agreement at will upon 24 months advance written notice to us subject to the terms of the Lonza Agreement. Under the initial work order, Lonza will perform cell therapy manufacturing activities for our CAR-T cell therapy product, rese-cel, for an initial term of 12 months with the ability to extend the manufacturing period on a rolling basis subject to the terms of the Lonza Agreement.
- *Cellares Agreement*. In January 2026, we entered into a Development and Clinical Manufacturing Services Agreement, or the Cellares Agreement, with Cellares to serve as one of our manufacturing partners for the clinical development of rese-cel in multiple indications, including potential late-stage clinical trials and preparations for commercial readiness. The Cellares Agreement has a term of five years. We can terminate the Cellares Agreement at will by providing a certain advance written notice to Cellares subject to the terms of the Cellares Agreement. Cellares can terminate the Cellares Agreement at will by providing a certain advance written notice to us subject to the terms of the Cellares Agreement. Under the initial work order, Cellares will perform clinical cell therapy manufacturing activities for our CAR-T cell therapy product, rese-cel.
- *Other Purchase Commitments*. In the normal course of business, we enter into various purchase commitments with third-party contract manufacturers for the manufacture and processing of our product candidates and related raw materials, contracts with contract research organizations for clinical trials and agreements with vendors for other services and products for operating purposes. These agreements generally provide for termination or cancellation other than for costs already incurred.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles, or GAAP. 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. We believe that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

While our significant accounting policies are described in more detail in Note 2 to our consolidated financial statements appearing elsewhere in this Annual Report, 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.

Research and Development Costs

We estimate costs of research and development activities conducted by service providers, which include the conduct of preclinical studies, contract manufacturing activities and clinical trial activities. We record the estimated costs of research and development activities based upon the estimated amount of services provided and include these costs in the accrued and other current liabilities on the balance sheets and within research and development expense on the statements of operations. Non-refundable advance payments made for goods or services that will be used or rendered for future research and development activities are deferred and capitalized and recognized as expense as the goods are received or the related services are rendered.

We estimate these costs based on factors such as estimates of the work completed and budget provided and in accordance with agreements established with our collaboration partners and third-party service providers. We make significant judgments and estimates in determining the accrued liabilities balance in each reporting period. As actual costs become known, we adjust our accrued liabilities. We have not experienced any material differences between accrued costs and actual costs incurred since our inception.

Smaller Reporting Company Status

We are a "smaller reporting company," as defined in Rule 12b-2 under the Securities Exchange Act of 1934, as amended. We would cease to be a smaller reporting company if we have a public float in excess of $250 million, or have annual revenues in excess of $100 million and a public float in excess of $700 million, determined on an annual basis. This status allows us to take advantage of many of the same exemptions from disclosure requirements including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements.

Recently Adopted Accounting Pronouncements

For a discussion of recently adopted accounting pronouncements please read Note 2, Summary of Significant Accounting Policies, to our consolidated financial statements included in this report.

Recently Issued Accounting Pronouncements

For a discussion of recently issued accounting pronouncements please read Note 2, Summary of Significant Accounting Policies, to our consolidated financial statements included in this report.

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

We are exposed to market risks in the ordinary course of our business. These risks primarily include interest rate sensitivities. We held cash and cash equivalents and investments of $133.6 million as of December 31, 2025. We generally hold our cash in interest-bearing money market treasury fund accounts and our investments are available-for-sale debt securities, which are invested in U.S. treasury securities. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. Due to the short-term maturities of our cash equivalents, an immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our cash equivalents. Declines in interest rates, however, would reduce future investment income.

We do not have any foreign currency or derivative financial instruments. Inflation generally affects us by increasing our cost of labor and program costs. Although we do not believe that inflation has had a material impact on our financial position or results of operations to date, we may experience some effect in the near future (especially if inflation rates continue to rise) due to an impact on the costs to conduct clinical trials, labor costs we incur to attract and retain qualified personnel, and other operational costs. Inflationary costs could adversely affect our business, financial condition and results of operations.

Item 8. Consolidated Financial Statements and Supplementary Data.

The consolidated financial statements required to be filed pursuant to this Item 8 are appended to this Annual Report. An index of those consolidated financial statements is found in Item 15.

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

There has been no change of accountants nor any disagreements with accountants on any matter of accounting principles or practices of financial disclosure required to be reported under this Item.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

The Company has established disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) designed to ensure that information required to be disclosed in the reports that the Company files or submits under the Securities Exchange Act of 1934, as amended, or Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and is accumulated and communicated to management, including the principal executive officer (our Chief Executive Officer) and principal financial officer (our Chief Financial Officer), to allow timely decisions regarding required disclosure. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated, as of December 31, 2025, the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). 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 and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our disclosure controls and procedures have been designed to provide reasonable assurance of achieving their objectives. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) were effective at the reasonable assurance level as of December 31, 2025.

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is a process designed to provide reasonable assurance of the reliability of financial reporting and of the preparation of consolidated financial statements for external reporting purposes, in accordance with U.S. generally accepted accounting principles.

Internal control over financial reporting includes policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect transactions and disposition of assets; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of consolidated financial statements in accordance with U.S. generally accepted accounting principles, and that receipts and expenditures are being made only in accordance with the authorization of its management and directors; and (3) provide reasonable assurance regarding the prevention or timely detection of unauthorized acquisition, use, or disposition of our assets that could have a material effect on its consolidated financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of the effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies and procedures included in such controls may deteriorate.

Our management has assessed the effectiveness of our internal control over financial reporting as of December 31, 2025. In making this assessment, management used the criteria established by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control - Integrated Framework (2013). These criteria are in the areas of control environment, risk assessment, control activities, information and communication, and monitoring. Management's assessment included extensive documentation, evaluating and testing the design and operating effectiveness of its internal controls over financial reporting.

Based on management's processes and assessment, as described above, management has concluded that, as of December 31, 2025, our internal control over financial reporting was effective.

Attestation Report of the Registered Public Accounting Firm

As a non-accelerated filer, we are not required to provide an attestation report of our independent registered public accounting firm on the effectiveness of our internal control over financial reporting.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting (as defined in Rule 13a-15(f) of the Exchange Act) that occurred during the fiscal quarter ended December 31, 2025 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

Rule 10b5-1 Trading Plans

During the fiscal quarter ended on December 31, 2025, none of our directors and officers (as defined in Rule 16a-1(f) under the Exchange Act) adopted, modified or terminated a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," as those terms are defined in Item 408(a) of Regulation S-K.

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

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Except as set forth below, the information required by this item is incorporated by reference from our definitive Proxy Statement to be filed with the SEC in connection with our 2026 Annual Meeting of Stockholders within 120 days after the end of the fiscal year ended December 31, 2025.

We have adopted a Code of Business Conduct and Ethics that applies to all of our directors, officers and employees, including our principal executive officer and principal financial officer. The Code of Business Conduct and Ethics is posted on our website at http://investors.cabalettabio.com/corporate-governance/governance-highlights.

We intend to satisfy the disclosure requirement under Item 5.05 of Form 8-K regarding an amendment to, or waiver from, a provision of this Code of Business Conduct and Ethics by posting such information on our website, at the address and location specified above and, to the extent required by the listing standards of The Nasdaq Global Select Market, by filing a Current Report on Form 8-K with the SEC, disclosing such information.

Item 11. Executive Compensation.

The information required by this Item 11 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2026 Annual Meeting of Stockholders within 120 days after the end of the fiscal year ended December 31, 2025 and is incorporated herein by reference.

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

The information required by this Item 12 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2026 Annual Meeting of Stockholders within 120 days after the end of the fiscal year ended December 31, 2025 and is incorporated herein by reference.

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

The information required by this Item 13 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2026 Annual Meeting of Stockholders within 120 days after the end of the fiscal year ended December 31, 2025 and is incorporated herein by reference.

Item 14. Principal Accounting Fees and Services.

The information required by this Item 14 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2026 Annual Meeting of Stockholders within 120 days after the end of the fiscal year ended December 31, 2025 and is incorporated herein by reference.

Our independent public accounting firm is Ernst & Young, Philadelphia, PA, PCAOB Auditor ID 42.

PART IV

Item 15. Exhibits, Consolidated Financial Statement Schedules.

(a) The following documents are filed as part of this Annual Report on Form 10-K:

(1) Consolidated Financial Statements:

(2) Consolidated Financial Statement Schedules:

All consolidated financial statement schedules have been omitted because they are not applicable, not required or the information required is shown in the consolidated financial statements or the notes thereto.

(3) Exhibits. The exhibits required by Item 601 of Regulation S-K and Item 15(b) of this Annual Report on Form 10-K are listed in the Exhibit Index immediately preceding the signature page of this Annual Report on Form 10-K. The exhibits listed in the Exhibit Index are incorporated by reference herein.

Item 16. Form 10-K Summary

None.

INDEX TO FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Cabaletta Bio, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Cabaletta Bio, Inc. (the Company) as of December 31, 2025 and 2024, the related consolidated statements of operations and comprehensive loss, stockholders' equity and cash flows for each of the two years in the period ended December 31, 2025, and 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 at December 31, 2025 and 2024, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2025, in conformity with U.S. generally accepted accounting principles.

The Company's Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has suffered recurring losses from operations and has stated that substantial doubt exists about the Company's ability to continue as a going concern. Management's evaluation of the events and conditions and management's plans regarding these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's 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 in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the 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 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 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 financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Accounting for Accrued Clinical Trial Expenses

Description of the Matter

As disclosed in Note 2 to the consolidated financial statements, the Company expenses research and development costs as incurred, which include costs relating to clinical trial activities. The Company's accrued clinical trial expenses are based on factors such as estimates of the work completed in accordance with agreements established with a contract research organization. As disclosed in Note 5 to the consolidated financial statements, the Company's total accrued expenses and other current liabilities related to clinical trial research and development services were $5.3 million at December 31, 2025.

Auditing the Company's accrued clinical trial expenses required subjective auditor judgement due to the estimation required by management in determining the services provided but not yet invoiced. Specifically, the amount of accrued clinical trial expenses recognized is sensitive to the availability of information to make the estimate, including the estimate of the period over which services will be performed, the associated cost of such services, and the level of services performed and progress in the period for which the Company has not yet received an invoice

How We Addressed the Matter in Our Audit

To test the accrued clinical trial expenses our audit procedures included, among others, reviewing a sample of agreements with the service providers to corroborate key financial and contractual terms, and testing the accuracy and completeness of the underlying data used in the accrual expense computations. We also evaluated management's estimates of the progress of a sample of clinical trial activities by making inquiries of the Company's operations personnel that oversee the clinical trials and confirming information directly with the contract research organization. To evaluate the completeness of the accruals, we also examined subsequent invoices from the service providers and cash disbursements to the service providers, to the extent such invoices were received, or payments were made prior to the date that the consolidated financial statements were issued.

Accounting for Common Stock Warrants

Description of the Matter

As discussed in Note 10 to the consolidated financial statements, in June 2025, concurrent with the issuance of common stock and pre-funded warrants, the Company issued a total of 53,090,190 common stock warrants. The common stock warrants were classified as a component of permanent stockholders' equity within additional paid-in capital.

Auditing management's evaluation of whether the common stock warrants required classification as a liability or equity is especially challenging and required significant audit effort and judgment due to the complex assessment of provisions within the warrants under authoritative guidance.

How We Addressed the Matter in Our Audit

To test the classification of the common stock warrants, our audit procedures included, among others, reviewing terms and conditions of the common stock warrant agreements, evaluating management's application of authoritative accounting guidance and related judgments, and testing the accuracy of underlying data supporting management's assertions. We involved our

internal accounting subject matter resources to assist in evaluating the Company's assessment and judgments applied in its evaluation of the classification for the warrants.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2018.
Philadelphia, Pennsylvania
March 23, 2026

CABALETTA BIO, INC.
Consolidated Balance Sheets
(in thousands, except share and per share amounts)

	Year Ended December 31,	
	2025	2024
Assets		
Current assets:		
Cash and cash equivalents	$ 82,982	$ 163,962
Short-term investments	50,617	—
Prepaid expenses and other current assets	5,272	2,713
Total current assets	138,871	166,675
Property and equipment, net	1,922	2,743
Finance lease right-of-use assets	15,700	7,020
Operating lease right-of-use assets	3,431	6,315
Other assets	5,159	2,293
Total assets	$ 165,083	$ 185,046
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 6,636	$ 4,923
Accrued and other current liabilities	19,298	12,188
Finance lease liabilities, current portion	20,758	5,989
Operating lease liabilities, current portion	3,461	3,986
Total current liabilities	50,153	27,086
Finance lease liabilities, net of current portion	2,879	3,241
Operating lease liabilities, net of current portion	—	2,384
Total liabilities	53,032	32,711
Commitments and contingencies (see Notes 6 and 7)		
Stockholders' equity:		
Preferred stock, $0.00001 par value: 10,000,000 shares authorized as of December 31, 2025 and December 31, 2024; no shares issued or outstanding at December 31, 2025 and December 31, 2024	—	—
Voting and non-voting common stock, $0.00001 par value: 300,000,000 (293,590,481 voting and 6,409,519 non-voting) shares authorized as of December 31, 2025 and 150,000,000 (143,590,481 voting and 6,409,519 non-voting) shares authorized as of December 31, 2024; 100,479,323 voting shares issued and outstanding as of December 31, 2025 and 50,743,101 voting shares issued and outstanding as of December 31, 2024	1	1
Additional paid-in capital	628,982	501,435
Accumulated other comprehensive income	25	—
Accumulated deficit	(516,957)	(349,101)
Total stockholders' equity	112,051	152,335
Total liabilities and stockholders' equity	$ 165,083	$ 185,046

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

CABALETTA BIO, INC.
Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except share and per share amounts)

	Year Ended December 31,	
	2025	2024
Operating expenses:		
Research and development	$ 142,674	$ 97,203
General and administrative	29,567	27,938
Total operating expenses	172,241	125,141
Loss from operations	(172,241)	(125,141)
Other income (expense):		
Interest income	6,031	10,025
Interest expense	(2,004)	(748)
Other income, net	358	—
Net loss	$ (167,856)	$ (115,864)
Other comprehensive income:		
Net unrealized gain (loss) on available-for-sale investments, net of tax	25	(39)
Net comprehensive loss	$ (167,831)	$ (115,903)
Net loss per share of voting and non-voting common stock, basic and diluted	$ (2.10)	$ (2.34)

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

CABALETTA BIO, INC.
Consolidated Statements of Stockholders' Equity
(in thousands, except share amounts)

	Common Stock					
	Shares	Amount	Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
Balance—December 31, 2023	47,823,232	$ —	$ 469,396	$ 39	$ (233,237)	$ 236,198
Issuance of common stock, net of issuance costs of $252	1,483,070	1	10,875	—	—	10,876
Issuance of common stock in connection with exercise of stock options	210,695	—	1,430	—	—	1,430
Issuance of common stock under employee stock purchase plan	58,056	—	269	—	—	269
Issuance of common stock upon exercise of pre-funded warrants	1,168,048	—	—	—	—	—
Stock-based compensation	—	—	19,465	—	—	19,465
Net unrealized losses on available-for-sale securities	—	—	—	(39)	—	(39)
Net loss	—	—	—	—	(115,864)	(115,864)
Balance—December 31, 2024	50,743,101	$ 1	$ 501,435	$ —	$ (349,101)	$ 152,335
Issuance of common stock, warrants and pre-funded warrants, net of issuance costs of $6,442	39,200,000	—	93,558	—	—	93,558
Issuance of common stock from ATM offering, net of sales agent commission and fees	5,545,041	—	12,745	—	—	12,745
Issuance of common stock upon exercise of pre-funded warrants	4,799,971	—	—	—	—	—
Issuance of common stock under employee stock purchase plan	177,876	—	291	—	—	291
Issuance of common stock in connection with exercise of stock options	13,334	—	14	—	—	14
Stock-based compensation	—	—	20,939	—	—	20,939
Net unrealized gains on available-for-sale securities	—	—	—	25	—	25
Net loss	—	—	—	—	(167,856)	(167,856)
Balance—December 31, 2025	100,479,323	$ 1	$ 628,982	$ 25	$ (516,957)	$ 112,051

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

CABALETTA BIO, INC.
Consolidated Statements of Cash Flows
(in thousands)

	Year Ended December 31,	
	2025	2024
Cash flows from operating activities:		
Net loss	$ (167,856)	$ (115,864)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	20,939	19,465
Depreciation	1,646	1,711
Non-cash finance lease expense	11,697	3,102
Non-cash operating lease expense	3,671	2,838
Accretion of operating lease liabilities	532	405
Amortization of discount on investments	(1,555)	(1,528)
Loss on foreign currency exchange rates	225	38
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(2,559)	528
Other assets	(2,866)	(584)
Accounts payable	1,550	1,011
Accrued and other current liabilities	7,432	3,947
Lease liabilities	(4,227)	(3,291)
Accrued interest payable under finance lease	291	—
Net cash used in operating activities	(131,080)	(88,222)
Cash flows from investing activities:		
Purchases of property and equipment	(1,229)	(2,211)
Purchases of investments	(99,037)	—
Proceeds from maturities of investments	50,000	49,500
Net cash (used in) provided by investing activities	(50,266)	47,289
Cash flows from financing activities:		
Proceeds from the issuance of common stock, warrants and pre-funded warrants, net of issuance costs	93,558	—
Issuance of common stock from ATM offering, net of sales agent commission and fees	12,745	10,875
Proceeds from issuance of common stock under employee stock purchase plan	291	269
Proceeds from issuance of common stock in connection with the exercise of stock options	14	1,430
Principal payments on finance leases	(6,261)	(897)
Net cash provided by financing activities	100,347	11,677
Effect of exchange rate changes on cash and cash equivalents	19	(20)
Net decrease in cash and cash equivalents	(80,980)	(29,276)
Cash and cash equivalents—beginning of period	163,962	193,238
Cash and cash equivalents—end of period	$ 82,982	$ 163,962
Supplemental disclosures		
Cash paid for interest	$ 1,713	$ 748
Property and equipment purchases included in accounts payable and accrued expenses	$ —	$ 404
Right-of-use assets obtained in exchange for finance lease obligations	$ 21,071	$ 10,963
Right-of-use assets obtained in exchange for operating lease obligations	$ 787	$ 4,242

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

1. Basis of Presentation

Cabaletta Bio, Inc. (the Company or Cabaletta) was incorporated in April 2017 in the State of Delaware as Tycho Therapeutics, Inc. and, in August 2018, changed its name to Cabaletta Bio, Inc. The consolidated financial statements include the accounts of Cabaletta and its wholly owned subsidiaries: Cabaletta Bio GmbH and Cabaletta Bio (Germany) GmbH.

The Company is headquartered in Philadelphia, Pennsylvania. Cabaletta is a clinical-stage biotechnology company focused on the discovery and development of engineered T cell therapies for autoimmune diseases. Principal operations commenced in April 2018.

Risks and Uncertainties

The Company does not expect to generate revenue from sales of engineered T cell therapies for autoimmune diseases or any other revenue unless and until the Company completes preclinical and clinical development and obtains regulatory approval for one or more product candidates. If the Company seeks to obtain regulatory approval for any of its product candidates, the Company expects to incur significant commercialization expenses.

The Company is subject to risks common to companies in the biotechnology industry including, but not limited to, new technological innovations, protection of proprietary technology, dependence on key personnel, compliance with government regulations and the need to obtain additional financing. As a result, the Company is unable to predict the timing or amount of increased expenses or when or if the Company will be able to achieve or maintain profitability. Further, the Company is dependent on third parties for certain research and development activities, including manufacturing services (Note 6 and Note 7). Product candidates currently under development will require significant additional research and development efforts, including extensive preclinical and clinical testing and regulatory approval, prior to commercialization. Even if the Company is able to generate revenues from the sale of its product candidates, if approved, it may not become profitable. If the Company fails to become profitable or is unable to sustain profitability on a continuing basis, then it may be unable to continue its operations at planned levels and be forced to reduce its operations.

Liquidity and Going Concern

In accordance with Accounting Standards Codification (“ASC”) 205-40, Going Concern, ("ASC 205-40") the Company evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about the Company’s ability to continue as a going concern. The Company has sustained annual operating losses since inception and expects to continue to generate operating losses for the foreseeable future. As of December 31, 2025, the Company has incurred an accumulated deficit of $516,957 and has cash, cash equivalents and investments of $133,599. The Company’s ultimate success depends on the outcome of its research and development activities. Management expects to incur additional losses in the future as it continues its research and development and will need to raise additional capital to fully implement its business plan and to fund its operations. The Company intends to raise such additional capital through a combination of equity offerings, debt financings, government funding arrangements, strategic alliances or other sources. However, if such financing is not available at adequate levels and on a timely basis, or such agreements are not available on favorable terms, or at all, as and when needed, the Company will need to reevaluate its operating plan and may be required to delay or discontinue the development of one or more of its product candidates or operational initiatives. Based on the Company’s current operating plan, there is substantial doubt about the Company’s ability to continue as a going concern for at least twelve months from the issuance date of this Annual Report on Form 10-K, and the Company will need to obtain additional funding. The Company's cash forecast contains estimates and assumptions based on success of ongoing clinical trials, and management cannot predict the amount or timing of all expenditures with certainty. Accordingly, the Company has concluded that substantial doubt exists about the Company’s ability to continue as a going concern. The accompanying financial statements have been

prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the ordinary course of business.

2. Summary of Significant Accounting Policies

Principles of Consolidation

The accompanying consolidated financial statements have been prepared in conformity with generally accepted accounting principles in the United States (GAAP) and under the rules and regulations of the U.S. Securities and Exchange Commission (SEC). All intercompany balances and transactions have been eliminated in consolidation.

Use of Estimates

The preparation of consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities as of the date of the consolidated financial statements and the reported amounts of expenses during the reporting period. Significant estimates and assumptions made in the accompanying consolidated financial statements include but are not limited to advance payments and accruals related to the Company's research and development expenses. 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 differ from those estimates.

Off-Balance Sheet Risk and Concentrations of Credit Risk

Financial instruments, which potentially subject the Company to significant concentrations of credit risk, consist of cash and cash equivalents, which are invested in U.S. treasury-based money market funds, and available-for-sale debt securities, which are invested in U.S. treasury securities. A portion of the Company's cash is maintained at federally insured financial institutions, and account balances may at times exceed federally insured limits. The Company has not experienced any losses in such accounts and management believes that the Company is not exposed to significant credit risk. The Company has no off-balance sheet risk, such as foreign exchange contracts, option contracts, or other foreign hedging arrangements.

The Company considers all highly liquid investments purchased with original maturities of three months or less from the purchase date to be cash equivalents. Cash equivalents consist primarily of amounts invested in money market accounts and U.S. treasury securities.

Investments

Investments are available-for-sale and carried at estimated fair value. The Company's valuations of available-for-sale debt securities are generally derived from independent pricing services based upon quoted prices in active markets for similar securities, with prices adjusted for yield and number of days to maturity, or based on industry models using data inputs, such as interest rates and prices that can be directly observed or corroborated in active markets. Management determines the appropriate classification of its investments in debt securities at the time of purchase and at the end of each reporting period. Investments with original maturities beyond three months at the date of purchase and which mature at, or less than, twelve months from the balance sheet date are classified as current.

Unrealized gains and losses are excluded from earnings and are reported as a component of comprehensive income. The Company periodically evaluates whether declines in fair values of its available-for-sale securities below their book value are other-than-temporary. This evaluation consists of several qualitative and quantitative factors including the severity and duration of the unrealized loss as well as the Company's ability and intent to hold the available-for-sale security until a forecasted recovery occurs. Additionally, the Company assesses whether it has plans to sell the security or if more likely than not it will be required to sell any available-for-sale securities before recovery of its amortized cost basis. Realized gains and losses and declines in fair value judged to be other-than-temporary, if any, on available-for-sale securities are included in interest and other income, net. The cost of investments sold is based on the specific-identification method. Interest income on investments as well as amortization of discount or premium is included in interest income.

Property, Plant and Equipment

Property, plant and equipment are recorded at cost less accumulated depreciation. Cost includes the acquisition costs and all costs necessary to bring the asset to the location and working condition necessary for its intended use. Depreciation expense is recognized using the straight-line method over the estimated useful life of each asset. Upon retirement or sale, the cost of assets disposed of and the related accumulated depreciation are removed from the accounts and any resulting gain or loss is included in the accompanying statements of operations. Expenditures for normal, recurring or periodic repairs and maintenance related to property and equipment are charged to expense as incurred. The cost for planned major maintenance activities, including the related acquisition or construction of assets, is capitalized if it will result in future economic benefits.

Estimated useful lives for property and equipment are as follows:

Property and equipment	Estimated useful life
Laboratory equipment	Three years
Furniture and fixtures	Three years
Computer equipment	Three years
Leasehold improvements	Lesser of estimated useful life or remaining lease term

Fair Value Measurement

Assets and liabilities recorded at fair value on a recurring basis in the balance sheets are categorized based upon the level of judgment associated with the inputs used to measure their fair values. Fair value is defined as the exchange price that would be received for an asset or an exit price that would be paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. The authoritative guidance on fair value measurements establishes a three-tier fair value hierarchy for disclosure of fair value measurements as follows:

Level 1—Observable inputs such as unadjusted, quoted prices in active markets for identical assets or liabilities at the measurement date.

Level 2—Inputs (other than quoted prices included in Level 1) that are either directly or indirectly observable for the asset or liability. These include quoted prices for similar assets or liabilities in active markets and quoted prices for identical or similar assets or liabilities in markets that are not active.

Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

Leases

The Company has leases related to its facilities used for offices and laboratory space, which are classified as operating leases as well as leases related to its manufacturing arrangements, which are classified as finance leases.

At the inception of an arrangement, the Company determines whether the arrangement is or contains a lease and its classification based on the unique facts and circumstances present in the arrangement. Leases with a term greater than one year are recognized on the balance sheet as right-of-use assets and current and non-current lease liabilities, as applicable.

Lease liabilities and their corresponding right-of-use assets are initially recorded based on the present value of lease payments over the expected remaining lease term. Certain adjustments to the right-of-use asset may be required for items such as incentives received. The interest rate implicit in lease contracts is typically not readily determinable. As a result, the Company utilizes its incremental borrowing rate to discount lease payments. Subsequent to the initial measurement, the Company will continue to account for:

- the lease liability at the net present value using the incremental borrowing rate that was in effect as of the lease commencement, lease modification, or transition date, and;
- the finance lease and operating lease expense on a straight line basis.

