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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 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: 001-40631

Caribou Biosciences, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**45-3728228**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
2929 7th Street, Suite 105 Berkeley, California	**94710**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (510) 982-6030

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.0001 per share	CRBU	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 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 are restatements. ☐

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

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the Registrant on June 30, 2025, based on the closing price of the shares of common stock on the Nasdaq Global Select Market on such date, was $112.5 million This calculation does not reflect a determination that certain persons are affiliates of the Registrant for any purpose.

The number of shares of Registrant's Common Stock outstanding as of February 27, 2026 was 96,637,202.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's definitive proxy statement for the 2026 Annual Meeting of Stockholders are incorporated by reference into Part III.

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Risk Factors Summary

Our business is subject to a number of risks of which you should be aware before making a decision to invest in our common stock. These risks are more fully described in the "Risk Factors" section in Part I, Item 1A of this Annual Report on Form 10-K. These risks include, among others, the following:

Risks Relating to our Financial Position and Need for Additional Capital

- We have incurred significant operating losses since our inception and anticipate that we will incur continued operating losses for the foreseeable future and we may not be able to achieve or sustain profitability.
- We will need substantial additional financing to conduct our planned pivotal clinical trial for vispa-cel and to implement our operating plans. If we fail to obtain additional financing, we will be unable to complete the development and commercialization of our vispa-cel and/or CB-011 product candidates.
- Raising additional capital may cause dilution to our stockholders, restrict our operations, and/or require us to relinquish rights to our genome-editing technologies or product candidates.

Risks Relating to our Business, Government Regulation, Technology, and Industry

- Our CAR-T cell therapy product candidates are in clinical development and it will be many years before we commercialize a product candidate, if ever. If we are unable to advance our product candidates through clinical trials, obtain regulatory approval, and ultimately commercialize our product candidates, or if we experience significant delays in doing so, our business will be materially harmed.
- The FDA or other regulatory agencies may disagree with our regulatory plans and we may fail to obtain regulatory approval of our CAR-T cell therapy product candidates.
- Changes at the FDA may hinder the agency's ability to hire and retain key leadership and other personnel, slow the time necessary for new product candidates to be reviewed and/or approved, or otherwise prevent these agencies from performing normal business functions on which our operations rely, which would adversely affect our business.
- The regulatory landscape that will govern our product candidates is uncertain; regulations relating to more established gene therapy and cell therapy products are still developing, and changes in regulatory requirements could result in delays or discontinuation of development of our product candidates or unexpected costs in obtaining regulatory approval.
- In the event that we are unable to continue to fund the clinical development of one or both of our product candidates, and/or if one or both of our clinical-stage product candidates is not clinically successful, does not receive regulatory approval, and/or is not commercially competitive, we currently do not have a research pipeline from which to generate new product candidates.
- Manufacturing our product candidates is complex and we could experience manufacturing problems during our clinical trials, which could delay or limit development and/or commercialization of our product candidates.
- If we experience delays or difficulties enrolling patients in the clinical trials for our product candidates, our ability to advance our product candidates through clinical development and the regulatory process could be delayed or prevented.
- Our clinical trials may fail to adequately demonstrate the safety and efficacy of any of our product candidates and, if this happens, the development of our product candidates may be delayed or unsuccessful, which could prevent or delay regulatory approval and commercialization.
- If our product candidates cause serious adverse events or undesirable side effects, including injury and death, or have other properties that could delay or prevent regulatory approval, our product candidates could have limited or no commercial potential.
- Our allogeneic CAR-T cell therapy product candidates will be regulated as biologics, and therefore may be subject to uncertainty regarding nonpatent regulatory exclusivity or maintaining regulatory approval.

- We face significant competition from other biotechnology and pharmaceutical companies, which may result in other companies developing or commercializing products before, or more successfully than, we do, thus rendering our product candidates non-competitive or reducing the size of the market for our product candidates. Our operating results will suffer if we fail to compete effectively.

Risks Relating to Intellectual Property

- Third-party claims of intellectual property infringement may prevent or delay our ability to commercialize our product candidates.
- If we do not possess the necessary intellectual property rights covering our CRISPR chRDNA genome-editing technology, our product candidates, or other proprietary technologies, we may not be able to block competitors or to compete effectively in the market.
- Our rights to develop and commercialize our product candidates are subject to the terms and conditions of our licenses and assignments with third parties. If we fail to comply with our obligations under these agreements, we could lose intellectual property rights and be subject to litigation from our licensors or assignors.

Risks Relating to our Relationships with Third Parties

- We rely on third parties to supply the materials for, and the manufacturing of, our clinical product candidates, and, if such product candidates receive regulatory approval, we may continue our reliance on third parties for manufacturing our commercial products. Our continued success is subject to the performance of these third parties.
- We rely and will continue to rely on third parties to conduct our clinical trials. If these third parties do not successfully carry out their contractual duties or do not meet deadlines, we may not be able to obtain regulatory approval of, or commercialize, our product candidates.

Risks Relating to Employee Matters, Managing Growth, and Other Risks Relating to our Business

- Our future success depends on our ability to retain our executive officers and to attract, retain, and motivate qualified personnel.
- Our internal computer systems, or those of third parties with which we interact, may fail or suffer security breaches, which could result in a material disruption of the development of our product candidates, compromise sensitive information related to our business, or prevent us from accessing critical information, potentially exposing us to liability or otherwise adversely affecting our business.
- As a public company, we are obligated to develop and maintain proper and effective internal controls over financial reporting, and any failure to maintain the adequacy of these internal controls may adversely affect investor confidence in our company and, as a result, the value of our common stock.

Risks Relating to Ownership of our Common Stock

- The market price of our common stock has been, and may continue to be, volatile, and our investors may suffer substantial losses if the price of our common stock drops significantly.
- We may not remain in compliance with the continued listing requirements of Nasdaq, and, if we are not able to remain in compliance, our common stock will be subject to delisting.
- We may be subject to securities class action litigation, and our officers and directors may be subject to shareholder derivative lawsuits, which will result in substantial costs and a diversion of management's attention and resources, which could harm our business.

Throughout this Annual Report on Form 10-K, "Company," "Caribou," "Caribou Biosciences," "we," "us," and "our," except where the context requires otherwise, refer to Caribou Biosciences, Inc. and its consolidated subsidiaries, and "our board of directors" refers to the board of directors of Caribou Biosciences, Inc.

Special Note Regarding Forward-Looking Statements

This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. All statements, other than statements of historical facts, contained in this Annual Report on Form 10-K are forward-looking statements, including statements regarding our business strategy, plans, and objectives; expectations regarding our clinical-stage product candidates, including our expectations about the development timelines for such product candidates; the expected timing of disclosure of clinical trial data; the safety, efficacy, and potential advantages of our product candidates; expectations about our future regulatory filings and interactions with regulatory authorities; our results of operations and financial position; plans and objectives of management for future operations; and the like. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project," "contemplate," "believe," "estimate," "predict," "potential," or "continue," or the negative of these terms or other similar expressions, although not all forward-looking statements contain these words. Forward-looking statements include, but are not limited to, statements concerning:

- our expectations regarding the initiation, enrollment, timing, progress, and results of our ANTLER and CaMMouflage clinical trials, as well as timing for the initiation of succeeding clinical phases of these trials, including the expected design, protocol, and timing of initiation of our planned pivotal clinical trial for vispa-cel, as well as the outcome of our ongoing engagement with the FDA regarding our vispa-cel planned pivotal clinical trial;
- our ability to successfully develop our vispa-cel and CB-011 product candidates and to obtain and maintain regulatory approval for these product candidates;
- the projected manufacturing costs for our vispa-cel and for CB-011 product candidates;
- the likelihood of our clinical trials demonstrating safety and efficacy of our vispa-cel and CB-011 product candidates;
- the beneficial characteristics, therapeutic effects, and potential advantages of our vispa-cel and CB-011 product candidates;
- the timing or likelihood of regulatory filings and approvals for our vispa-cel and CB-011 product candidates;
- our ability to take advantage of expedited regulatory pathways for our vispa-cel and CB-011 product candidates;
- our strategic plans for our business, our vispa-cel and CB-011 product candidates, and our CRISPR chRDNA genome-editing technology;
- the expected benefits of potential strategic collaborations with third parties, including our agreements with Pfizer, and our ability to attract new collaborators;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our vispa-cel and CB-011 product candidates and our CRISPR chRDNA genome-editing technology;
- anticipated developments related to our competitors and our industry;
- our ability to adequately secure our information technology systems and the regulated data stored therein, as required by law;

- the impact of global economic and political developments on our business, including rising inflation, tariffs, and capital market disruptions; changes in U.S. governmental agencies and funding and in such agencies' policies, procedures, and priorities; the ongoing war between Ukraine and Russia, conflicts in the Middle East, including the recent hostilities involving Iran, tension between China and Taiwan, geopolitical tensions in Europe, South America, and elsewhere; and economic sanctions and economic slowdowns or recessions that may result from such developments and that could harm our clinical development efforts as well as the value of our common stock and our ability to access capital markets;

- estimates regarding the sufficiency of our existing capital resources to fund our future operating expenses and capital expenditure requirements; and

- our anticipated use of our existing resources, capital requirements, and the timing of and need for additional financing to fund our planned pivotal clinical trial for vispa-cel and further clinical development of CB-011 beyond dose expansion.

The forward-looking statements in this Annual Report on Form 10-K are only predictions and are based largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition, and results of operations. These forward-looking statements speak only as of the date this Annual Report on Form 10-K is filed and are subject to a number of known and unknown risks, uncertainties, and assumptions, including those described in the "Risk Factors" section in Part I, Item 1A of this Annual Report on Form 10-K and in the "Management's Discussion and Analysis of Financial Condition and Results of Operations" section in Part II, Item 7 of this Annual Report on Form 10-K. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or may not occur and actual results could differ materially from those projected in the forward-looking statements. Moreover, we operate in a very competitive and rapidly evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances, or otherwise.

Trademarks and Service Marks

We have registered CARIBOU BIOSCIENCES®, CARIBOU®, SITE-SEQ®, and our logo as trademarks in the United States and certain other jurisdictions. This Annual Report on Form 10-K contains references to our trademarks and service marks and to those belonging to other entities. Solely for convenience, trademarks and service marks referred to in this Annual Report on Form 10-K, including logos, artwork, and other visual displays, may appear without the ® or ™ symbols, but in the case of our trademarks and service marks, such references are not intended to indicate in any way that we will not assert, to the fullest extent under applicable law, our rights to these trademarks and service marks. We do not intend our use or display of other entities' trademarks or service marks to imply a relationship with, or endorsement or sponsorship of us by, any other entity.

PART I

Item 1. Business.

Overview

We are a clinical-stage **C**lustered **R**egularly **I**nterspaced **S**hort **P**alindromic **R**epeats ("CRISPR") genome-editing biopharmaceutical company dedicated to developing transformative therapies for patients with devastating diseases. Our genome-editing platform is based on our novel chRDNA (**C**RISPR **h**ybrid **R**NA-**DNA**, or "chRDNA," pronounced "chardonnay") genome-editing technology, which enables more precise genome editing of allogeneic cell therapies.

Our allogeneic, or off-the-shelf, chimeric antigen receptor ("CAR") -T ("CAR-T") cell therapy product candidates are manufactured in advance with cells from healthy donors, with the goal of enabling broad patient access, rapid patient treatment, and increased manufacturing scale. Our allogeneic CAR-T cell therapy product candidates in clinical development are directed at CD19 and B cell maturation antigen ("BCMA"), established cell surface targets against which autologous CAR-T cell therapeutics have already demonstrated clinical proof of concept. We use our chRDNA technology to armor our cell therapy product candidates through genome-editing strategies, such as checkpoint disruption and immune cloaking, to enhance activity against hematologic malignancies.

We are advancing two clinical-stage allogeneic CAR-T cell therapy product candidates for the treatment of patients with hematologic malignancies:

- Vispacabtagene regedleucel ("vispa-cel," formerly CB-010): an allogeneic anti-CD19 CAR-T cell therapy that has been evaluated in patients with relapsed or refractory B cell non-Hodgkin lymphoma ("r/r B-NHL") in our ANTLER phase 1 clinical trial.
- CB-011: an allogeneic anti-BCMA CAR-T cell therapy that is being evaluated in patients with relapsed or refractory multiple myeloma ("r/r MM") in our CaMMouflage phase 1 clinical trial.

We believe vispa-cel, if approved, will have several advantages over commercially available autologous CAR-T cell therapies, including broad patient access, shorter time to treatment with an off-the-shelf product, significantly lower manufacturing costs, and a substantially smaller footprint for manufacturing. Vispa-cel has received regenerative medicine advanced therapy ("RMAT") designation for relapsed or refractory large B cell lymphoma ("r/r LBCL"), fast track designation for r/r B-NHL, and orphan drug designation for follicular lymphoma ("FL") from the U.S. Food and Drug Administration ("FDA").

We believe CB-011, if approved, will have several advantages over both commercially available bispecific antibody therapies and commercially available autologous CAR-T cell therapies, including a single-dose treatment regimen, potentially low rates of grade 3 or greater infections, and rapid immune recovery compared to bispecific antibody therapies, as well as broader patient access, shorter time to treatment with an off-the-shelf product, significantly lower manufacturing costs, and a substantially smaller footprint for manufacturing compared to autologous CAR-T cell therapies. CB-011 has received fast track and orphan drug designations for r/r MM from the FDA.

On April 24, 2025, we announced a strategic pipeline prioritization with workforce and cost reduction initiatives to focus resources on our vispa-cel and CB-011 product candidates. At that time, we disclosed that we had discontinued our GALLOP phase 1 trial of vispa-cel for the treatment of lupus prior to dosing the first patient; our AMpLify phase 1 clinical trial of CB-012, an allogeneic anti-C-type lectin-like molecule-1 ("CLL-1") CAR-T cell therapy for the treatment of relapsed or refractory acute myeloid leukemia ("r/r AML"), as additional data would be needed to advance this program; and our preclinical research. Patients treated in the AMpLify phase 1 clinical trial continue to be followed as part of our long-term follow-up study. Additionally, we announced that our workforce was reduced by 47 employees, or approximately 32% of our workforce. In connection with the discontinuation of the AMpLify phase 1 clinical trial for our CB-012 product candidate, we terminated our Exclusive License Agreement, dated November 13, 2020, with Memorial Sloan Kettering Cancer Center ("MSKCC") (as amended, "MSKCC Agreement"), effective August 11, 2025.

Allogeneic CAR-T Cell Therapies

Allogeneic, or off-the-shelf, CAR-T cell therapies offer several advantages over commercially available autologous CAR-T cell therapies, including broad patient access, shorter time to treatment and increased manufacturing scale with a substantially smaller footprint:

- *Broad patient access:* Only 25% of second-line ("2L") relapsed or refractory large B cell lymphoma ("LBCL") patients currently receive commercially available autologous CAR-T cell therapies. Many patients cannot wait weeks to months for autologous CAR-T cell therapy or their T cells are too dysfunctional to manufacture their individual therapy. With allogeneic CAR-T cell therapy, many more patients could be served as these cell therapies are manufactured in advance from healthy donor T cells, making them readily available off-the-shelf for rapid patient treatment. Additionally, commercially available autologous CAR-T cell therapies are primarily available at academic centers of excellence in metropolitan areas, whereas most patients are cared for in the community hospital setting and not at academic centers. Allogeneic CAR-T cell therapies can be administered in academic centers of excellence and in appropriate community hospital settings, suggesting broader patient access to treatment.

- *Rapid patient treatment:* Commercially available autologous CAR-T cell therapies are manufactured from the patient's own T cells and require weeks to months for apheresis, manufacturing, product release, and delivery back to the patient for treatment. Given the long wait time, more than 50% of patients who receive autologous CAR-T cells require bridging therapy, adding additional therapies to their treatment. With allogeneic CAR-T cell therapy, patients can begin the treatment regimen the same day they become eligible.

- *Increased manufacturing scale with smaller footprint:* For autologous CAR-T cell therapy, manufacturing requires multiple large plants to meet the needs of the patient population, and one manufacturing batch yields one treatment for one patient, which cannot be further scaled. In addition, manufacturing failures can prevent a patient from receiving their treatment. In contrast, our allogeneic CAR-T cell therapy product candidates are manufactured from cells from healthy donors, prepared in advance of treatment in a single suite at a contract manufacturing organization ("CMO") at significantly lower cost of manufacturing than autologous CAR-T cell therapies. These manufacturing attributes allow the number of doses per manufacturing batch to be scaled for broad patient access.

Our CRISPR chRDNA Genome-Editing Technology

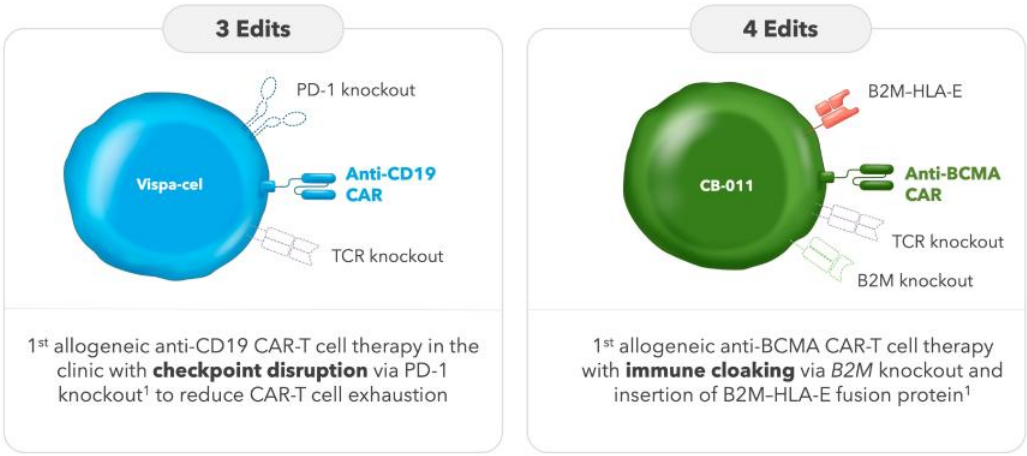
Genome-editing technologies used to date have limited efficiency, specificity, and versatility for performing the multiple, precise genomic edits necessary for allogeneic CAR-T cell therapy manufacturing. Our CRISPR chRDNA genome-editing technology is designed to address these limitations and enables us to apply armoring strategies to enhance allogeneic CAR-T cell therapy activity against diseases.

Using our chRDNA genome-editing technology, we have successfully demonstrated multiplex genome editing while maintaining genomic integrity. Our allogeneic CAR-T cell therapy product candidates incorporate increasing numbers of genome edits, as shown in the figure below. We believe this level of editing sophistication and editing fidelity can unlock the broad potential of allogeneic cell therapies by:

- *Mitigating the risk of graft-versus-host disease ("GvHD")*: Development of an allogeneic CAR-T cell therapy requires genome editing to remove proteins from donor T cells that may recognize and attack a patient's tissue, which, without removal, would pose a risk of GvHD. To mitigate the risk of GvHD, we engineer our allogeneic CAR-T cell therapies with a knockout of the T cell receptor alpha constant ("*TRAC*") gene in order to eliminate expression of the T cell receptor ("TCR") from the surface of the CAR-T cells.

- *Enhancing the activity of allogeneic cell therapies for potentially durable activity*: Our chRDNA technology enables us to apply tailored armoring strategies to our allogeneic CAR-T cells, including (i) checkpoint disruption, through the knockout of programmed cell death protein 1 ("PD-1") to enhance the activity of CAR-T cells by disrupting a pathway that leads to CAR-T cell exhaustion; and (ii) immune cloaking, through removal of the endogenous beta-2 microglobulin ("B2M") protein and insertion of a beta-2-microglobulin–human-leukocyte-antigen-E–("B2M–HLA-E") peptide fusion, to reduce rejection by the patient's immune system.

- *Improving the genomic integrity of our products:* We have observed that our cell therapy product candidates have significantly lower levels of off-target edits compared to those made using first-generation CRISPR-Cas9 genome editing, and we believe we maintain genomic integrity, including during multiplex editing.

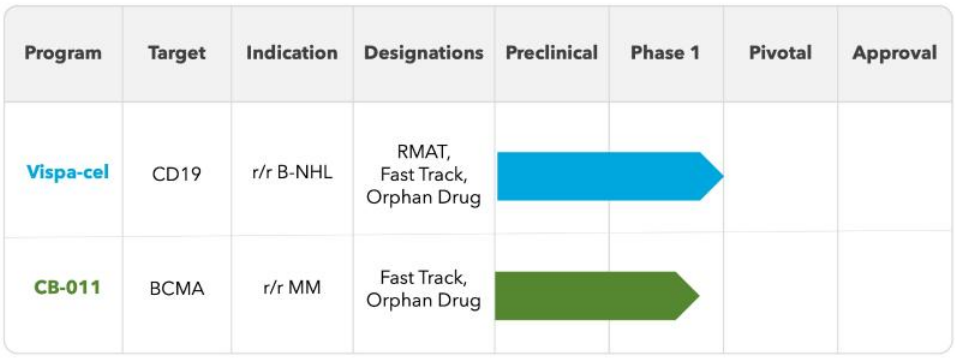


[1]To Caribou's knowledge

We believe that our chRDNA genome-editing technology has broad potential to generate *ex vivo* and *in vivo* cell and gene therapies. We own a robust worldwide patent portfolio protecting our Cas9 chRDNA and our Cas12a chRDNA compositions and genome-editing methods.

Our Pipeline

We are focused on the development of our pipeline of allogeneic CAR-T cell therapies. We are advancing two clinical-stage allogeneic CAR-T cell therapies for the treatment of patients with hematologic malignancies. Our pipeline is shown below:



Our Strategy

Our mission is to develop innovative, transformative therapies for patients with devastating diseases through the use of our novel chRDNA genome-editing technology. Our overarching goal is to build an integrated company that develops, manufactures, and commercializes genome-edited cell therapies that have the potential to treat patients with significant unmet needs. Our current focus is on two clinical-stage allogeneic CAR-T cell therapies for treating patients with hematologic malignancies; our chRDNA technology also has the potential for additional applications. Key components of our strategy include:

- *Applying our chRDNA genome-editing technology to engineer allogeneic CAR-T cell therapies that have the potential for durable activity against multiple diseases.* Our chRDNA technology enables us to develop allogeneic cell therapies with the potential to achieve enhanced activity against diseased cells through the use of armoring strategies, including (i) mitigation of the risk of GvHD through prevention of TCR expression; (ii) checkpoint disruption through a knockout of PD-1 to enhance the activity of CAR-T cells by disrupting a pathway that leads to CAR-T cell exhaustion; and (iii) immune cloaking through removal of the B2M protein and insertion of a B2M–HLA-E-peptide fusion to reduce rejection by the lymphoid compartment of a patient's immune system.

- *Developing allogeneic CAR-T cell therapies against clinically validated targets to derisk our clinical programs.* Vispa-cel, directed to the CD19 antigen, has been evaluated in our ANTLER phase 1 clinical trial in patients with r/r B-NHL. CB-011, directed to the BCMA antigen, is being evaluated in our CaMMouflage phase 1 clinical trial in patients with r/r MM. CD19 and BCMA antigens are the targets of several commercially available autologous CAR-T cell therapies, which reduces target risk as we evaluate the safety and efficacy of our allogeneic CAR-T cell therapies in clinical trials.

- *Pursuing select applications of our technology and indications on our own and through new strategic collaborations.* We believe that our technology has broad potential to generate cell and gene therapies in oncology, autoimmune diseases, and additional therapeutic areas. Potential applications include *in vivo* and *ex vivo* therapies. We may selectively pursue these indications and applications through new strategic collaborations.

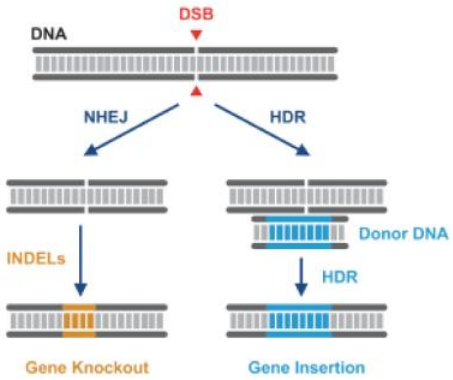
Our Team

Our team and our culture are critical to our mission to develop innovative, transformative therapies for patients with devastating diseases through the use of our novel CRISPR chRDNA genome-editing technology. Our mission-driven team includes leaders who have significant experience in the development of cell and gene therapies, including driving global clinical and regulatory strategies for commercially available autologous CAR-T cell therapies through all phases of development.

We were founded in 2011 by globally-recognized pioneers in CRISPR genome editing and nucleic acid biology: Jennifer A. Doudna, Ph.D., who was a co-recipient of the 2020 Nobel Prize in Chemistry for the development of CRISPR-Cas9 as a method for genome editing; Martin Jinek, Ph.D., Associate Professor at the University of Zurich in the Department of Biochemistry; James Berger, Ph.D., Professor in the Department of Biophysics and Biophysical Chemistry at the Johns Hopkins University School of Medicine; and Rachel E. Haurwitz, Ph.D., who has served as our president and chief executive officer since our formation. Drs. Doudna and Jinek serve on our scientific advisory board ("SAB"), which also includes world experts in CAR-T cell development, immunotherapies, oncology, patient care, and clinical trial development to support commercialization.

Genome-Editing Background

Genome editing is a class of technologies that facilitate engineering specific changes to deoxyribonucleic acid ("DNA") sequences inside living cells. Genome editing can occur in two steps, as shown in the figure below. In the first step, a double-stranded break ("DSB") is made at the location of the genome where the edit is desired. A cell typically has two ways to repair the DSB, which results in the knockout of a gene or the insertion of new genetic material: non-homologous end joining ("NHEJ") and homology-directed repair ("HDR"), respectively. NHEJ is an error-prone process in which the broken DNA ends are reattached. During NHEJ, the cell typically inserts or deletes nucleotides at the DSB. These insertions and deletions ("indels") generally disrupt the coding sequence for the targeted gene, resulting in the knockout of the targeted sequence. HDR, by contrast, is a more controlled repair system where the cell incorporates donor DNA delivered during the editing process into the DSB, resulting in the site-specific insertion of the provided DNA sequence.



The canonical CRISPR system utilizes a CRISPR-associated ("Cas") protein Cas9, which can cut genomic DNA. Cas9 is targeted to a specific site in a genome by a guide ribonucleic acid ("RNA"). One of the disadvantages of CRISPR-Cas9 genome editing is the occurrence of off-target editing, edits that occur at sites in the genome other than at the intended target site due to the ability of RNA guides to bind to DNA sequences similar to the target DNA sequence. Off-target edits throughout the genome can alter an oncogene or tumor suppressor gene, impact the biology of the target cell, or have other negative consequences on therapeutic development. Additionally, the simultaneous occurrence of both on-target and off-target edits may lead to genomic rearrangements, including chromosomal translocations, that may be problematic for immune cell therapeutics, especially for ones requiring multiple edits.

Our CRISPR chRDNA Technology

Overview

We deploy a new, next-generation CRISPR genome-editing platform, our novel chRDNA technology, which uses hybrid guides containing both RNA and DNA for editing genomic DNA to engineer our allogeneic CAR-T cell therapies. The presence of DNA in a chRDNA guide significantly improves editing specificity relative to an all-RNA guide. The addition of DNA into the guide increases the fidelity by reducing the binding of the guide to the target sequence, thereby resulting in even less binding of the chRDNA guide to non-target sequences that may be similar to, but different from, the intended target sequence. Our chRDNA technology uses the canonical *Streptococcus pyogenes* Cas9 protein or the *Acidaminococcus sp*. Cas12a protein and a guide that is composed of a mixture of RNA and DNA nucleotides in both the region that interacts with the chromosomal target DNA and in the region that does not interact with the target DNA. Like Cas9, Cas12a is a Cas protein used to edit genomic DNA site-specifically. The advantages of our chRDNA technology include:

- *Specificity:* Our chRDNA guides mediate higher genome-editing specificity as compared to all-RNA guides. Significantly fewer off-target events are observed using our chRDNA guides versus first-generation CRISPR-Cas9 or CRISPR-Cas12a systems using all-RNA guides. The improved genome-editing specificity from the use of our chRDNA guides leads to a high degree of editing specificity with lower levels of off-target events.

  Our chRDNA guides retain high affinity to edit a genome at the intended location; however, these guides have lower affinity for potential off-target sites to reduce the likelihood of a genome edit at an unintended location. We evaluated the integrity and performance of chRDNA guides by employing two unique assays, the SITE-Seq® assay and the VINE assay, on two genes known from the scientific literature to exhibit high rates of off-target editing with either the Cas9 or Cas12a protein and all-RNA guides. All-RNA guides generated both robust on-target and off-target editing. In contrast to the all-RNA guides, the chRDNA guides maintained robust on-target editing but induced minor to no detectable off-target editing. We developed chRDNA guides that target the exact same genomic locations that achieve equivalent on-target editing compared to the all-RNA guides.

- *High efficiency:* We achieve a high degree of on-target gene knockout and site-specific gene insertion efficiency, facilitating robust multiplex editing, including multiple gene insertions. For example, Cas12a chRDNA genome editing used in generating CB-011 leads to approximately 76-80% gene insertion rates for two separate site-specific gene insertions, which represent both high and reproducible gene insertion rates, and greater than 60% of manufacturing-scale CAR-T cells have all four intended edits (two knockouts and two site-specific knock-ins).

  Achieving high efficiency gene insertion is more challenging than achieving high efficiency gene knockout. To insert genes into T cells with our chRDNA technology, we transduce the cells with adeno-associated virus serotype 6 ("AAV6"), which contains the DNA template of interest to facilitate the integration of the DNA into the double-stranded break generated by the Cas9 chRDNA complex or the Cas12a chRDNA complex via the HDR pathway. Our chRDNA genome-editing technology does not rely on lentiviral or retroviral genome-editing methods, which are used in commercially available autologous CAR-T cell therapies to insert the CAR gene randomly into the genome and which may increase the risk of genomic mutagenesis.

- *Versatility*: Our chRDNA guides are compatible with, and offer utility across, multiple cell types, including T cells.

- *Simplicity*: Our chRDNA guides are manufactured using standard, scalable solid-phase phosphoramidite chemistry.

Genome-Editing Strategies for Allogeneic CAR-T Cell Therapies

CAR-T cells will generally proliferate in response to antigen engagement via the specificity of their respective CAR. However, allogeneic CAR-T cells are rapidly rejected by a patient's immune system due to their divergent donor-derived genetic profile and cell surface human leukocyte antigen ("HLA") presentation. We believe engineering CAR-T cells to achieve enhanced target cell killing activity is necessary for the realization of the full potential of allogeneic cell therapies. Furthermore, development of an allogeneic CAR-T cell therapy requires genome editing to prevent TCR expression on donor T cells that would otherwise pose a risk of GvHD.

Checkpoint Disruption Strategy

One of the approaches we deploy to increase the activity of CAR-T cells is to remove PD-1 from the CAR-T cell surface. Engagement of the PD-1/PD-L1 axis leads to rapid exhaustion of T cells. This occurs when a T cell expressing PD-1 interacts with another cell expressing the ligand PD-L1. Diseased cells and the patient's own cells can express PD-L1, leading to interaction with PD-1 and subsequent exhaustion of the CAR-T cells. We use our chRDNA technology to knock out the programmed cell death protein 1 (*"PDCD1")* gene to prevent PD-1 expression on the CAR-T cell surface, thereby disrupting PD-1/PD-L1-mediated exhaustion. We believe that knocking out PD-1 results in greater activity against disease in the patient, thereby enabling a potentially better therapeutic index relative to PD-1-expressing CAR-T cells.