Leases with terms of 12 months or less are considered short-term leases and right-of-use assets and lease obligations are not recognized. Payments associated with short-term leases are expensed on a straight-line basis over the lease term.

In accordance with ASC 842, components of a lease should be split into three categories: lease components, non-lease components and non-components. The fixed and in-substance fixed contract consideration (including any consideration related to non-components) must be allocated based on the respective relative fair values to the lease components and non-lease components. Entities may elect not to separate lease and non-lease components. Rather, entities would account for each lease component and related non-lease component together as a single lease component. The Company has elected to aggregate all lease and non-lease components for each class of underlying assets into a single lease component for real-estate leases and embedded manufacturing arrangements.

ASC 842 allows for the use of judgment in determining whether the assumed lease term is for a major part of the remaining economic life of the underlying asset and whether the present value of lease payments represents substantially all of the fair value of the underlying asset. The Company applies the guidance in ASC 842-10-55-2 to assist in determining lease classification across its leases.

Research and Development Expenses

Research and development costs include costs incurred for internal and external research and development activities and are expensed as incurred in the accompanying statements of operations. Research and development costs consist of salaries and benefits, including associated stock-based compensation, and laboratory supplies and facility costs, as well as fees paid to entities that conduct certain research and development and clinical trial activities on the Company's behalf.

The Company records accrued liabilities for estimated costs of research and development activities conducted by service providers, which include preclinical studies, contract manufacturing activities and clinical trial activities. The Company records the estimated costs of research and development activities based upon the estimated amount of services provided and in accordance with agreements established with service providers and includes these costs in accrued and other current liabilities in the accompanying balance sheets and within research and development expense in the accompanying statements of operations. Non-refundable advance payments made for goods or services that will be used or rendered for future research and development activities are deferred and capitalized and recognized as expense as the goods are received or the related services are rendered. The Company makes significant judgments and estimates in determining the accrued liabilities and prepaid expenses in each reporting period. As actual costs become known, the Company adjusts its accrued liabilities and prepaid expenses. The Company has not experienced any material differences between accrued costs and actual costs incurred since its inception.

Stock-based Compensation

The Company measures its stock-based awards granted to employees and non-employees based on the estimated fair values of the awards on the respective grant dates. The Company uses the Black-Scholes option-pricing model (Black-Scholes) to estimate the fair value of its stock-based awards. The Company recognizes compensation expense for time-based awards on a straight-line basis over the requisite service period, which is generally the vesting period of the award. The Company accounts for forfeitures of stock option awards as they occur.

Income Taxes

The Company uses the asset and liability method of accounting for income taxes. Deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to temporary differences between the consolidated financial statement carrying amounts of existing assets and liabilities and their respective tax base, as well as for net operating loss carryforwards and research and development credits, and are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled.

Valuation allowances are established when necessary to reduce deferred tax assets where, based upon the available evidence, the Company concludes that it is more-likely-than-not that the deferred tax assets will not be realized. In evaluating its ability to recover deferred 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. Because of the uncertainty of the realization of deferred tax assets, the Company has recorded a full valuation allowance against its deferred tax assets.

Reserves are provided for tax benefits for which realization is uncertain. Such benefits are only recognized when the underlying tax position is considered more-likely-than-not to be sustained on examination by a taxing authority, assuming they possess full knowledge of the position and facts. Interest and penalties related to uncertain tax positions are recognized in the provision of income taxes; however, the Company currently has no interest or penalties related to uncertain income tax benefits.

Net Loss Per Share

The Company calculates basic and diluted net loss per share in conformity with the two-class method required for participating securities because the Company had both voting and non-voting common stock outstanding for a portion of 2024. The rights, including the liquidation and dividend rights, of the holders of the voting and non-voting common stock are identical, except with respect to voting. Each share of non-voting common stock may be converted at any time into one share of voting common stock at the option of its holder by providing written notice to the Company, subject to the limitations provided for in the amended and restated certificate of incorporation. As of December 31, 2024, no shares of non-voting common stock remain outstanding.

Basic net loss per share attributable to common stockholders is computed by dividing the net loss by the weighted average number of shares of common stock, including any pre-funded warrants to purchase shares of common stock that may be outstanding. The undistributed loss for each year is allocated to common stockholders based on the contractual participation rights of the voting and non-voting common stock as if the losses for the year had been distributed. As the liquidation and dividend rights are identical, the undistributed losses are allocated on a proportionate basis. Diluted net loss per share attributable to common stockholders is computed under the if-converted method and assumes that all non-voting common stock has been converted to common stock. Since the Company was in a loss position for all periods presented, the effects of the other potentially dilutive securities are antidilutive.

Segments

Operating segments are defined as components of an entity for which separate financial information is available and that is regularly reviewed by the Chief Operating Decision Maker (CODM) in deciding how to allocate resources to an individual segment and in assessing performance. The Company's CODM is its Chief Executive Officer (CEO). The Company has determined it operates in a single operating segment and has one reportable segment. Refer to Note 8 – Segment Reporting for further information related to our segment.

Deferred Offering Costs

The Company capitalizes certain legal, professional accounting and other third-party fees that are directly associated with in-process equity financings as deferred offering costs until such financings are consummated.

After consummation of the equity financing, these costs are recorded as a reduction to the carrying value of stockholders' equity as a reduction of additional paid-in capital or equity generated as a result of such offering. Should an in-process equity financing be abandoned, the deferred offering costs will be expensed immediately as a charge to operating expenses in the statements of operations and comprehensive loss.

Recently Adopted Accounting Pronouncements

In December 2023, the FASB issued ASU 2023-09, *Improvements to Income Tax Disclosures*. ASU 2023-09 enhances the transparency about income tax information through improvements to income tax disclosures primarily related to the rate reconciliation and income taxes paid information. The Company adopted this ASU for the annual period ended December 31, 2025 and the amendments have been applied retrospectively to all prior periods presented in the financial statements. Refer to Note 11 – Income Taxes for further information.

Recently Issued Accounting Pronouncements

In November 2024, the FASB issued ASU 2024-03, Income Statement (Subtopic 220-40): Reporting Comprehensive Income-Expense Disaggregation Disclosures. ASU 2024-03 requires enhanced disclosures about components of expense captions on the face of the income statement. This standard will be effective for fiscal years beginning after December 15, 2026. Early adoption is permitted. ASU 2024-03 applies on a prospective basis for periods beginning after the effective date. However, retrospective application to any or all prior periods presented is permitted. The Company is currently planning to adopt this guidance when effective and is assessing the impact of the adoption on the Company's consolidated financial statements and accompanying footnotes.

There have been no other new accounting pronouncements or changes to accounting pronouncements that, if adopted, would have or may have a material impact on the Company's consolidated statements or disclosures.

3. Fair Value Measurements

As of December 31, 2025 and 2024, the Company's financial instruments included cash and cash equivalents, available-for-sale debt securities, accounts payable and accrued expenses. The carrying amounts for cash and cash equivalents, accounts payable and accrued expenses reported in the Company's consolidated financial statements for these instruments approximate their respective fair values because of the short-term nature of these instruments.

The following tables present information about the Company's financial assets measured at fair value on a recurring basis and indicate the level of the fair value hierarchy utilized to determine such fair values:

	December 31, 2025			
	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Financial assets				
Cash equivalents:				
Money market funds	$ 81,470	$ 81,470	$ —	$ —
Short-term investments:				
U.S. Treasury securities	50,617	—	50,617	—
Total	$ 132,087	$ 81,470	$ 50,617	$ —

	December 31, 2024			
	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Financial assets				
Cash equivalents:				
Money market funds	$ 162,634	$ 162,634	$ —	$ —
Total	$ 162,634	$ 162,634	$ —	$ —

Money market funds are measured at fair value on a recurring basis using quoted prices and are classified as Level 1 inputs. Investments are measured at fair value based on inputs other than quoted prices that are derived from observable market data and are classified as Level 2 inputs.

For debt securities classified as available-for-sale investments, the Company records unrealized gains or losses resulting from changes in fair value between measurement dates as a component of other comprehensive income. The Company did not hold any available-for-sale securities as of December 31, 2024.

	December 31, 2025		
	Amortized Cost	Gross Unrealized Gains	Fair value
Financial assets			
Cash	$ 1,512	$ —	$ 1,512
Money market funds	81,470	—	81,470
Included in cash and cash equivalents	82,982	—	82,982
U.S. Treasury securities - due in one year or less			
Included in short-term investments	50,592	25	50,617
Total	$ 133,574	$ 25	$ 133,599

4. Property, Plant and Equipment

Property, plant and equipment consists of the following:

	December 31,	
	2025	2024
Laboratory equipment	$ 8,488	$ 7,663
Furniture and fixtures	277	277
Computer equipment	196	196
Leasehold improvements	113	113
Total property, plant and equipment	9,074	8,249
Less: accumulated depreciation	(7,152)	(5,506)
Property, plant and equipment, net	$ 1,922	$ 2,743

Depreciation expense was $1,646 and $1,711 for the years ended December 31, 2025 and 2024, respectively.

5. Accrued and Other Current Liabilities

Accrued and other current liabilities consist of the following:

	December 31,	
	2025	2024
Compensation expense	$ 9,716	$ 8,315
Clinical trial research and development services	5,335	1,236
Manufacturing and other research and development services	3,774	2,255
General and administrative services	393	342
Other	80	40
	$ 19,298	$ 12,188

6. Collaborations, Licensing Agreements and Other Agreements

Amended and Restated License Agreement with the Trustees of the University of Pennsylvania and Children's Hospital of Philadelphia

In August 2018, the Company entered into a license agreement with the University of Pennsylvania (Penn), as amended and restated in July 2019 to include the Children's Hospital of Philadelphia (CHOP) as a party, and as amended in May 2020 and October 2021 (the License Agreement) pursuant to which the Company obtained (a) a non-exclusive, non-sublicensable worldwide license to certain of Penn's intellectual property to conduct research, product development, clinical trials, cell manufacturing and other activities, and (b) an exclusive, worldwide, royalty-bearing right and license, with a right to sublicense, on a target-by-target basis, under certain of Penn's intellectual property to make, use, sell, offer for sale, import, and otherwise commercialize products for the treatment of autoimmune and alloimmune diseases. Unless earlier terminated, the License Agreement expires on the expiration or abandonment or other termination of the last valid claim in Penn's intellectual property licensed by the Company. The Company may terminate the License Agreement at any time for convenience upon 60 days' written notice. In the event of an uncured, material breach, Penn may terminate the License Agreement upon 60 days' written notice. Under the terms of the License Agreement, the Company was obligated to pay $2,000 annually for three years beginning August 2018 for funding to the laboratories of each of Drs. Milone and Payne. This was satisfied through completed sponsored research agreements with a total cost of $12,560. During the term of the License Agreement until the first commercial sale of the first product, the Company is obligated to pay Penn a non-refundable, non-creditable annual license maintenance fee of $10. In May 2020, the Company paid Penn an additional, non-refundable, non-creditable license fee of $33 under the amended License Agreement.

The Company is required to pay certain milestone payments upon the achievement of specified clinical and commercial milestones. Milestone payments are reduced by a certain percentage for the second product that achieves a milestone, by an additional percentage for the third product that achieves a milestone, and so on, for each subsequent product that achieves a milestone. In the event that the Company is able to successfully develop and launch multiple products under the License Agreement, total milestone payments could be approximately $21,000. Penn is also eligible to receive tiered royalties at percentage rates in the low single-digits, subject to an annual minimum royalty, on annual worldwide net sales of any products that are commercialized by the Company or its sublicensees that contain or incorporate, or are covered by, the intellectual property licensed by the Company. To the extent the Company sublicenses its license rights under the License Agreement, Penn would be eligible to receive tiered sublicense income at percentage rates in the mid-single to low double-digits. There were no amounts due under the License Agreement as of December 31, 2025.

Master Translational Research Services Agreements

In October 2018 and February 2023, the Company entered into services agreements (the CAART and CARTA Services Agreements) with Penn for research, development and manufacturing services from various laboratories within Penn. The activities are detailed in separately executed Penn organization-specific addenda. In May 2020, the Company amended its Addendum with the Center for Advanced Retinal and Ocular Therapeutics (CAROT) to expand access to vector manufacturing.

Research and development expense recognized under executed addenda to the master translational research services agreements with Penn was $5,062 and $3,250 for the years ended December 31, 2025 and 2024, respectively. As of December 31, 2025, the Company had no remaining commitments under the CARTA Services Agreement.

Exclusive License Agreement with IASO Biotherapeutics

On October 7, 2022, the Company entered into an Exclusive License Agreement (the IASO Agreement) with Nanjing IASO Biotherapeutics Co., Ltd. (IASO). Pursuant to the IASO Agreement, the Company received an exclusive, worldwide license under certain IASO intellectual property to use a novel clinical-stage anti-CD19 binder to develop, manufacture, commercialize and otherwise exploit T cell products directed to CD19 for the purpose of diagnosis, prevention or treatment of any autoimmune or alloimmune indications in humans. As partial consideration for the exclusive license, IASO received an upfront payment of $2,500. IASO is also eligible to receive up to mid double digit millions in milestone payments based upon the achievement of specified pre-clinical, development and regulatory milestones, and up to an additional low triple digit millions in milestone payments based upon achievement of specified sales milestones, for a total consideration, inclusive of the upfront payment, of up to $162,000, along with tiered mid-single digit royalties on future net sales for licensed products that may result from the IASO Agreement. Upon the U.S. Food and Drug Association's clearance of the rese-cel Investigational New Drug application for the treatment of systemic lupus erythematosus in March 2023, a milestone payment of $1,000 was recognized in the accompanying statements of operations. A milestone payment of $1,500 was paid to IASO in the first quarter of 2024 after the first patient in a rese-cel trial was dosed.

IASO has the right of first negotiation if the Company desires to grant a third party an exclusive license to develop, manufacture, commercialize or otherwise exploit the licensed products in the Greater China region. Pursuant to the IASO Agreement, each of IASO and the Company have agreed, subject to certain exceptions, to refrain from engaging in certain competitive activities with respect to certain programs. The Company also may sublicense through multiple tiers the rights granted to it by IASO under the IASO Agreement at any time, however, it must pay IASO a low double-digit percentage of any revenue obtained from sublicenses or options to third parties, subject to certain customary exclusions. The IASO Agreement will continue on a country-by-country, licensed product-by-licensed product basis until the expiration of the royalty term as identified in the IASO Agreement, unless earlier terminated. Each of the Company and IASO may terminate the Agreement for a material, uncured breach or insolvency of the other party. The Company may also terminate the Agreement at will upon advance written notice and in the event IASO rejects the Agreement due to bankruptcy-related matters. IASO may also terminate the Agreement if the Company fails to achieve certain specified diligence milestones in a timely manner and/or if the Company commences any patent challenges with respect to the patents and patent applications relating to the licensed sequence, in each case upon advance written notice.

Licence and Supply Agreement with Oxford Biomedica

In December 2021, the Company entered into a Licence and Supply agreement (LSA) with Oxford Biomedica (UK) Limited (Oxford), wherein the LSA grants the Company a non-exclusive license to Oxford's LentiVector® platform for its application in the Company's DSG3-CAART program and put in place a multi-year vector supply agreement. Oxford is eligible to receive regulatory and sales milestones in the low tens of millions and royalties in the low single digits on net sales of products that incorporate the Oxford technology. In May 2023, the Company amended the LSA with Oxford to expand the license to include the Company's rese-cel program for an upfront fee of $500. In August 2023, the Company and Oxford entered into a vector supply agreement for rese-cel, and a related second amendment to the LSA, with a total cost under the vector supply agreement of up to approximately $5,000, which has been fully expensed as of December 31, 2024. In February 2024, the Company and Oxford entered into a third amendment to the LSA to update the patent schedule. In June 2024, the Company and Oxford entered into a fourth amendment to the LSA eliminating royalties on net sales of products that incorporate the Oxford technology if Oxford manufactures the vector. Starting in December 2024, the Company and Oxford entered into work orders with a cost of approximately $23,000 for certain process characterization and process performance qualification activities as part of commercial readiness activities. As of December 31, 2025, the Company has recognized project to date expense of $8,673 related to these activities. The Company can terminate the LSA or any work order under the LSA at will upon advance written notice and subject to certain cancellation fees.

Option and License Agreement with Autolus

In January 2023, the Company entered into an Option and License Agreement (Autolus Agreement) with Autolus Holdings (UK) Limited (Autolus), wherein the Autolus Agreement granted the Company a non-exclusive license to access Autolus' RQR8 technology in its CD19-CAR T cell therapy program, and subject to additional nominal option exercise fees, up to four additional targets. In January 2025, the Company and Autolus agreed to novate the Autolus Agreement with both Autolus and Autolus Limited jointly assuming the rights, obligations and liabilities of Autolus, under the Autolus Agreement. Under the terms of the Autolus Agreement, the Company was required to pay Autolus an upfront license fee of $1,200 that was recognized as expense in the first quarter of 2023 in the accompanying statements of operations, of which $1,100 was paid in 2023 and $100 was paid in January 2024. Autolus is also eligible to receive regulatory milestones of up to $12,000 for each licensed target, sales milestones of up to a total of $15,000 and royalties in the low single digits on net sales of all products that incorporate the RQR8 technology. The Autolus Agreement will continue on a country-by-country, licensed product-by-licensed product basis until the expiration of the royalty term as identified in the Autolus Agreement, unless earlier terminated. The Company can terminate the Autolus Agreement at will upon advance written notice. Each of the Company and Autolus may terminate the Agreement for a material, uncured breach or insolvency of the other party.

7. Commitments and Contingencies

Manufacturing Agreements

In January 2021, the Company entered into a Development and Manufacturing Services Agreement (Minaris Agreement) with Minaris Advanced Therapies, LLC, or Minaris (f/k/a WuXi Advanced Therapies, Inc.) to serve as an additional cell processing manufacturing partner for the MuSK-CAART Phase 1 clinical trial, or MusCAARTes™ trial. The Minaris Agreement is scheduled to expire upon completion of Minaris' services related to MuSK-CAART and rese-cel. In August 2023, and as extended in August 2024, the Company entered into an agreement with Minaris to serve as one of the Company's manufacturing partners for the global clinical development of rese-cel in multiple indications, including potential late-stage clinical trials and commercial readiness activities for rese-cel. Under the August 2023 work orders, Minaris converted the Company's non-dedicated suite to a dedicated suite for GMP manufacturing for the Company's rese-cel and MuSK-CAART programs, or the Dedicated Suite, for an initial term of 18 months with two 18-month extensions at the Company's sole option on six months' notice prior to the end of the term. In August 2024, the Company sent a notice to Minaris to extend the initial term of the Minaris Agreement by 18 months through August 2026. In addition, the Company agreed to certain monthly minimum runs. In August 2024, the 2023 work order related to GMP manufacturing was amended to reduce the minimum monthly runs through the end of 2024. In lieu of the original $1,500 termination fee under the terms of the Minaris Agreement, the Company would incur up to a $1,080 termination fee if it terminates both the rese-cel and MuSK-CAART work orders for any reason. The Company may terminate for convenience the Minaris Agreement or any work order with six months' prior written notice. However, the Company may not terminate the Dedicated Suite without terminating

both the MuSK-CAART and rese-cel GMP run work orders. Minaris may terminate for convenience the Minaris Agreement or any work order on 18 months' prior written notice, but such notice may not be effective prior to February 2028. In February 2026, the Company notified Minaris that it intended to permit the term to expire in August 2026.

In December 2024, the Company entered into a Development and Manufacturing Services Agreement (the Lonza Agreement) with Lonza Houston Inc. (Lonza) to serve as one of the Company's manufacturing partners for the global clinical development of rese-cel in multiple indications, including potential late-stage clinical trials and preparations for commercial readiness. The Lonza Agreement has a term of five years and can be extended for an additional three year term upon notice to Lonza at least 18 months prior to the expiration of the Lonza Agreement. The Company can terminate the Lonza Agreement at will upon nine months advance written notice to Lonza subject to the terms of the Lonza Agreement. Lonza can terminate the Lonza Agreement at will upon 24 months advance written notice to Cabaletta subject to the terms of the Lonza Agreement. Under the initial work order, Lonza will perform cell therapy manufacturing activities for Cabaletta's CAR-T cell therapy product, rese-cel, for an initial term of 12 months with the ability to extend the manufacturing period on a rolling basis subject to the terms of the Lonza Agreement.

Other Purchase Commitments

In the normal course of business, the Company enters into various purchase commitments with third-party contract manufacturers for the manufacture and processing of its product candidates and related raw materials, contracts with contract research organizations for clinical trials and agreements with vendors for other services and products for operating purposes. These agreements generally provide for termination or cancellation, other than for costs already incurred.

Indemnification

The Company enters into certain types of contracts that contingently require the Company to indemnify various parties against claims from third parties. These contracts primarily relate to (i) the Company's Amended and Restated Bylaws, as amended, (bylaws) under which the Company must indemnify directors and executive officers, and may indemnify other officers and employees, for liabilities arising out of their relationship, (ii) contracts under which the Company must indemnify directors and certain officers and consultants for liabilities arising out of their relationship, (iii) contracts under which the Company may be required to indemnify partners against certain claims, including claims from third parties asserting, among other things, infringement of their intellectual property rights, and (iv) procurement, consulting, or license agreements under which the Company may be required to indemnify vendors, consultants or licensors for certain claims, including claims that may be brought against them arising from the Company's acts or omissions with respect to the supplied products, technology or services. From time to time, the Company may receive indemnification claims under these contracts in the normal course of business. In addition, under these contracts, the Company may have to modify the accused infringing intellectual property and/or refund amounts received.

In the event that one or more of these matters were to result in a claim against the Company, an adverse outcome, including a judgment or settlement, may have a material adverse effect on the Company's future business, operating results or financial condition. It is not possible to determine the maximum potential amount under these contracts due to the limited history of prior indemnification claims and the unique facts and circumstances involved in each particular agreement.

Litigation

From time to time, the Company may become involved in litigation or legal proceedings. While the outcome of any such proceedings cannot be predicted with certainty, as of December 31, 2025, the Company is not involved in any material litigation or legal proceedings that it would expect to have a material adverse impact on its financial position, results of operations, or cash flows.

8. Segment Information

Operating segments are defined as components of an entity for which separate financial information is available and that is regularly reviewed by the CODM in deciding how to allocate resources to an individual segment and in assessing performance. The Company's CODM is the CEO. The Company has determined it operates in a single operating segment and has one reportable segment. The segment consists of the development of clinical and preclinical product candidates for the discovery and development of innovative engineered T cell therapies and related administrative activities. The CODM assesses performance and allocates resources based on the Company's consolidated statement of operations, which is reported on the income statement as consolidated net loss and considers forecast-to-actuals variances on a quarterly basis for expenses that are deemed significant. Further, the CODM reviews the segment's assets based on the consolidated balance sheet to assess liquidity and funding capacity. The majority of the Company's assets are located in the United States.

The Company's CODM views specific categories within expenses as significant given the direct correlation between cash burn and profitability as a pre-revenue company. Significant segment expenses, as provided to the CODM, are presented below. For additional information on the year over year change of segment expenses refer to Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

	Year Ended December 31,	
	2025	2024
	(in thousands)	
Research and development expenses:		
Personnel	$ 46,934	$ 39,239
Clinical trials	39,581	22,286
Manufacturing of preclinical and clinical supplies	38,240	15,523
Development services	15,350	16,417
License of intellectual property	—	1,523
Other research and development costs [1]	2,569	2,215
General and administration expenses	29,567	27,938
Interest income	(6,031)	(10,025)
Interest expense	2,004	748
Other income, net	(358)	—
Net loss	$ 167,856	$ 115,864

[1] Other research and development costs includes costs associated with information technology, travel, medical and scientific symposiums and conferences.

9. Leases

The Company leases office and laboratory space and has two manufacturing agreements that have been determined to include embedded leases.

Operating lease commitments

The Company leases office and laboratory space which include rent escalations and are subject to additional variable charges, including common area maintenance, property taxes and property insurance. Given the variable nature of such costs, they are recognized as expense as incurred. Additionally, some of the Company's leases are subject to certain fixed fees which the Company has determined to be non-lease components. The Company has elected the practical expedient to account for lease and non-lease components as a single-lease component and has included fixed payments related to non-lease components in calculating the operating lease liability. The lease term

for our laboratory space was extended in October 2025 through November 2026 resulting in an increase of the right-of-use asset and lease liability of $787.

Finance lease commitments - Embedded leases

As described further in Note 7, in August 2023, the Company entered into new work orders under the Minaris Agreement for Minaris to serve as one of the Company's cell processing manufacturing partners for the global clinical development of rese-cel. Minaris converted the Company's non-dedicated suite to a Dedicated Suite for GMP manufacturing for the Company's rese-cel and MuSK-CAART programs, for an initial term of 18 months. The terms of the August 2023 work orders included both fixed costs and contingent variable costs. The lease commenced October 1, 2023. In 2024, the Company remeasured the lease following the resolution of the contingency related to variable costs and an amendment to the 2023 work order, which extended the term of the agreement by an additional 18 months through August 2026. The Company may terminate the Dedicated Suite lease for convenience with six months' prior written notice and up to a $1,080 termination fee if both the rese-cel and MuSK-CAART work orders are terminated. In February 2026, the Company notified Minaris that it intended to permit the term to expire in August 2026.

As described further in Note 7, in December 2024, the Company entered into the Lonza Agreement with Lonza to serve as one of the Company's cell processing manufacturing partners. Under the initial work order, Lonza will perform cell therapy manufacturing activities for the CAR-T cell therapy product rese-cel for a term of 12 months with the ability to extend the manufacturing period subject to the terms of the Lonza Agreement. The Lonza Agreement was evaluated under ASC 842 and determined to contain an embedded finance lease commencing in March 2025, resulting in the recognition of a right-of-use asset and lease liability of $14,934. As of December 31, 2025, the Company extended the lease term in accordance with the Lonza Agreement resulting in an increase of the right-of-use asset and lease liability of $6,137.

Summary of leases under ASC 842

The following table contains information pertaining to the Company's operating and finance leases for the years ended December 31, 2025 and 2024.