Immune-Cloaking Strategy

Another approach we deploy to increase the persistence of our CAR-T cells is to immune cloak them to reduce their rapid immune-mediated rejection. The goal of immune cloaking is to maintain the allogeneic CAR-T cells in circulation for an extended period of time. Allogeneic CAR-T cells are foreign to the patient's immune system and, unless modified, will be rapidly rejected. We use our Cas12a chRDNA technology to make multiple edits to T cells to immune cloak them and limit the rapid rejection by both the patient's cytotoxic T cells and natural killer ("NK") cells. Our edits remove all endogenous HLA class I antigens from the CAR-T cell surface and lead to the overexpression of HLA-E, a minor HLA antigen, on the CAR-T cell surface. The lack of endogenous HLA class I antigens and the presence of only HLA-E are designed to prevent the patient's T cells and NK cells from rapidly rejecting the allogeneic therapy. These cells are unlikely to persist indefinitely, and ultimately other types of immune cells in the patient will eliminate the allogeneic CAR-T cells. Our edits are designed to maintain the CAR-T cells in circulation longer to enhance the activity of the CAR-T cell therapy to destroy a larger proportion of the targeted cells.

Our Clinical Programs

Our current focus is on advancing two clinical-stage allogeneic CAR-T cell therapies for treating patients with hematologic malignancies.

Vispa-cel

Overview: Strategy and Rationale

Our vispa-cel CAR-T cell therapy product candidate is an allogeneic CAR-T cell therapy targeting CD19-positive hematologic malignancies. Vispa-cel has been evaluated in our first-in-human, open-label, multicenter ANTLER phase 1 clinical trial (NCT04637763) in the United States, Australia, and Israel in adults with r/r B-NHL.

To our knowledge, our vispa-cel product candidate is the first allogeneic CAR-T cell therapy in a clinical trial with a PD-1 knockout, and we believe the PD-1 knockout enhances the potential for durable activity of an allogeneic CAR-T cell therapy. Other CAR-T cell therapies that express endogenous PD-1 could become rapidly exhausted and lose activity due to the interaction between PD-1 and its ligand PD-L1. PD-1/PD-L1 engagement leads to rapid exhaustion in T cells. This occurs when a T cell expressing PD-1 interacts with another cell expressing PD-L1. B cell tumors and the patient's own cells express PD-L1, leading to interaction with PD-1 and subsequent exhaustion of the CAR-T cells. We prevent PD-1 expression on the vispa-cel CAR-T cells, thereby disrupting PD-1/PD-L1-mediated exhaustion. More than half of B-NHL tumors express PD-L1, correlating with poorer outcomes. We believe that knocking out PD-1 results in greater activity against disease in the patient, thereby enabling a potentially better therapeutic index relative to PD-1-expressing CAR-T cells.

Vispa-cel has received RMAT designation for r/r large B cell lymphoma ("LBCL"), fast track designation for r/r B-NHL, and orphan drug designation for FL from the FDA.

Target Indication

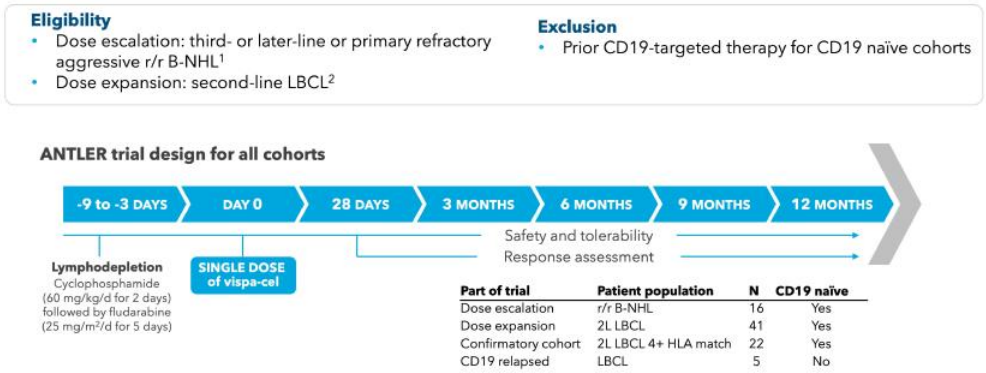
We are developing vispa-cel for the treatment of r/r B-NHL, with a focus on 2L LBCL patients who are primary refractory patients or who have relapsed after receiving one prior line of therapy.

NHL is the most common hematologic malignancy with an estimated 80,350 individuals, or approximately 4% of all cancers, diagnosed in the United States in 2025 according to the National Cancer Institute SEER database. LBCL is a subtype of B-NHL and typically presents as a rapidly growing mass or enlarging lymph nodes in a nodal or extranodal site. LBCL subtypes include diffuse large B cell lymphoma not otherwise specified ("DLBCL NOS"), high-grade B cell lymphoma ("HGBL"), primary mediastinal large B cell lymphoma ("PMBCL"), transformed follicular lymphoma ("tFL"), and transformed marginal zone lymphoma ("tMZL"). In the United States in 2025, approximately 34,000 people with LBCL were treated with first-line therapies and approximately 12,000 patients received second-line treatments.

Overall, for aggressive r/r B-NHL, newer immunologically-mediated therapies under investigation include checkpoint inhibitors, bispecific antibodies, and CAR-T cells. Commercially available autologous anti-CD19 CAR-T cell therapies have shown encouraging complete response ("CR") rates, progression-free survival ("PFS"), and overall survival; however, there are many barriers preventing most 2L LBCL patients from receiving autologous CAR-T cell therapy, including limited patient access, length of time to treatment, and manufacturing capacity and scale limitations. Thus, there remains a significant unmet medical need for patients with r/r B-NHL.

ANTLER Phase 1 Clinical Trial for vispa-cel in r/r B-NHL

We evaluated vispa-cel in our ANTLER phase 1 clinical trial for the treatment of adult patients with aggressive forms of r/r B-NHL. Our ANTLER phase 1 clinical trial consisted of two parts: Part A was the dose escalation portion that followed a standard 3 + 3 design, with sequential, increasing single doses of vispa-cel, and was completed with 16 patients dosed at dose level 1 ($40x10^6$ viable CAR-T cells), dose level 2 ($80x10^6$ viable CAR-T cells), or dose level 3 ($120x10^6$ viable CAR-T cells). Part B was the dose expansion portion where vispa-cel was evaluated in additional patients to determine the recommended phase 2 dose ("RP2D") in 2L LBCL patients. Dose level 2 ($80x10^6$ viable CAR-T cells) was selected as the RP2D. The ANTLER phase 1 clinical trial study design was as follows:



[1]B-NHL subtypes include: DLBCL, HGBL, tFL, PMBCL, FL (follicular lymphoma, with POD24 (high risk)), MCL, MZL
[2]LBCL subtypes include: DLBCL NOS (not otherwise specified), HGBL, transformed DLBCL from FL or MZL, and PMBC
Definitions: "DLBCL": diffuse large B cell lymphoma; "FL": follicular lymphoma; "POD24": progression of disease within 24 months; "MCL": mantle cell lymphoma; "MZL": marginal zone lymphoma

On November 3, 2025, we announced results from our ANTLER phase 1 clinical trial evaluating vispa-cel in 2L LBCL patients, including the first data disclosure on 22 patients enrolled in the phase 1 confirmatory cohort to prospectively evaluate patients who received a dose of vispa-cel manufactured from a donor with at least four matching HLA alleles (of 12 total alleles) with the patient ("partial HLA matching") as well as on additional LBCL patients from dose escalation and dose expansion.

As of September 2, 2025, the safety data cutoff date, our ANTLER clinical trial had enrolled 84 patients, including the confirmatory cohort of 22 2L LBCL patients designed to prospectively confirm the positive outcomes of partial HLA matching observed in earlier retrospective analyses. Following a lymphodepletion ("LD") regimen of 60 mg/kg/day of cyclophosphamide for two days and 25 mg/m^2/day of fludarabine for five days, each patient in the confirmatory cohort received a dose of vispa-cel at the RP2D ($80x10^6$ viable CAR-T cells) such that the patient and the T cell donor shared at least four of 12 HLA alleles. As of September 29, 2025, the efficacy data cutoff date, the results for the 22-patient confirmatory cohort were as follows:

- 82% (18/22) overall response rate ("ORR")

- 64% (14/22) CR rate
- 51% 12-month PFS

Median follow-up time for the confirmatory cohort was 6.0 months.

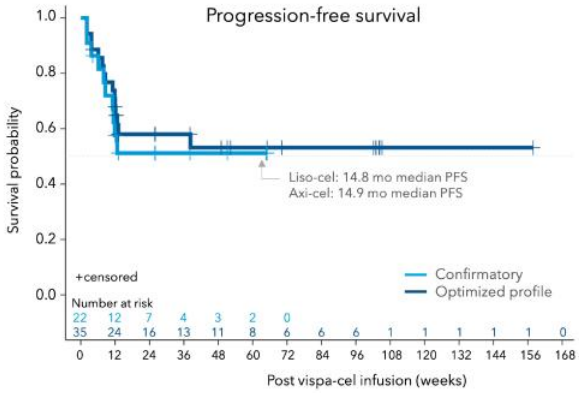
The announced results included an analysis of the 35 CD19-naïve, LBCL patients enrolled our ANTLER phase 1 clinical trial who received a dose of vispa-cel that met the criteria for our optimized product profile, which criteria are a young T cell donor under the age of 30 and a minimum of two of 12 HLA alleles matched between the patient and the T cell donor. Twenty of these 35 patients were enrolled in the confirmatory cohort, and the remaining 15 patients were enrolled in dose escalation or dose expansion. Thirty-two of the 35 patients were 2L patients and three of the 35 patients were third-line or later ("3L+") patients. As of September 29, 2025, the efficacy data cutoff date, the results for the 35-patient optimized product cohort were as follows:

- 86% (30/35) ORR
- 63% (22/35) CR rate
- 53% 12-month PFS

Median follow-up time for the optimized cohort was 11.8 months.

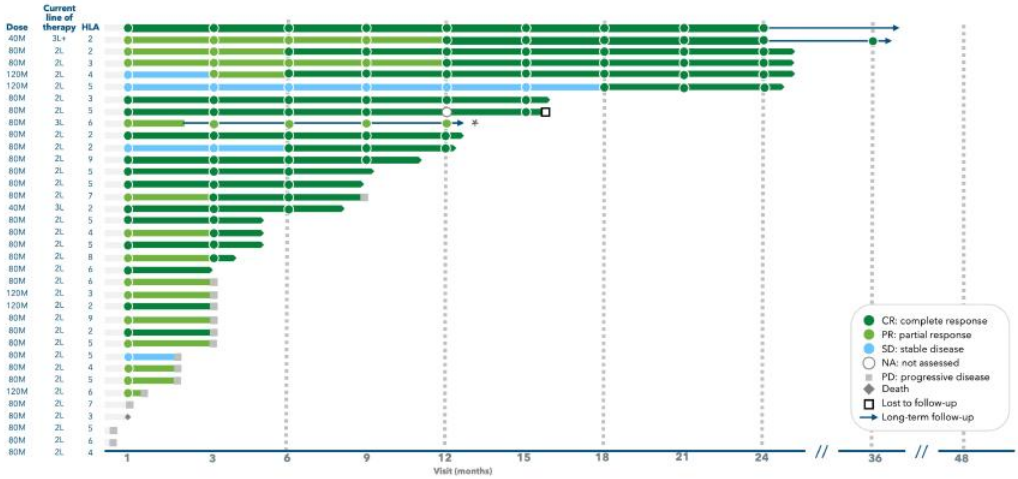
The following is a summary of results for the confirmatory cohort and the optimized profile cohort for vispa-cel as of the September 29, 2025, efficacy data cutoff date:

	Vispa-cel	
	Confirmatory cohort [1] N=22	Optimized profile [2] N=35
ORR	**82%**	**86%**
CR rate	**64%**	**63%**
Median PFS [3] (95% CI)	**NR** (2.0, NE)	**NR** (2.8, NE)
12-month PFS (95% CI)	**51%** (28, 70)	**53%** (34, 69)
Median DoR [4] (95% CI)	**NR** (1.7, NE)	**NR** (2.1, NE)



[1]2L LBCL 4+ HLA matched, dosed with $80x10^6$ viable CAR-T cells
[2]2L (N=32) and 3L+ (N=3) LBCL patients treated $40x10^6$ viable CAR-T cells, $80x10^6$ viable CAR-T cells, or $120x10^6$ viable CAR-T cells, optimized for multiple factors, including 2+ HLA matched and young donor
[3]Median follow up 6.0 months for confirmatory; 11.8 months for optimized
[4]Median follow up 5.1 months for confirmatory; 7.9 months for optimized
Definitions: "DoR": duration of response; "NE": not evaluable; "NR": not reached; "mo": month; "CI": confidence interval

The results are further summarized in the following swimmer plot for the optimized profile cohort[1]:



[1] 2L (N=32) and 3L+ (N=3) LBCL patients treated with 40x10^6 viable CAR-T cells, 80x10^6 viable CAR-T cells, or 120x10^6 viable CAR-T cells, optimized for multiple factors, including 2+ HLA matching and young donor-derived

* Patient diagnosed with lung adenocarcinoma after day 28 scan revealed a non-responsive lung nodule and was enrolled in our long-term follow-up study. As of the data cutoff date, patient was in continued response without additional anti-lymphoma therapy at one year post-vispa-cel treatment

Additional information:

- Long-term follow-up data reflect the last known response; marked time points indicate confirmation of no disease progression
- One vispa-cel-related grade 5 IEC-HS occurred on day 25 post-infusion
- Median duration of complete response ("DoCR") was not reached in this cohort
- Certain patients converted from CR or partial response ("PR") to progressive disease ("PD") at various assessment time points as indicated in the chart above
- Efficacy data cutoff date: September 29, 2025

Definition: "IEC-HS": immune effector cell-associated hemophagocytic lymphohistiocytosis-like syndrome

Vispa-cel was generally well tolerated. As of September 2, 2025, the safety data cutoff date, treatment emergent adverse events ("TEAEs") at any grade in 25% or greater of all 84 patients who received vispa-cel were thrombocytopenia (62%), cytokine release syndrome ("CRS") (55%), anemia (52%), neutropenia (39%), hypokalemia (26%), and leukopenia (26%). In the confirmatory and optimized profile cohorts, there were no cases of GvHD or grade 3 or greater immune effector cell-associated neurotoxicity syndrome ("ICANS"), 1% of patients experienced grade 3 or greater CRS, and 28% (out of 80 patients) experienced prolonged cytopenias.

The following is a summary of notable adverse events for all three cohorts in the ANTLER phase 1 clinical trial as of the September 2, 2025, safety data cutoff date:

Events, n (%)	Vispa-cel					
	All treated N=84		**Confirmatory cohort** N=22[1]		**Optimized profile** N=35[2]	
	All grade	≥Gr 3	All grade	≥Gr 3	All grade	≥Gr 3
Neurotoxicity, n (%)	12 (14)	4 (5)	1 (5)	0 (0)	1 (3)	0 (0)
CRS, n (%)	46 (55)	1 (1)	13 (59)	1 (5)	19 (54)	1 (3)
Infections, n (%)	43 (51)	21 (25)	9 (41)	4 (18)	20 (57)	6 (17)
Prolonged cytopenias[3]	NA	22/80 (28)	NA	5/19 (26)	NA	7/32 (22)
IEC-HS, n (%)[4]	2 (2)	2 (2)	1 (5)	1 (5)	1 (3)	1 (3)

[1]2L LBCL 4+ HLA matched, dosed with $80x10^6$ viable CAR-T cells
[2]2L (N=32) and 3L+ (N=3) LBCL patients treated with $40x10^6$ viable CAR-T cells, $80x10^6$ viable CAR-T cells, or $120x10^6$ viable CAR-T cells, optimized for multiple factors, including 2+ HLA matching and young donor-derived
[3]Prolonged cytopenias are defined as grade 3 or grade 4 neutropenia, thrombocytopenia, or anemia ongoing at day 28 (+/- 5 days) post-CAR-T cell infusion, based on laboratory data, distinct from investigator-reported clinical adverse events
[4]Includes one vispa-cel-related grade 5 IEC-HS that occurred day 25 post-infusion

A cohort of 3L+ LBCL patients with prior exposure to CD19-targeted therapy enrolled five patients as of the September 2, 2025, safety data cutoff date. Enrollment in this cohort has been paused to focus on CD19-naïve patients.

Planned Pivotal Phase 3 Clinical Trial in 2L r/r LBCL

Based on these data, we are planning to conduct a randomized, controlled pivotal phase 3 clinical trial of vispa-cel in approximately 250 2L LBCL CD19-naïve patients who are ineligible for autologous stem cell transplant and autologous CAR-T cell therapy. We believe there is a meaningful commercial opportunity within this population, as approximately 60% of the 12,000 2L LBCL patients treated annually in the United States are considered ineligible for autologous stem cell transplant and autologous CAR-T cell therapy. Patients randomized to the study arm would receive a single dose of vispa-cel at the RP2D of $80x10^6$ viable CAR-T cells following lymphodepletion with 60 mg/kg/day of cyclophosphamide for two days and 25 mg/m^2/day of fludarabine for five days. Patients randomized to the comparator arm would be treated with the investigator's choice of standard of care immunochemotherapy agents. The primary endpoint would be PFS, and an interim analysis is planned. Secondary endpoints would include ORR, CR rate, DoR, DoCR, overall survival, quality of life, and safety. We are in ongoing engagement with the FDA regarding the design of our pivotal trial for vispa-cel; however, we cannot provide any assurance that our proposed pivotal trial design will ultimately meet FDA requirements and/or recommendations or lead to regulatory approval.

CB-011

Overview: Strategy and Rationale

CB-011 is an allogeneic CAR-T cell therapy targeting BCMA-positive malignancies that is being evaluated in our ongoing open-label, multicenter CaMMouflage phase 1 clinical trial (NCT05722418) in the United States in adults with r/r MM. We acquired a novel humanized single-chain variable fragment ("scFv") directed to BCMA that we use for the generation of the BCMA-specific CAR in CB-011.

To our knowledge, CB-011 is the first anti-BCMA CAR-T cell therapy incorporating an immune cloaking approach that includes both the removal of the B2M protein and insertion of a B2M–HLA-E-peptide fusion. This immune cloaking armoring strategy results in no endogenous class I HLA alleles expressed on the CAR-T cell surface. This reduces the number of potential mismatched HLA alleles to six from 12, resulting in a reduced risk of rapid immunologic clearing of the CAR-T cells by the patient.

CB-011 has received fast track and orphan drug designations for r/r MM from the FDA.

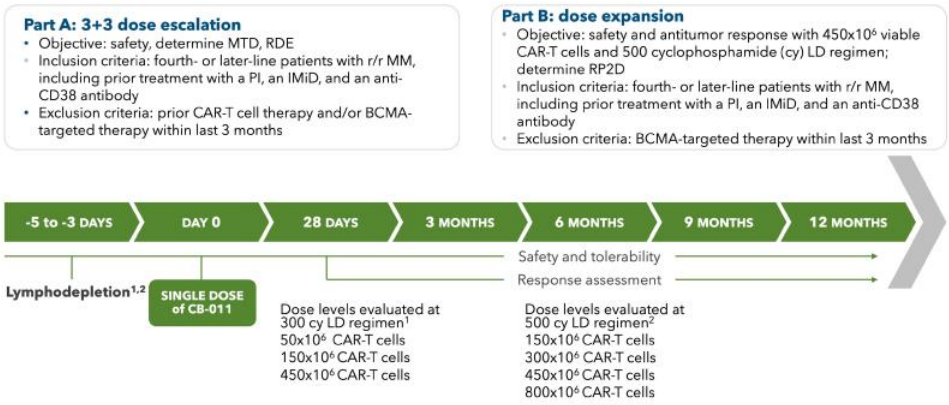
Target Indication

We are developing CB-011 for the treatment of r/r MM. In 2025, 1.8% of all cancers in the United States were MM according to the National Cancer Institute SEER database. The median age of diagnosis is 69 years, and there were an estimated 36,110 new cases in 2025 in the United States with an estimated 12,030 deaths in 2025. Five-year survival in these patients is approximately 62%.

There has been significant interest in and activity against BCMA as a target, and autologous CAR-T cell therapy products and bispecific antibodies targeting BCMA are commercially available. Commercially available anti-BCMA autologous CAR-T cell therapies have shown encouraging CR rates, PFS, and overall survival; however, there are many barriers limiting the number of patients who receive autologous CAR-T cell therapy, including restricted patient access, length of time to treatment, and manufacturing capacity and scale limitations. Approximately 10% of patients with r/r MM receive an autologous CAR-T cell therapy. Commercially available bispecific antibodies require patients to receive frequent treatments and are associated with high infection rates. Additionally, many treatments for r/r MM are multi-drug regimens comprising varying routes of administration and/or complicated dosing schedules; these regimens can be complex and burdensome for both patients and physicians. Due to limited patient access and treatment burden, there is a need for an off-the-shelf, readily available, single-dose treatment for patients with r/r MM.

CaMMouflage Phase 1 Clinical Trial for CB-011 in r/r MM

We are evaluating CB-011 in our CaMMouflage phase 1 clinical trial in adult patients with r/r MM. Our CaMMouflage phase 1 clinical trial is being conducted in two parts: Part A was the dose escalation part following a standard 3 + 3 design, with sequential, increasing single doses of CB-011 with the ability to add additional patients at safe dose levels to further evaluate activity and safety. Part B is the dose expansion portion where anti-BCMA treatment-naïve and anti-BCMA treatment-exposed r/r MM patients receive CB-011 at the recommended dose for expansion ("RDE") determined in Part A. The CaMMouflage phase 1 clinical trial study design is as follows:

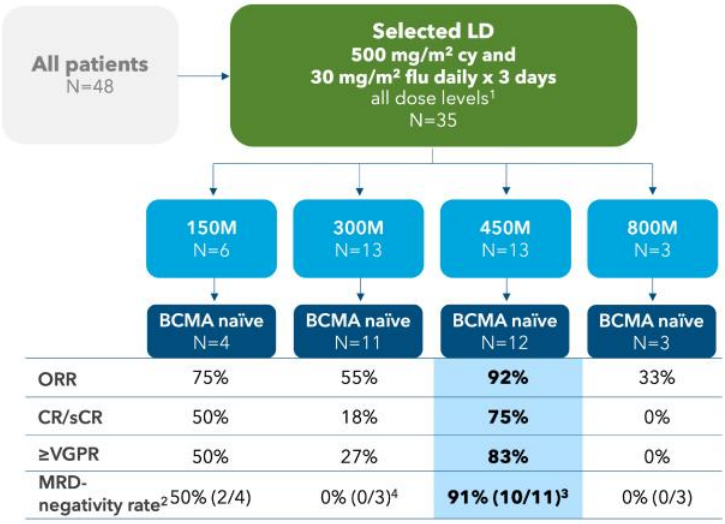


[1]300 mg/m^2 cyclophosphamide and 30 mg/m^2 fludarabine daily for three days
[2]500 mg/m^2 cyclophosphamide and 30 mg/m^2 fludarabine daily for three days

Definition: "IMiD": immunomodulatory drug; "MTD": maximum tolerated dose; "PI": proteasome inhibitor

On November 3, 2025, we announced results from the dose escalation portion of our ongoing CaMMouflage phase 1 trial evaluating CB-011 in r/r MM patients. As of the data cutoff date of September 24, 2025, 48 patients were enrolled in the dose escalation portion of the trial, which is now completed. The dose escalation portion enrolled patients who were fourth- or later-line ("4L+") and all patients had received prior treatment with a proteasome inhibitor, an immunomodulatory drug, and an anti-CD38 antibody. In dose escalation, prior treatment with an autologous CAR-T cell therapy was not permitted and no BCMA-targeted therapy was permitted within the prior three months.

We evaluated two different LD regimens and multiple CAR-T cell dose levels. Thirty-five patients were treated with an LD regimen of 500 mg/m^2 cyclophosphamide and 30 mg/m^2 fludarabine daily for three days (the "selected LD regimen"). A single dose of CB-011 preceded by the selected LD regimen resulted in responses at all dose levels evaluated (150x10^6 viable CAR-T cells, N=6; 300x10^6 viable CAR-T cells, N=13; 450x10^6 viable CAR-T cells, N=13; and 800x10^6 viable CAR-T cells, N=3). Also on November 3, 2025, we announced that the 450x10^6 viable CAR-T cell dose with the selected LD regimen is our RDE.



ORR	75%	55%	**92%**	33%
CR/sCR	50%	18%	**75%**	0%
≥VGPR	50%	27%	**83%**	0%
MRD-negativity rate[2]	50% (2/4)	0% (0/3)[4]	**91% (10/11)[3]**	0% (0/3)

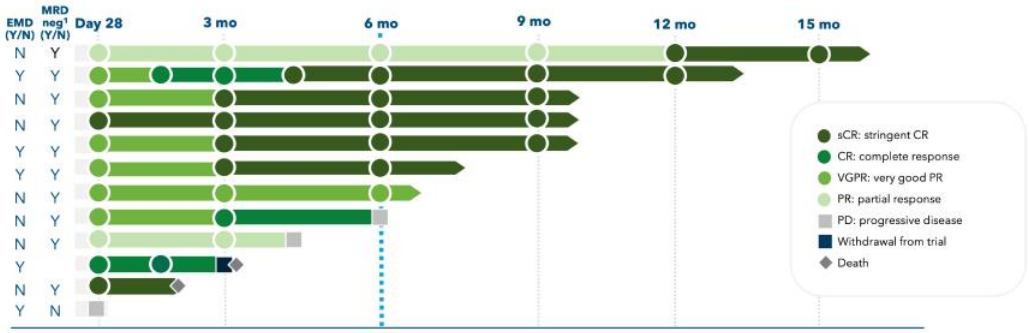
[1]150x10^6, 300x10^6, 450x10^6, or 800x10^6 viable CAR-T cells
[2]MRD negative at ≤10^{-5}
[3]MRD not evaluable in one patient
[4]MRD available for three patients
Definitions: "MRD": minimal residual disease; "sCR": stringent complete response; "VGPR": very good partial response

The results for the 12-patient, BCMA-naïve cohort treated with the selected LD regimen and the 450x10^6 viable CAR-T cell dose were as follows:

- 92% (11/12) ORR
- 75% (9/12) CR/sCR rate
- 91% (10/11) evaluable patients achieved MRD negativity (≤10^{-5})
- Seven of the 12 patients remain on study as of the data cutoff date in VGPR or better six months or longer following receipt of a single dose of CB-011

The median follow-up for patients dosed with the RDE was 8.3 months, and the longest responding patient in this cohort was, as of the data cut off date, in an sCR at 15 months post-infusion.

The results are further summarized in the following swimmer plot for the 12-patient, BCMA-naïve cohort treated with the selected LD regimen and the 450x10^6 viable CAR-T cell dose:



[1]MRD negative at ≤10^{-5}

Additional information:

- One patient who had previously withdrawn from the trial died on day 90 of treatment-related ICAHT; one patient died of pneumonia on day 50 (not treatment-related)
- Data shown are from BCMA-naïve patients dosed at the 450x10^6 viable CAR-T cell dose with the selected LD regimen

Definitions: "EMD": extramedullary disease; "ICAHT": immune effector cell-associated hematotoxicity; "mo": months

CB-011 had a manageable safety profile across all dose levels and lymphodepletion regimens (N=48), with no cases of GvHD, immune effector cell-associated enterocolitis ("IEC-EC"), parkinsonism, or cranial nerve palsies. TEAEs in 25% or greater of all patients treated with CB-011 following the selected LD regimen (N=35) were as follows: neutropenia (80%), anemia (60%), thrombocytopenia (49%), infections (49%), dizziness (31%), cytokine release syndrome (31%), fatigue (31%), leukopenia (29%), decreased appetite (29%), constipation (26%), and pyrexia (26%). Notable adverse events in the RDE cohort included one CB-011-related grade 5 ICAHT on day 90, one grade 5 pneumonia not related to CB-011 on day 50, and one grade 4 CB-011-related Guillain-Barré Syndrome on day 129, which is resolving. In the cohort evaluating the 300x10^6 viable CAR-T cell dose level following the selected LD regimen, there was one grade 5 respiratory syncytial virus not related to CB-011 on day 73. Prophylactic measures for cytopenias and infections and early intervention for IEC-HS have been successfully implemented in our clinical protocol.

The following is a summary of notable adverse events in the CaMMouflage phase 1 clinical trial as of the September 24, 2025 data cutoff date:

Adverse events	**All at selected LD[1]** (N=35)		**BCMA-naïve 450M at selected LD[1]** (N=12)	
	Any grade n (%)	Grade ≥3 n (%)	Any grade n (%)	Grade ≥3 n (%)
Infections	17 (49)	5 (14)	8 (67)	3 (25)
CRS	11 (31)	1 (3)	4 (33)	1 (8)
ICANS	3 (9)	--	3 (25)	--
IEC-HS	3 (9)	1 (3)	1 (8)	1 (8)
IEC-EC	--	--	--	--
GvHD	--	--	--	--
Prolonged cytopenias[2]	NA	11/33 (33)	NA	5/12 (42)

[1]LD regimen of 500 mg/m^2 cyclophosphamide and 30 mg/m^2 fludarabine daily for three days
[2]Any continued ≥ grade 3 cytopenia based on laboratory data at ≥ day 35; denominator is those evaluable at day 35 (+/-5 days)

We initiated the dose expansion portion of the CaMMouflage phase 1 clinical trial in late 2025.

Strategic Agreements

We recognize the broad opportunity presented by our genome-editing technologies to benefit patients, and we appreciate that we do not have sufficient resources to fully exploit this potential across multiple indications and applications. As part of our strategy to maximize the value and benefit of our technologies, we are exploring mutually beneficial strategic collaborations with other biotechnology or pharmaceutical companies. Additionally, we have in-licensed or taken assignment of key technologies important for the development of our product candidates.

Pfizer Investment

On June 29, 2023, we entered into a Securities Purchase Agreement ("Securities Purchase Agreement") with Pfizer Inc. ("Pfizer"), pursuant to which we, in a private placement transaction, sold to Pfizer 4,690,431 shares of our common stock, par value $0.0001 per share, at a purchase price of $5.33 per share, for aggregate gross proceeds of approximately $25.0 million ("Pfizer Investment"). The issuance and sale of the shares to Pfizer closed on June 30, 2023. We granted certain registration rights to Pfizer under the Securities Purchase Agreement covering the resale of the shares. Unless otherwise agreed by Pfizer, we have agreed to use the proceeds from the Pfizer Investment solely in connection with (i) the development program for our allogeneic anti-BCMA CAR-T cell therapy known as CB-011 that is being evaluated in our CaMMouflage clinical trial and/or (ii) any other single-targeted anti-BCMA CAR-T cell therapy using an anti-BCMA scFv owned or controlled by us (collectively, cell therapies described in clauses (i) and (ii) are referred to as a "BCMA Product Candidate"), for 36 months expiring on June 29, 2026.