	Year Ended December 31,	
	2025	2024
Finance leases		
Interest expense	$ 2,004	$ 748
Amortization expense	12,391	3,102
Total fixed finance lease cost	$ 14,395	$ 3,850
Variable lease cost	5,508	930
Total finance lease cost	$ 19,903	$ 4,780
Operating leases		
Fixed lease cost	$ 4,211	$ 3,247
Total fixed operating lease cost	$ 4,211	$ 3,247
Variable lease cost	171	296
Short-term lease cost	34	750
Total operating lease cost	$ 4,416	$ 4,293
Cash paid in the measurement of lease liabilities		
Operating cash flows used for operating leases	$ 4,227	$ 3,291
Operating cash flows used for finance leases	1,713	748
Financing cash flows for finance leases	6,261	897
Other information		
Weighted average remaining lease term - finance leases (in years)	1.1	1.7
Weighted average discount rate - finance leases	10.7%	11.5%
Weighted average remaining lease term - operating leases (in years)	0.9	1.7
Weighted average discount rate - operating leases	10.3%	11.0%

For finance leases embedded in CDMO arrangements, interest expense is recognized using the effective interest method, applying the Company's incremental borrowing rate as required by ASC 842, and amortization expense is recognized on a straight-line basis over the shorter of the life of the asset or the term of the lease.

Future lease payments under the non-cancelable leases as of December 31, 2025 are as follows**:**

	Finance Leases	Operating Leases
2026	$ 21,914	$ 3,633
2027	3,280	—
Total undiscounted lease payments	25,194	3,633
Less imputed interest	(1,557)	(172)
Total lease liability	$ 23,637	$ 3,461

10. Common Stock

Common Stock

Pursuant to the Company's Third Amended and Restated Certificate of Incorporation, as amended, the Company is authorized to issue 293,590,481 shares of voting common stock and 6,409,519 shares of non-voting common stock. In May 2024, the remaining 1,444,295 shares of non-voting common stock were converted to voting common stock and no shares of non-voting common stock are outstanding as of December 31, 2025.

June 2025 Financing

In June 2025, the Company issued (i) 39,200,000 shares of its common stock and accompanying warrants to purchase an aggregate of 39,200,000 shares of common stock (or pre-funded warrants in lieu thereof) and (ii) in lieu of common stock, to certain investors, pre-funded warrants to purchase an aggregate of up to 10,800,000 shares of its common stock and accompanying warrants to purchase an aggregate of 10,800,000 shares of common stock (or pre-funded warrants in lieu thereof), at an exercise price of $0.00001 per pre-funded warrant. An additional 3,090,190 common stock warrants were issued in the financing for shares purchased by the underwriters in the market to cover overallotment demand. The combined offering price of each share of common stock and accompanying common stock warrant was $2.00. The combined offering price of each pre-funded warrant and accompanying common stock warrant was $1.99999. The pre-funded warrants are exercisable immediately. The common stock and pre-funded warrants were sold in combination with an accompanying common stock warrant to purchase one share of common stock (or a pre-funded warrant in lieu thereof) for each share of common stock or pre-funded warrant sold. Each common stock warrant has an exercise price per share of $2.50. The common stock warrants are immediately exercisable from the date of issuance and will expire on September 12, 2026, fifteen months from the date of issuance. Aggregate net proceeds were $93,558 after deducting underwriting discounts and commissions and offering expenses. As of December 31, 2025, 4,800,000 pre-funded warrants had been exercised and 6,000,000 remain outstanding. As of December 31, 2025, no common stock warrants had been exercised and 53,090,190 remain outstanding. Subsequent to December 31, 2025, 2,775,100 common stock warrants were exercised for proceeds of $6,938.

The pre-funded warrants and common stock warrants were classified as a component of permanent stockholders' equity within additional paid-in capital and were recorded at the issuance date using a relative fair value allocation method. The pre-funded warrants and common stock warrants are equity classified because they (i) are freestanding financial instruments that are legally detachable and separately exercisable from the equity instruments, (ii) are immediately exercisable, (iii) do not embody an obligation for the Company to repurchase its shares, (iv) permit the holders to receive a fixed number of shares of common stock upon exercise, (v) are indexed to the Company's common stock and (vi) meet the equity classification criteria. In addition, such pre-funded warrants and common stock warrants do not provide any guarantee of value or return.

At-the-Market Offering

On March 31, 2025, the Company converted the Form S-3ASR to a Form S-3 (File No. 333-278126) by post-effective amendments. This Form S-3 was declared effective on March 31, 2025. The Company had a Sales Agreement with TD Securities (USA) LLC (as successor to Cowen and Company, LLC) (TD Cowen) to provide for the offering, issuance and sale of up to an aggregate amount of $200.0 million of common stock from time to time in "at-the-market" offerings (2024 ATM Program) pursuant to its S-3, and subject to the limitations thereof. On June 11, 2025, the 2024 ATM Program with TD Cowen was terminated. Prior to termination, the Company sold an aggregate of 2,609,865 shares pursuant to the 2024 ATM Program for total net proceeds of $7,724, consisting of $5,129 in 2024 and $2,595 in 2025.

On August 7, 2025, the Company filed a Registration Statement (File No. 333-289339) with the Securities and Exchange Commission (SEC), which was declared effective on August 15, 2025 (2025 Shelf Registration Statement), in relation to the registration of common stock, preferred stock, debt securities, warrants and/or units of any combination thereof for the purposes of selling, from time to time, the Company's common stock, debt securities or other equity securities in one or more offerings. The Company also simultaneously entered into a Sales Agreement with TD Cowen to provide for the offering, issuance and sale of up to an aggregate amount of $150.0 million of the Company's common stock from time to time in "at-the-market" offerings (the 2025 ATM Program) under the 2025 Shelf Registration Statement and subject to the limitations thereof (the 2025 Sales Agreement). During the year ended December 31, 2025, the Company sold 4,160,176 shares pursuant to the 2025 ATM Program for net proceeds of $10,151. Subsequent to December 31, 2025, the Company sold 8,055,260 additional shares, for net proceeds of $22,568.

2018 Stock Option and Grant Plan

In September 2018, the Company adopted the 2018 Stock Option and Grant Plan (the 2018 Plan), which provided for the Company to sell or issue common stock, or other stock-based awards, to employees, members of the board of directors and consultants of the Company. The Company generally granted stock-based awards with service conditions only (service-based awards), although there was one grant with performance conditions. As of December 31, 2020, there were no unvested options with performance conditions. Stock options granted under the 2018 Plan generally vest over three to four years. A total of 1,959,411 options were granted under the 2018 Plan prior to the Company's IPO in October 2019. No further grants may be made under the 2018 Plan subsequent to the IPO.

2019 Stock Option and Incentive Plan

The 2019 Stock Option and Incentive Plan (2019 Plan) was approved by the Company's board of directors on October 14, 2019, and became effective on October 23, 2019. The 2019 Plan provides for the grant of incentive stock options, nonqualified stock options, stock appreciation rights, restricted stock units, restricted stock awards, unrestricted stock awards, cash-based awards and dividend equivalent rights to the Company's officers, employees, directors and consultants. The number of shares initially reserved for issuance under the 2019 Plan was 2,342,288, which will be increased each January 1 thereafter by 4% of the number of shares of the Company's common stock outstanding on the immediately preceding December 31 or such lesser number of shares determined by the Company's board of directors or compensation committee of the board of directors. On June 1, 2023, at the 2023 Annual Meeting of Stockholders of the Company, the stockholders of the Company approved Amendment No. 1 to the 2019 Plan, increasing the number of shares of common stock reserved for issuance under the 2019 Plan by 3,000,000 shares. On January 1, 2026, the total number of shares under the 2019 Plan was increased by 4,019,172 shares pursuant to the 2019 Plan Evergreen Provision. As of December 31, 2025, there were 1,066,471 shares remaining available for issuance under the 2019 Plan.

2025 Inducement Plan

In October 2025, the Company adopted the 2025 Inducement Plan (Inducement Plan). The Inducement Plan was adopted by the Compensation Committee of the Company's board of directors without stockholder approval pursuant to Nasdaq Listing Rule 5635(c)(4). In accordance with Rule 5635(c)(4), awards made under the Inducement Plan, including stock options and restricted stock units, may only be granted to newly hired employees as a material inducement to accept employment with the Company. Stock options granted under the Inducement Plan expire no

later than ten years from the date of grant. The number of shares reserved for issuance under the Inducement Plan was 275,000 shares. As of December 31, 2025, there were no shares available for issuance under the Inducement Plan.

Stock Option Repricing

On May 19, 2025, the Company's Board of Directors approved the repricing of certain outstanding vested and unvested stock options. Pursuant to the repricing, all options granted under the 2018 Plan and 2019 Plan held by current employees, non-employee directors and certain consultants were repriced to $1.92, the closing price of the Company's common stock on May 19, 2025, to the extent such options had an exercise price in excess of 1.5x the $1.92 closing price per share. To exercise the repriced options at the reduced exercise price, eligible participants must remain employed with the Company through a retention period of 12 months that begins on May 19, 2025.

As a result of the repricing, 9,900,096 vested and unvested stock options outstanding as of May 19, 2025, with original exercise prices ranging from $2.88 to $23.97, were repriced. The repricing resulted in incremental stock-based compensation expense of $3,021, of which $1,813 related to vested stock option awards and is being amortized over the retention period, and $1,208 related to unvested stock option awards and is being amortized on a straight-line basis over the remaining vesting period of those awards.

Stock Option Activity

A summary of stock option activity is presented below:

	Number of Shares	Weighted Average Exercise Price [1]	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value [1]
Outstanding as of January 1, 2025	11,231,148	$ 10.63	7.4	$ 989
Granted	3,469,050	1.78		
Exercised	(13,334)	1.01		9
Forfeited/Cancelled	(851,492)	8.29		
Outstanding as of December 31, 2025	13,835,372	$ 8.57	7.1	$ 2,371
Options Exercisable at December 31, 2025	7,860,610	$ 9.45	5.8	$ 899

[1] The weighted average exercise prices and aggregate intrinsic values in this table will not reflect the impact of the May 2025 repricing until the retention period is complete in May 2026.

The aggregate intrinsic value of options is calculated as the difference between the exercise price of the options and the fair value of the Company's common stock. The weighted average grant-date fair value of stock options granted during the years ended December 31, 2025 and 2024 was $1.52 and $13.44, respectively.

The fair value of each award is estimated using Black-Scholes based on the following assumptions:

	Year Ended December 31,	
	2025	2024
Risk-free interest rate	3.72%—4.46%	3.43%—4.60%
Expected term	5.5 years—6.1 years	5.5 years—6.2 years
Expected volatility	112%—118%	106%—111%
Expected dividend yield	0%	0%

Black-Scholes requires the use of subjective assumptions which determine the fair value of stock-based awards. These assumptions include:

Expected term—The expected term represents the period that stock-based awards are expected to be outstanding. The expected term for option grants is determined using the simplified method, which is the midpoint between the vesting period and the contractual term of the option.

Expected volatility—Expected volatility is estimated using the Company's stock price since its IPO in October 2019.

Risk-free interest rate—The risk-free interest rate is based on the U.S. Treasury zero coupon issues in effect at the time of grant for periods corresponding with the expected term of a stock-based award.

Expected dividend—The Company has never paid dividends on its common stock and has no plans to pay dividends on its common stock. Therefore, the Company used an expected dividend yield of zero.

Stock-based Compensation

The Company has recorded stock-based compensation in the accompanying statements of operations as follows:

	Year Ended December 31,	
	2025	2024
Research and development	$ 11,470	$ 10,163
General and administrative	9,469	9,302
Total	$ 20,939	$ 19,465

As of December 31, 2025, there was $35,159 of unrecognized compensation cost related to unvested option awards and vested option awards subject to the twelve month retention period, which is expected to be recognized over a weighted-average period of 2.1 years.

2019 Employee Stock Purchase Plan

The 2019 Employee Stock Purchase Plan (2019 ESPP) was approved by the Company's board of directors on October 14, 2019, and became effective on October 23, 2019. A total of 234,229 shares of common stock were initially reserved for issuance under the 2019 ESPP, and such number of shares will be increased each January 1 thereafter through January 1, 2029 by the least of (i) 234,229 shares of common stock, (ii) 1% of the number of shares of the Company's common stock outstanding on the immediately preceding December 31 or (iii) such lesser number of shares determined by the 2019 ESPP's administrator. On January 1, 2026, the total number of shares available under the 2019 ESPP was increased by 234,229 shares pursuant to the 2019 Plan Evergreen Provision. As of December 31, 2025, there were 136,383 shares remaining available for issuance under the 2019 ESPP.

Employee contributions are made through payroll deductions of up to 15% of eligible compensation over the offering period. A participant may not accrue rights to purchase more than $25 worth of the Company's common stock for each calendar year in which such right is outstanding. At the end of each offering period, shares of the Company's common stock may be purchased at 85% of the lesser of the Company's common stock on (i) the first trading day of the relevant offering period and (ii) the last trading day of the relevant offering period. Each offering period will be six months in duration and will commence on each December 1 and June 1.

11. Income Taxes

The reconciliation of federal statutory income tax rate to the Company's effective income tax rate is as follows:

	Year Ended December 31,			
	2025		2024	
U.S. Statutory Tax Rate	$ (35,304)	21.0%	$ (24,331)	21.0%
State and Local Income Taxes, Net of Federal Income Tax Effect [1]	—	0.0%	—	0.0%
Foreign Tax Effects	24	0.0%	(4)	0.0%
Effect of Cross-Border Tax Laws	94	-0.1%	6	0.0%
Tax Credits	(9,489)	5.6%	(5,769)	5.0%
Change in Valuation Allowances (Domestic)	43,489	-25.9%	29,176	-25.2%
Nontaxable or Nondeductible Items	983	-0.6%	951	-0.8%
Other Adjustments	203	0.0%	(29)	0.0%
Actual income tax benefit effective tax rate	$ —	0.0%	$ —	0.0%

[1] Within the State Income Tax category, Pennsylvania and Philadelphia accounted for the majority, representing over 50% of the total reconciling impact.

Consistent with the Company's cumulative loss position and absence of taxable income in federal, state, and local jurisdictions, the Company made no income tax payments and received no income tax refunds in the current fiscal year.

Deferred income taxes reflect the net effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. The principal components of the Company's deferred tax assets and liabilities consisted of the following:

	Year Ended December 31,	
	2025	2024
Deferred tax assets:		
Federal, state and local net operating loss carryforwards	$ 83,014	$ 44,369
Capitalized research and development costs	31,333	36,646
Research and development tax credits	25,050	16,296
Stock-based compensation deductions	13,299	9,919
License fee deductions	186	221
Operating lease liabilities	7,357	4,607
Accrued expenses	2,805	2,603
Gross deferred tax assets	163,044	114,661
Less: valuation allowance	(157,850)	(110,723)
Total deferred tax assets	5,194	3,938
Deferred tax liabilities:		
Operating lease right-of-use assets	(5,194)	(3,938)
Net deferred tax assets	$ —	$ —

The Company increased its valuation allowance by $47,127 for the year ended December 31, 2025 in order to maintain a full valuation allowance against its deferred tax assets. Based on the Company's history of losses, the Company recorded a full valuation allowance against its deferred tax assets as of December 31, 2025. The Company intends to maintain a valuation allowance until sufficient positive evidence exists to support a reversal of the allowance.

As of December 31, 2025, the Company had federal, state and local net operating loss carryforwards of $319,886, $255,101 and $257,607, respectively; $319,636 of the federal net operating losses do not expire, and the remaining $250 expire in 2037. The state net operating losses begin to expire in 2037. The local net operating losses begin to expire in 2042.

As of December 31, 2025, the Company had federal and state research and development tax credit carryforwards of $25,044 and $6, respectively. The research and development credits begin to expire in 2038. The Company's federal

research credits consist of approximately $13,821 of Research and Development credits and $11,223 of Orphan Drug credits.

Under the provisions of Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, these net operating losses, credit carryforwards and other tax attributes may be subject to limitation based on previous significant changes in ownership and upon future significant changes in ownership of the Company, as defined by the Code.

The Company files income tax returns in the U.S. federal jurisdiction and in multiple state and local jurisdictions; however, Pennsylvania and Philadelphia constitute the Company's most significant tax jurisdictions due to the concentration of its operational footprint and the resulting apportionment profile. The tax years 2024, 2023 and 2022 remain open to examination by the jurisdictions where the Company is subject to tax.

The Company evaluates tax positions for recognition using a more-likely-than-not recognition threshold, and those tax positions eligible for recognition are measured as the largest amount of tax benefit that is greater than 50% likely of being realized upon the effective settlement with a taxing authority that has full knowledge of all relevant information. As of December 31, 2025, the Company had no unrecognized income tax benefits that would affect the Company's effective tax rate if recognized.

12. Net Loss Per Share

The Company calculates basic and diluted net loss per share in conformity with the two-class method required for participating securities. In May 2024, the remaining 1,444,295 shares of non-voting common stock were converted to voting common stock and no shares of non-voting common stock remain outstanding. Since the rights of the voting and non-voting common stock are identical, except with respect to voting, the undistributed losses of the Company have been allocated on a proportionate basis to the two classes. Basic net loss per share of common stock is computed by dividing the net loss per share of common stock by the weighted average number of shares of common stock outstanding for the period. The weighted-average shares of common stock outstanding as of December 31, 2025 included outstanding pre-funded warrants to purchase up to an aggregate of 6,000,000 shares of common stock. No pre-funded warrants were outstanding as of December 31, 2024.

Diluted net loss per share is calculated using the if-converted method as of December 31, 2024, which assumes conversion of all non-voting common stock to voting common stock.

	Year ended December 31, 2025 Voting common stock
Basic and diluted net loss per share:	
Net loss	$ (167,856)
Weighted average number of shares outstanding	79,903,224
Net loss per share, basic and diluted	$ (2.10)

	Year ended December 31, 2024	
	Voting common stock	Non-voting common stock
Basic net loss per share:		
Numerator		
Allocation of undistributed losses	$ (114,728)	$ (1,136)
Denominator		
Weighted average number of shares used in basic per share computation	49,038,726	485,378
Net loss per share, basic	$ (2.34)	$ (2.34)
Diluted net loss per share:		
Numerator		
Allocation of undistributed losses for basic computation	$ (114,728)	$ (1,136)
Reallocation of undistributed losses as a result of conversion of non-voting to voting common shares	(1,136)	—
Allocation of undistributed losses	$ (115,864)	$ (1,136)
Denominator		
Weighted average number of shares used in basic per share computation	49,038,726	485,378
Add: conversion of non-voting to voting common shares outstanding	485,378	—
Weighted average number of shares used in diluted per share computation	49,524,104	485,378
Net loss per share, diluted	$ (2.34)	$ (2.34)

The following outstanding potentially dilutive shares have been excluded from the calculation of diluted net loss per share, as their effect is anti-dilutive:

	Year Ended December 31,	
	2025	2024
Stock options to purchase common stock	13,835,372	11,231,148
Warrants to purchase common stock	53,090,190	—
Total	66,925,562	11,231,148

13. 401(k) Savings Plan

The Company maintains a defined-contribution savings plan under Section 401(k) of the IRC, or the 401(k) Plan. The 401(k) Plan covers all employees who meet defined minimum age and service requirements and allows participants to defer a portion of their annual compensation on a pretax basis. Effective January 1, 2020, the Plan provided for matching contributions on a portion of participant contributions pursuant to the 401(k) Savings Plan's matching formula, up to 4% of eligible compensation. All matching contributions and participant contributions vest immediately. Contributions totaled $1,063 and $894 for the years ended December 31, 2025 and 2024, respectively, and have been recorded in the statements of operations.

EXHIBIT INDEX

Exhibit Number	Description
3.1	Third Amended and Restated Certificate of Incorporation of the Registrant, as currently in effect (incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K (File No. 001-39103) filed on October 30, 2019)
3.2	Certificate of Amendment to the Third Amended and Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's current report on Form 8-K (File No. 001-39103) filed with the SEC on June 10, 2025)
3.3	Amended and Restated Bylaws of the Registrant, as currently in effect (incorporated by reference to Exhibit 3.2 of the Registrant's Current Report on Form 8-K (File No. 001-39103) filed on October 30, 2019)
3.4	Amendment No. 1 to the Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.3 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-39103) filed with the SEC on May 12, 2022)
4.1	Specimen Common Stock Certificate (incorporated by reference to Exhibit 4.1 of the Registrant's Registration Statement on Form S-1 (File No. 333-234017) filed on October 16, 2019)
4.2*	Description of Securities
4.3	Form of Pre-Funded Warrant (incorporated by reference to Exhibit 4.1 of the Registrant's Current Report on Form 8-K (File No. 001-39103) filed with the SEC on December 12, 2022
4.4	Form of Pre-Funded Warrant (incorporated by reference to Exhibit 4.1 to the Registrant's current report on Form 8-K (File No. 001-39103) filed with the SEC on June 12, 2025)
4.5	Form of Common Stock Warrant (incorporated by reference to Exhibit 4.2 to the Registrant's current report on Form 8-K (File No. 001-39103) filed with the SEC on June 12, 2025)
10.1#	2018 Stock Option and Grant Plan, as amended, and form of award agreements thereunder (incorporated by reference to Exhibit 10.1 of the Registrant's Registration Statement on Form S-1 (File No. 333-234017) filed on September 30, 2019)
10.2#	2019 Stock Option and Incentive Plan, and form of award agreements thereunder. (incorporated by reference to Exhibit 10.2 of the Registrant's Registration Statement on Form S-1/A (File No. 333-234017) filed on October 16, 2019)
10.3#	Amendment No. 1 to the Cabaletta Bio, Inc. 2019 Stock Option and Incentive Plan (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on June 1, 2023)
10.4#	2019 Employee Stock Purchase Plan. (incorporated by reference to Exhibit 10.3 of the Registrant's Registration Statement on Form S-1/A (File No. 333-234017) filed on October 16, 2019)
10.5#	Senior Executive Cash Incentive Bonus Plan (incorporated by reference to Exhibit 10.4 of the Registrant's Quarterly Report on Form 10-Q filed on December 5, 2019)
10.6#	Form of Indemnification Agreement between the Registrant and each of its directors (incorporated by reference to Exhibit 10.5 of the Registrant's Registration Statement on Form S-1, filed with the SEC on September 30, 2019)

10.7#	Form of Indemnification Agreement between the Registrant and each of its executive officers (incorporated by reference to Exhibit 10.4 of the Registrant's Registration Statement on Form S-1, filed with the SEC on September 30, 2019)
10.8#*	Cabaletta Bio, Inc. 2025 Inducement Plan
10.9+	Amended and Restated License Agreement, dated as of July 23, 2019, among the Registrant, the Trustees of the University of Pennsylvania and the Children's Hospital of Philadelphia (incorporated by reference to Exhibit 10.6 to the Registrant's Registration Statement on Form S-1, filed with the SEC on September 30, 2019)
10.10+	Master Translational Research Services Agreement, dated as of October 2018, between the Registrant and the Trustees of the University of Pennsylvania (incorporated by reference to Exhibit 10.9 to the Registrant's Registration Statement on Form S-1, filed with the SEC on September 30, 2019)
10.11+	CVPF Master Services Addendum to Master Translational Research Services Agreement, dated as of October 22, 2018, between the Registrant and the Trustees of the University of Pennsylvania (incorporated by reference to Exhibit 10.11 to the Registrant's Registration Statement on Form S-1, filed with the SEC on September 30, 2019)
10.12	Lease, dated as of February 11, 2019, between the Registrant and Brandywine Cira, L.P. (incorporated by reference to Exhibit 10.13 to the Registrant's Registration Statement on Form S-1, filed with the SEC on September 30, 2019)
10.13#	Employment Agreement between the Registrant and Steven Nichtberger (incorporated by reference to Exhibit 10.16 to the Registrant's Registration Statement on Form S-1, filed with the SEC on September 30, 2019)
10.14#	Employment Agreement between the Registrant and Anup Marda (incorporated by reference to Exhibit 10.17 to the Registrant's Registration Statement on Form S-1, filed with the SEC on September 30, 2019)
10.15#	Employment Agreement between the Registrant and Gwendolyn Binder (incorporated by reference to Exhibit 10.18 to the Registrant's Registration Statement on Form S-1, filed with the SEC on September 30, 2019)
10.16#	Employment Agreement between the Registrant and David Chang (incorporated by reference to Exhibit 10.19 to the Registrant's Registration Statement on Form S-1, filed with the SEC on September 30, 2019)
10.17#	Fourth Amended and Restated Non-Employee Director Compensation Policy (incorporated by reference to Exhibit 10.17 to the Registrant's Annual Report on Form 10-K (File No. 001-39103) filed on March 31, 2025)
10.18+	First Amendment, dated May 27, 2020, to the Amended and Restated License Agreement, dated July 23, 2019, among the Registrant, the Trustees of the University of Pennsylvania and the Children's Hospital of Philadelphia (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K (File No. 001-39103) filed on May 28, 2020)
10.19+	Second Amendment, dated October 19, 2021, to the First Amended and Restated License Agreement, dated May 27, 2020, among the Registrant, the Trustees of the University of Pennsylvania and the Children's Hospital of Philadelphia (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-39103) filed on November 1, 2021)
10.20	First Amendment, dated February 15, 2022, to the Lease, dated as of February 11, 2019, between the Registrant and Brandywine Cira, L.P. (incorporated by reference to Exhibit 10.26 to the Registrant's Annual Report on Form 10-K (File No. 001-39103) filed on March 17, 2022)

10.21#	Form of Employment Agreement (incorporated by reference to Exhibit 10.28 to the Registrant's Annual Report on Form 10-K (File No. 001-39103) filed on March 17, 2022)
10.22+	Option Agreement, dated December 23, 2021, by and between the Registrant and the Trustees of the University of Pennsylvania (incorporated by reference to Exhibit 10.30 to the Registrant's Annual Report on Form 10-K (File No. 001-39103) filed on March 17, 2022)
10.23+	Licence and Supply Agreement, dated December 30, 2021, by and between the Registrant and Oxford Biomedica (UK) Limited (incorporated by reference to Exhibit 10.31 to the Registrant's Annual Report on Form 10-K (File No. 001-39103) filed on March 17, 2022)
10.24+	First Amendment to the Licence and Supply Agreement, dated as of May 2, 2023, between the Registrant and Oxford Biomedica (UK) Limited (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-39103) filed on August 10, 2023)
10.25+	Second Amendment to the Licence and Supply Agreement, dated as of August 18, 2023, between the Registrant and Oxford Biomedica (UK) Limited (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-39103) filed on November 9, 2023)
10.26+	Exclusive License Agreement, dated October 7, 2022, by and between the Registrant and Nanjing IASO Biotherapeutics Co., LTD (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-39103) filed on November 10, 2022)
10.27+	Development, Manufacturing, and Testing Services Agreement, dated January 11, 2021, between the Registrant and WuXi Advanced Therapies Inc. (incorporated by reference to Exhibit 10.34 to the Registrant's Annual Report on Form 10-K (File No. 001-39103) filed on March 16, 2023)
10.28+	Master Translational Research Services Agreement, dated as of February 9, 2023, between the Registrant and the Trustees of the University of Pennsylvania (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-39103) filed on May 11, 2023)
10.29+	Third Amendment to the Licence and Supply Agreement, dated as of February 21, 2024, between the Registrant and Oxford Biomedica (UK) Limited (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-39103) filed on May 15, 2024)
10.30+	Fourth Amendment to the Licence and Supply Agreement, dated as of June 24, 2024, between the Registrant and Oxford Biomedica (UK) Limited (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-39103) filed on August 8, 2024)
10.31+	Services Agreement, dated as of February 1, 2019, between the Registrant and CIC Innovation Communities, LLC (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-39103) filed on November 14, 2024)
10.32+	Amendment to the Services Agreement, dated as of December 1, 2021, between the Registrant and CIC Innovation Communities, LLC (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-39103) filed on November 14, 2024)
10.33+	Amendment to the Services Agreement, dated as of September 30, 2024, between the Registrant and CIC Innovation Communities, LLC (incorporated by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-39103) filed on November 14, 2024)
10.34+	Second Amendment, dated September 24, 2024, to the Lease, dated as of February 11, 2019, between the Registrant and Brandywine Cira, L.P., as amended. (incorporated by reference to Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-39103) filed on November 14, 2024)

10.35+	Development and Manufacturing Services Agreement, dated as of December 19, 2024, between the Registrant and Lonza Houston Inc. (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-39103) filed on August 7, 2025)
10.38+*	Development and Manufacturing Services Agreement, dated as of January 11, 2026, between the Registrant and Cellares Corporation
19.1	Insider Trading Policy (incorporated by reference to Exhibit 19.1 to the Registrant's Annual Report on Form 10-K (File No. 001-39103) filed on March 31, 2025)
21.1*	List of Subsidiaries of the Registrant
23.1*	Consent of Ernst & Young, independent registered public accounting firm
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as amended
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as amended
32.1**	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to 18 U.S.C. Section 1350, as adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2**	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to 18 U.S.C. Section 1350, as adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
99.7	Cabaletta Bio, Inc.'s Compensation Recovery Policy (incorporated by reference to Exhibit 99.7 to the Registrant's Annual Report on Form 10-K (File No. 001-39103) filed on March 21, 2024)
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 with applicable taxonomy extension information contained in Exhibits 101*)

Management Contract or compensatory plan or arrangement.

+ Portions of this exhibit (indicated by asterisks) have been omitted pursuant to Item 601(b)(10) of Regulation S-K.

* Filed herewith.

** The certifications furnished in Exhibit 32.1 and 32.2 hereto are deemed to accompany this Annual Report on Form 10-K and will not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended. Such certifications will not be deemed to be incorporated by reference into any filings under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, except to the extent that the Registrant specifically incorporates it by reference.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized**.**

Cabaletta Bio, Inc.

Date: March 23, 2026

By: /s/ Steven Nichtberger
Steven Nichtberger, M.D.
Chief Executive Officer and President

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Annual Report on Form 10-K has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

Name	Title	Date
/s/ Steven Nichtberger **Steven Nichtberger, M.D.**	*Director, Chief Executive Officer and President (Principal Executive Officer)*	March 23, 2026
/s/ Anup Marda **Anup Marda**	*Chief Financial Officer (Principal Financial and Accounting Officer)*	March 23, 2026
/s/ Catherine Bollard **Catherine Bollard, M.D.**	*Director*	March 23, 2026
/s/ Scott Brun **Scott Brun, M.D.**	*Director*	March 23, 2026
/s/ Richard Henriques **Richard Henriques**	*Director*	March 23, 2026
/s/ Mark Simon **Mark Simon**	*Director*	March 23, 2026
/s/ Shawn Tomasello **Shawn Tomasello**	*Director*	March 23, 2026

Exhibit 4.2

Description of the Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934, as amended

The following summary of the general terms and provisions of the registered capital stock of Cabaletta Bio, Inc. ("Cabaletta", "we", "our") does not purport to be complete and is subject to, and qualified in its entirety by, reference to our Third Amended and Restated Certificate of Incorporation, or certificate of incorporation, our Amended and Restated Bylaws, or bylaws, each of which is incorporated by reference as an exhibit to our most recent Annual Report on Form 10-K filed with the Securities and Exchange Commission, and applicable provisions of the Delaware General Corporation Law, or the DGCL. Our common stock, par value $0.00001 per share is registered pursuant to Section 12(b) of the Securities and Exchange Act of 1934 and trades on the Nasdaq Global Select Market under the symbol CABA. The summaries below do not purport to be complete statements of the relevant provisions of the certificate of incorporation, the bylaws or the DGCL.

General

Our authorized capital stock consists of three hundred and ten million (310,000,000) shares, of which (i) two hundred and ninety three million five hundred and ninety thousand four hundred and eighty-one (293,590,481) shares are designated as voting common stock, par value $0.00001 per share, or the common stock, (ii) six million four hundred and nine thousand five hundred and nineteen (6,409,519) shares are designated as non-voting common stock, par value $0.00001 per share, or the non-voting common stock, and (iii) ten million (10,000,000) shares are designated as undesignated preferred stock, par value $0.00001 per share, or the preferred stock.

Common Stock and Non-Voting Common Stock

The holders of our common stock and non-voting common stock have identical rights, provided that, (i) except as otherwise expressly provided in our certificate of incorporation or as required by applicable law, on any matter that is submitted to a vote by our stockholders, holders of our common stock are entitled to one vote per share of common stock, and holders of our non-voting common stock are not entitled to any votes per share of non-voting common stock, including for the election of directors, and (ii) holders of our common stock have no conversion rights, while holders of our non-voting common stock shall have the right to convert each share of our non-voting common stock into one share of common stock at such holder's election, 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 4.99% of our common stock immediately prior to and following such conversion, unless otherwise as expressly provided for in our certificate of incorporation. However, this ownership limitation may be increased or decreased to any other percentage designated by such holder of non-voting common stock upon 61 days' notice to us.

Holders of our common stock and non-voting common stock are entitled to receive ratably any dividends declared by our board of directors out of funds legally available for that purpose, subject to any preferential dividend rights of any outstanding preferred stock. Our common stock and non-voting common stock have no preemptive rights or other subscription rights or redemption or sinking fund provisions.

In the event of our liquidation, dissolution or winding up, holders of our common stock and non-voting common stock will be entitled to share ratably in all assets remaining after payment of all debts and other liabilities and any liquidation preference of any outstanding preferred stock.

Our common stock is listed on the Nasdaq Global Select Market under the trading symbol "CABA."

The transfer agent and registrar for our common stock is Equiniti Trust Company, LLC.

Preferred Stock

Our board of directors will have the authority, from time to time, without further action by our stockholders, to issue up to 10,000,000 shares of preferred stock in one or more series and to fix the rights, preferences, privileges and restrictions thereof. These rights, preferences and privileges could include dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences, sinking fund terms and the number of shares constituting, or the designation of, such series, any or all of which may be greater than the rights of common stock and non-voting common stock. The issuance of our preferred stock could adversely affect the voting power of holders of common stock and the likelihood that such holders and holders of our non-voting common stock will receive dividend payments and payments upon our liquidation. In addition, the issuance of preferred stock could have the effect of delaying, deferring or preventing a change in control of our company or other corporate action.

Pre-funded Warrants and Warrants

In June 2025, we issued (i) 39,200,000 shares of our common stock and accompanying warrants to purchase an aggregate of 39,200,000 shares of common stock (or pre-funded warrants in lieu thereof) at a combined price of $2.00 and (ii) to certain investors in lieu of common stock, pre-funded warrants to purchase 10,800,000 shares of our common stock and accompanying warrants to purchase an aggregate of 10,800,000 shares of common stock (or pre-funded warrants in lieu thereof) at a combined price of $1.99999 per pre-funded warrant. The accompanying warrant has an exercise price of $2.50 per share, is immediately exercisable from the date of issuance and will expire fifteen months from the date of issuance. As of December 31, 2025, all pre-funded warrants and warrants remain outstanding.

A holder of the pre-funded warrants will not be entitled to exercise any portion of any pre-funded warrant, (i) if immediately prior to exercise the holder (together with its affiliates) beneficially owns an aggregate number of shares of our common stock greater than 4.5%, 4.99% or 9.99%, as applicable, of the number of shares of our common stock outstanding immediately before giving effect to the exercise of any pre-funded warrant or (ii) to the extent that immediately following exercise, the holder (together with its affiliates) would beneficially own in excess of 4.5%, 4.99% or 9.99%, as applicable, of the number of shares of common stock outstanding immediately after giving effect to the issuance of such shares of common stock, and without taking account any other pre-funded warrants. However, any holder may increase or decrease such percentage to any other percentage not in excess of 19.99% upon at least 61 days' prior notice from the holder to us.

The exercise price per whole share of our common stock purchasable upon the exercise of the pre-funded warrants is $0.00001 per share of common stock. The exercise price of the pre-funded warrants and the number of shares of our common stock issuable upon exercise of the pre-funded warrants is subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting our common stock. The exercise price will not be adjusted below the par value of our common stock. The pre-funded warrants will not expire.

Except by virtue of such holder's ownership of shares of our common stock, the holder of a pre-funded warrant does not have the rights or privileges of a holder of our common stock, including any voting rights, until such holder exercises the pre-funded warrant.

A holder of the common stock warrants will not be entitled to exercise any portion of any common stock warrant, (i) if immediately prior to exercise the holder (together with its affiliates) beneficially owns an aggregate number of shares of our common stock greater than 4.5%, 4.99% or 9.99%, as applicable, of the number of shares of our common stock outstanding immediately before giving effect to the exercise of any common stock warrant or (ii) to the extent that immediately following exercise, the holder (together with its affiliates) would beneficially own in excess of 4.5%, 4.99% or 9.99%, as applicable, of the number of shares of common stock outstanding immediately after giving effect to the issuance of such shares of common stock. However, any holder may increase or decrease such percentage to any other percentage not in excess of 19.99% upon at least 61 days' prior notice from the holder to us. If the holder is not permitted to exercise a common stock warrant due to the foregoing limitation, then the holder may exercise such warrant for an equivalent number of pre-funded warrants with an exercise price of $0.00001 in substantially the same form of pre-funded warrant to purchase shares of common stock described above.

The initial exercise price per whole share of our common stock purchasable upon the exercise of the common stock warrants is $2.50 per share of common stock (or, if the purchaser elects, $0.00001 per pre-funded warrant). The exercise price of the common stock warrants and the number of shares of our common stock (or, if the purchaser elects, pre-funded warrants) issuable upon exercise of the common stock warrants is subject to appropriate adjustment in the event of certain stock dividends, subdivisions, stock splits, stock combinations, reclassifications, reorganizations or similar events affecting our common stock. The common warrants will expire on September 12, 2026.

Except by virtue of such holder's ownership of shares of our common stock, the holder of a common stock warrant does not have the rights or privileges of a holder of our common stock, including any voting rights, until the holder exercises the common stock warrant to receive shares of our common stock.

Anti-Takeover Effects of our Certificate of Incorporation and Bylaws and Delaware Law

Our certificate of incorporation and bylaws include a number of provisions that may have the effect of delaying, deferring or preventing another party from acquiring control of us and encouraging persons considering unsolicited tender offers or other unilateral takeover proposals to negotiate with our board of directors rather than pursue non-negotiated takeover attempts. These provisions include the items described below.

Board Composition and Filling Vacancies

Our certificate of incorporation provides for the division of our board of directors into three classes serving staggered three-year terms, with one class being elected each year. Our certificate of incorporation provides that directors may be removed only for cause and then only by the affirmative vote of the holders of 75% or more of the outstanding shares then entitled to vote at an election of directors. Furthermore, any vacancy on our board of directors, however occurring, including a vacancy resulting from an increase in the size of our board, may only be filled by the affirmative vote of a majority of our directors then in office even if less than a quorum. The

classification of directors, together with the limitations on removal of directors and treatment of vacancies, has the effect of making it more difficult for stockholders to change the composition of our board of directors.

No Written Consent of Stockholders

Our certificate of incorporation provides that all stockholder actions are required to be taken by a vote of the stockholders at an annual or special meeting, and that stockholders may not take any action by written consent in lieu of a meeting. This limit may lengthen the amount of time required to take stockholder actions and would prevent the amendment of our bylaws or removal of directors by our stockholders without holding a meeting of stockholders.

Meetings of Stockholders

Our certificate of incorporation and bylaws provide that only a majority of the members of our board of directors then in office may call special meetings of stockholders and only those matters set forth in the notice of the special meeting may be considered or acted upon at a special meeting of stockholders. Our 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

Our bylaws establish advance notice procedures with regard to stockholder proposals relating to the nomination of candidates for election as directors or new business to be brought before meetings of our stockholders. These procedures provide that notice of stockholder proposals must be timely given in writing to our corporate secretary prior to the meeting at which the action is to be taken. Generally, to be timely, notice must be received at our principal executive offices not less than 90 days nor more than 120 days prior to the first anniversary date of the annual meeting for the preceding year. Our bylaws specify the requirements as to form and content of all stockholders' notices. These requirements may preclude stockholders from bringing matters before the stockholders at an annual or special meeting.

Amendment to Certificate of Incorporation and Bylaws

Any amendment of our certificate of incorporation must first be approved by a majority of our board of directors, and, if required by law, our certificate of incorporation must thereafter be approved by a majority of the outstanding shares entitled to vote on the amendment and a majority of the outstanding shares of each class entitled to vote thereon as a class, except that the amendment of the provisions relating to stockholder action, board composition, limitation of liability and the amendment of our bylaws and certificate of incorporation must be approved by not less than 75% of the outstanding shares entitled to vote on the amendment, and not less than 75% of the outstanding shares of each class entitled to vote thereon as a class. Our bylaws may be amended by the affirmative vote of a majority of the directors then in office, subject to any limitations set forth in the bylaws; and may also be amended by the affirmative vote of at least 75% of the outstanding shares entitled to vote on the amendment, or, if our board of directors recommends that the stockholders approve the amendment, by the affirmative vote of the majority of the outstanding shares entitled to vote on the amendment, in each case voting together as a single class.

Undesignated Preferred Stock

Our certificate of incorporation authorizes 10,000,000 shares of preferred stock. The existence of authorized but unissued shares of preferred stock may enable our board of directors to discourage an attempt to obtain control of us by means of a merger, tender offer, proxy contest or otherwise. For example, if in the due exercise of its fiduciary obligations, our board of directors were to determine that a takeover proposal is not in the best interests of our stockholders, our board of directors could cause shares of preferred stock to be issued without stockholder approval in one or more private offerings or other transactions that might dilute the voting or other rights of the proposed
acquirer or insurgent stockholder or stockholder group. In this regard, our certificate of incorporation grants our board of directors broad power to establish the rights and preferences of authorized and unissued shares of preferred stock. The issuance of shares of preferred stock could decrease the amount of earnings and assets available for distribution to holders of shares of common stock. The issuance may also adversely affect the rights and powers, including voting rights, of these holders and may have the effect of delaying, deterring or preventing a change in control of us.

Choice of forum

Our bylaws provide that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for any state law claim for: (1) any derivative action or proceeding brought on our behalf; (2) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers, or other employees to us or our stockholders; (3) any action asserting a claim arising pursuant to any provision of the DGCL or our certificate of incorporation or bylaws (including the interpretation, application or validity thereof); or (4) any action asserting a claim governed by the internal affairs doctrine, or the Delaware Forum Provision. The choice of forum provision does not apply to any actions arising under the Securities

Act or the Exchange Act. Our bylaws further provide that, unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States of America are the sole and exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, or the rules and regulations promulgated thereunder, or the Federal Forum Provision. In addition, our bylaws provide that any person or entity purchasing or otherwise acquiring any interest in shares of our common stock is deemed to have notice of and consented to the foregoing Delaware Forum Provision and Federal Forum Provision; provided, however, that stockholders cannot and will not be deemed to have waived our compliance with the U.S. federal securities laws and the rules and regulations thereunder.

The Delaware Forum Provision and the Federal Forum Provision may impose additional litigation costs on stockholders in pursuing any such claims. Additionally, these forum selection clauses may limit our stockholders' ability to bring a claim in a judicial forum that they find favorable for disputes with us or our directors, officers or employees, which may discourage the filing of lawsuits against us and our directors, officers and employees even though an action, if successful, might benefit our stockholders. While the Delaware Supreme Court and other states have upheld the validity of federal forum selection provisions purporting to require claims under the Securities Act be brought in federal court, there is uncertainty as to whether other courts will enforce our Federal Forum Provision. If the Federal Forum Provision is found to be unenforceable, we may incur additional costs with resolving such matters. The Federal Forum Provision may also impose additional litigation costs on us and/or our stockholders who assert that the provision is invalid or unenforceable. The Court of Chancery of the State of Delaware or the federal district courts of the United States of America may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments may be more or less favorable to us than our stockholders.

Section 203 of the DGCL

We are subject to the provisions of Section 203 of the DGCL. In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a three-year period following the time that this stockholder becomes an interested stockholder, unless the business combination is approved in a prescribed manner. Under Section 203, a business combination between a corporation and an interested stockholder is prohibited unless it satisfies one of the following conditions:

- before the stockholder became interested, our board of directors approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;\

- upon consummation of the transaction which resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock

- outstanding, shares owned by persons who are directors and also officers, and employee stock plans, in some instances, but not the outstanding voting stock owned by the interested stockholder; or

- at or after the time the stockholder became interested, the business combination was approved by our board of directors and authorized at an annual or special meeting of the stockholders by the affirmative vote of at least two-thirds of the outstanding voting stock which is not owned by the interested stockholder.

Section 203 defines a business combination to include:

- any merger or consolidation involving the corporation and the interested stockholder;

- any sale, transfer, lease, pledge or other disposition involving the interested stockholder of 10% or more of the assets of the corporation;

- subject to exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;

- subject to exceptions, any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder; and

- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines an interested stockholder as any entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by the entity or person.

Exhibit 10.8

CABALETTA BIO, INC.

2025 INDUCEMENT PLAN

SECTION 1. GENERAL PURPOSE OF THE PLAN; DEFINITIONS

The name of the plan is the Cabaletta Bio, Inc. 2025 Inducement Plan (the "Plan"). The purpose of the Plan is to enable Cabaletta Bio, Inc. (the "Company") to grant equity awards to induce highly qualified prospective officers and employees who are not currently employed by the Company and its Affiliates to accept employment and provide them with a proprietary interest in the Company. It is anticipated that providing such persons with a direct stake in the Company's welfare will assure a closer identification of their interests with those of the Company and its stockholders, thereby stimulating their efforts on the Company's behalf and strengthening their desire to remain with the Company. The Company intends that the Plan be reserved for persons to whom the Company may issue securities without stockholder approval as an inducement pursuant to Rule 5635(c)(4) of the Marketplace Rules of the NASDAQ Stock Market, Inc.

The following terms shall be defined as set forth below:

"Act" means the Securities Act of 1933, as amended, and the rules and regulations thereunder.

"Administrator" means either the Board or the compensation committee of the Board or a similar committee performing the functions of the compensation committee and which is comprised of not less than two Non-Employee Directors who are independent.

"*Affiliate*" means, at the time of determination, any "parent" or "subsidiary" of the Company as such terms are defined in Rule 405 of the Act. The Board will have the authority to determine the time or times at which "parent" or "subsidiary" status is determined within the foregoing definition.

"Award" or *"Awards,"* except where referring to a particular category of grant under the Plan, shall include Non-Qualified Stock Options, Stock Appreciation Rights, Restricted Stock Units, Restricted Stock Awards, Unrestricted Stock Awards, and Dividend Equivalent Rights.

"Award Certificate" means a written or electronic document setting forth the terms and provisions applicable to an Award granted under the Plan. Each Award Certificate is subject to the terms and conditions of the Plan.

"Board" means the Board of Directors of the Company.

"Code" means the Internal Revenue Code of 1986, as amended, and any successor Code, and related rules, regulations and interpretations.

"Consultant" means a consultant or adviser who provides *bona fide* services to the Company or an Affiliate as an independent contractor and who qualifies as a consultant or advisor under Instruction A.1.(a)(1) of Form S-8 under the Act.

"Dividend Equivalent Right" means an Award entitling the grantee to receive credits based on cash dividends that would have been paid on the shares of Stock specified in the Dividend Equivalent Right (or other award to which it relates) if such shares had been issued to and held by the grantee.

"Effective Date" means the date on which the Plan is approved by the Board as set forth in Section 19.

"Exchange Act" means the Securities Exchange Act of 1934, as amended, and the rules and regulations thereunder.

"Fair Market Value" of the Stock on any given date means the fair market value of the Stock determined in good faith by the Administrator; provided, however, that if the Stock is listed on the National Association of Securities Dealers Automated Quotation System ("Nasdaq"), Nasdaq Global Market, The New York Stock Exchange or another national securities exchange or traded on any established market, the determination shall be made by reference to market quotations. If there are no market quotations for such date, the determination shall be made by reference to the last date preceding such date for which there are market quotations.

"*NASDAQ Inducement Exception*" means Rule 5635(c)(4) of the Marketplace Rules of the NASDAQ Stock Market, Inc., or any successor rule, and related guidance thereunder.

"Non-Employee Director" means a member of the Board who is not also an employee of the Company or any Subsidiary.

"Non-Qualified Stock Option" means any Stock Option that is not an "incentive stock option" as defined in Section 422 of the Code.

"Option" or *"Stock Option"* means any option to purchase shares of Stock granted pursuant to Section 5.

"Restricted Shares" means the shares of Stock underlying a Restricted Stock Award that remain subject to a risk of forfeiture or the Company's right of repurchase.

"Restricted Stock Award" means an Award of Restricted Shares subject to such restrictions and conditions as the Administrator may determine at the time of grant.

"Restricted Stock Units" means an Award of stock units subject to such restrictions and conditions as the Administrator may determine at the time of grant.

"Sale Event" shall mean (i) the sale of all or substantially all of the assets of the Company on a consolidated basis to an unrelated person or entity, (ii) a merger, reorganization or consolidation pursuant to which the holders of the Company's outstanding voting power and outstanding stock immediately prior to such transaction do not own a majority of the outstanding voting power and outstanding stock or other equity interests of the resulting or successor entity (or its ultimate parent, if applicable) immediately upon completion of such transaction, (iii) the sale of all of the Stock of the Company to an unrelated person, entity or group thereof acting in concert, or (iv) any other transaction in which the owners of the Company's outstanding voting power immediately prior to such transaction do not own at least a majority of the outstanding voting power of the Company or any successor entity immediately upon completion of the transaction other than as a result of the acquisition of securities directly from the Company.

"*Sale Price*" means the value as determined by the Administrator of the consideration payable, or otherwise to be received by stockholders, per share of Stock pursuant to a Sale Event.

"Section 409A" means Section 409A of the Code and the regulations and other guidance promulgated thereunder.

"Service Relationship" means any relationship as an employee, director or Consultant of the Company or any Affiliate (e.g., a Service Relationship shall be deemed to continue without interruption in the event an individual's status changes from full-time employee to part-time employee or Consultant).

"Stock" means the Common Stock, par value $0.00001 per share, of the Company, subject to adjustments pursuant to Section 3.

"Stock Appreciation Right" means an Award entitling the recipient to receive shares of Stock (or cash, to the extent explicitly provided for in the applicable Award Certificate) having a value equal to the excess of the Fair Market Value of the Stock on the date of exercise over the exercise price of the Stock Appreciation Right multiplied by the number of shares of Stock with respect to which the Stock Appreciation Right shall have been exercised.

"Subsidiary" means any corporation or other entity (other than the Company) in which the Company has at least a 50 percent interest, either directly or indirectly.

"Unrestricted Stock Award" means an Award of shares of Stock free of any restrictions.

SECTION 2. ADMINISTRATION OF PLAN; ADMINISTRATOR AUTHORITY TO SELECT GRANTEES AND DETERMINE AWARDS

(a) Administration of Plan. The Plan shall be administered by the Administrator.

(b) Powers of Administrator. The Administrator shall have the power and authority to grant Awards consistent with the terms of the Plan, including the power and authority:

(i) to select the individuals to whom Awards may from time to time be granted;

(ii) to determine the time or times of grant, and the extent, if any, of Non-Qualified Stock Options, Stock Appreciation Rights, Restricted Stock Awards, Restricted Stock Units, Unrestricted Stock Awards, Cash-Based Awards, and Dividend Equivalent Rights, or any combination of the foregoing, granted to any one or more grantees;

(iii) to determine the number of shares of Stock to be covered by any Award;

(iv) to determine and modify from time to time the terms and conditions, including restrictions, not inconsistent with the terms of the Plan, of any Award, which terms and conditions may differ among individual Awards and grantees, and to approve the forms of Award Certificates;

(v) to accelerate at any time the exercisability or vesting of all or any portion of any Award;

(vi) subject to the provisions of Section 5(c), to extend at any time the period in which Stock Options may be exercised; and

(vii) at any time to adopt, alter and repeal such rules, guidelines and practices for administration of the Plan and for its own acts and proceedings as it shall deem advisable; to interpret the terms and provisions of the Plan and any Award (including related written instruments); to make all determinations it deems advisable for the administration of the Plan; to decide all disputes arising in connection with the Plan; and to otherwise supervise the administration of the Plan.

All decisions and interpretations of the Administrator shall be binding on all persons, including the Company and Plan grantees.

(c) Delegation of Authority to Grant Awards. Subject to applicable law and the NASDAQ Inducement Exception, the Administrator, in its discretion, may delegate to a committee consisting of one or more officers of the Company including the Chief Executive Officer of the Company all or part of the Administrator's authority and duties with respect to the granting of Awards to individuals who are (i) not subject to the reporting and other provisions of Section 16 of the Exchange Act and (ii) not members of the delegated committee. Any such delegation by the Administrator shall include a limitation as to the amount of Stock underlying Awards that may be granted during the period of the delegation and shall contain guidelines as to the determination of the exercise price and the vesting criteria. The Administrator may revoke or amend the terms of a delegation at any time but such action shall not invalidate any prior actions of the Administrator's delegate or delegates that were consistent with the terms of the Plan.

(d) Award Certificate. Awards under the Plan shall be evidenced by Award Certificates that set forth the terms, conditions and limitations for each Award which may include, without limitation, the term of an Award and the provisions applicable in the event employment or service terminates.