On June 29, 2023, in connection with the Pfizer Investment, we and Pfizer also entered into an Information Rights Agreement, having a 36-month term and expiring on June 29, 2026. Under the Information Rights Agreement, we granted Pfizer a 30-calendar day right of first negotiation ("ROFN") if we commence or engage with any third party with respect to a potential grant of rights to develop and/or commercialize a BCMA Product Candidate, including, without limitation, a license agreement, a co-promotion/co-commercialization agreement, a profit share agreement, a joint venture agreement, or an asset sale agreement (a "Grant of Program Rights"). If we and Pfizer do not reach an agreement with respect to a Grant of Program Rights within the 30-day period, then we may pursue negotiations and enter into an agreement with any third party. If we and such third party do not reach agreement on the Grant of Program Rights within a specified time period, Pfizer's right of first negotiation will be reinstated. Under the Information Rights Agreement, we also agreed to grant Pfizer the right to designate one representative to serve on our SAB. Through an information sharing committee, we provide calendar quarter updates to Pfizer regarding the development program for a BCMA Product Candidate. Additionally, we agreed to provide Pfizer access to any preclinical or interim or final clinical data (including raw data) and results generated as part of the development program for a BCMA Product Candidate at the same time that we provide such data to a third party (other than to our service providers or the FDA or other regulatory authorities), subject to certain confidentiality exceptions.

ProMab Biotechnologies, Inc. ("ProMab")

On January 31, 2020, we entered into a Sale and Assignment Agreement with ProMab (as amended, "ProMab Agreement") under which we purchased a humanized scFv targeting BCMA and a patent family related thereto for an upfront cash payment of $0.4 million and the potential payments of future royalties to ProMab. To date, six U.S. patents have granted (U.S. Patent Nos. 10,927,182; 11,021,542; 11,142,583; 11, 299,549; 11,472,884; and 12,435,152) in this patent family. Our anti-BCMA CB-011 CAR-T cell therapy product candidate contains this BCMA scFv. Under the terms of the ProMab Agreement, in the event that CB-011 is approved by the FDA, we will owe ProMab low-single-digit percent royalties on net sales until the expiration, abandonment, or invalidation of the last patent within the assigned patent family (i.e., 2040, without patent term adjustment ("PTA") or patent term extension ("PTE")). Such royalties may be reduced by no more than 50% if we must pay royalties to a third party for other intellectual property covering our product. Either party may terminate the ProMab Agreement in the event of an uncured material breach or bankruptcy of the other party. If ProMab terminates the ProMab Agreement due to our uncured material breach or bankruptcy, we must cease the manufacture, use, and sale of any products or product candidates incorporating the purchased anti-BCMA scFv.

Pioneer Hi-Bred International, Inc. ("Pioneer," now Corteva Agriscience)

On July 13, 2015, we entered into an Amended and Restated Collaboration and License Agreement (as amended, "Pioneer Agreement") with Pioneer (then a DuPont company) that superseded and replaced a prior Collaboration and License Agreement entered into on September 10, 2014. Under the terms of the Pioneer Agreement, we and Pioneer cross-licensed background CRISPR intellectual property portfolios. Pioneer granted us an exclusive worldwide license, with the right to sublicense, to its background CRISPR intellectual property in the field of research tools, and a non-exclusive license, with the right to sublicense, for CRISPR in therapeutics and all fields outside of the Pioneer field, including in the field of human and animal therapeutics. We granted Pioneer an exclusive license, with the right to sublicense, to our background CRISPR intellectual property, including the CVC IP discussed below, in certain agricultural crops, specified microorganisms, a defined industrial bio field, and certain nutrition and health applications ("Pioneer Exclusive Field"), and a non-exclusive license, with the right to sublicense, to Pioneer for CRISPR in certain defined fields outside of research reagents. The Pioneer Agreement continues until the expiration, abandonment, or invalidation of the last patent or patent application within the licensed intellectual property; provided, however, that the parties may terminate the Pioneer Agreement by mutual consent or either party may unilaterally terminate the Pioneer Agreement if there is an uncured breach of a payment obligation, bankruptcy, or failure to maintain or own licensed intellectual property by the other party if the non-breaching party is materially adversely affected by such failure. Under the terms of the Pioneer Agreement, we are obligated to pay low-single-digit percent royalties to Pioneer for our research tool products as well as certain sublicensing revenue in that field. We are eligible to receive milestone payments from Pioneer in the event certain regulatory and commercial milestones are met, for a total of up to $22.4 million, related to specified row crops and we are also eligible to receive low-single-digit percent royalties for defined agricultural products and certain sublicensing revenue in that field.

The chRDNA patent family was developed under a three-year research collaboration between us and Pioneer, which ended December 31, 2016. Initially, this patent family was owned by Pioneer under the terms of the Pioneer Agreement, and we and Pioneer split the costs of patent prosecution and maintenance equally. Pioneer granted us an exclusive license to the chRDNA patent family in the fields of human and animal therapeutics and research tools as well as a non-exclusive license in certain other fields outside of the Pioneer Exclusive Field. Through an amendment to the Pioneer Agreement, dated December 18, 2020, Pioneer assigned the chRDNA patent family to us. Pioneer retained all of its existing rights (including its sublicensing rights) to the chRDNA patent family despite the change in ownership. As consideration for the assignment, we made an upfront payment of $0.5 million and are obligated to pay all patent prosecution and maintenance costs going forward; up to $2.8 million in regulatory milestone payments and up to $20.0 million in sales milestones for any therapeutic products that are covered by the chRDNA patent family; and a low-single-digit percentage of licensing revenue we receive for licensing the chRDNA patent family in the therapeutic field after December 2020. The sublicensing agreements that we entered into prior to December 18, 2020 (for example, the Intellia Agreement discussed below) are not subject to these economics.

Intellia Therapeutics, Inc. ("Intellia")

On July 16, 2014, we entered into a License Agreement (as amended, "Intellia Agreement") with Intellia, LLC (now Intellia Therapeutics, Inc.), under which we granted Intellia an exclusive worldwide license, with the right to sublicense, to certain CRISPR-Cas9 technology for a defined field of human therapeutics in exchange for Intellia stock. The Intellia Agreement included a license to certain of our future CRISPR-Cas9 intellectual property until such time as our direct or indirect ownership percentage in Intellia dropped below 10%, called the IP cut-off date, which occurred on January 30, 2018. Intellia granted us an exclusive worldwide license, with the right to sublicense, to its CRISPR-Cas9 technology for all fields outside of the defined field of human therapeutics, including a license to certain of Intellia's future CRISPR-Cas9 intellectual property until the IP cut-off date. Each party had the right to opt in to any licenses in its field of use entered into by the other party prior to the IP cut-off date, subject to the terms and conditions of such license, and Intellia opted into our Pioneer Agreement and thus has a license to the Pioneer background CRISPR-Cas9 intellectual property. Under the Intellia Agreement, each party is responsible for 30% of the other party's expenses for prosecution and maintenance of the licensed intellectual property, including 30% reimbursement of the patent prosecution and maintenance costs that we pay to UC/Vienna as described below. The milestones and royalties set forth in the Intellia Agreement are those in the UC/Vienna Agreement and so we pass through any payments received from Intellia to UC/Vienna. The Intellia Agreement continues for the life of the licensed patents and patent applications; provided, however that either party may terminate upon the occurrence of certain events.

In 2018, Intellia initiated an arbitration proceeding over whether two patent families relating, respectively, to CRISPR-Cas9 chRDNA guides and Cas9 scaffolds, were included in the Intellia Agreement. An interim award from the arbitration panel in 2019 determined that both patent families are included in the Intellia Agreement, but the panel granted us an exclusive leaseback to Cas9 chRDNA guides under economic terms to be negotiated by the parties. On June 16, 2021, we entered into a leaseback agreement with Intellia ("Leaseback Agreement"), which resolved the arbitration proceeding. Pursuant to the Leaseback Agreement, in exchange for Intellia's grant to us of an exclusive license to certain intellectual property relating to CRISPR-Cas9, including Cas9 chRDNAs, for use solely in the manufacture of our vispa-cel product candidate, we paid Intellia an upfront cash payment of $1.0 million and we will owe up to $23.0 million in potential future regulatory and sales milestones. Additionally, we will owe Intellia low- to mid- single-digit percent royalties on net sales of our vispa-cel product candidate until the expiration, abandonment, or invalidation of the last patent within the intellectual property relating to CRISPR-Cas9, including that relating to Cas9 chRDNAs (i.e., 2036, without PTA or PTE).

The Regents of the University of California ("UC") and the University of Vienna ("Vienna")

On April 16, 2013, we entered into an Exclusive License for Methods and Compositions for RNA-Directed Target DNA Modification and for RNA-Directed Modulation of Transcription with UC and Vienna (as amended, "UC/Vienna Agreement"), under which we received an exclusive worldwide license, with the right to sublicense, in all fields to the foundational CRISPR-Cas9 patent family co-owned by UC, Vienna, and Dr. Emmanuelle Charpentier ("CVC IP"). Dr. Charpentier has not granted us any rights to the CVC IP, either directly or indirectly. The UC/Vienna Agreement continues until the last-to-expire patent or last-to-be-abandoned patent application of the CVC IP; provided, however, that UC/Vienna may terminate the UC/Vienna Agreement upon the occurrence of certain events, including our uncured material breach of a material term of the UC/Vienna Agreement, and we may terminate the UC/Vienna Agreement at our sole discretion upon written notice. Without PTA or PTE, the CVC IP will expire in 2033. For products and services sold by us that are covered by the CVC IP, we will owe low- to mid-single-digit percent royalties on net sales, subject to a minimum annual royalty. Prior to such time that we are selling products, we owe UC/Vienna an annual license maintenance fee. We will owe UC/Vienna up to $3.1 million in potential regulatory and clinical milestone payments in the field of human therapeutics and diagnostics. Additionally, we pay UC/Vienna a specified percentage of sublicensing revenue we receive including cash and equity under our sublicensing agreements, subject to certain exceptions. If we include intellectual property owned or controlled by us in such sublicense, we pay UC/Vienna a low-double-digit percentage of sublicensing revenues received under the sublicense. If we do not include intellectual property owned or controlled by us in such sublicense, we pay UC/Vienna 50% of sublicensing revenues received under the sublicense. To date, we have entered into over 30 sublicensing agreements in a variety of fields such as human therapeutics, animal therapeutics, agriculture, forestry, research reagents, transgenic animals, certain livestock targets, internal research, bioproduction, cell lines, and microbial applications that include the CVC IP as well as other Cas9 intellectual property owned or controlled by us. We are obligated to reimburse UC for its prosecution and maintenance costs of the CVC IP. The CVC IP is currently involved in administrative proceedings at the U.S. Patent and Trademark Office ("USPTO") and at the European Patent Office ("EPO"). See Risk Factors - *"Our ability to continue to receive licensing revenue and to enter into new licensing arrangements related to the foundational CRISPR-Cas9 intellectual property will be substantially impaired if such intellectual property is limited by administrative patent proceedings or other patent challenges,*" in Item 1A of this Annual Report on Form 10-K.

On December 15, 2016, we entered into a Consent to Assignments, Licensing and Common Ownership and Invention Management Agreement ("IMA") with UC, Vienna, Dr. Emmanuelle Charpentier, Intellia Therapeutics, CRISPR Therapeutics AG, ERS Genomics Ltd., and TRACR Hematology Ltd. relating to the CVC IP. Under the IMA, each of the owners of the CVC IP (i.e., UC, Vienna, and Dr. Charpentier) retroactively consented to all licenses and sublicenses granted by the other owners and their licensees and also gave prospective consent to any licenses and sublicenses that may be granted in the future. Additionally, the IMA provides for, among other things, (i) good faith cooperation among the parties regarding patent maintenance, defense, and prosecution of the CVC IP; (ii) cost-sharing under which CRISPR Therapeutics AG reimburses us for 50% of what we reimburse UC for patent prosecution and maintenance costs; and (iii) notice of and coordination in the event of third-party infringement of the subject patents and with respect to certain adverse claimants of the CRISPR-Cas9 intellectual property. Unless earlier terminated by the parties, the IMA will continue in effect until the later of the last expiration or abandonment date of the CVC IP.

On March 14, 2019, we entered into a Memorandum of Understanding with UC/Vienna, wherein we agreed that, for sublicensees in the fields of human therapeutics and companion diagnostics, we would pay UC/Vienna the royalties and milestones set forth in the UC/Vienna Agreement for products sold by our sublicensees, not the specified percentage of such sublicensing income received by us. We also agreed to various provisions that must be included in all future sublicensing agreements, including specific provisions for exclusive sublicenses.

Intellectual Property

We seek and obtain patent protection for our chRDNA genome-editing technology and product candidates. We also rely on trade secrets to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. Our success will depend significantly on our ability to obtain and maintain patent and trade secret protection for our chRDNA genome-editing technology and product candidates, our ability to defend and enforce our intellectual property rights, and our ability to operate without infringing any valid and enforceable intellectual property rights of third parties.

As of February 27, 2026, we owned 66 granted U.S. patents, 254 granted foreign patents, and 147 pending patent applications throughout the world. The patent portfolio owned by us includes U.S. and foreign patents and patent applications covering methods and compositions relating generally to our Cas9 chRDNA and Cas12a chRDNA technology (which, for granted U.S. patents, without PTA or PTE, will expire in 2036). Additionally, our portfolio includes U.S. and foreign patents and patent applications covering methods and compositions relating to the anti-BCMA binding domain of our CB-011 product candidate (which, for granted U.S. patents, without PTA or PTE, will expire in 2040). In general, we file our patent applications in the United States and Europe as well as in numerous other foreign patent jurisdictions.

Additionally, we have substantial patent protection on CRISPR-Cas9 methods and compositions, CRISPR Type I systems, and other genome-editing technologies. The patent term in the United States and other countries is 20 years from the date of filing of the first non-provisional application to which priority is claimed. In the United States, patent term may be lengthened by a PTA, which compensates a patentee for administrative delays by the USPTO in granting a patent or may be shortened if a patent is terminally disclaimed over an earlier-filed patent. Additionally, under the Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch-Waxman Amendments"), the term of a patent that covers an FDA-approved biologic may also be eligible for a PTE of up to five years, which is designed to compensate for the patent term lost during clinical trials and the FDA regulatory review process. A PTE cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only one patent claiming a drug or biologic, methods of use, or methods of manufacturing may be restored. Moreover, a patent can only be restored once and, if a single patent is applicable to multiple products, it can only be extended based on one product. Similar provisions to extend the term of a patent that covers an approved product are available in Europe and certain other foreign jurisdictions. Without any PTE, the earliest expiration date of our granted U.S. patents is in 2032 and the latest expiration date of our granted U.S. patents is in 2043.

As of February 27, 2026, we owned 27 trademark registrations worldwide, including 7 U.S. trademark registrations. We have registered "CARIBOU," "CARIBOU BIOSCIENCES," "SITE-SEQ," and the Caribou logo as trademarks in relevant classes in the United States, European Union ("EU"), and certain other jurisdictions.

We also rely upon trade secrets, know-how, continuing technological innovation and potential in-licensing opportunities to develop and maintain our competitive position. We seek to protect these trade secrets and other confidential information, in part, by entering into confidentiality agreements with parties who have access to them. We also enter into confidentiality and invention assignment agreements with our employees and our agreements with consultants include invention assignment obligations.

Competition

We currently compete across the fields of cell therapy and genome editing. We believe that our novel CRISPR-Cas12a chRDNA genome-editing technology has broad potential applicability across human therapeutic indications, including *in vivo* and *ex vivo* applications.

The biopharmaceutical industry, in particular the cell therapy and genome editing fields, is characterized by intense investment and competition aimed at rapidly advancing new technologies. Our vispa-cel and CB-011 product candidates will face substantial competition from multiple technologies, marketed products, and numerous other therapies being developed by other biopharmaceutical companies, larger and better funded pharmaceutical companies, academic research institutions, governmental agencies, and private research institutions. Many of our competitors, either alone or with their collaborators, have substantially greater financial, technical, and other resources, such as larger research and development staff, and/or greater expertise in research and development, nonclinical testing, conducting clinical trials, established manufacturing capabilities and facilities, and experienced marketing organizations with well-established sales forces. In addition, there is extensive patent infringement litigation in the biopharmaceutical industry and, in the future, we may bring or defend such litigation against our competitors.