(e) Indemnification. Neither the Board nor the Administrator, nor any member of either or any delegate thereof, shall be liable for any act, omission, interpretation, construction or determination made in good faith in connection with the Plan, and the members of the Board and the Administrator (and any delegate thereof) shall be entitled in all cases to indemnification and reimbursement by the Company in respect of any claim, loss, damage or expense (including, without limitation, reasonable attorneys' fees) arising or resulting therefrom to the fullest extent permitted by law and/or under the Company's articles or bylaws or any directors' and officers' liability insurance coverage which may be in effect from time to time and/or any indemnification agreement between such individual and the Company.

(f) Foreign Award Recipients. Notwithstanding any provision of the Plan to the contrary, in order to comply with the laws in other countries in which the Company and its Subsidiaries operate or have employees or other individuals eligible for Awards, the Administrator, in its sole discretion, shall have the power and authority to: (i) determine which Subsidiaries shall be covered by the Plan; (ii) determine which individuals outside the United States are eligible to participate in the Plan; (iii) modify the terms and conditions of any Award granted to individuals outside the United States to comply with applicable foreign laws; (iv) establish subplans and modify exercise procedures and other terms and procedures, to the extent the Administrator determines such actions to be necessary or advisable (and such subplans and/or modifications shall be attached to this Plan as appendices); provided, however, that no such subplans and/or modifications shall increase the share limitations contained in Section 3(a) hereof; and (v) take any action, before or after an Award is made, that the Administrator determines to be necessary or advisable to obtain approval or comply with any local governmental regulatory exemptions or approvals. Notwithstanding the foregoing, the Administrator may not take any actions hereunder, and no Awards shall be granted, that would violate the Exchange Act or any other applicable United States securities law, the Code, or any other applicable United States governing statute or law.

SECTION 3. STOCK ISSUABLE UNDER THE PLAN; MERGERS; SUBSTITUTION

(a) Stock Issuable. The maximum number of shares of Stock reserved and available for issuance under the Plan shall be 275,000 shares, subject to adjustment as provided in Section 3(b). For purposes of this limitation, the shares of Stock underlying any awards under the Plan that are forfeited, canceled, held back upon exercise of an Option or settlement of an Award to cover the exercise price or tax withholding, reacquired by the Company prior to vesting, satisfied without the issuance of Stock or otherwise terminated (other than by exercise) shall be added back to the shares of Stock available for issuance under the Plan. In the event the Company repurchases shares of Stock on the open market, such shares shall not be added to the shares of Stock available for issuance under the Plan. Subject to such overall limitations, shares of Stock may be issued up to such maximum number pursuant to any type or types of Award. The shares available for issuance under the Plan may be authorized but unissued shares of Stock or shares of Stock reacquired by the Company.

(b) Changes in Stock. Subject to Section 3(c) hereof, if, as a result of any reorganization, recapitalization, reclassification, stock dividend, stock split, reverse stock split or other similar change in the Company's capital stock, the outstanding shares of Stock are increased or decreased or are exchanged for a different number or kind of shares or other securities of the Company, or additional shares or new or different shares or other securities of the Company or other non-cash assets are distributed with respect to such shares of Stock or other securities, or, if, as a result of any merger or consolidation, sale of all or substantially all of the assets of the Company, the outstanding shares of Stock are converted into or exchanged for securities of the Company or any successor entity (or a parent or subsidiary thereof), the Administrator shall make an appropriate or proportionate adjustment in (i) the maximum number of shares reserved for issuance under the Plan, (ii) the number and kind of shares or other securities subject to any then outstanding Awards under the Plan, (iii) the repurchase price, if any, per share subject to each outstanding Restricted Stock Award, and (iv) the exercise price for each share subject to any then outstanding Stock Options and Stock Appreciation Rights under the Plan, without changing the aggregate exercise price (i.e., the exercise price multiplied by the number of shares subject to Stock Options and Stock Appreciation Rights) as to which such Stock Options and Stock Appreciation Rights remain exercisable. The Administrator shall also make equitable or proportionate adjustments in the number of shares subject to outstanding Awards and the exercise price and the terms of outstanding Awards to take into consideration cash dividends paid other than in the ordinary course or any other extraordinary corporate event. The adjustment by the Administrator shall be final, binding and conclusive. No fractional shares of Stock shall be issued under the Plan resulting from any such adjustment, but the Administrator in its discretion may make a cash payment in lieu of fractional shares.

(c) Mergers and Other Transactions. In the case of and subject to the consummation of a Sale Event, the parties thereto may cause the assumption or continuation of Awards theretofore granted by the successor entity, or the substitution of such Awards with new Awards of the successor entity or parent thereof, with appropriate adjustment as to the number and kind of shares and, if appropriate, the per share exercise prices, as such parties shall agree. To the extent the parties to such Sale Event do not provide for the assumption, continuation or substitution of Awards, upon the effective time of the Sale Event, the Plan and all outstanding Awards granted hereunder shall terminate. In such case, except as may be otherwise provided in the relevant Award Certificate, all Options and Stock Appreciation Rights with time-based vesting conditions or restrictions that are not vested and/or exercisable immediately prior to the effective time of the Sale Event shall become fully vested and exercisable as of the effective time of the Sale Event, all other Awards with time-based vesting, conditions or restrictions shall become fully vested and nonforfeitable as of the effective time of the Sale Event, and all Awards with conditions and restrictions relating to the attainment of performance goals may become vested and nonforfeitable in connection with a Sale Event in the Administrator's discretion or to the extent specified in the relevant Award Certificate. In the event of such termination, (i) the Company shall have the option (in its sole discretion) to make or provide for a payment, in cash or in kind, to the grantees holding Options and Stock Appreciation Rights, in exchange for the cancellation thereof, in an amount equal to the difference between (A) the Sale Price multiplied by the number of shares of Stock subject to outstanding Options and Stock Appreciation Rights (to the extent then exercisable at prices not in excess of the Sale Price) and (B) the aggregate exercise price of all such outstanding Options and Stock Appreciation Rights (provided that, in the case of an Option or Stock Appreciation Right with an exercise price equal to or greater than the Sale Price, such Option or Stock Appreciation Right shall be cancelled for no consideration); or (ii) each grantee shall be permitted, within a specified period of time prior to the consummation of the Sale Event as determined by the Administrator, to exercise all outstanding Options and Stock Appreciation Rights (to the extent then exercisable) held by such grantee. The Company shall also have the option (in its sole discretion) to make or provide for a payment, in cash or in kind, to the grantees holding other Awards in an amount equal to the Sale Price multiplied by the number of vested shares of Stock under such Awards.

SECTION 4. ELIGIBILITY

Grantees under the Plan will be such individuals to whom the Company may issue securities without stockholder approval in accordance with the NASDAQ Inducement Exception, as are selected from time to time by the Administrator in its sole discretion; provided that Awards may not be granted to employees who are providing services to any "parent" of the Company, as such term is defined in Rule 405 of the Act, unless (i) the Stock underlying the Awards is treated as "service recipient stock" under Section 409A or (ii) the Company has determined that such Awards are exempt from or otherwise comply with Section 409A.

SECTION 5. STOCK OPTIONS

(a) Award of Stock Options. The Administrator may grant Stock Options under the Plan. Any Stock Option granted under the Plan shall be a Non-Qualified Stock Option, and shall be in such form as the Administrator may from time to time approve.

Stock Options granted pursuant to this Section 5 shall be subject to the following terms and conditions and shall contain such additional terms and conditions, not inconsistent with the terms of the Plan, as the Administrator shall deem desirable.

(b) Exercise Price. The exercise price per share for the Stock covered by a Stock Option granted pursuant to this Section 5 shall be determined by the Administrator at the time of grant but shall not be less than 100 percent of the Fair Market Value on the date of grant. Notwithstanding the foregoing, Stock Options may be granted with an exercise price per share that is less than 100 percent of the Fair Market Value on the date of grant (i) to individuals who are not subject to U.S. income tax on the date of grant, or (ii) if the Stock Option is otherwise compliant with Section 409A.

(c) Option Term. The term of each Stock Option shall be fixed by the Administrator, but no Stock Option shall be exercisable more than ten years after the date the Stock Option is granted.

(d) Exercisability; Rights of a Stockholder. Stock Options shall become exercisable at such time or times, whether or not in installments, as shall be determined by the Administrator at or after the grant date. The Administrator may at any time accelerate the exercisability of all or any portion of any Stock Option. An optionee shall have the rights of a stockholder only as to shares acquired upon the exercise of a Stock Option and not as to unexercised Stock Options.

(e) Method of Exercise. Stock Options may be exercised in whole or in part, by giving written or electronic notice of exercise to the Company, specifying the number of shares to be purchased. Payment of the purchase price may be made by one or more of the following methods except to the extent otherwise provided in the Option Award Certificate:

(i) In cash, by certified or bank check or other instrument acceptable to the Administrator;

(ii) Through the delivery (or attestation to the ownership following such procedures as the Company may prescribe) of shares of Stock that are not then subject to restrictions under any Company plan. Such surrendered shares shall be valued at Fair Market Value on the exercise date;

(iii) By the optionee delivering to the Company a properly executed exercise notice together with irrevocable instructions to a broker to promptly deliver to the Company cash or a check payable and acceptable to the Company for the purchase price; provided that in the event the optionee chooses to pay the purchase price as so provided, the optionee and the broker shall comply with such procedures and enter into such agreements of indemnity and other agreements as the Company shall prescribe as a condition of such payment procedure; or

(iv) By a "net exercise" arrangement pursuant to which the Company will reduce the number of shares of Stock issuable upon exercise by the largest whole number of shares with a Fair Market Value that does not exceed the aggregate exercise price.

Payment instruments will be received subject to collection. The transfer to the optionee on the records of the Company or of the transfer agent of the shares of Stock to be purchased pursuant to the exercise of a Stock Option will be contingent upon receipt from the optionee (or a purchaser acting in his stead in accordance with the provisions of the Stock Option) by the Company of the full purchase price for such shares and the fulfillment of any other requirements contained in the Option Award Certificate or applicable provisions of laws (including the satisfaction of any withholding taxes that the Company is obligated to withhold with respect to the optionee). In the event an optionee chooses to pay the purchase price by previously-owned shares of Stock through the attestation method, the number of shares of Stock transferred to the optionee upon the exercise of the Stock Option shall be net of the number of attested shares. In the event that the Company establishes, for itself or using the services of a third party, an automated system for the exercise of Stock Options, such as a system using an internet website or interactive voice response, then the paperless exercise of Stock Options may be permitted through the use of such an automated system.

SECTION 6. STOCK APPRECIATION RIGHTS

(a) Award of Stock Appreciation Rights. The Administrator may grant Stock Appreciation Rights under the Plan. A Stock Appreciation Right is an Award entitling the recipient to receive shares of Stock (or cash, to the extent explicitly provided for in the applicable Award Certificate) having a value equal to the excess of the Fair Market Value of a share of Stock on the date of exercise over the exercise price of the Stock Appreciation Right multiplied by the number of shares of Stock with respect to which the Stock Appreciation Right shall have been exercised.

(b) Exercise Price of Stock Appreciation Rights. The exercise price of a Stock Appreciation Right shall not be less than 100 percent of the Fair Market Value of the Stock on the date of grant.

(c) Grant and Exercise of Stock Appreciation Rights. Stock Appreciation Rights may be granted by the Administrator independently of any Stock Option granted pursuant to Section 5 of the Plan.

(d) Terms and Conditions of Stock Appreciation Rights. Stock Appreciation Rights shall be subject to such terms and conditions as shall be determined on the date of grant by the Administrator. The term of a Stock

Appreciation Right may not exceed ten years. The terms and conditions of each such Award shall be determined by the Administrator, and such terms and conditions may differ among individual Awards and grantees.

SECTION 7. RESTRICTED STOCK AWARDS

(a) Nature of Restricted Stock Awards. The Administrator may grant Restricted Stock Awards under the Plan. A Restricted Stock Award is any Award of Restricted Shares subject to such restrictions and conditions as the Administrator may determine at the time of grant. Conditions may be based on continuing employment (or other Service Relationship) and/or achievement of pre-established performance goals and objectives.

(b) Rights as a Stockholder. Upon the grant of the Restricted Stock Award and payment of any applicable purchase price, a grantee shall have the rights of a stockholder with respect to the voting of the Restricted Shares and receipt of dividends; provided that if the lapse of restrictions with respect to the Restricted Stock Award is tied to the attainment of performance goals, any dividends paid by the Company during the performance period shall accrue and shall not be paid to the grantee until and to the extent the performance goals are met with respect to the Restricted Stock Award. Unless the Administrator shall otherwise determine, (i) uncertificated Restricted Shares shall be accompanied by a notation on the records of the Company or the transfer agent to the effect that they are subject to forfeiture until such Restricted Shares are vested as provided in Section 7(d) below, and (ii) certificated Restricted Shares shall remain in the possession of the Company until such Restricted Shares are vested as provided in Section 7(d) below, and the grantee shall be required, as a condition of the grant, to deliver to the Company such instruments of transfer as the Administrator may prescribe.

(c) Restrictions. Restricted Shares may not be sold, assigned, transferred, pledged or otherwise encumbered or disposed of except as specifically provided herein or in the Restricted Stock Award Certificate. Except as may otherwise be provided by the Administrator either in the Award Certificate or, subject to Section 16 below, in writing after the Award is issued, if a grantee's employment (or other Service Relationship) with the Company and its Subsidiaries terminates for any reason, any Restricted Shares that have not vested at the time of termination shall automatically and without any requirement of notice to such grantee from or other action by or on behalf of, the Company be deemed to have been reacquired by the Company at its original purchase price (if any) from such grantee or such grantee's legal representative simultaneously with such termination of employment (or other Service Relationship), and thereafter shall cease to represent any ownership of the Company by the grantee or rights of the grantee as a stockholder. Following such deemed reacquisition of Restricted Shares that are represented by physical certificates, a grantee shall surrender such certificates to the Company upon request without consideration.

(d) Vesting of Restricted Shares. The Administrator at the time of grant shall specify the date or dates and/or the attainment of pre-established performance goals, objectives and other conditions on which the non-transferability of the Restricted Shares and the Company's right of repurchase or forfeiture shall lapse. Subsequent to such date or dates and/or the attainment of such pre-established performance goals, objectives and other conditions, the shares on which all restrictions have lapsed shall no longer be Restricted Shares and shall be deemed "vested."

SECTION 8. RESTRICTED STOCK UNITS

(a) Nature of Restricted Stock Units. The Administrator may grant Restricted Stock Units under the Plan. A Restricted Stock Unit is an Award of stock units that may be settled in shares of Stock (or cash, to the extent explicitly provided for in the Award Certificate) upon the satisfaction of such restrictions and conditions at the time of grant. Conditions may be based on continuing employment (or other Service Relationship) and/or achievement of pre-established performance goals and objectives. The terms and conditions of each such Award shall be determined by the Administrator, and such terms and conditions may differ among individual Awards and grantees. Except in the case of Restricted Stock Units with a deferred settlement date that complies with Section 409A, at the end of the vesting period, the Restricted Stock Units, to the extent vested, shall be settled in the form of shares of Stock. Restricted Stock Units with deferred settlement dates are subject to Section 409A and shall contain such additional terms and conditions as the Administrator shall determine in its sole discretion in order to comply with the requirements of Section 409A.

(b) Rights as a Stockholder. A grantee shall have the rights as a stockholder only as to shares of Stock acquired by the grantee upon settlement of Restricted Stock Units; provided, however, that the grantee may be credited with Dividend Equivalent Rights with respect to the stock units underlying his Restricted Stock Units, subject to the provisions of Section 11 and such terms and conditions as the Administrator may determine.

(c) Termination. Except as may otherwise be provided by the Administrator either in the Award Certificate or, subject to Section 16 below, in writing after the Award is issued, a grantee's right in all Restricted Stock Units that have not vested shall automatically terminate upon the grantee's termination of employment (or cessation of Service Relationship) with the Company and its Subsidiaries for any reason.

SECTION 9. UNRESTRICTED STOCK AWARDS

Grant or Sale of Unrestricted Stock. The Administrator may grant (or sell at par value or such higher purchase price determined by the Administrator) an Unrestricted Stock Award under the Plan. An Unrestricted Stock Award is an Award pursuant to which the grantee may receive shares of Stock free of any restrictions under the Plan. Unrestricted Stock Awards may be granted in respect of past services or other valid consideration, or in lieu of cash compensation due to such grantee.

SECTION 10. RESERVED

SECTION 11. DIVIDEND EQUIVALENT RIGHTS

(a) Dividend Equivalent Rights. The Administrator may grant Dividend Equivalent Rights under the Plan. A Dividend Equivalent Right is an Award entitling the grantee to receive credits based on cash dividends that would have been paid on the shares of Stock specified in the Dividend Equivalent Right (or other Award to which it relates) if such shares had been issued to the grantee. A Dividend Equivalent Right may be granted hereunder to any grantee as a component of an award of Restricted Stock Units or as a freestanding award. The terms and conditions of Dividend Equivalent Rights shall be specified in the Award Certificate. Dividend equivalents credited to the holder of a Dividend Equivalent Right may be paid currently or may be deemed to be reinvested in additional shares of Stock, which may thereafter accrue additional equivalents. Any such reinvestment shall be at Fair Market Value on the date of reinvestment or such other price as may then apply under a dividend reinvestment plan sponsored by the Company, if any. Dividend Equivalent Rights may be settled in cash or shares of Stock or a combination thereof, in a single installment or installments. A Dividend Equivalent Right granted as a component of an Award of Restricted Stock Units shall provide that such Dividend Equivalent Right shall be settled only upon settlement or payment of, or lapse of restrictions on, such other Award, and that such Dividend Equivalent Right shall expire or be forfeited or annulled under the same conditions as such other Award.

(b) Termination. Except as may otherwise be provided by the Administrator either in the Award Certificate or, subject to Section 16 below, in writing after the Award is issued, a grantee's rights in all Dividend Equivalent Rights shall automatically terminate upon the grantee's termination of employment (or cessation of Service Relationship) with the Company and its Subsidiaries for any reason.

SECTION 12. TRANSFERABILITY OF AWARDS

(a) Transferability. Except as provided in Section 12(b) below, during a grantee's lifetime, his or her Awards shall be exercisable only by the grantee, or by the grantee's legal representative or guardian in the event of the grantee's incapacity. No Awards shall be sold, assigned, transferred or otherwise encumbered or disposed of by a grantee other than by will or by the laws of descent and distribution or pursuant to a domestic relations order. No Awards shall be subject, in whole or in part, to attachment, execution, or levy of any kind, and any purported transfer in violation hereof shall be null and void.

(b) Administrator Action. Notwithstanding Section 12(a), the Administrator, in its discretion, may provide either in the Award Certificate regarding a given Award or by subsequent written approval that the grantee (who is an employee or director) may transfer his or her Non-Qualified Stock Options to his or her immediate family members, to trusts for the benefit of such family members, or to partnerships in which such family members are the

only partners, provided that the transferee agrees in writing with the Company to be bound by all of the terms and conditions of this Plan and the applicable Award. In no event may an Award be transferred by a grantee for value.

(c) Family Member. For purposes of Section 12(b), "family member" shall mean a grantee's child, stepchild, grandchild, parent, stepparent, grandparent, spouse, former spouse, sibling, niece, nephew, mother-in-law, father-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law, including adoptive relationships, any person sharing the grantee's household (other than a tenant of the grantee), a trust in which these persons (or the grantee) have more than 50 percent of the beneficial interest, a foundation in which these persons (or the grantee) control the management of assets, and any other entity in which these persons (or the grantee) own more than 50 percent of the voting interests.

(d) Designation of Beneficiary. To the extent permitted by the Company, each grantee to whom an Award has been made under the Plan may designate a beneficiary or beneficiaries to exercise any Award or receive any payment under any Award payable on or after the grantee's death. Any such designation shall be on a form provided for that purpose by the Administrator and shall not be effective until received by the Administrator. If no beneficiary has been designated by a deceased grantee, or if the designated beneficiaries have predeceased the grantee, the beneficiary shall be the grantee's estate.

SECTION 13. TAX WITHHOLDING

(a) Payment by Grantee. Each grantee shall, no later than the date as of which the value of an Award or of any Stock or other amounts received thereunder first becomes includable in the gross income of the grantee for income tax purposes, pay to the Company, or make arrangements satisfactory to the Administrator regarding payment of, any Federal, state, or local taxes of any kind required by law to be withheld by the Company with respect to such income. The Company and its Subsidiaries shall, to the extent permitted by law, have the right to deduct any such taxes from any payment of any kind otherwise due to the grantee. The Company's obligation to deliver evidence of book entry (or stock certificates) to any grantee is subject to and conditioned on tax withholding obligations being satisfied by the grantee.

(b) Payment in Stock. The Administrator may require the Company's tax withholding obligation to be satisfied, in whole or in part, by the Company withholding from shares of Stock to be issued pursuant to any Award a number of shares with an aggregate Fair Market Value (as of the date the withholding is effected) that would satisfy the withholding amount due; provided, however, that the amount withheld does not exceed the maximum statutory tax rate or such lesser amount as is necessary to avoid liability accounting treatment. For purposes of share withholding, the Fair Market Value of withheld shares shall be determined in the same manner as the value of Stock includible in income of the Participants. The Administrator may also require the Company's tax withholding obligation to be satisfied, in whole or in part, by an arrangement whereby a certain number of shares of Stock issued pursuant to any Award are immediately sold and proceeds from such sale are remitted to the Company in an amount that would satisfy the withholding amount due.

SECTION 14. SECTION 409A AWARDS

Awards are intended to be exempt from Section 409A to the greatest extent possible and to otherwise comply with Section 409A. The Plan and all Awards shall be interpreted in accordance with such intent. To the extent that any Award is determined to constitute "nonqualified deferred compensation" within the meaning of Section 409A (a "409A Award"), the Award shall be subject to such additional rules and requirements as specified by the Administrator from time to time in order to comply with Section 409A. In this regard, if any amount under a 409A Award is payable upon a "separation from service" (within the meaning of Section 409A) to a grantee who is then considered a "specified employee" (within the meaning of Section 409A), then no such payment shall be made prior to the date that is the earlier of (i) six months and one day after the grantee's separation from service, or (ii) the grantee's death, but only to the extent such delay is necessary to prevent such payment from being subject to interest, penalties and/or additional tax imposed pursuant to Section 409A. Further, the settlement of any 409A Award may not be accelerated except to the extent permitted by Section 409A.

SECTION 15. TERMINATION OF SERVICE RELATIONSHIP, TRANSFER, LEAVE OF ABSENCE, ETC.

(a) Termination of Service Relationship. If the grantee's Service Relationship is with an Affiliate and such Affiliate ceases to be an Affiliate, the grantee shall be deemed to have terminated his or her Service Relationship for purposes of the Plan.

(b) For purposes of the Plan, the following events shall not be deemed a termination of a Service Relationship:

(i) a transfer to the employment of the Company from an Affiliate or from the Company to an Affiliate, or from one Affiliate to another; or

(ii) an approved leave of absence for military service or sickness, or for any other purpose approved by the Company, if the employee's right to re-employment is guaranteed either by a statute or by contract or under the policy pursuant to which the leave of absence was granted or if the Administrator otherwise so provides in writing.

SECTION 16. AMENDMENTS AND TERMINATION

The Board may, at any time, amend or discontinue the Plan and the Administrator may, at any time, amend or cancel any outstanding Award for the purpose of satisfying changes in law or for any other lawful purpose, but no such action shall materially and adversely affect rights under any outstanding Award without the holder's consent. Except as provided in Section 3(b) or 3(c), without prior stockholder approval, in no event may the Administrator exercise its discretion to reduce the exercise price of outstanding Stock Options or Stock Appreciation Rights or effect the repricing of such Awards through cancellation and re-grants or cancel such Awards in exchange for cash or other Awards. Nothing in this Section 16 shall limit the Administrator's authority to take any action permitted pursuant to Section 3(b) or 3(c).

SECTION 17. STATUS OF PLAN

With respect to the portion of any Award that has not been exercised and any payments in cash, Stock or other consideration not received by a grantee, a grantee shall have no rights greater than those of a general creditor of the Company unless the Administrator shall otherwise expressly determine in connection with any Award or Awards. In its sole discretion, the Administrator may authorize the creation of trusts or other arrangements to meet the Company's obligations to deliver Stock or make payments with respect to Awards hereunder, provided that the existence of such trusts or other arrangements is consistent with the foregoing sentence.

SECTION 18. GENERAL PROVISIONS

(a) No Distribution. The Administrator may require each person acquiring Stock pursuant to an Award to represent to and agree with the Company in writing that such person is acquiring the shares without a view to distribution thereof.

(b) Issuance of Stock. To the extent certificated, stock certificates to grantees under this Plan shall be deemed delivered for all purposes when the Company or a stock transfer agent of the Company shall have mailed such certificates in the United States mail, addressed to the grantee, at the grantee's last known address on file with the Company. Uncertificated Stock shall be deemed delivered for all purposes when the Company or a Stock transfer agent of the Company shall have given to the grantee by electronic mail (with proof of receipt) or by United States mail, addressed to the grantee, at the grantee's last known address on file with the Company, notice of issuance and recorded the issuance in its records (which may include electronic "book entry" records). Notwithstanding anything herein to the contrary, the Company shall not be required to issue or deliver any evidence of book entry or certificates evidencing shares of Stock pursuant to the exercise or settlement of any Award, unless and until the Administrator has determined, with advice of counsel (to the extent the Administrator deems such advice necessary or advisable), that the issuance and delivery is in compliance with all applicable laws, regulations of governmental authorities and, if applicable, the requirements of any exchange on which the shares of Stock are listed, quoted or traded. Any Stock issued pursuant to the Plan shall be subject to any stop-transfer orders and other restrictions as the Administrator deems necessary or advisable to comply with federal, state or foreign jurisdiction, securities or other laws, rules and quotation system on which the Stock is listed, quoted or traded. The Administrator

may place legends on any Stock certificate or notations on any book entry to reference restrictions applicable to the Stock. In addition to the terms and conditions provided herein, the Administrator may require that an individual make such reasonable covenants, agreements, and representations as the Administrator, in its discretion, deems necessary or advisable in order to comply with any such laws, regulations, or requirements. The Administrator shall have the right to require any individual to comply with any timing or other restrictions with respect to the settlement or exercise of any Award, including a window-period limitation, as may be imposed in the discretion of the Administrator.

(c) Stockholder Rights. Until Stock is deemed delivered in accordance with Section 18(b), no right to vote or receive dividends or any other rights of a stockholder will exist with respect to shares of Stock to be issued in connection with an Award, notwithstanding the exercise of a Stock Option or any other action by the grantee with respect to an Award.

(d) Other Compensation Arrangements; No Employment Rights. Nothing contained in this Plan shall prevent the Board from adopting other or additional compensation arrangements, including trusts, and such arrangements may be either generally applicable or applicable only in specific cases. The adoption of this Plan and the grant of Awards do not confer upon any employee any right to continued employment with the Company or any Subsidiary.

(e) Trading Policy Restrictions. Option exercises and other Awards under the Plan shall be subject to the Company's insider trading policies and procedures, as in effect from time to time.

(f) Clawback Policy. Awards under the Plan shall be subject to the Company's clawback policy, as in effect from time to time.

SECTION 19. EFFECTIVE DATE OF PLAN

This Plan shall become effective immediately upon approval by the Board.

SECTION 20. GOVERNING LAW

This Plan and all Awards and actions taken thereunder shall be governed by, and construed in accordance with the General Corporation Law of the State of Delaware, applied without regard to conflict of law principles.

DATE APPROVED BY BOARD OF DIRECTORS: October 1, 2025

Exhibit 10.38

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT HAVE BEEN OMITTED AND REPLACED WITH "[***]". SUCH IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS (I) NOT MATERIAL AND (II) THE TYPE OF INFORMATION THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

Cabaletta Bio

DEVELOPMENT AND CLINICAL MANUFACTURING SERVICES AGREEMENT

This Development and Manufacturing Services Agreement (this "***Agreement***") is entered into as of the date of the last signature below (the "***Effective Date***"), by and between Cellares Corporation, a Delaware corporation, with offices located at 345 Allerton Avenue, South San Francisco, CA 94080 ("***Cellares***"), and Cabaletta Bio, Inc., a Delaware corporation, with offices located at 2929 Arch St Suite 600, Philadelphia, PA 19104 ("***Partner***"). Cellares and Partner are sometimes referred to herein, individually, as a "***Party***" and, together, as the "***Parties***".

1. Background.

1.1 The Parties entered into that certain Technology Transfer Agreement, dated as of November 3, 2023 (the "***TTA***"), pursuant to which Cellares will perform certain technology transfer, validation and other services with respect to the manufacture of Partner's cell therapy product.

1.2 Partner desires to engage Cellares to perform certain Services (as defined below) relating to the further development and manufacture of the Product (as defined below) as described in this Agreement, and Cellares is prepared to perform such Services for Partner upon the terms and conditions set forth herein.

1.3 As of the Effective Date, Statement of Work No. 4 under the TTA ("SOW No. 4"), shall be governed under this Agreement rather than the TTA. In the event of a conflict between defined terms in SOW No. 4 and this Agreement the definition ascribed in this Agreement shall govern.

2. Definitions.

2.1 "***Affiliate***" means, with respect to either Party, any corporation, company, partnership or other business entity that, directly or indirectly through one or more intermediaries, controls or is controlled by, or is under common control with such Party. For the purpose of this definition, "control" (including, with correlative meanings, "controlled by" and "under common control with") means the possession, directly or indirectly, of (a) the power to direct or cause the direction of management or policies of such Party (whether through ownership of securities or partnership or other ownership interests, by contract or otherwise) or (b) at least fifty percent (50%) of the issued share capital (partnership or ownership capital – whether directly or pursuant to any option, warrant or other similar arrangement – or otherwise) of such Party.

2.2 "***Applicable Law***" means all relevant federal, state and local government laws, statutes, rules and regulations in the United States and any other jurisdictions which are applicable to the Services, including all relevant laws, statutes, rules and regulations in all countries in which Partner commercializes the Products, which countries are expressly set forth in the applicable SOW or otherwise mutually agreed in writing by the Parties, whether in effect as of the Effective Date or adopted thereafter, including the applicable regulations and guidelines of any applicable Regulatory Authority and all applicable cGMP, in each case together with

all amendments thereto.

2.3 "***Batch***" means the Product produced from a single run of the Manufacturing Process.

2.4 "***Batch Records***" means the executed version of a given Master Batch Record containing the production record or, as applicable, relevant portions thereof, pertaining to a given Batch.

2.5 "***Calendar Quarter***" means the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 and December 31.

2.6 "***Calendar Year***" means each twelve (12)-month period commencing on January 1, except that the first "Calendar Year" of the Term shall be the period commencing on the Effective Date and ending on December 31 of the year during which the Effective Date occurs, and the last Calendar Year of the Term shall commence on January 1 of the year in which the Term ends and ends on the last day of the Term.

2.7 "***cGMP***" means current Good Manufacturing Practices applicable in the United States (and any other countries specified in an applicable SOW) relating to the manufacture of medicinal products for human use, as specified in applicable International Council for Harmonisation ("***ICH***") guidelines and the FD&C Act at 21 CFR (Chapters 210, 211, and applicable parts of 600, 610 and 820).

2.8 "***cGMP Batch***" means a Batch of Product that is required under the applicable SOW to meet cGMP.

2.9 "***Cell Bank***" means, with respect to a Cell Line, the cell stock of such Cell Line.

2.10 "***Cell Bank Storage***" means the storage of the Cell Bank in accordance with Section 4.7.

2.11 "***Cell Line***" means the cell line that is provided by Partner or developed under this Agreement by Cellares to produce Product.

2.12 "***Cell Shuttle***" means Cellares' automated cell therapy manufacturing platform.

2.13 "***Cellares Operating Documents***" means the corporate standards, standard operating procedures, standard manufacturing procedures, drug master file, Cellares-customized manufacturing procedures, electronic programs and files, raw material specifications, protocols, validation documentation, and supporting documentation used by Cellares, including with respect to, without limitation, environmental monitoring, for operation and maintenance of the Facility and Cellares equipment used in the process of producing the Product. Cellares Operating Documents shall be deemed Cellares' Confidential Information. For the avoidance of doubt, the Cellares Operating Documents shall not include any information within the Partner Manufacturing Process information.

2.14 "***Certificate of Analysis***" or "***CoA***" means a certificate of analysis prepared by or for Cellares listing the Specifications of a Product, tests performed on such Product, and the results of such testing, in a form agreed to by the Parties.

2.15 "***Certificate of Compliance***" or "***CoC***" means a document prepared by Cellares: (i) listing the manufacturing date, unique Batch number and dose level of Product in such Batch; and (ii) certifying that such Batch was manufactured in accordance with processing instructions, the Specifications, the Master Batch Record and Applicable Law (including cGMP, if applicable).

2.16 "***Deliver***," "***Delivered***," or "***Delivery***," shall have the meaning ascribed in Section 8.3.

2.17 "***Development Batch***" means a Batch of Product which is expressly designated in the applicable SOW as a development or pilot Batch and which shall not be required to comply with cGMP nor meet the

applicable Specifications.

2.18 "***EMA***" means the European Medicines Agency, or any successor agency thereto.

2.19 "Engineering Batch" or "Engineering Run" means a cGMP Batch that is intended to demonstrate the reproducible performance of the Manufacturing Process within analytic limits and while performed under cGMP conditions.

2.20 "***Facility***" means Cellares' facility as set forth in the relevant SOW.

2.21 "***FD&C Act***" means the U.S. Food, Drug, and Cosmetic Act, as amended, and any regulations promulgated thereunder.

2.22 "***FDA***" means the U.S. Food and Drug Administration, or any successor agency thereto.

2.23 "***Manufacturing Process***" means the production process for the manufacture of Product as such process may be improved or modified from time to time.

2.24 "***Master Batch Record***" means the set of documents, proposed by Cellares and approved by Partner, which defines the manufacturing methods, test methods and other procedures, directions and controls associated with the manufacture and testing of Product which are designed to ensure that the Products have the identity, strength, quality and purity they purport or are represented to possess, and is used to ensure uniformity from Batch to Batch and compliance with cGMPs.

2.25 "***Partner Manufacturing Process***" means Partner's proprietary process for manufacturing the Product as disclosed by Partner to Cellares in writing pursuant to the TTA. Notwithstanding anything herein to the contrary, the Partner Manufacturing Process information is Confidential Information of Partner and not Cellares.

2.26 "***Partner Materials***" has the meaning ascribed in Section 3.5(b).

2.27 "***Product***" means the product identified in the applicable SOW and manufactured by Cellares under this Agreement.

2.28 "***Quality Agreement***" means the quality agreement, including any amendments thereto, executed by the Parties pursuant to Section 5.1, setting out the responsibilities of the Parties in relation to quality as required for compliance with cGMP. Upon signature by both Parties, the Quality Agreement is incorporated into and shall be an integral part of this Agreement.

2.29 "***Raw Materials***" means all materials required to perform the Manufacturing Process or Services set forth in the applicable SOW (other than Starting Materials), including without limitation ingredients, reagents, primary packaging materials, consumables (including cartridges for Cell Shuttle), sterile liquid transfer devices and other components of the Product.

2.30 "***Regulatory Authority***" means the FDA, EMA and any other similar applicable regulatory authorities.

2.31 "***Services***" means all or any part of the services to be performed by Cellares under this Agreement, as set out in the relevant SOW, and which may include, to the extent specified in an SOW, process and analytical method transfer, process development and automation, process optimization, validation, clinical manufacturing of Batches, as well as quality control and quality assurance activities.

2.32 "***Starting Materials***" means all materials required to perform the Manufacturing Process or Services set forth in the applicable SOW (other than Raw Materials), which may include human biologic materials, including apheresis or peripheral blood mononuclear cells (PBMCs), and lentiviral vectors.

2.33 "***Statement of Work***" or "***SOW***" means a statement of work describing the Services to be performed by Cellares under this Agreement, including any amendments to such statement of work, in each case in writing and as executed by the Parties pursuant to this Agreement.

2.34 "***Specifications***" means the written specifications for the Product as set forth in the applicable SOW.

2.35 "***Third Party***" means any person or entity other than the Parties or their respective Affiliates.

3. Services.

3.1 Scope of Agreement; SOWs. As a master agreement, this Agreement allows the Parties to contract for Services through the issuance of multiple SOWs that reference this Agreement, which shall be separately specified in writing on terms acceptable to the Parties. Each SOW shall upon execution thereof by both Parties become part of this Agreement and incorporated herein. Each SOW shall set forth the specific Services to be performed by Cellares, the Product to be manufactured, the Specifications, the protocol for the applicable Manufacturing Process, the timeline and schedule for the performance of such Services, and the compensation to be paid by Partner to Cellares for the provision of such Services (including fees and reimbursable expenses), as well as any other relevant terms and conditions. If the Services include development of specific deliverables, such deliverables and the specifications thereof shall be set forth on the relevant SOW.

3.2 Amendments to SOWs. Each SOW may be amended from time to time upon the mutual written agreement of the Parties. If a Party becomes aware of any unforeseen or unusual events or assumptions, factors, or criteria not previously taken into consideration that would affect the outcome of the budget, timeline, or other aspects of the Services set forth in the applicable SOW, or would require additional or different services not originally contemplated, such Party shall promptly notify the other Party and the Parties shall confer in good faith to address such matter. Cellares shall not be required to perform any additional or different work until the Parties execute an applicable amendment. Notwithstanding the foregoing, no change in the Services or Quality Agreement shall be implemented by Cellares without the prior written consent of Partner in each instance.

3.3 Conduct of Services. Cellares will conduct the Services in accordance with the terms of this Agreement (including the applicable SOW) and Applicable Law, and in a professional and workmanlike manner. Cellares does not guarantee any particular outcome or results with respect to developmental services. Cellares shall use **⌊***⌋** to conduct the Services in accordance with the time frames and budget set forth in the applicable SOW. Cellares shall adhere to the Specifications agreed to by both parties in an applicable SOW. Cellares shall retain appropriately qualified and trained personnel with the requisite knowledge and experience to perform the Services in accordance with this Agreement. Cellares may delegate or subcontract any part of the Services to an Affiliate or subcontractor **⌊***⌋;** provided that (i) such work is performed in accordance with this Agreement and the applicable SOW and (ii) Cellares shall remain fully responsible to Partner for the acts or omissions of such subcontractor in connection with the performance of such work; provided further that, in the event the subcontractor is required by Partner, Cellares shall not be responsible for any liability to the extent resulting from the performance of services by such subcontractor.

3.4 Governance.

(a) Project Manager. With respect to each SOW, each Party will appoint a project manager (each, a "***Project Manager***") who will be responsible for overseeing the performance of such SOW on behalf of such Party.

(b) Joint Project Committee. The Parties shall appoint a joint project committee composed of an equal number of senior representatives from each Party such as Manufacturing, Quality, Process and Analytical Development, and Business Development (the "***Joint Project Committee***"). The Joint Project Committee shall meet in person or by teleconference based on the needs of the project(s) as determined by the Project Managers or Joint Project Committee. Cellares shall be responsible for coordinating meetings

and meeting minutes and circulating to Joint Project Committee members as soon as reasonably practicable for comments and approval of the meeting minutes. The Joint Project Committee shall function as an information sharing body only and shall not have any decision-making authority. In the event of a dispute under this Agreement, the Parties shall first work in good faith for a period of up to [***] to resolve such dispute through the Joint Project Committee. For avoidance of doubt, the Joint Project Committee shall not have the authority to amend or modify this Agreement or any SOW.

3.5 Partner Materials.

(a) To the extent not already provided by Partner to Cellares under the TTA, Partner will provide to Cellares, at Partner's sole cost and expense, all information regarding Partner's current cell therapy manufacturing process as required by Cellares to perform the Services, including process flow diagrams, an equipment list for each piece of equipment used in the current cell therapy manufacturing process, and process-associated documents, such as documents related to analytical methods and Specifications, or comparable documents.

(b) Each applicable SOW will specify necessary amounts of all Cell Lines (including any Cell Lines intended for use in a Cell Bank or for Cell Bank Storage pursuant to Section 4.7(a)), Raw Materials, Starting Materials and other materials of any nature to be provided by Partner (collectively, "***Partner Materials***"), and Partner at its sole cost shall provide such Partner Materials meeting the relevant specifications as necessary for Cellares to perform the applicable Services. Each applicable SOW will also provide an estimated cost for any Raw Materials to be procured by Cellares on behalf of Partner.

(c) Unless otherwise specified in the applicable SOW, Partner shall be solely responsible for all testing, quality control, defects and regulatory compliance with respect to Partner Materials prior to delivery of such Partner Materials to Cellares, and Cellares shall be solely responsible for all testing, quality control, defects and regulatory compliance with respect to Raw Materials other than Partner Materials.

(d) Prior to delivery of any Partner Materials, Partner shall provide to Cellares all relevant environmental, health and safety information related to such Partner Materials in Partner's possession and reasonably necessary to perform the Services, including details of any hazards relating to the Partner Materials of which Partner is aware. Such documentation shall include all applicable safety data sheets, toxicology reports issued by authoritative third parties, internal toxicology evaluation reports and other supporting documents with respect to environmental, health and safety matters concerning such Partner Materials. If Partner becomes aware of any changes to the aforesaid information or hazards during the performance of the Services, Partner shall promptly and accurately inform Cellares of such changes and provide relevant information and supporting documentation thereof. Any cell samples that are intended to be transferred to Cellares by Partner as part of this Agreement must include an original vendor Certificate of Analysis. If any cell sample has been adulterated or otherwise modified from its original vendor composition or format, then, Partner shall provide Cellares with three aliquots of such samples for safety and pathogen analysis and other quality assurance testing.

(e) Partner shall deliver to Cellares all Partner Materials Delivery Duty Paid (DDP) Facility (Incoterms 2020). For the avoidance of doubt, DDP (Facility) means Partner is responsible for delivery to the Facility and pays all shipping costs including import duties and taxes. Partner is responsible for regulatory release and inspection of Partner Materials prior to delivery to Cellares. All costs associated with procuring, shipping, inspecting, handling and disposal of the Partner Materials prior to delivery to Cellares shall be the responsibility of Partner. Following delivery to Cellares, Cellares shall be responsible for all applicable visual inspecting and review of CoA, releasing, storage, handling and disposal of the Partner Materials.

(f) Partner shall be solely responsible for procuring, at Partner's cost, all licenses or other rights to all Partner Materials as necessary for Cellares to perform the applicable Services under this Agreement. Cellares shall not be responsible for any delays resulting from Partner's failure to provide such Partner Materials.

(g) All Partner Materials shall remain the sole property of Partner and are the Confidential Information of Partner. Partner shall be solely responsible for and shall bear the risk of loss of any Partner Materials while in Cellares' possession or control, except for any loss of Partner Materials due to Cellares' gross negligence or willful misconduct. Cellares will use ⌊***⌋ to protect the Partner Materials from loss, damage and theft while in Cellares' possession and control. Cellares shall use the Partner Materials solely to perform its obligations under this Agreement and shall not transfer the Partner Materials to any Third Party (except to an Affiliate or subcontractor of Cellares performing Services hereunder to the extent permitted under Section 3.3) without Partner's prior written consent. Cellares shall only use any data arising from its use of the Partner Materials to conduct the Services and for Cellares' internal research and development purposes, subject to Section 11.2(b).

(h) Cellares shall, at Partner's option and expense, destroy, return to Partner or otherwise dispose of unused Partner Materials promptly after the earlier of (a) completion of the Services for which the Partner Materials were provided (unless such Partner Materials are anticipated to be used for future Services), or (b) termination of the applicable SOW. Notwithstanding the foregoing, if Partner provides no response to Cellares' written notice of such unused Partner Materials, then Cellares may dispose of them at its sole discretion after ⌊***⌋ of such written notice to Partner. Partner is responsible for return shipping of Partner Materials. Cellares is responsible for disposing of Partner Materials at Partner's expense.

4. Manufacturing.

4.1 Specifications; Manufacturing Process. Cellares shall, in accordance with the terms of this Agreement and the Quality Agreement, manufacture each Product in accordance with the applicable Specifications and Manufacturing Process, Applicable Law, and, to the extent set forth in the applicable SOW, cGMP.

i. If a Batch of Product fails to comply with the applicable Specifications, Manufacturing Process or cGMP, and Cellares is responsible for such failure as provided in this Section 4.1, then [***].

ii. Without limiting the generality of the foregoing, Cellares shall not be responsible for the failure of any Product or the manufacture thereof to comply with the applicable Specifications, Manufacturing Process or cGMP to the extent due to (a) the Partner Manufacturing Process, (b) any specimens, samples, Partner Materials, information, instructions or intellectual property provided by Partner, or (c) the inherent properties of such Product.

iii. Any change or modification to the Specifications or Manufacturing Process must be agreed in writing in advance by the Parties and will be made in accordance with the provisions of the Quality Agreement (if applicable) and this Agreement; provided that deviations from the Manufacturing Process may be made by Cellares for technical, safety, regulatory or emergency reasons upon written notification to Partner only to the extent explicitly permitted under the Quality Agreement, and provided that the applicable Product meets the applicable Specifications and is manufactured in accordance with cGMP, as applicable.

iv. Partner shall be responsible for any costs or expenses incurred by Cellares in connection with implementing any change to the Specifications or Manufacturing Process.

v. If Cellares makes any Cellares-requested change without Partner's consent (except as such change is otherwise permitted under this Agreement) and such change results in a Non-Conformance, then in addition to the remedies in Article 9, [***].

4.2 Development Batches; Engineering Batches.

i. Development Batches. Cellares shall manufacture each Development Batch in accordance with the applicable SOW, but for clarity, unless otherwise set forth in the SOW, Cellares shall have no obligation to manufacture each Development Batch to meet Specifications nor comply with cGMP. At Partner's option, Cellares shall deliver such Development Batches to Partner or dispose of such Development Batches, in each case at Partner's sole cost and expense. Partner shall use Development Batches only in accordance with the applicable SOW and with Applicable Law and shall not use any Development Batch in humans.

ii. Engineering Batches. Engineering Batches may be used for analytical characterization and comparability studies. The Parties shall jointly define the objectives, success criteria, and reporting requirements for each Engineering Batch. The number, scope, and timing of Engineering Batches shall be set forth in a mutually agreed Statement of Work.

4.3 Process Assumptions; Finalization of Process and Specifications. Prior to commencement of cGMP manufacturing, the Parties shall review the technical, process and other assumptions underlying the Specifications and Manufacturing Process. If there is a material difference in such assumptions as compared with the Specifications or process results demonstrated during the manufacture of the

applicable Development Batches, the Parties shall meet to discuss in good faith the consequences of such differences and any necessary changes to the Manufacturing Process or Specifications. Any agreed changes will be reflected in an amendment to the Manufacturing Process or Specifications. The final Manufacturing Process and Specifications shall be subject to each Party's review and approval prior to commencement of manufacturing of cGMP Batches.

4.4 cGMP Batches. Cellares shall manufacture cGMP Batches in accordance with this Agreement (including the applicable Quality Agreement and SOW), cGMP, Applicable Law, the approved manufacturing Batch Records, and the applicable Specifications. Cellares shall deliver to Partner a Certificate of Analysis and Certificate of Compliance with respect to each cGMP Batch.

4.5 Raw Materials. Cellares shall procure all required Raw Materials ⌊***⌋. Partner will be asked to approve the type, quantity and pricing of such Raw Materials in writing prior to purchase. Partner and Cellares will develop specifications for Raw Materials based on assessed risk.

4.6 Hazardous Materials. Cellares shall be responsible, at Cellares' sole cost and expense (without reimbursement), for the generation, collection, storage, handling, transport, and release of hazardous materials and waste generated by or on behalf of Cellares in connection with any SOW unless otherwise specified in this Agreement or an SOW.

4.7 Cell Bank and Product Storage.

(a) If Cell Bank Storage services are included within the Services under an SOW, Cellares shall perform such Cell Bank Storage of the applicable Cell Banks at no charge for up to ⌊***⌋ and shall notify Partner of the start date of such ⌊***⌋ storage period as soon as possible prior to such date. Cellares shall store finished Product made available to Partner pursuant to Section 8.2 (and any unused Partner Materials that are not going to be used in subsequent Services) ⌊***⌋ after Release and shall notify Partner of the start date of such ⌊***⌋ storage period as soon as possible prior to such date. After such ⌊***⌋ period, if Partner wishes Cellares to continue Cell Bank Storage or storage of finished Product (or other Partner Materials), such storage shall be subject to availability and, if storage is available, a mutually agreed storage fee will be charged to Partner.

(b) Cellares shall store any stored Cell Banks and finished Product (or other Partner Materials) in a safe and environmentally controlled manner in accordance with Partner's instructions and the requirements of the applicable SOW and Applicable Law. Cellares shall not transfer the Cell Bank or such finished Product (or other Partner Materials) to a Third Party or Affiliate of Cellares without Partner's prior written consent. Upon Partner's prior written consent, Cellares may perform such testing of the Cell Bank or Product as mutually agreed by the Parties in accordance with the Quality Agreement for quality assurance, regulatory or safety purposes. Cellares shall disclose the results of such testing within a reasonable time following Partner's request. Upon expiration of the storage period set forth in Section 4.7(a), Cellares shall have the right, upon prior written notice to Partner, to dispose of any such Cell Banks, finished Product or unused Partner Materials.

(c) Without limiting Section 3.5(e) with respect to the Cell Bank, Cellares' liability for loss, theft or damage of any Cell Bank or finished Product stored by or on behalf of Cellares hereunder shall not exceed ⌊***⌋ with respect to such Cell Bank or Product storage pursuant to Section 4.7(a). Further, for any loss, theft or damage of any finished Product stored by or on behalf of Cellares during the first ⌊***⌋ storage period, Cellares also agrees to ⌊***⌋. Cellares will at all times label (or otherwise designate) the Product and Partner Materials as the property of Partner. Cellares shall keep the Product and Partner Materials free and clear of all claims, encumbrances, and liens. Cellares bears all risk of loss for Partner Materials (including Product) while in Cellares' or its contractors' possession or control.

(d) The price for and other terms applicable to Cell Bank Storage or storage of finished Product following the expiration of the free storage period described in Section 4.7(a) shall be as mutually agreed

by the Parties pursuant to Section 4.7(a). Any changes to such Cell Bank Storage or finished Product storage Services shall be made via an amendment to the applicable SOW as set forth in Section 3.2. If Partner does not timely pay all fees due for such storage, Partner shall within **[***]** of Cellares' written notice arrange collection and shipping of the applicable Cell Bank or finished Product at Partner's sole cost and Cellares shall not be obliged to continue such storage at the end of such **[***]** period.

(e) Upon expiration or termination of this Agreement or the SOW(s) pursuant to which Cellares provides Cell Bank Storage or storage of finished Product as described in Section 4.7(d) (or completion of such storage Services), Cellares shall destroy, return to Partner or otherwise dispose of the Cell Bank or such finished Product pursuant to Section 3.5(h) at Partner's expense.

5. Quality; Regulatory.

5.1 Quality Agreement. The Parties shall enter into the Quality Agreement within ⌊***⌋ of the Effective Date. Responsibility for quality assurance and quality control of Product shall be allocated between Partner and Cellares as set forth in the Quality Agreement and in Cellares' standard operating procedures. If there is a conflict between the terms and conditions of this Agreement and the Quality Agreement, the terms and conditions of this Agreement shall prevail with the exception that the Quality Agreement shall control for matters relating to the quality and disposition of the Product. If the Quality Agreement is not in place within ⌊***⌋ of the Effective Date, Cellares and Partner commit to enter into the Quality Agreement in a timely manner, but in no event later than the commencement of cGMP manufacturing.

5.2 Regulatory Inspections and Audits. The Parties' responsibilities regarding inspections by Regulatory Authorities and audits shall be set out in the Quality Agreement (but in no case shall the Quality Agreement reduce the scope of any audit rights provided herein or impose any fee on Partner).

5.3 Partner Inspections. During the Term and subject to reasonable prior written notice by Partner to Cellares, Partner or Partner's representatives shall be granted access to (i) each portion of the Facility where Cellares performs Services, (ii) relevant personnel involved in performing Services and (iii) relevant records pursuant to Section 5.4, in each case solely for the purpose of observing process performance and verifying that Cellares is performing Services in accordance with cGMP (as applicable) and all other Applicable Laws, the applicable SOW, the Quality Agreement and the Master Batch Records, as applicable with ⌊***⌋ prior written notification. Audits shall be designed to minimize disruption of operations at the Facility. Such inspections shall be limited to no more than ⌊***⌋ (other than for cause), conducted by ⌊***⌋ representatives of Partner and over the course of no more than ⌊***⌋ per inspection. Partner will pay Cellares a ⌊***⌋ fee, as set forth in the relevant SOW, to cover Partner audits exceeding ⌊***⌋ Partner audit per year; provided that, Cellares shall permit a for-cause audit by Partner and/or its representatives ⌊***⌋ given reasonable timely notification as agreed by the Parties in the Quality Agreement. ⌊***⌋.