We believe that, if approved, our CAR-T cell therapy product candidates have the potential to offer beneficial products to patients due to genome edits we make with our chRDNA technology with the goal of extending robust CAR-T cell activity in patients. Because of the promising therapeutic effect of cell therapies, including the potential benefit of allogeneic treatment alternatives, we expect increasing competition from companies such as:

- *Autologous T cell therapy*: Autologous T cell therapies directed at CD19 have been commercialized by Novartis AG (Kymriah®), Kite Pharma, Inc., a Gilead Sciences, Inc. company (Yescarta®, Tecartus®), and Bristol-Myers Squibb Company (Breyanzi®). Autologous cell therapies directed at BCMA have been commercialized by Bristol-Myers Squibb Company (Abecma®) and Legend Biotech Corporation with their partner Johnson & Johnson (Carvykti®). Autologous T cell therapies are being developed by a number of additional companies, including but not limited to AbelZeta Pharma Inc., Arcellx, Inc., Arsenal Biosciences, Inc., Astellas Pharma Inc., Autolus Therapeutics plc, AvenCell Therapeutics, Inc., Bristol-Myers Squibb Company, Cabaletta Bio, Inc., Eureka Therapeutics, Inc., Gracell Biotechnologies Inc., an AstraZeneca PLC company, Iovance Biotherapeutics, Inc., Johnson & Johnson, Kite Pharma, Inc. (a Gilead Sciences Inc. company), Kyverna Therapeutics, Inc., Legend Biotech Corporation, Lyell Immunopharma, Inc., March Biosciences, Inc., Miltenyi Biotec, Mustang Bio, Inc., Novartis AG, Precigen, Inc., Regeneron Pharmaceuticals, Inc. (through its acquisition of the 2seventy bio, Inc. research pipeline), F. Hoffman-La Roche Ltd (through its acquisition of Poseida Therapeutics, Inc.), TCR² Therapeutics Inc., Triumvira Immunologics Inc., and TScan Therapeutics, Inc.;

- *Allogeneic T cell therapy:* Other companies are developing allogeneic T cell therapies, including Allogene Therapeutics, Inc., Atara Biotherapeutics, Inc., AvenCell Therapuetics, Inc., Cellectis S.A., CRISPR Therapeutics AG, Fate Therapeutics, Inc., Gracell Biotechnologies (an AstraZeneca PLC company), Imugene Limited, Kite Pharma, Inc. (a Gilead Sciences, Inc. company), Legend Biotech Corporation, March Biosciences, Inc., F. Hoffman La-Roche Ltd (through its acquisition of Poseida Therapeutics, Inc.), and Sana Biotechnology, Inc.;

- *In vivo T cell therapy*: Companies such as AbbVie Inc. (through its acquisition of Capstan Therapeutics, Inc.), Bristol-Myers Squibb Company (through its acquisition of Orbital Therapeutics), CREATE Medicines, Inc., GigaMune, Inc., Kite Pharma, Inc. (a Gilead Sciences Inc. company) (through its acquisition of Interius BioTherapeutics, Inc.), Kelonia Therapeutics, Inc., Legend Biotech Corporation, and Umoja Biopharma, Inc. are developing *in vivo* T cell therapies;

- *Allogeneic NK cell therapy:* Companies are developing allogeneic NK cell therapies, including Artiva Biotherapeutics, Inc., Celularity Inc., Century Therapeutics, Inc., Fate Therapeutics, Inc., ImmunityBio, Inc., Nkarta, Inc., NKGen Biotech, Inc., and Senti Biosciences, Inc.; and

- *Other cell therapies:* Other companies are developing CAR-expressing immune cell therapies derived from regulatory T cells, including Cabaletta Bio and Kyverna Therapeutics, Inc., and from gamma-delta T cells, including Adicet Bio, Inc., CytoMed Therapeutics Limited, and IN8bio, Inc.

Additionally, multiple biotechnology and pharmaceutical companies are developing other directly competitive technologies, such as small molecules, antibodies, bispecific antibodies, trispecific antibodies, and antibody-drug conjugates. Bispecific antibodies have received regulatory approval and are also in development for different lines of therapy for patients with relapsed or refractory DLBCL, including those from AbbVie Inc. (Epkinly®), F. Hoffman-La Roche Ltd (Columnvi® and Lunsumio®) and for different lines of therapy for patients with r/r MM, including those from Johnson & Johnson (Tecvayli® and Talvey®), Pfizer (Elrexfio®), and Regeneron Pharmaceuticals, Inc. (Lynozyfic®).

Compared to first-generation CRISPR genome-editing approaches, our chRDNA genome-editing technology has shown improved specificity, a reduction in off-target edits and translocations and, when paired with Cas12a, an advanced capability to perform multiplexed edits, in particular multiplexed insertions. Although we believe that our novel technologies and intellectual property position offer competitive advantages, we face competition from multiple other genome-editing technologies and companies. Other companies developing CRISPR-based technologies include, among others, Arbor Biotechnologies, Inc., Beam Therapeutics Inc., CRISPR Therapeutics AG, Editas Medicine, Inc., Intellia Therapeutics, Inc., Mammoth Biosciences, Inc., Metagenomi Therapeutics, Inc., and Scribe Therapeutics, Inc. Companies developing other genome-editing technologies include, among others, Allogene Therapeutics, Inc., Cellectis S.A., Precision BioSciences, Inc., Prime Medicine, Inc., Sangamo Therapeutics, Inc., and Wave Life Sciences Ltd.

Manufacturing

Manufacturing CAR-T cell therapies requires multiple components. Our allogeneic CAR-T cell therapies are manufactured starting with cells from healthy donors, and clinical product candidates are prepared, qualified, released, and available on an off-the-shelf basis prior to patient dosing. Our allogeneic CAR-T therapies are cryogenically stored in freezers, making them readily available for patient treatment on demand. To date, we have successfully scaled our manufacturing processes so that one manufacturing run from a healthy donor can produce sufficient cell yield for approximately 200-300 doses of vispa-cel and 50-100 doses for CB-011.This is in contrast to commercially available autologous CAR-T cell therapy where one manufacturing run is required for each patient to be treated using the patient's cells that may have already been depleted by prior treatments, a process that can take several weeks to months to deliver product for patient treatment.

For our CAR-T product candidates, we have optimized the manufacturing process that we developed in-house and have transferred these processes to CMOs that manufacture current good manufacturing practices ("cGMP")-grade material for our clinical trials. Additionally, we have developed analytical methods to characterize and test the safety, purity, and potency of our cells based upon our manufacturing processes and regulatory requirements. We have made a significant investment in process development to optimize and control our product candidate characteristics and to also improve our supply capabilities.

For the manufacturing of our allogeneic CAR-T cell therapy product candidates, we have developed a platform process that is scaled to support commercial manufacturing. Our process development and manufacturing core competencies and advantages include:

- optimization and learnings across all of our product candidates, allowing for consistency and increased process robustness;
- internal process development to facilitate optimization of manufacturing processes and technical transfers to manufacturing sites;
- readily available and commercially-established equipment that further enables the transfer from our process development lab to cGMP operations;
- custom engineering and development to create the necessary specific requirements for our product candidates, while leveraging the broader platform to ensure robust processes;
- removal of residual TCR-positive T cells after genome editing to minimize the risk of GvHD in patients;
- process understanding and cell manufacturing control for continuous optimization of productivity and product candidate quality;
- product candidate optimization from translational learnings across one of the largest allogeneic clinical efficacy and safety data sets;
- closed manufacturing systems;
- highly specific development efforts focused on enhancing cell viability;
- extensive core process knowledge of gene knockout, CAR expression, and gene insertion;
- process control and optimization, allowing for increased retention of early memory T cell phenotypes; and
- platform scale and efficiency to accommodate commercial high yield per batch, with further yield optimization processes available.

The CMOs that are currently manufacturing the clinical supplies of our product candidates are located in the United States and are subject to cGMP requirements. We have dedicated cGMP suites at our CMOs for the manufacture of our cell therapy product candidates. We use multiple CMOs to individually manufacture the critical and starting materials for our product candidates, including cGMP chRDNA guides, Cas9 and Cas12a proteins, and AAV6 vectors used in the manufacture of our CAR-T cells. Our chRDNA genome-editing is a next-generation CRISPR technology that does not rely on lentiviral or retroviral genome-editing methods, which are used in commercially available autologous CAR-T cell therapies to insert the CAR gene randomly into the genome, which may increase the risk of genomic mutagenesis. We expect to rely on CMOs for manufacturing our product candidates to expedite readiness for future clinical trials, and most of the CMOs we currently contract with have demonstrated capabilities for commercial manufacturing. Additionally, we may decide to build our own manufacturing facility in the future, or we may deploy a hybrid approach to manufacturing, to provide us with greater flexibility and control over our clinical or commercial manufacturing needs.

Government Regulation

As a biotechnology company, we are subject to extensive legal and regulatory requirements, including those related to research, development, testing, manufacture, product approval and licensure, quality control, packaging, storage, record keeping, labeling, advertising, promotion, distribution, marketing, post-approval monitoring and reporting, and import and export of our product candidates. Relevant regulatory authorities include, but are not limited to, the FDA; the European Medicines Agency ("EMA"), an agency of the EU in charge of the evaluation and supervision of medicinal products; the European Commission, which is the executive arm of the EU; and other national, state, local, and provincial regulatory authorities. The United States and certain jurisdictions outside the United States also regulate the pricing and reimbursement of such products. The processes for obtaining marketing approvals in the United States and in other countries and jurisdictions, along with subsequent compliance with applicable statutes and regulations and other regulatory authorities, require the expenditure of substantial time and financial resources. In addition, the regulatory framework for the collection, use, safeguarding, sharing, transfer, and other processing of information worldwide is rapidly evolving and is likely to remain uncertain for the foreseeable future.

Licensure and Regulation of Biologics in the United States

In the United States, our product candidates are regulated as biological products, or biologics, under the Public Health Service Act ("PHSA"), and the Federal Food, Drug, and Cosmetic Act ("FDCA"), and their implementing regulations promulgated by the FDA. Failure to comply with the applicable requirements at any time during the product development process, including nonclinical testing, clinical testing, the approval process, or post-approval process, may subject us to delays in the conduct of a clinical trial, delays in regulatory review and approval, and/or administrative or judicial sanctions. Such sanctions may include, but are not limited to, the FDA's refusal to allow us to proceed with clinical testing of our product candidates, refusal to approve pending applications, license suspension or revocation, withdrawal of an approval, receipt of untitled or warning letters, adverse publicity, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, and civil or criminal investigations and penalties brought by the FDA, U.S. Department of Justice ("DOJ"), or other governmental entities.

As we seek approval to market and distribute a new biologic in the United States, we generally must satisfactorily complete each of the following steps:

- nonclinical studies performed in accordance with the FDA's current Good Laboratory Practice ("cGLP") regulations;
- manufacture and testing of clinical investigational product according to cGMPs;
- submission to the FDA of an investigational new drug ("IND") application for human clinical testing, which must become effective before human clinical trials may begin;
- approval by an independent institutional review board ("IRB"), representing each clinical trial site before each clinical trial may be initiated, or by a central IRB if appropriate;
- performance of adequate and well-controlled human clinical trials required to establish the safety and efficacy of the product candidate for each proposed indication, in accordance with the FDA's current Good Clinical Practice ("cGCP") regulations including, but not limited to, informed consent and investigator financial disclosure requirements;

- preparation and submission to the FDA of a biologics license application ("BLA") seeking approval of our product candidates for one or more proposed indications, including submission of detailed information on the manufacture and composition of our product candidates and proposed labeling;
- review of the BLA by an FDA advisory committee, where applicable;
- satisfactory completion of one or more FDA inspections of the manufacturing facility or facilities, including those of any third-party manufacturers, at which the product, or components thereof, are produced in order to assess compliance with cGMP requirements and to ensure that the facilities, methods, and controls are adequate to preserve and ensure the product's safety, purity, and potency, and, if applicable, the FDA's current Good Tissue Practice ("cGTP"), for the use of human cell and tissue products;
- satisfactory completion of any FDA audits of the nonclinical study and clinical trial sites to ensure compliance with cGLPs and cGCPs, respectively, and the integrity of nonclinical and clinical data in support of a BLA;
- payment of any user fees and securing FDA approval of a BLA; and
- compliance with any post-approval requirements, including the potential requirement to implement Risk Evaluation and Mitigation Strategy ("REMS"), adverse event reporting, and compliance with any post-approval studies required or requested by the FDA.

Nonclinical Studies and IND Applications

Before testing any investigational biologic candidate in humans, we must submit an IND application and receive clearance from the FDA to initiate a clinical trial. The results of our nonclinical testing, including laboratory evaluation of product chemistry, formulation and toxicity, as well as animal trials to assess the characteristics and potential safety and efficacy of the product, together with manufacturing information, are submitted to the FDA as part of the IND application. An IND is an exemption from the restrictions of the FDCA, which would otherwise preclude an unapproved biologic candidate from being shipped in interstate commerce. Under a cleared IND, the unapproved biologic candidate may be shipped in interstate commerce for use in an investigational clinical trial, provided that the product candidate meets certain quality and labeling requirements. An IND automatically becomes effective 30 calendar days after receipt by the FDA, unless before that time the FDA places the trial on clinical hold. In such a case, the IND sponsor must correct the deficiencies cited in the hold letter or otherwise satisfy the FDA that the investigation may proceed before the clinical trial can begin. When the sponsor submits a response to the issues identified in the hold letter, the FDA should respond in writing to the sponsor within 30 days of the complete response by either removing or maintaining the clinical hold. The FDA may impose a partial or full clinical hold with respect to our product candidate. A partial clinical hold is a delay or suspension of fewer than all of the investigational clinical trial, or certain parts of the investigational clinical trial, subject to the IND.

Human Clinical Trials in Support of a BLA

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

If we wish to conduct a clinical trial outside of the United States, we may, but need not, obtain FDA authorization to conduct the clinical trial under an IND. When a foreign clinical trial is conducted under an IND, FDA IND requirements must be met unless waived. If a non-U.S. clinical trial is not conducted under an FDA IND, we may submit data from a well-designed and well-conducted clinical trial to the FDA in support of our BLA as long as the clinical trial is conducted in compliance with cGCP and the FDA is able to validate the data from the clinical trial through an onsite inspection if the FDA deems it necessary.

For clinical trials conducted in the United States, each clinical trial must be reviewed and approved by an IRB, either centrally or individually at each institution at which our clinical trials will be conducted. The IRB will consider, among other things, our clinical trial design, subject informed consent, ethical factors, and the safety of human subjects. The IRB must operate in compliance with FDA regulations governing IRBs. The FDA, the applicable IRB, or we may suspend or terminate a clinical trial, in whole or in part, at any time for various reasons, including a finding that the clinical trial is not being conducted in accordance with FDA requirements or that the subjects or patients are being exposed to an unacceptable health risk. Some clinical trials receive additional oversight by an independent group of qualified experts organized by us, known as a data safety monitoring board or committee. This group receives and reviews data from the clinical trial on an ongoing basis and may recommend continuation of the clinical trial as planned, changes in clinical trial conduct, or cessation of the clinical trial at designated check points based on such data.

In addition to the submission of an IND application to the FDA before initiation of a clinical trial in the United States, certain human clinical trials involving recombinant or synthetic nucleic acid molecules may be subject to oversight of institutional biosafety committees ("IBCs"), as set forth in the National Institutes of Health ("NIH") Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules ("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 qualifying 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. Although 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.

Furthermore, the Food and Drug Omnibus Reform Act of 2022 ("FDORA") requires a clinical trial sponsor to submit a diversity action plan for pivotal clinical trials, unless a waiver is granted by the FDA. The action plan must include information such as the sponsor's goal for enrollment (by sex, ethnic characteristics, age), the rationale behind the enrollment goals, the subject patient population, potential barriers for enrollment, among others. This requirement is not yet in effect as it will become applicable to all clinical trials that begin enrollment 180 days after FDA publishes its final guidance on this topic. The final guidance has not yet been published. In January 2025, the FDA removed its June 2024 draft guidance on clinical trial diversity action plans from its website, and it is not clear how the FDA will enforce the statutory requirement under FDORA.

Clinical trials typically are conducted in three sequential phases.

- Phase 1 clinical trials are initially conducted in a limited population of healthy humans or, for our product candidates, in patients, such as cancer patients, in order to test the product candidate for safety, including adverse effects, dose tolerance, absorption, metabolism, distribution, excretion, and pharmacodynamics, and to identify a recommended phase 2 dose.

- Phase 2 clinical trials are generally conducted in a limited patient population to identify possible adverse effects and safety risks, evaluate the efficacy of the product candidate for specific targeted indications, and to determine dose tolerance and optimal dosage. We may conduct multiple phase 2 clinical trials to obtain information prior to beginning larger and costlier phase 3 clinical trials. In appropriate circumstances, a phase 2 clinical trial may serve as the basis for an application, in which case a separate phase 3 clinical trial may not be necessary.

- Phase 3 clinical trials are undertaken within an expanded patient population to gather the additional information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the product candidate and to provide an adequate basis for physician labeling.

These phases may overlap or be combined. For example, a phase 1/2 clinical trial may contain both a dose-escalation stage and a dose-expansion stage, the latter of which may confirm tolerability at the recommended dose for expansion in future clinical trials (as in traditional phase 1 clinical trials) and provide insight into the anti-tumor effects of the investigational therapy in selected subpopulation(s). Typically, during the development of oncology therapies, all subjects enrolled in phase 1 clinical trials are disease-affected patients and, as a result, considerably more information on clinical activity may be collected during such trials than during Phase 1 clinical trials for non-oncology therapies. In most cases, the FDA requires two adequate and well-controlled phase 3 clinical trials to demonstrate the safety and efficacy of the biologic. In rare instances, a single phase 3 trial may be sufficient when either (i) the trial is a large, multicenter trial demonstrating internal consistency and a statistically very persuasive finding of a clinically meaningful effect on mortality, irreversible morbidity or prevention of a disease with a potentially serious outcome and confirmation of the result in a second trial would be practically or ethically impossible, or (ii) the single trial is supported by confirmatory evidence. Approval on the basis of a single trial may be subject to a requirement for additional post-approval studies.

In addition, the manufacturer of an investigational biologic in a phase 2 or phase 3 clinical trial for a serious or life-threatening disease is required to make available, such as by posting on its website, its policy on evaluating and responding to requests for expanded access to such investigational biologic.

During all phases of clinical development, regulatory agencies require extensive monitoring and auditing of all clinical activities, clinical data, and clinical trial investigators. Annual progress reports detailing the status of clinical trials must be submitted to the FDA. Written IND safety reports must be submitted to the FDA and the investigators within 15 calendar days of receipt by us after determining that the information qualifies for such expedited reporting. IND safety reports are required for suspected unexpected serious adverse reactions ("SUSARs"), findings from other studies or animal or *in vitro* testing that suggest a significant risk to humans in our clinical trials, and any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. Additionally, we must notify FDA within seven calendar days after receiving information concerning any unexpected fatal or life-threatening suspected adverse reaction.

Guidance Governing Gene Therapy Products

The FDA has defined a gene therapy product as one that mediates its effects by transcription and/or translation of transferred genetic material or by specifically altering host (human) genetic sequences. Examples of gene therapy products include nucleic acids (e.g., plasmids, *in vitro* transcribed ribonucleic acid), genetically modified microorganisms (e.g., viruses, bacteria, fungi), engineered site-specific nucleases used for human genome editing, and *ex vivo* genetically modified human cells. The products may be used to modify cells *in vivo* or transferred to cells *ex vivo* prior to administration to the recipient. Within the FDA, the Center for Biologics Evaluation and Research ("CBER") regulates gene therapy products. Within CBER, the review of gene therapy and related products is consolidated in the Office of Therapeutic Products, and the FDA has established the Cellular, Tissue and Gene Therapies Advisory Committee to advise CBER on its reviews. The FDA and the NIH have published guidance documents with respect to the development and submission of gene therapy protocols.

For example, in January 2024, the FDA issued a guidance document titled "Considerations for the Development of Chimeric Antigen Receptor T Cell Products; Guidance for Industry," which provides recommendations regarding collection and handling of cellular starting materials, vector manufacturing and testing processes, CAR-T cell design and development considerations, pharmacology and toxicology, clinical trial considerations, manufacturing processes, analytical comparability, etc. In this guidance the FDA outlined factors that sponsors should consider in conducting clinical trials using CAR-Ts, including defining appropriate study populations based on potential toxicities of CAR-T cells, such as cytokine-release syndrome and neurological toxicities, diagnostic tests that can identify patients with tumors that have the target antigens, selection of appropriate dosage levels based on viable transduced CAR-T cells, etc. The FDA also issued a guidance document titled "Human Gene Therapy Products Incorporating Human Genome Editing" in January 2024, which provides recommendations for sponsors that are developing gene therapy products involving genetic editing of somatic cells, as well as information that sponsors should provide to the FDA prior to beginning a clinical trial, including information on the design of the gene editing component; delivery mechanisms for the gene editing components; information on chemistry, manufacturing, and controls ("CMC"); risk of unregulated proliferation; potential implications of off-site gene editing; etc. The FDA also has issued other guidance documents that relate to gene therapies, such as "Human Gene Therapy for Rare Diseases," and it is likely that the FDA will continue to issue additional guidelines with respect to the development and regulatory submission of cell and gene therapy products in the future that may affect our product candidates.

The guidance documents provide additional factors that the FDA will consider at each of the above stages of development and relate to, among other things, the proper nonclinical assessment of gene therapies; the CMC information that should be included in an IND; the proper design of tests to measure product potency in support of a BLA; and measures to observe delayed adverse effects in subjects who have been exposed to investigational gene therapies when the risk of such effects is elevated. The FDA usually recommends that sponsors observe subjects for potential gene therapy-related delayed adverse events. Depending on the product type, long term follow up can be up to 15 years or as short as five years.

Clinical Trial Registry

There also are requirements governing the reporting of ongoing clinical trials and completed clinical trial results to the U.S. government-sponsored database, www.ClinicalTrials.gov, within certain timeframes. We are required to register and disclose certain clinical trial information, including the product information, patient population, phase of investigation, clinical trial sites and investigators, and other aspects of the clinical trial on www.ClinicalTrials.gov. We are also obligated to disclose the results of our clinical trials after completion. Disclosure of the results of these clinical trials can be delayed until the new product candidate or new indication being studied has been approved, up to a maximum of two years.

Compliance with cGMP and cGTP Requirements

Before approving a BLA, the FDA typically will inspect the facility or facilities where our product candidates are manufactured. The FDA will not approve a BLA unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to ensure consistent production of the product within required specifications. The PHSA emphasizes the importance of manufacturing controls for products such as biologics whose attributes cannot be precisely defined. Material changes in manufacturing equipment, location, or process post-approval may result in additional regulatory review and require approval.

The FDA also will not approve a product if our manufacturing is not in compliance with cGTPs, which are requirements found in FDA regulations that govern the methods used in, and the facilities and controls used for, the manufacture of human cells, tissues, and cellular and tissue-based products ("HCT/Ps"), which are human cells or tissue intended for implantation, transplant, infusion, or transfer into a human recipient. The primary intent of the cGTP requirements is to ensure that cell- and tissue-based products are manufactured in a manner designed to prevent the introduction, transmission, and spread of communicable disease. FDA regulations also require tissue establishments to register and list their HCT/Ps with the FDA and, when applicable, to evaluate donors through screening and testing.

Review and Approval of a BLA

The results of product candidate development, nonclinical testing, and clinical trials, including negative or ambiguous results as well as positive findings, are submitted to the FDA as part of a BLA requesting a license to market the product. A BLA must contain sufficient manufacturing information and detailed information on the composition of the product candidate and proposed labeling as well as payment of a user fee, unless the criteria for a fee waiver or exemption are met. Under the PHSA, the FDA will approve a BLA if it determines that our product candidate is safe, pure, and potent and the manufacturing facility meets standards designed to ensure that our product continues to be safe, pure, and potent.

The FDA has 60 calendar days after submission of a BLA to conduct an initial review to determine whether the BLA is acceptable for filing based on the agency's threshold determination that the BLA is sufficiently complete to permit substantive review. Once the submission has been filed, the FDA begins an in-depth review of the application. Under the goals agreed to by the FDA under the Prescription Drug User Fee Act ("PDUFA"), for a new molecular entity, the FDA has 10 months from the date that BLA is filed in which to complete its initial review of a standard application and respond to us, and six months from such filing date for a priority review of the application. The FDA does not always meet its PDUFA goal dates for standard and priority BLAs. The review process and the PDUFA goal date may be extended by three months if the FDA determines that we have submitted a major amendment.

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

On the basis of the FDA's evaluation of the application and accompanying information, including the results of the inspection of the manufacturing facilities and any FDA audits of nonclinical study and clinical trial sites to ensure compliance with cGMPs, cGLPs, and cGCPs, respectively, the FDA will issue an approval letter or a complete response letter. An approval letter authorizes commercial marketing of our product candidate with specific prescribing information for specific indications. If our BLA is not approved, the FDA will issue a complete response letter, which will contain the deficiencies that preclude approval of the application and outline recommended actions we might take to obtain approval of our BLA. If we receive a complete response letter, we may submit to the FDA information that represents a complete response to the issues identified by the FDA. Such resubmissions are classified under the PDUFA as either class 1 or class 2. The classification of a resubmission is based on the information submitted by us in response to the complete response letter. Under the goals and policies agreed to by the FDA under the PDUFA, the FDA has two months to review a class 1 resubmission and six months to review a class 2 resubmission. The FDA will not approve an application until deficiencies identified in the complete response letter have been addressed. Alternatively, if we receive a complete response letter, we may either withdraw our BLA or request a hearing.

As a condition of a BLA approval, the FDA may limit the approved indications for use of our products. The FDA may also require that contraindications, warnings, or precautions be included in the product labeling. In addition, the FDA may require or request post-approval studies, including phase 4 clinical trials. The FDA may also require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution restrictions or other risk management mechanisms, including REMS, to help ensure that the benefits of the product outweigh the potential risks. REMS can include medication guides, communication plans for healthcare professionals, and elements to ensure safe use ("ETASU"). ETASU can include, but are not limited to, specific or special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring, and the use of patient registries. The FDA may prevent or limit further marketing of a product based on the results of post-marketing studies or surveillance programs. After approval, many types of changes to the approved product, such as adding new indications, certain manufacturing changes, and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Fast Track, Breakthrough Therapy, Priority Review, and RMAT Designations

The FDA is authorized to facilitate and expedite development and review of new biologics intended to address an unmet medical need in the treatment of a serious or life-threatening disease or condition. These programs include fast track designation, breakthrough therapy designation, priority review, and RMAT designation. These designations are not mutually exclusive, and our product candidates may qualify for one or more of these programs. Although these programs are intended to expedite product development and approval, they do not alter the standards for FDA approval.

The FDA may designate one or more of our product candidates as a fast track product if our product candidate is intended, whether alone or in combination with one or more other products, for the treatment of a serious or life-threatening disease or condition, and it can be demonstrated that our product candidate has the potential to address an unmet medical need for such a disease or condition. Our current product candidates have been designated as fast track products, which means we may have greater interactions with the FDA, and the FDA may initiate review of sections of our fast track product candidate's application before the application is complete. This rolling review may be available if the FDA determines, after preliminary evaluation of clinical data submitted by us, that a fast track product candidate may be effective. We must also provide, and the FDA must approve, a schedule for the submission of the remaining information, and we must pay applicable application user fees. However, the FDA's goal timeline for reviewing a rolling submission does not begin until the last section of the application is submitted. In addition, the fast track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process, or if our designated product candidate development program is no longer being pursued.

Our product candidates may obtain breakthrough therapy designations if they are intended, either alone or in combination with one or more other products, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that our product candidates may demonstrate substantial improvement over available therapies on one or more clinically significant endpoints. The FDA may take certain actions with respect to product candidates with such designations, including holding meetings with us throughout the development process, providing timely advice to us regarding development and approval, involving more senior staff in the review process, assigning a cross-disciplinary project lead for the review team, and taking other steps to provide guidance on the design of the clinical trials in an efficient manner. Breakthrough therapy designation may be rescinded if our product candidate no longer meets the qualifying criteria.

The FDA may determine that an application will receive priority review designation if the application is for a product candidate that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. The FDA makes such determination on a case-by-case basis, compared with other available therapies. Significant improvement may be illustrated by evidence of increased effectiveness in the treatment of a condition, elimination or substantial reduction of a treatment-limiting adverse reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes, or evidence of safety and effectiveness in a new subpopulation. A priority review designation is intended to direct overall attention and resources to the evaluation of such applications, and to shorten the FDA's goal for acting on a marketing application from 10 months to six months following filing of the application.

The FDA may grant product candidates RMAT designations if such product candidates are regenerative medicine therapies intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition and preliminary clinical evidence indicates that they have the potential to address unmet medical needs for such disease or condition. RMAT designation provides potential benefits that include early interactions and more frequent meetings with the FDA to discuss the development plan for the product candidate and eligibility for rolling review and priority review. Product candidates granted RMAT designation may also be eligible for accelerated approval on the basis of surrogate or intermediate clinical trial endpoints reasonably likely to predict long-term clinical benefit, or reliance upon data obtained from a meaningful number of sites, including through expansion to additional sites. RMAT-designated products that receive accelerated approval may, as appropriate, fulfill their post-approval requirements through the submission of clinical evidence, clinical trials, patient registries, or other sources of real-world evidence such as electronic health records, through the collection of larger confirmatory data sets as agreed with the FDA, or via post-approval monitoring of all patients treated with such therapy prior to approval of the therapy. RMAT designation may be rescinded if our product candidate no longer meets the qualifying criteria.

Accelerated Approval Pathway

The FDA may grant accelerated approval to our product candidates for a serious or life-threatening condition that provides meaningful therapeutic advantage to patients over existing treatments based upon a determination that our product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. The FDA may also grant accelerated approval when our product candidate has an effect on an intermediate clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality ("IMM") and that is reasonably likely to predict an effect on IMM or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition, and the availability or lack of alternative treatments. Product candidates granted accelerated approval must meet the same statutory standards for safety and efficacy as those granted traditional approval.

For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit but is not itself a measure of clinical benefit. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. An intermediate clinical endpoint is a measurement of a therapeutic effect that is considered reasonably likely to predict the clinical benefit of a product candidate, such as an effect on IMM. The FDA has limited experience with accelerated approvals based on intermediate clinical endpoints but has indicated that such endpoints generally could support accelerated approval where a clinical trial demonstrates a relatively short-term clinical benefit in a chronic disease setting in which assessing long-term clinical benefit is essential for traditional approval, but the short-term benefit is considered reasonably likely to predict long-term benefit.

The accelerated approval pathway is most often used in settings in which the course of a disease is long and an extended period of time is required to measure the intended clinical benefit of a product candidate, even if the effect on the surrogate or intermediate clinical endpoint occurs rapidly. Thus, accelerated approval has been used extensively in the development and approval of products for treatment of a variety of cancers in which the goal of therapy is generally to improve survival or decrease morbidity and the duration of the typical disease course requires lengthy and sometimes large trials to demonstrate a clinical or survival benefit.