5.4 Recordkeeping. Cellares will maintain complete and accurate records of the production of each Batch of Product (including without limitation Batch Records) in electronic form accessible to Partner and as required by Applicable Laws, including without limitation cGMP, and in accordance with the Quality Agreement. Cellares will retain possession of the Master Batch Record and Batch Records and will make copies of the Master Batch Record and Batch Records available to Partner. Cellares Operating Documents will remain Cellares' Confidential Information. Cellares will make the Cellares Operating Documents available during site visits by Partner but Partner will not be permitted to make copies of and/or remove Cellares Operating Documents from the Facility. In connection with a filing or correspondence with a Regulatory Authority in connection with a Product, Cellares will provide Partner with the documents necessary or reasonably useful for Partner to address an inquiry from a Regulatory Authority. If any Confidential Information of Cellares is necessary for Partner to include in a filing for regulatory approval of the Product or to address an inquiry from a Regulatory Authority, Cellares shall provide the Confidential Information to Partner for the specific purpose of disclosure to the applicable Regulatory Authority, provided that Cellares shall have the right to provide such information only to such

Regulatory Authority to extent permitted by Applicable Law. Cellares will promptly provide to Partner such regulatory support, including data and documentation, as reasonably requested by Partner in connection with regulatory filings relating to the Facility or equipment to the extent used to manufacture Product hereunder.

5.5 Facility Approvals. Cellares shall maintain all manufacturing licenses and other regulatory and governmental permits, licenses and approvals for the Facility that may be necessary to manufacture and supply Products under this Agreement.

5.6 Product Approvals. Partner shall be solely responsible for obtaining and maintaining regulatory approval of the Product. Prior to Partner's submission of any applicable substantive information to any Regulatory Authority related in any way to Cellares that has not previously been reviewed or provided by Cellares, the Manufacturing Process or the Services provided under this Agreement (including information related to a Regulatory Authority's request for additional information or an inspection, and Partner's answer or other response thereto), Partner shall provide to Cellares, for Cellares' review , otherwise relevant copies of what is intended to be submitted, provided that such copies may be redacted with respect to information not pertinent to Cellares' potential rights and obligations under this Agreement. Partner shall consider in good faith any comments provided by Cellares. Subject to Section 5.4, Cellares will promptly provide to Partner such support, including data and documentation, as reasonably requested by Partner in connection with regulatory filings relating to the Product or the manufacture thereof. Cellares shall timely respond to any requests received by Cellares from a Regulatory Authority that relate to this Agreement, including the Cellares Operating Documents, the Manufacturing Process, the Product or the Services provided under this Agreement, and shall timely provide all documents and information requested by the applicable Regulatory Authority in any such request, in each case in a timely manner sufficient to meet any applicable statutory deadlines or deadlines requested by the applicable Regulatory Authority.

6. Orders.

6.1 Forecasts.

(a) Partner shall provide Cellares with a rolling [***] forecast of its requirements for manufacturing of all Products (each, a "***Rolling Forecast***") at least [***] prior to the beginning of each month during the Term representing Partner's good-faith estimate of the type and quantity of such Products that Partner expects to place a Purchase Order for manufacturing of such Products on a monthly basis within each of the following [***]. Except as specified in an applicable SOW, the initial Rolling Forecast will be provided at least [***] prior to the manufacturing of Product hereunder, or at such other date as the Parties mutually agree in an applicable SOW. With respect to any Calendar Quarter for which Partner at any time does not provide a Rolling Forecast pursuant to this Section 6.1, or provides a Rolling Forecast that is otherwise not compliant with this Article 6 or is not accompanied by a Purchase Order for the Commitment Amount in accordance with Section 6.3, then (a) Cellares shall have no obligation to accept any Purchase Order during such Calendar Quarter and the lead time pursuant to Section 6.5 for fulfillment by Cellares of any Purchase Orders it elects to accept shall be at Cellares' sole discretion, provided that Partner may cancel any Purchase Order if Cellares' proposed lead time for such Purchase Order is not reasonably acceptable to Partner in light of the timing required for administration of such Product to a patient, and in which case Partner shall notify Cellares of the same and the Parties shall discuss the matter in good faith.

(b) Upon progression of the Product to the next clinical phase of development or commercialization, to the extent a material change in demand is reasonably anticipated, at the request of either Party, the Parties will renegotiate the Forecast structure in good faith.

6.2 Binding Forecast.

(a) With respect to each Rolling Forecast, the first [***] of such Rolling Forecast (the "***Binding***

Forecast") shall be a binding commitment on Partner to purchase the Products described in such Rolling Forecast; provided that the quantity of Products projected to be purchased during the ⌊***⌋ may only be adjusted by Partner in subsequent Rolling Forecasts ⌊***⌋ (the "***Collar***"). Partner shall be required to issue a Purchase Order for ⌊***⌋ of the quantities of such Products described in the Binding Forecast (the "***Commitment Amount***"); and the quantities of Products described in the remaining ⌊***⌋ in the Rolling Forecast shall be non-binding and for planning purposes only (subject to the Collar).

(b) Upon progression of the Product to the next clinical phase of development or commercialization, to the extent a material change in demand is reasonably anticipated, at the request of either Party, the Parties will renegotiate the Binding Forecast structure in good faith.

(c) Within ⌊***⌋ of receipt of a Rolling Forecast, Cellares shall notify Partner if Cellares has a ⌊***⌋ belief that Cellares' manufacturing capacity will be insufficient to meet the forecasted quantities reflected in the non-binding portion of such Rolling Forecast. and shall use good faith efforts to accept such Rolling Forecast. Once accepted, the Binding Forecast will be a binding commitment on Cellares to manufacture the Products and a binding commitment by Partner to issue a Purchase Order(s) to purchase such Products. Notwithstanding anything to the contrary, Cellares will accept any Rolling Forecast that falls within the applicable Minimum Capacity and the Commitment Amount and otherwise is compliant with this Article 6.

6.3 Purchase Orders. From time to time, Partner may issue purchase orders for manufacturing of volumes of Product (each, a "***Purchase Order***") consistent with the Rolling Forecast. For each month, Partner shall submit Purchase Orders for at least the Commitment Amount corresponding to the first month of the most recent Binding Forecast for delivery in such month concurrently with the Rolling Forecast (i.e., at least ⌊***⌋ prior to the beginning of each month). Partner may submit additional Purchase Orders from time to time. Each such Purchase Order shall specify: (i) the quantity of each Product desired, (ii) the destination of Delivery, and (iii) the requested Initiation Date (defined below) (to the extent known by Partner and subject to change by the Partner within the same Calendar Quarter for the Products under such Purchase Order (which shall comply with Section 6.5). Once a Purchase Order is accepted by Cellares, the Purchase Order is non-cancelable by Partner or Cellares and no changes may be made to the Purchase Order by either Party without written consent by the other Party.

6.4 Acceptance of Purchase Orders.

(a) No later than ⌊***⌋ after receipt of a Purchase Order, Cellares shall confirm in writing its receipt of the Purchase Order, provided that (1) if (i) the type and quantity of Products described in a Purchase Order are consistent with the most recent Binding Forecast, (ii) the quantities of such Products described in such Purchase Order are no more than (when aggregated with all other Purchase Orders for the applicable Calendar Quarter) ⌊***⌋ of the Commitment Amount, (iii) the requested Initiation Dates of such Products complies with the lead-time requirements described in Section 6.5, and (iv) the Purchase Order otherwise complies with the terms of this Agreement, then Cellares shall accept such Purchase Order by sending an acknowledgement to Partner (any such accepted or deemed accepted Purchase Order, a "***Confirmed Order***") and (2) Cellares may reject the portion of any Purchase Order covering any Calendar Quarter outside the Binding Forecast or in excess of (when aggregated with all other Purchase Orders for the applicable Calendar Quarter) ⌊***⌋ of the quantity set forth in the Binding Forecast. Any Purchase Order that is compliant with (i) - (iv) above but not accepted in writing by Cellares within ⌊***⌋ after its receipt thereof shall be deemed accepted. Any Purchase Order that is not compliant with (i) - (iv) above but not accepted in writing by Cellares within ⌊***⌋ after its receipt thereof shall be deemed rejected.

(b) Subject to the foregoing, Cellares shall use commercially reasonable efforts (but shall otherwise have no obligation) to accommodate Purchase Orders for quantities of Products that in the aggregate with all other Purchase Orders for the applicable Calendar Quarter exceed ⌊***⌋ but are no more than ⌊***⌋ of the Commitment Amount for the applicable Calendar Quarter. Cellares shall notify Partner whether or not Cellares will agree to supply the additional amount of Products requested in any such Purchase Order, the estimated Delivery Dates for such excess Product, and if the remainder of such

Purchase Order is acceptable in accordance with this Section 6.4, then upon such written notice, such additional amount of Products accepted by Cellares shall be included in the Confirmed Order. Cellares shall not be considered to have accepted any Purchase Order for such additional Product quantities without written confirmation. Cellares shall have no obligation to accommodate any Purchase Orders for quantities of Products that in the aggregate exceed [***] of the Commitment Amount.

6.5 Lead Time; Delivery Date. Partner will issue Purchase Orders that specify requested date(s) of initiation of manufacturing (the "***Initiation Date***"), and Cellares' written confirmation of Purchase Orders (if any) shall set forth a delivery date for each Product ordered (the "***Delivery Date***"). For each Product, the time between the Initiation Date and the Delivery Date shall be not less than the lead time as specified in the applicable SOW, unless otherwise agreed by Cellares. Cellares shall use [***] to comply with any maximum turnaround time specified in the applicable SOW. The Initiation Date and Delivery Date for each Product shall be binding on Cellares once such Purchase Order is accepted by Cellares unless otherwise mutually agreed; provided that, in the event Cellares reasonably anticipates that it will be unable to meet any Initiation Date or Delivery Date for any accepted Purchase Order due to circumstances outside of Cellares' control, Cellares shall promptly notify Partner and the Parties shall work together in good faith to find a mutually agreeable alternative Initiation Date or Delivery Date to the extent feasible based on bona fide patient needs.

6.6 Failure to Comply with Binding Forecast. Unless otherwise set forth in an applicable SOW, if Partner does not purchase the full quantity of Products in the Commitment Amount during a given Calendar Quarter as set forth in the Binding Forecast, [***].

6.7 No Other Terms and Conditions. If a sales acknowledgment, invoice, Purchase Order, or other document submitted by either Party contains terms or conditions conflicting with or additional to the terms and conditions of this Agreement, the Parties hereby reject such terms and conditions, and the terms and conditions of this Agreement shall prevail unless otherwise expressly agreed to in writing by both Parties.

6.8 Supply Shortfall; Minimum Capacity Guarantee.

(a) Supply Shortfall. In the event Cellares' reasonably believes its manufacturing capacity will be insufficient to supply the Commitment Amount of Product, Cellares shall have the right to allocate its manufacturing capacity (including raw materials) between Partner and Cellares' other customers [***].

(b) Minimum Capacity Guarantee. Notwithstanding anything herein to the contrary, provided that Partner complies with the forecasting structure set forth above (as may be amended from time to time in writing), Cellares shall provide Partner with manufacturing capacity, [***]: (i) [***], or (ii) [***].

7. Pricing; Payment.

7.1 Service Fees. Partner will pay Cellares the fees and other costs for all Services properly performed (the "***Service Fees***") and Product Delivered hereunder (the "***Product Price***") (comprised of a Batch fee and Raw Materials pass-through costs as set forth on the applicable SOW) following receipt by Partner of Cellares' invoices for such Product pursuant to Section 7.3 or as otherwise set forth in the applicable SOW. Unless otherwise expressly set forth in the applicable SOW, all Service Fees are non-refundable. The initial Batch fee is set forth on **Exhibit A** hereto.

7.2 Price Adjustments.

i. Following the [***], or (b) [***]. No later than [***], Cellares shall notify Partner of any such changes with respect to the next Calendar Year.

7.3 Invoicing. Cellares shall invoice Partner on a monthly basis for the total Product Price of all

Products Delivered to Partner in the prior month and, except as otherwise set forth in the applicable SOW, for all other Service Fees incurred or otherwise due in such prior month. Each invoice issued by Cellares hereunder shall specify: [***]. Partner may withhold disputed amounts subject to a good faith dispute. In the event of a payment dispute, Partner shall nevertheless pay the undisputed portion of the applicable invoice and the parties will work reasonably and in good faith to resolve the dispute as quickly as possible. All undisputed amounts not paid by Partner when due shall accrue interest from the applicable due date until paid, at the rate of [***] (or, if less, the maximum rate allowed under the law). Additionally, Cellares may stop performing the applicable Services and withhold Products and other deliverables until payment of all undisputed invoices is made.

Cellares shall submit all invoices to:	Partner shall remit payment in US dollars (USD) via wire transfer or ACH:
Cabaletta Bio, Inc. [***]	Cellares Corporation [***]

7.4 Tax. Unless otherwise agreed by the Parties in an applicable SOW, all fees are exclusive of all sales, use, services, Value Added Taxes (VAT) or similar taxes which shall be charged to Partner at the prevailing rate. The fees also exclude the cost of import, export, insurance and transportation of Partner Materials and other samples or specimens (including the return thereof) which shall be the sole responsibility of Partner.

7.5 Equipment. Any capital or other equipment required for the performance of the Services, including without limitation to a Cell Shuttle and associated cartridges shall be solely the expense of Cellares unless otherwise agreed by the Parties in an applicable SOW, such as equipment that is specific to Partner's Process.

8. Release and Delivery.

8.1 Quality Release. Cellares shall provide to Partner the applicable Batch Records, CoA, CoC and such other documentation for Product as is reasonably required to meet all applicable regulatory requirements of the Regulatory Authorities and completion of other release activities completed per the Quality Agreement upon Delivery ("***Release***").

8.2 Delivery Without Batch Documentation. Upon Partner's request, Cellares shall Deliver restricted Product prior to Release, provided that such request must be accompanied by Partner's written acknowledgement that (a) the Product has been Delivered without a CoA or CoC or other applicable documentation, (b) accordingly, the Product cannot be administered to humans until transmittal of such certificates and documentation, and (c) Partner nevertheless accepts full risk of loss, title and ownership of the Product. Cellares shall have no liability or responsibility for any such Product or the use thereof by or on behalf of Partner provided without the applicable documentation. Cellares shall deliver the CoA, CoC and such other documentation as required pursuant to Applicable Law and the applicable SOW as soon as such documentation is available.

8.3 Delivery. All Products shall be delivered EXW (Facility) (Incoterms 2020) ("***Deliver***," "***Delivered***," or "***Delivery***," as appropriate), in each case no later than the Delivery Date specified on Cellares' written confirmation of the applicable Purchase Order (or, if no such Delivery Date is specified, the Delivery Date shall be consistent with the turnaround time set forth in the applicable SOW and Section 6.5) (unless the Delivery Date is changed by written agreement of the Parties or a Force Majeure occurs). Partner shall be responsible for all loading, transit, export and import from the Facility, including the selection of a carrier and management thereof. Title and risk of loss for the Products shall pass from Cellares to Partner upon Delivery. Partner shall be solely responsible, in its discretion and at its expense, for procuring any insurance it desires for shipping and transportation after Release. In the event Cellares stores any

Product pursuant to Section 4.7 as a result of Partner's failure to take Delivery of such Product within **[***]**, then Cellares shall have a right to invoice Partner for such storage at mutually agreed rates for any storage beyond **[***]** and up to a maximum of **[***]**, and Partner shall pay each such invoice within **[***]** following receipt thereof. Except as specified in the applicable SOW, Cellares shall have no obligation to store or retain any Product for more than **[***]** of such Product.

8.4 Packaging and Labeling. Cellares will package and label Product for Delivery in accordance with Cellares Operating Documents and the applicable Specifications.

8.5 Samples. Cellares shall retain quality control samples of each Batch of Product Delivered hereunder in accordance with the Quality Agreement and Applicable Law.

8.6 Manufacturing Issues. Cellares shall not be responsible or liable for any carrier or other delays or factors adversely impacting its performance hereunder due to Force Majeure.

9. Acceptance/Rejection of Product.

9.1 Acceptance. Following Delivery of each shipment of Product pursuant to Section 8.3, Partner shall have the right to inspect and test Product to determine compliance with this Agreement, including the Product Warranty (defined below). If Partner believes that any Product in any shipment does not conform to the Product Warranty ("***Non-Conformance***"), [***]. The mere failure of a Product to have a particular therapeutic or other effect in and of itself shall not be grounds for deeming such Product to have a Non-Conformance. If Partner fails to notify Cellares of a Non-Conformance within the timelines set forth above in this Section 9.1, such Product shall be deemed accepted by Partner.

9.2 Rejection and Remedy for Non-Conformance.

(a) Rejection for Non-Conformance. Upon timely receipt of a Deficiency Notice pursuant to Section 9.1, if Cellares believes in good faith that (i) rejected Product complies with the Product Warranty or (ii) such Non-Conformance is attributable to the Partner Manufacturing Process, any specimens, samples, Partner Materials, information, instructions or intellectual property provided by Partner or the inherent properties of such Product (this clause (ii), "***Partner Fault***"), the Parties shall initiate an investigation of such Non-Conformance which will be conducted, upon mutual agreement of the Parties, by either Party, the Parties jointly, or a Third Party independent laboratory agreed by the Parties, provided that Cellares notifies Partner of its belief that rejected Product complies with the Product Warranty within [***] after receipt of the Deficiency Notice, after which time Cellares shall have waived its right to challenge the rejection. Partner shall provide Cellares with reasonable assistance in such investigation, including the return of all such Non-Conforming Product at Cellares' expense. If the investigation determines that (i) such Non-Conformance does exist, then the applicable Products shall be deemed to be properly rejected or (ii) such Non-Conformance does not exist or is the result of any Partner Fault or cannot be definitively established, then Partner shall be deemed to have accepted Delivery of such Products (and Partner shall be obligated to pay for such Products as set forth in this Agreement and Partner shall reimburse expenses paid by Cellares pursuant to the immediately preceding sentence). The costs of the investigation related to such Deficiency Notice shall be borne by Partner, unless it is determined by the Parties that a Non-Conformance not resulting from any Partner Fault exists, in which case Cellares shall pay such costs. If the foregoing investigation is conducted by a Third Party independent laboratory as set forth in this Section 9.2(a), the determination by such independent laboratory shall be binding on the Parties, absent manifest error.

(b) Disagreement Regarding Non-Conformance. In the event Partner provides a timely Deficiency Notice and Cellares timely challenges such Deficiency Notice, and following an investigation by either Party or the Parties jointly under Subsection 9.2(a) either Party in good faith disagrees with the determination that the Product was or was not Non-Conforming or whether any Non-Conformance was the result of any Partner Fault, then the Party that disagrees with such determination may cause an independent third-party laboratory agreeable to both Parties to perform comparative tests and/or

analyses on samples of the alleged Non-Conforming Product to determine whether such Product is Non-Conforming and if so, whether such Non-Conformance was the result of any Partner Fault, in which case such laboratory's results shall be in writing and shall be final and binding on the Parties absent manifest error on the face of its report. Unless otherwise agreed to by the Parties in writing, the costs associated with such third-party testing and review shall be borne by the Party against whom the independent third-party laboratory rules or, if the laboratory does not rule in favor of either Party, then the Parties shall share equally the expenses of the laboratory.

(c) Remedy for Non-Conformance. [***].

9.3 Delivery of Non-Conforming Product. Notwithstanding the foregoing, Partner may upon its request take delivery of Non-Conforming Product, or any Product that otherwise does not meet the applicable Specifications or cGMP (including any Development Batch), at Partner's sole risk and cost. Cellares shall have no liability or responsibility for any such Product or the use thereof by or on behalf of Partner.

10. Confidentiality.

10.1 Each Party (a "***Disclosing Party***") may disclose or otherwise make available, directly or indirectly, to the other Party (the "***Receiving Party***") confidential information of the Disclosing Party ("***Confidential Information***") during the term of this Agreement, whether disclosed or otherwise made available hereunder or under the Quality Agreement, whether written, graphic, oral, visual, tangible or intangible, in any form or format. The existence and terms of this Agreement are deemed to be the Confidential Information of both Parties. The Receiving Party shall (a) maintain all Confidential Information in confidence and employ commercially reasonable procedures to prevent its unauthorized publication or disclosure, (b) only disclose Confidential Information to those of its officers, directors, employees, consultants and advisors who have a need to know such Confidential Information for purposes permitted under this Agreement and who are subject to written obligations of confidentiality and non-use at least as protective as those set forth therein (except that each Party may disclose the terms of this Agreement to bona fide actual or prospective underwriters, investors (which are not competitors of Partner), lenders or other financing sources or to potential acquirers of the business to which this Agreement relates, and who in each case have a specific need to know such Confidential Information and who are bound by an obligation of confidentiality and restrictions on use that are at least as protective of the Disclosing Party as those in this Article 10, and (c) Confidential Information of Cellares to Regulatory Authorities solely as contemplated and permitted under Article 5); provided that the Receiving Party shall be liable for any failure to comply with the Receiving Party's obligations hereunder and use the Confidential Information only for any purposes permitted under this Agreement and the Quality Agreement. Subject to the requirements of the preceding sentence, Partner also may disclose Confidential Information of Cellares to third parties (each, a "***Collaboration Partner***") with whom Partner has (or is negotiating) a marketing and/or development collaboration agreement ("***Collaboration Agreement***"), provided that (i) the specific Collaboration Partner and scope of necessary disclosure is identified to Cellares in advance, and (ii) notwithstanding clause (c) of the preceding sentence, the Collaboration Partner's use of the Cellares Confidential Information is solely to evaluate and (if executed) to perform the Collaboration Agreement. In addition, if Cellares identifies a Collaboration Partner as a competitor to or customer of Cellares, then the parties will discuss specific ways to mitigate Cellares' concerns with respect to the disclosure of Cellares Confidential Information in such context. The Receiving Party's obligations under this Article 10 will survive termination or expiration of this Agreement for a period of [***]; provided that with respect to any trade secret of the Disclosing Party, such obligations shall survive and continue for as long as such Confidential Information qualifies as a trade secret of the Disclosing Party under Applicable Law. Confidential Information shall include any "Confidential Information" as defined under the TTA. For clarity, Partner Background IP, Partner Materials, Partner Arising IP, and the Partner Manufacturing Process are the Confidential Information of Partner, and Cellares Background IP, Cellares Technology and Cellares Inventions are the Confidential information of Cellares.

10.2 The Receiving Party's obligations under this Article 10 shall not apply to any Confidential

Information that, as demonstrated by contemporaneous written evidence, (a) is known to the Receiving Party without obligation of confidentiality at the time it was obtained from the Disclosing Party; (b) is acquired without obligation of confidentiality by the Receiving Party from a third party having a right to so disclose such Confidential Information; (c) is or becomes published or otherwise in the public domain other than by violation of this Agreement by the Receiving Party; or (d) is independently developed by the Receiving Party without reference to or reliance upon the Confidential Information disclosed by the Disclosing Party. The Receiving Party may disclose Confidential Information that it is required to disclose under Applicable Law or an order by a court or other regulatory body having competent jurisdiction (including the rules of any securities exchange); provided that except where not legally permitted, the Receiving Party shall give the Disclosing Party reasonable advance notice of such disclosure requirement and shall cooperate with the Disclosing Party to oppose, limit or secure confidential treatment for such required disclosure. In the event of any such required disclosure, the Receiving Party shall disclose only that portion of the Confidential Information that the Receiving Party is legally required to disclose, and any such Confidential Information required to be disclosed shall remain subject to the obligations of this Article 10 in all other respects.

10.3 Cellares will provide Partner with access to an encrypted data storage platform for the transfer, storage, use, or processing of personal data in connection with the applicable SOW. The Receiving Party shall immediately notify the Disclosing Party of any unauthorized disclosure or use Confidential Information and reasonably cooperate with the Disclosing Party in the response thereto. In the event of a conflict between the terms of this Article 10 and the terms of the TTA, the terms of this Agreement shall control.

10.4 Each Party expressly agrees that any breach or threatened breach by a Receiving Party of this Article 10 may cause irreparable harm to the Disclosing Party and that money damages may not provide a sufficient remedy to the Disclosing Party for any breach or threatened breach. In the event of any such breach and/or threatened breach, then, in addition to all other remedies available at law or in equity, the Disclosing Party shall be entitled to seek injunctive relief and any other relief deemed appropriate by the Disclosing Party.

11. Intellectual Property.

11.1 Background IP. Each Party shall retain ownership of all technology or intellectual property rights owned or controlled by a Party as of the Effective Date or developed by or on behalf of such Party independent of this Agreement (such Party's "***Background IP***"), and the other Party shall have no rights in such Party's Background IP except as expressly provided in this Agreement.

11.2 Inventions.

(a) Any Partner Materials and/or Confidential Information of Partner provided to Cellares by or on behalf of Partner in connection with this Agreement, in any form whatsoever, shall remain the sole and exclusive property of Partner ("***Partner Property***"). Cellares shall not acquire any right, title or interest in the Partner Property as a result of its performance of the Services.

(b) All data, documentation, information, know-how, procedures, discoveries, inventions and/or techniques ("***Inventions***") developed by or on behalf of Cellares, solely or jointly with others, in the course of performing the Services that do not rely on and/or are not specifically related to the Product or Partner Property (for clarity, Inventions are not specifically related to the Product or Partner Property where they: (i) are generally applicable to the development or manufacture of chemical or biological products or products components, (ii) relate to or improve Cellares' Confidential Information or Background IP, including the Manufacturing Process (other than the Partner Manufacturing Process) or (iii) relate to the conduct of Cellares' business, Cellares' products or services or the use of materials in connection therewith) shall be collectively referred to as the "***Cellares Inventions***" (together with Cellares' Background IP, the "***Cellares Technology***"), are and shall remain solely owned by Cellares.

(c) Any Inventions developed by or on behalf of Cellares, solely or jointly with others, in the course of

performing the Services, and which rely on and/or are specifically related to the Product or Partner Property ("***Partner Arising IP***") shall be solely owned by Partner, and Cellares hereby assigns to Partner all of Cellares' right, title and interest in such Partner Arising IP; provided that Cellares shall retain the right to use such Partner Arising IP to the extent necessary to conduct the Services and for Cellares' internal research and development purposes, subject in each case to the obligations of Cellares under Article 10. Cellares shall, at Partner's request and expense, use reasonable efforts to assist Partner to obtain, maintain and enforce the patents and other intellectual property covering the Partner Arising IP. Cellares shall ensure that its personnel, Affiliates, subcontractors or agents involved in the performance of the Services assign to Cellares all Partner Arising IP to enable Cellares' assignment to Partner as described above.

11.3 Licenses.

(a) Partner hereby grants to Cellares a limited, non-exclusive, non-sublicensable, royalty-free, fully paid-up license under Partner's Background IP (to the extent actually disclosed to Cellares hereunder by or on behalf of Partner) and Partner Arising IP solely to the extent necessary to perform the Services.

(b) To the extent any Cellares Technology is incorporated into any Product, Cellares hereby grants to Partner a limited, non-exclusive, worldwide, royalty-free, fully paid-up, sublicensable (solely with Cellares' prior written consent) and non-transferrable (except as set forth in Section 15.4) license, during the term of this Agreement, under such Cellares Technology solely as necessary for Partner to sell, have sold, offer for sale, import, and otherwise commercialize such Product. For clarity, Partner shall have no license or right to use or authorize the use of any Cellares Technology to make or have made any Product or product or perform or perform or authorize the performance of any services.

11.4 Patent Filings. Each Party shall have the right to file and prosecute patents covering inventions to be owned by such Party pursuant to Section 11.2, and the other Party shall reasonably cooperate with the filing Party at the filing Party's expense. Notwithstanding the foregoing, neither Party shall have the right to disclose any Confidential Information of the other Party in any patent filing without the other Party's prior consent.

11.5 Notice of Infringement; Infringement Claims.

(a) Each Party shall promptly notify the other Party of any claims that any Product, the practice of the Manufacturing Process of the performance of the Services infringes, misappropriates or otherwise violates the valid intellectual property rights of any Third Party. In the event that either Party notifies the other Party of its reasonable belief that the Services infringe, misappropriate or otherwise violate the valid intellectual property rights of any Third Party, then the Parties shall meet to discuss in good faith (x) the existence of such infringement or misappropriation, (y) the risk of a third-party claim based on such potential infringement or misappropriation, and (z) any steps that can be taken (including modifications to the manner of performance of the Services) to mitigate the risk of such a claim.

(b) If a Third Party claim is initiated against Cellares in a court of competent jurisdiction alleging the Product infringes, misappropriates or otherwise violates the valid intellectual property rights of such Third Party (such claim a "***Product Infringement Claim***," the applicable country over which the court has jurisdiction, the "***Applicable Product Jurisdiction***"), then Cellares may suspend the infringing Services for the Applicable Product Jurisdiction by providing Partner with [***] written notice; provided that Cellares: (i) may shorten such notice to [***] in the event that Partner fails to fulfill its obligations under Section 13.2 to defend, indemnify and hold harmless Cellares Indemnitees from and against such Product Infringement Claim and fails to cure within such notice period, and (ii) shall continue performance of the Services for the balance of the Term if the risk of such Product Infringement Claim has been reasonably mitigated (e.g. dismissal,

abandonment or release).

(c) If a Third Party claim is initiated against Cellares in a court of competent jurisdiction alleging the Services (not the Product) infringes, misappropriates or otherwise violates the valid intellectual property rights of such Third Party (such claim a "***Services Infringement Claim***," the applicable country over which the court has jurisdiction, the "***Applicable Services Jurisdiction***"), then subject to the following, Cellares shall use reasonable commercial efforts to revise the Services to render them non-infringing (without materially changing the Services), and/or to secure rights, at Cellares' cost, to the Third Party claimant's intellectual property to allow performance to continue. If after using reasonable commercial efforts, Cellares decides in good faith, and based on advice of competent counsel, that it cannot secure either of the foregoing solutions in a reasonably timely manner and/or on commercially reasonable terms, then Cellares may suspend the infringing Services for the Applicable Services Jurisdiction by providing Partner with [***] written notice; provided that Cellares shall continue performance of the Services for the balance of the Term if the risk of such Services Infringement Claim has been reasonably mitigated (e.g. dismissal, abandonment or release).

12. Warranties; Disclaimer.

12.1 Mutual. Each Party represents and warrants that:

(a) (i) it validly exists under the laws of the jurisdiction in which it was organized, (ii) it has the full power, right and authority to execute and deliver this Agreement and to perform its obligations under this Agreement, (iii) this Agreement once executed will constitute a legal, valid and binding agreement enforceable against it, and (iv) its performance of this Agreement will not conflict with any obligations it may have to any other person; and

(b) (i) it will not employ, contract with, or retain any person directly or indirectly in connection with the performance of the Services if, to such Party's knowledge, such person is presently debarred by the FDA pursuant to the Generic Drug Enforcement Act of 1992, as amended (21 U.S.C. § 301, et seq.), or are ineligible to participate in any federal and/or state healthcare programs or federal procurement or non-procurement programs (as defined in 42 U.S.C. § 1320a-7b(f)), or is disqualified by any other governmental or Regulatory Authority or pursuant to foreign equivalents thereof; and (ii) it has not knowingly engaged in any conduct or activity that could lead to any debarment actions. If during the Term, such Party or, to such Party's knowledge, any person employed or retained by it in connection with the performance of the Services (x) is debarred or becomes subject of an investigation for debarment, or (y) engages in any conduct or activity that would result in debarment, such Party shall, to the extent that it is legally able to do so, promptly notify the other Party of the same.

12.2 By Partner. Partner represents, warrants and (as applicable) covenants that:

(a) it will perform its obligations under this Agreement and use all Products and other results of the Services in compliance with Applicable Law; and

(b) Partner has the right to supply the Partner Materials and Partner's Confidential Information to Cellares and the necessary rights to grant to Cellares the license to use the same as granted hereunder;

(c) to Partner's actual knowledge, all Partner Materials supplied by Partner shall (i) be manufactured in accordance with cGMP (if applicable), (ii) meet other testing requirements and/or specifications as set forth in the applicable SOW or as otherwise agreed in writing by the Parties, and (iii) not be adulterated or misbranded within the meaning of the FD&C Act or similar provisions of any Applicable Laws; and

(d) Partner has the right to supply the Partner Materials to Cellares and the necessary rights to license or permit Cellares to use the same for the purpose of the Services.

12.3 By Cellares. Cellares represents, warrants and (as applicable) covenants that:

(a) the Services shall be performed in a professional manner, with due care, and in compliance with all Applicable Laws and the terms of this Agreement, and shall not be performed in violation of any agreement, judgment, order or decree to which Cellares is a party;

(b) except as otherwise provided in Section 4.4, all cGMP Batches delivered by Cellares hereunder shall, upon Delivery: (i) conform to the applicable Specifications; (ii) be manufactured, stored, tested, labelled, packed and delivered in accordance with the Quality Agreement, cGMP, all relevant Applicable Laws, and the Manufacturing Process described in the Master Batch Record; (iii) not be adulterated or misbranded within the meaning of the FD&C Act or similar provisions of any Applicable Laws in any country where the Product is manufactured or distributed; and (iv) be free of any lien or encumbrance granted by Cellares to any Third Party (this clause (b), the "***Product Warranty***");

(c) all of Cellares' and its Affiliates' employees and subcontractors that perform Services hereunder are under an obligation to assign to Cellares all right, title and interest in and to any and all Partner Arising IP and to protect Confidential Information in accordance with Article 10 (and, for clarity, any such rights in Partner Arising IP shall be assigned to Partner through Cellares hereunder in accordance with Article 11);

(d) to Cellares' knowledge, Cellares' use of Cellares' Background IP in the performance of the Services does not and will not infringe or misappropriate any third-party intellectual property or other rights; and

(e) the CoA, CoC, and Batch Records (as applicable) provided by Cellares with respect to each Batch will (i) reflect the results of the tests conducted on the Batch to which they relate,
(ii) be accurate and true, and (iii) accurately reflect the processes and procedures followed by Cellares in manufacturing the applicable Batch

(f) as of the Effective Date, it is not a party to any litigation, inspection, warning letter, arbitration or mediation involving the research, development, or commercialization of pharmaceutical products or medical devices that could have an adverse impact on its performance of this Agreement, and Cellares will promptly notify Partner in the event Cellares becomes a party to any such litigation, inspection, warning letter, arbitration or mediation

(g) it will implement industry standard physical and technological measures to prevent Confidential Information of Partner from being disclosed to or accessed by Third Parties, and it will use commercially reasonable technical measures to detect and eliminate computer viruses and other destructive code introduced to any computer systems used in connection with the Services and to correct any reproducible error in any computer systems used in connection with the Services reported to Cellares by Partner during the Term; and

(h) it or its Affiliates hold all necessary permits, approvals, consents and licenses to enable it to perform the Services at the Facility.

12.4 DISCLAIMER. EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, EACH PARTY DISCLAIMS ALL WARRANTIES, EXPRESS, IMPLIED OR STATUTORY, INCLUDING BUT NOT LIMITED TO ANY WARRANTIES OF MERCHANTABILITY, TITLE, FITNESS FOR A PARTICULAR PURPOSE, NONINFRINGEMENT, OR COURSE OF PERFORMANCE OR COURSE OF DEALING. CELLARES DISCLAIMS ALL WARRANTIES, EXPRESS, IMPLIED OR STATUTORY REGARDING ACCEPTANCE OR APPROVAL OF ANY APPLICATIONS, PRODUCTS, PROCESSES OR TREATMENTS BY A REGULATORY OR GOVERNMENTAL AGENCY, OR THAT THE RESULTS OF ANY SERVICES WILL ENABLE PARTNER TO FURTHER DEVELOP OR COMMERCIALIZE THE MANUFACTURING PROCESS OR THE PRODUCTS, OR ANY OTHER PROCESS, PRODUCT OR SERVICE. CELLARES SHALL NOT BE RESPONSIBLE FOR ANY DELAYS OR OTHER ADVERSE IMPACTS TO PARTNER'S DEVELOPMENT (INCLUDING CLINICAL) OR COMMERCIAL PROGRAMS ARISING FROM THIS AGREEMENT. IN ADDITION, ANY EXPRESS WARRANTIES OF

CELLARES HEREUNDER ARE LIMITED OR DISCLAIMER TO THE EXTENT THAT SUCH WARRANTIES ARE NOT MET DUE TO ALL PARTNER MATERIALS NOT (I) NOT BEING MANUFACTURED IN ACCORDANCE WITH CGMP, (II) NOT MEETING OTHER TESTING REQUIREMENTS AND/OR SPECIFICATIONS AS SET FORTH IN THE APPLICABLE SOW OR AS OTHERWISE AGREED IN WRITING BY THE PARTIES, OR (III) BEING ADULTERATED OR MISBRANDED WITHIN THE MEANING OF THE FD&C ACT OR SIMILAR PROVISIONS OF ANY APPLICABLE LAWS.

13. Indemnities; Insurance.

13.1 By Cellares. Subject to the limitations of liability contained in Section 13.5, Cellares will defend, indemnify and hold harmless Partner and its Affiliates and their respective directors, officers, employees and agents ("***Partner Indemnitees***") from and against any losses, damages, fines and liabilities, including reasonable attorney fees ("***Losses***") arising from Third Party claims, demands, suits, actions or causes of action ("***Claims***") which may be asserted against such Partner Indemnitees by Third Parties to the extent arising out of: (a) the gross negligence, willful misconduct or violation of Applicable Law of or by any Cellares Indemnitee during the Term; or (b) any claims alleging that the use of the Cellares Background IP in the performance of the Services (for avoidance of doubt excluding use by any Cellares Indemnitees of any Partner Property in accordance with Partner's instructions) infringes any intellectual property rights of a Third Party; except, in each case of (a) through (b), to the extent such Claim is subject to indemnification by Partner pursuant to Section 13.2.

13.2 By Partner. Partner will defend, indemnify and hold harmless Cellares and its Affiliates and their respective directors, officers, employees and agents ("***Cellares Indemnitees***") from and against any Losses arising from Claims which may be asserted against such Cellares Indemnitees by Third Parties to the extent arising out of: (a) the research, development, use, sales or distribution by or on behalf of Partner, or any distributor, collaborator, customer, patient, licensee, representative or agent of Partner, of any Product or product containing the Product, (b) any claims alleging that the use of the Partner Property in accordance with Partner's instructions infringes any intellectual property rights of Third Parties, (c) the gross negligence or willful misconduct of any Partner Indemnitee during the Term, or (d) any injuries suffered by Partner's employee or representative while at the Facility or elsewhere; except to the extent such Claim is subject to indemnification by Cellares pursuant to Section 13.1.

13.3 Procedure. Each indemnified party shall give the indemnifying Party prompt notice of any Claim for which indemnification is sought hereunder. The indemnifying Party shall have the right to control the defense and settlement of a Claim, at its sole expense, provided the indemnified party shall reasonably cooperate in the investigation, defense and settlement of such Claim at the indemnifying Party's expense. Neither Party will enter into any settlement agreement that attributes fault or negligence to the other Party, requires any payment by the other Party, or restricts the future actions or activities of the other Party, without the other Party's prior written consent, which shall not be unreasonably withheld. Any indemnified party shall have the right to participate in the defense and settlement of a Claim and to employ separate legal counsel of its own choice at the indemnified party's own expense. The costs and expenses, including reasonable fees and disbursements of counsel, incurred by any indemnified party in connection with any Claim shall be reimbursed on a monthly basis by the indemnifying Party subject to refund in the event the indemnifying Party is ultimately held not to be obligated to indemnify the indemnified party.

13.4 Insurance. Each Party shall carry insurance sufficient to cover its interest or potential liabilities hereunder including, but not limited to worker's compensation, if applicable, and comprehensive general liability.

13.5 Limitation of Liability.

(a) EXCEPT WITH RESPECT TO (i) ANY FRAUD, GROSS NEGLIGENCE OR WILLFUL MISCONDUCT, (ii) ANY BREACH OF SECTION 10 (CONFIDENTIALITY) OR SECTION 11 (INTELLECTUAL PROPERTY), OR (iii) LIABILITY FOR DEATH OR PERSONAL INJURY, IN NO EVENT WILL EITHER PARTY BE LIABLE UNDER THIS AGREEMENT FOR ANY CONSEQUENTIAL,

INDIRECT, EXEMPLARY, SPECIAL, PUNITIVE, OR INCIDENTAL DAMAGES OR LOST PROFITS ARISING FROM OR RELATING TO THIS AGREEMENT, EVEN IF ADVISED OF THE POSSIBILITY OF SUCH DAMAGES OR IF SUCH DAMAGES ARE FORESEEABLE, WHETHER IN CONTRACT OR TORT OR OTHERWISE. FOR THE AVOIDANCE OF DOUBT, THE AMOUNTS PAID AS LOSSES TO THIRD PARTY CLAIMANTS UNDER THE PARTIES' INDEMNIFICATION OBLIGATIONS ARE NOT PRECLUDED BY THIS 13.5(a).

(b) EXCEPT WITH RESPECT TO (i) ANY FRAUD, GROSS NEGLIGENCE OR WILLFUL MISCONDUCT, (ii) ANY BREACH OF SECTION 10 (CONFIDENTIALITY) OR SECTION 11 (INTELLECTUAL PROPERTY), (iii) INDEMNIFICATION OBLIGATIONS UNDER SECTION 12, OR (iv) LIABILITY FOR DEATH OR PERSONAL INJURY, CELLARES' TOTAL CUMULATIVE LIABILITY IN CONNECTION WITH THIS AGREEMENT, WHETHER IN CONTRACT OR TORT OR OTHERWISE, WILL NOT EXCEED THE AGGREGATE AMOUNT OF FEES PAID BY PARTNER TO CELLARES IN THE [***] PRECEDING THE CLAIM UNDER THE APPLICABLE SOW FOR THE SERVICES GIVING RISE TO THE LIABILITY.

14. Term; Termination.

14.1 Term. This Agreement shall commence upon the Effective Date and continue until the later of (a) the fifth (5th) anniversary of the Effective Date, or (b) completion of all Services set forth in all SOWs entered into prior to expiration of the Term, unless earlier terminated in accordance with this Article 14 (the "***Term***").

14.2 Termination.

(a) Either Party may terminate this Agreement or any SOW at any time upon ninety [***] ([***] for non-payment) prior written notice to the other Party for material breach of this Agreement by the other Party if such breach is not cured to the non-breaching Party's reasonable satisfaction within the applicable notice period; provided, however, that such [***] period shall be extended an additional [***] as agreed by the Parties in writing if the identified breach is incapable of cure within [***] and if the breaching Party provides a plan and timeline to cure the breach, promptly commences efforts to cure the breach and diligently prosecutes such cure (it being understood that this extended period shall be unavailable for any breach regarding non-payment).

(b) Partner may terminate this Agreement or any SOW for any reason or no reason upon [***] prior written notice to Cellares.

(c) Cellares may terminate this Agreement or any SOW for any reason or no reason upon [***] prior written notice to Partner.

(d) Either Party may terminate this Agreement if the other Party enters into administration, becomes insolvent, is dissolved or liquidated, makes a general assignment for the benefit of its creditors, or files or has filed against it, a petition in bankruptcy or has an administrator or receiver appointed for a substantial part of its assets, except in the event such petition, appointment or action is withdrawn within [***].

14.3 Effect of Termination. Upon expiration or termination of this Agreement or any SOW, the following shall apply:

(a) Partner shall promptly pay Cellares (i) any Service Fees due in connection with Services properly rendered through the effective date of expiration or termination, and (ii) all non-cancellable commitments, such as time and materials and pass through costs, made prior to the date of notice of such termination or expiration, in each case solely to the extent such costs are expressly authorized in the SOW; provided, however, that Partner shall have no payment obligations under the foregoing (ii) in the event of termination by Partner for Cellares' material breach pursuant to Section 14.2(a), unless to the extent the non-cancellable commitments are specific to the Product;

(b) Cellares shall deliver, and Partner shall pay for, all finished but undelivered Product;

(c) Cellares will, at Partner's election and expense, dispose of or deliver to Partner (i) all Partner Material (including Cell Lines and Cell Banks) in accordance with Section 3.5(f), and (ii) any retained samples (except for samples Cellares is required to retain pursuant to Applicable Law), and any records, reports and other deliverables required to be provided to Partner under the applicable SOW;

(d) neither Party shall be relieved of any obligation accruing prior to such expiration or termination; and

(e) Section 3.5(e) and (f), Section 4.6(e), Article 5, Article 7 (with respect to any amounts payable prior to or in connection with expiration or termination), Article 9, Article 10, Article 11, Section 12.4, Article 13, Section 14.3 and Article 15 shall survive such expiration or termination.

15. Miscellaneous

15.1 Force Majeure. Except for the payment of monies due hereunder, neither Party shall be considered in default of the performance of any obligation hereunder to the extent that the performance of such obligation is prevented or delayed by fire, flood, earthquake, explosion, acts of terrorism, disease, war, insurrection, embargo, changes in Applicable Law that materially impacts that Party's performance of this Agreement, civil or military authority, act of God, or any other event, occurrence or condition which is not caused, in whole or in part, by that Party, and which is beyond the reasonable control of that Party ("***Force Majeure***"). A Party that is prevented from performing any of its obligations due to Force Majeure will promptly give notice to the other Party of the event and the obligations as to which performance is prevented or delayed, and shall use commercially reasonable efforts to mitigate such Force Majeure. If a Force Majeure continues for more than [***], the Parties will discuss an appropriate resolution that may include an amendment or termination of the affected SOW or this Agreement.

15.2 Notices. All notices from one Party to the other will be in writing sent to the Party's address set forth in the preamble above. For Partner, notices must be sent Attention: General Counsel, with a cc to [***]. Notices must be sent by overnight courier, certified mail, return receipt requested, or by other means of delivery requiring a written acknowledged receipt. All notices will be effective upon receipt.

15.3 Independent Contractor. The business relationship of Cellares to Partner is that of an independent contractor and not of a partner, joint venturer, employer, employee or any other kind of relationship. Neither Party shall at any time enter into, incur, or hold itself out to Third Parties as having authority to enter into or incur, on behalf of the other Party, any commitment, expense, or liability whatsoever.

15.4 Assignment. This Agreement, and the rights and obligations hereunder, may not be assigned or transferred by either Party without the prior written consent of the other Party, except that either Party may assign or transfer this Agreement to an Affiliate of such Party or to a purchaser of all or substantially all of its business or assets to which this Agreement relates, whether by way of sale of assets or stock of such Party or merger, acquisition, reorganization or otherwise. Any assignment not in compliance with this Section 15.5 is null and void.

15.5 Publicity. Neither Party shall use the other Party's name, symbol or trademarks in any publicity releases, advertising, sales or promotional material, including customer lists or in any publication without the other Party's prior written consent in each case, unless required by Applicable Law. For clarity, the foregoing does not apply with respect to any filings by Partner or its Affiliates to any Regulatory Authority.

15.6 Entire Agreement; Waiver; Severability. This Agreement, including each SOW and the Exhibits attached hereto, sets forth the entire agreement and understanding between the Parties, superseding any and all previous statements, negotiations, documents agreements and understandings, whether oral or written, as to the subject matter of this Agreement. No modification, amendment, or waiver of the

provisions of this Agreement shall be valid or binding on either Party unless in writing and signed by both Parties. No waiver of any term, right or condition under this Agreement on any one occasion shall be construed or deemed to be a waiver or continuing waiver of any such term, right or condition on any subsequent occasion or a waiver of any other term, right or condition hereunder. In the event that any one or more of the provisions contained in this Agreement will, for any reason, be held to be invalid, illegal or unenforceable in any respect, that invalidity, illegality or unenforceability will not affect any other provisions of this Agreement, and all other provisions will remain in full force and effect. In the event of conflict between the terms of this Agreement and the terms of any SOW, the terms of this Agreement will control.

15.7 Applicable Law. This Agreement and any claim, controversy or dispute arising under or related to this Agreement, the relationship of the parties under this Agreement, or the enforcement of the rights and obligations of the parties under this Agreement will be governed by the laws of the State of Delaware and shall be construed and governed under and in accordance with the laws of that State without regard to the provisions governing conflict of laws.

15.8 Counterparts. This Agreement may be executed in counterparts, each of which, when executed, shall be deemed to be an original and all of which, together with this writing, shall be deemed one and the same instrument. This Agreement may be executed by facsimile, PDF or electronic signatures, which signatures shall have the same force and effect as original signatures.

15.9 Further Actions. Each Party agrees to execute, acknowledge and deliver such further instruments, and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

[*Signature page follows.*]

IN WITNESS WHEREOF, the Parties have by duly authorized persons executed this Agreement as of the Effective Date.

Cellares Corporation	**Cabaletta Bio, Inc.**
By: /s/ Fabian Gerlinghaus	By: /s/ Steven Nichtberger
Name: Fabian Gerlinghaus	Name: Steven Nichtberger, M.D.
Title: Co-Founder & CEO	Title: Chairman and CEO
11 January 2026 | 3:28:59 PM PST	11 January 2026 | 3:28:59 PM PST

Exhibit A

Initial Batch Fee = [***]

Exhibit 21.1

Cabaletta Bio, Inc.

The following is a list of subsidiaries of Cabaletta Bio, Inc. as of December 31, 2025.

SUBSIDIARY	STATE OR OTHER JURISDICTION OF INCORPORATION OR ORGANIZATION
Cabaletta Bio, Inc.	Delaware
Cabaletta Bio GmbH	Switzerland
Cabaletta Bio (Germany) GmbH	Germany

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

(1) Registration Statement (Form S-8 No. 333-234367) pertaining to the Cabaletta Bio, Inc. 2018 Stock Option and Incentive Plan, the Cabaletta Bio, Inc. 2019 Stock Option and Incentive Plan, and the Cabaletta Bio, Inc. 2019 Employee Stock Purchase Plan,
(2) Registration Statement (Form S-8 No. 333-237484) pertaining to the Cabaletta Bio, Inc. 2019 Stock Option and Incentive Plan and the Cabaletta Bio, Inc. 2019 Employee Stock Purchase Plan,
(3) Registration Statement (Form S-8 No. 333-254342) pertaining to the Cabaletta Bio, Inc. 2019 Stock Option and Incentive Plan and the Cabaletta Bio, Inc. 2019 Employee Stock Purchase Plan,
(4) Registration Statement (Form S-8 No. 333-263637) pertaining to the Cabaletta Bio, Inc. 2019 Stock Option and Incentive Plan,
(5) Registration Statement (Form S-8 No. 333-270595) pertaining to the Cabaletta Bio, Inc. 2019 Stock Option and Incentive Plan,
(6) Registration Statement (Form S-8 No. 333-273863) pertaining to the Cabaletta Bio, Inc. 2019 Stock Option and Incentive Plan,
(7) Registration Statement (Form S-8 No. 333-278124) pertaining to the Cabaletta Bio, Inc. 2019 Stock Option and Incentive Plan,
(8) Registration Statement (Form S-8 No. 333-286246) pertaining to the Cabaletta Bio, Inc. 2019 Stock Option and Incentive Plan,
(9) Registration Statement (Form S-3 No. 333-278126) of Cabaletta Bio, Inc., and
(10) Registration Statement (Form S-3 No. 333-289339) of Cabaletta Bio, Inc.;

of our report dated March 23, 2026, with respect to the consolidated financial statements of Cabaletta Bio, Inc. included in this Annual Report (Form 10-K) of Cabaletta Bio, Inc. for the year ended December 31, 2025.

/s/ Ernst & Young LLP

Philadelphia, Pennsylvania
March 23, 2026

Exhibit 31.1

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Steven Nichtberger, certify that:

1. I have reviewed this Annual Report on Form 10-K for the year ended December 31, 2025 of Cabaletta Bio, Inc. (the "registrant");

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 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 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.

Date: March 23, 2026

By: /s/ Steven Nichtberger

Steven Nichtberger, M.D.
Chief Executive Officer and President
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Anup Marda, certify that:

1. I have reviewed this Annual Report on Form 10-K for the year ended December 31, 2025 of Cabaletta Bio, Inc. (the "registrant");

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 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 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.

Date: March 23, 2026

By: /s/ Anup Marda

Anup Marda
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION 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 of Cabaletta Bio, Inc. (the "Company") on Form 10-K for the fiscal year ended December 31, 2025 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: March 23, 2026

By: /s/ Steven Nichtberger

Steven Nichtberger, M.D.
Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION 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 of Cabaletta Bio, Inc. (the "Company") on Form 10-K for the fiscal year ended December 31, 2025 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: March 23, 2026

By: /s/ Anup Marda

Anup Marda
Chief Financial Officer
(Principal Accounting and Financial Officer)