The accelerated approval pathway is usually contingent on our agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe our product candidate's clinical benefit, and, in most cases, the FDA may require that the trial be designed, initiated, and/or fully enrolled prior to approval. As a result, a product candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or confirm a clinical benefit during post-marketing studies, would allow the FDA to withdraw the product from the market on an expedited basis. All promotional materials for product candidates approved under accelerated approval are subject to prior review by the FDA unless the FDA informs us otherwise.

The FDA is authorized to require a post-approval study to be underway prior to approval or within a specified time period following approval and is required to specify conditions of any required post-approval study, which may include milestones such as a target date of study completion. Sponsors are required to submit progress reports for required post-approval studies and any conditions required by the FDA not later than 180 calendar days following approval and not less frequently than every 180 days thereafter until completion or termination of the study. The FDA may initiate enforcement action for the failure to conduct with due diligence a required post-approval study, including a failure to meet any required conditions specified by the FDA or to submit timely reports.

Post-Approval Regulation

If regulatory approval for marketing of any of our product candidates is obtained, we will be required to comply with all regular post-approval regulatory requirements as well as any post-approval requirements that the FDA has imposed as part of the approval process. We will be required to report certain adverse reactions and manufacturing problems to the FDA, provide updated safety and efficacy information, and comply with requirements concerning advertising and promotion. Manufacturers of our products are required to register their establishments with the FDA and certain state agencies and are subject to periodic announced or ad hoc inspections by the FDA and certain state agencies for compliance with ongoing regulatory requirements, including cGMP regulations, which impose certain procedural and documentation requirements upon these manufacturers.

Our products may also be subject to official lot release, meaning that the manufacturer of our products is required to perform certain tests on each lot of the product before the product is released for distribution. If the product is subject to official lot release, the manufacturer must submit to the FDA samples of each lot, together with a release protocol showing a summary of the history of manufacture of the lot and the results of the manufacturer's tests performed on the lot. The FDA may in addition perform certain confirmatory tests on lots of some products before releasing the lots for distribution.

Once a marketing approval is granted for our product candidate, the FDA may withdraw the approval if compliance with regulatory requirements is not maintained or if problems occur after our product reaches the market. Later discovery of previously unknown problems with our product, including adverse events of unanticipated severity or frequency, issues with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information, imposition of post-marketing studies or clinical trials to assess new safety risks, or imposition of distribution or other restrictions under a REMS.

Other potential consequences of a failure to comply with regulatory requirements include:

- restrictions on the marketing or manufacturing of our product, complete withdrawal of our product from the market, or product recalls;
- fines, untitled or warning letters, or holds on post-approval clinical trials;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of our product license approvals;
- product seizure or detention, or refusal to permit the import or export of products or the raw materials or ingredients that are needed for product manufacture; or
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising, and promotion of licensed and approved products that are placed on the market. Pharmaceutical products may be promoted only for the approved indications and in accordance with the provisions of the approved labeling.

Orphan Drug Designation and Exclusivity

Orphan drug designation is available for drugs and biologics that are intended for rare diseases or conditions, defined as (i) a disease or condition that affects fewer than 200,000 individuals in the United States or (ii) a disease or condition that affects more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making available a biologic for the disease or condition will be recovered from sales of the product in the United States. If a drug or biologic becomes the first product that is approved for the same disease or condition for which the FDA has granted the designation, that product will be entitled to orphan drug exclusivity, which means the FDA may not approve any other application to market the same drug or biologic for the same orphan disease or condition for a period of seven years following the date of marketing approval, except in certain circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity by means of greater effectiveness, greater safety, or providing a major contribution to patient care, or in instances of product supply issues. In the case of a biologic, sameness is based on the principal molecular features of the product. Orphan drug exclusivity does not prevent FDA from approving a different drug or biologic for the same disease or condition, or the same drug or biologic for a different disease or condition.

To obtain an orphan drug designation, we must make a request before submitting our BLA for a particular product candidate. After the FDA grants orphan drug designation, the generic or trade name, or the chemical name or a meaningful description of the biologic, its designated orphan use and date of designation, and our company name 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. In addition, other financial incentives, such as tax credits or exemption from the BLA application fee, may be available.

Pediatric Studies and Exclusivity

Under the Pediatric Research Equity Act of 2003 (as amended, "PREA"), a BLA or supplement to a BLA for a product candidate with certain novel characteristics must contain data to assess the safety and effectiveness of the product candidate for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product candidate is safe and effective.

Sponsors must submit a pediatric study plan to FDA outlining the proposed pediatric study or studies they plan to conduct, including study objectives and design, any deferral or waiver requests, and other information required by regulation. The FDA must then review the information submitted, consult with the sponsor, and agree upon a final plan. The FDA or the sponsor may request an amendment to the plan at any time.

For products intended to treat a serious or life-threatening disease or condition, the FDA must, upon the request of a sponsor, meet to discuss preparation of the initial pediatric study plan or to discuss deferral or waiver of pediatric assessments. In addition, the FDA will meet early in the development process to discuss pediatric study plans with the sponsor and the FDA must meet with the sponsor by no later than the end-of-phase 1 meeting for serious or life-threatening diseases and by no later than 90 calendar days after FDA's receipt of the study plan. The FDA may, on its own initiative or at the request of the sponsor, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements, under specified circumstances. Unless otherwise required by regulation, the pediatric data requirements do not apply to products with orphan drug designation except a product with a new active ingredient that is a molecularly targeted cancer product intended for the treatment of an adult cancer and directed at a molecular target determined by the FDA to be substantially relevant to the growth or progression of a pediatric cancer.

Pediatric exclusivity is another type of nonpatent regulatory exclusivity for drugs and biologics in the United States and, if granted, provides for the attachment of an additional six months of marketing protection to the term of any existing nonpatent regulatory exclusivity, including orphan drug exclusivity. This six-month exclusivity may be granted if pediatric data is submitted that sufficiently responds to a written request from the FDA for such data. The data do not need to show a product to be effective in the pediatric population studied; rather, if the clinical trial is deemed to be responsive to the FDA's request, the additional protection is granted. If reports of requested pediatric studies are submitted to and accepted by the FDA within the statutory time limits, whatever statutory periods of exclusivity that cover the product are extended by six months.

Biosimilars and Exclusivity

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 ("Affordable Care Act") includes a subtitle called the Biologics Price Competition and Innovation Act of 2009 ("BPCIA"), which created an abbreviated approval pathway for biologics that are biosimilar to or interchangeable with an FDA-licensed reference biologic in the United States. Starting in 2015, the FDA commenced licensing biosimilars under the BPCIA, and there are currently numerous biosimilars approved in the United States as well as a number of interchangeable biosimilar products.

For the FDA to approve a biosimilar product, it must find that there are no clinically meaningful differences between the reference product and proposed biosimilar product in terms of safety, purity, and potency in at least one condition of use for which the reference product is approved. For the FDA to approve a biosimilar product as interchangeable with a reference product, the agency must find that the biosimilar product can be expected to produce the same clinical results as the reference product, and, for products administered multiple times, that the biologic and the reference biologic 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 biologic. Even after the FDA approves a biosimilar product, the product, its manufacturing processes, post-approval clinical data, labeling, advertising, and promotional activities for the product will be subject to continuous requirements of and review by the FDA or other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, including mandatory post-marketing safety reporting; registration and listing requirements; cGMP requirements relating to quality control, quality assurance, and corresponding maintenance of records and documents; and requirements regarding recordkeeping.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date of first licensure of the reference product. "First licensure" typically means the initial date the particular product at issue was licensed in the United States. The FDA may not approve a biosimilar product until 12 years from first licensure of the reference product. The FDA does not assign a date of first licensure or award a new period of exclusivity for a biologic if the licensure is for a supplement for the biologic or for a subsequent application by the same sponsor or manufacturer (or licensor, predecessor in interest, or other related entity) of the biologic for a change that results in a new indication, route of administration, dosing schedule, dosing form, delivery system, delivery device or strength, or for a modification to the structure of the biologic that does not result in a change in safety, purity, or potency. Even if a product is considered to be a reference product eligible for exclusivity, another company could market a competing version of that product if the FDA approves a full BLA for such product containing our own nonclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity, and potency of the product.

Patent Term Extension

A patent claiming a new biologic may be eligible for a limited PTE under the Hatch-Waxman Amendments, which permits a patent restoration of up to five years for patent term lost during product development and FDA regulatory review. The restoration period granted on a patent covering a product is typically 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 ultimate approval date, less any time during which due diligence was not conducted. PTE cannot be used to extend the remaining term of a patent past a total of 14 years from the product's regulatory approval date. Pursuant to 35 U.S.C. § 156, only one patent covering an approved product, or the use or manufacture thereof, is eligible for PTE, and the application for the extension must be submitted prior to the expiration of the patent in question and within 60 calendar days after regulatory approval. The patent, even if it covers multiple products for which approval is sought, can be extended only once. The USPTO reviews and approves the application for any PTE in consultation with the FDA. Similar provisions are available in Europe and other jurisdictions to extend the term of a patent that covers an approved biologic although the eligibility requirements for these extensions vary.

Regulation and Procedures Governing Approval of Medicinal Products in Other Countries

In order to market any product outside of the United States, we must also comply with numerous and comprehensive regulatory requirements of other countries and jurisdictions, regarding quality, safety, and efficacy, and governing, among other things, clinical trials, marketing authorization, post-authorization requirements, commercial sales, import and export, reimbursement, and distribution of products. Whether or not we obtain FDA approval for our product candidates, we will need to obtain the necessary approvals from health regulatory authorities in other countries or jurisdictions before we can initiate clinical trials or marketing of our products in those countries or jurisdictions. Specifically, the process governing approval of medicinal products in the EU generally follows the same lines as in the United States, although the approval of a medicinal product in the United States is no guarantee of approval of the same product in the EU, either at all or within the same timeframe as approval may be granted in the United States. The process entails satisfactory completion of nonclinical studies and adequate and well-controlled clinical trials to establish the safety and efficacy of a product candidate for each proposed indication. It also requires the submission to the EMA or the relevant member state competent authorities, of a marketing authorization application and granting of a marketing authorization by the EMA or these authorities before the product can be marketed and sold in the EU.

U.S. Export Control Licensing Requirements and Other U.S. and Foreign Trade Regulations, Sanctions Laws, Anti-Corruption, and Anti-Money Laundering Laws

We develop product candidates that may be subject to varying U.S. export control licensing requirements and foreign investment regulations. In addition, U.S. international trade laws, including the U.S. Foreign Corrupt Practices Act of 1977, as amended ("FCPA"), and similar anti-bribery or anti-corruption laws, regulations, and rules of other countries in which we may choose to operate, could apply to our international activities. Anti-corruption laws generally prohibit companies and their employees and certain other third parties from authorizing, promising, offering, or providing, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector in order to influence action. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the company and to devise and maintain an adequate system of internal accounting controls.

In addition, U.S. import and export regulations, anti-money laundering laws, and various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls could apply to any international activities we may undertake.

Coverage, Pricing, and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we may obtain regulatory approval by the FDA or other government authorities. In the United States and other countries, patients who are prescribed treatments for their conditions and providers performing the prescribed services often rely on third-party payors to reimburse all or part of the associated healthcare costs. Patients are unlikely to use any products we may develop unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products. In addition, direct or indirect governmental price regulation may affect the prices that we may charge for our products.

United States

Even if any product candidates we may develop obtain regulatory approval, sales of such products will depend, in part, on the extent to which third-party payors, including government healthcare programs in the United States, such as Medicare and Medicaid, commercial health insurers, and managed care organizations provide coverage and establish adequate reimbursement levels for such products.

In general, factors payors consider in determining coverage and reimbursement are based on whether the product is:

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

In the United States, no uniform policy of coverage and reimbursement for biologics, including cell and gene therapy products, exists among third-party payors. As a result, obtaining coverage and reimbursement approval for such a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide to each payor supporting scientific, clinical, and cost-effectiveness data regarding the product's clinical benefits, medical necessity, and risks on a payor-by-payor basis, and we cannot provide any assurance that coverage and adequate reimbursement will be obtained. A decision by a third-party payor not to cover any product candidates we may develop could reduce physician utilization of such product candidates once approved and have a material adverse effect on our sales, results of operations and financial condition. Additionally, a payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved, and inadequate reimbursement rates, including significant patient cost sharing obligations, may deter patients from selecting our products. One payor's determination to provide coverage for a product does not ensure that other payors will also provide coverage and reimbursement for the product, and the level of coverage and reimbursement can differ significantly from payor to payor. 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 marketing approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

European Union

In the EU, the approval process and requirements governing pricing and reimbursement for any product candidate vary greatly between countries and jurisdictions. Some countries allow biologics to be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional testing or studies that compare the cost effectiveness of a particular biologic to currently available treatments, or so-called health technology assessments, in order to obtain reimbursement or pricing approval. The EU HTA Regulation 2021/2282 became effective in January 2022, is applicable from January 2025 with a phased implementation until 2030, and aims to harmonize clinical and scientific aspects of HTA across the EU.

Some countries, including several EU member states, set prices and reimbursement for biologics, with limited participation from the marketing authorization holders. For example, the EU provides options for its member states to restrict the range of biologics for which their national health insurance systems provide reimbursement and to control the prices of biologics for human use. EU member states may approve a specific price for a biologic or may instead adopt a system of direct or indirect controls on the profitability of the company providing the biologic. Many European countries have increased the level of discounting required in relation to the pricing of biologics and these efforts could continue as countries attempt to manage healthcare expenditures.

Healthcare Law and Regulation

Healthcare providers and third-party payors play a primary role in the recommendation and prescription of pharmaceutical products that are granted marketing approval. Arrangements with providers, consultants, third-party payors, customers, and patients are subject to broadly applicable fraud and abuse laws including anti-kickback laws, false claims laws, and health care provider payment transparency laws, as well as data privacy and security laws and other healthcare laws that may constrain our business and/or financial arrangements. Violation of these laws may result in significant civil monetary penalties, possible exclusion from participation in U.S. federal health care programs, and/or criminal penalties. The current administration has signaled that in 2026 healthcare providers and suppliers can expect to see an increase in enforcement efforts based on these laws.

Restrictions under applicable U.S. federal and state healthcare laws and regulations, as well as equivalent international laws, include but are not limited to the following:

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

- the U.S. civil and criminal false claims laws, including the civil U.S. False Claims Act, and civil monetary penalties laws, which prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false, fictitious, or fraudulent or knowingly making, using, or causing to be made or used a false record or statement to avoid, decrease, or conceal an obligation to pay money to the federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the AKS or FDA promotional standards constitutes a false or fraudulent claim for purposes of the U.S. False Claims Act;

- the U.S. Beneficiary Inducement Statute, which prohibits, among other things, the offering or giving of remuneration, which includes, without limitation, any transfer of items or services for free or for less than fair market value, with limited exceptions, to a Medicare or Medicaid beneficiary that the person knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of items or services reimbursable by a federal or state health program;

- the U.S. Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH"), and their respective implementing regulations (collectively "HIPAA"), which imposes criminal and civil liability for knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private payors, or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services;

- HIPAA also imposes obligations with respect to safeguarding the privacy, security, and transmission of individually identifiable information that constitutes protected health information, including mandatory contractual terms and restrictions on the use and/or disclosure of such information without proper authorization;

- the federal transparency requirements known as the U.S. Physician Payments Sunshine Act, or Open Payments program, created under the Affordable Care Act, which requires certain manufacturers of drugs, devices, biologics, and medical supplies to report annually to the Centers for Medicare & Medicaid Services ("CMS") information related to payments, including certain product development activities such as clinical trials, and other transfers of value made by that entity to covered recipients, currently defined to include doctors, dentists, optometrists, podiatrists, chiropractors, teaching hospitals, physician assistants, nurse practitioners, and certain other healthcare providers and requires certain manufacturers and applicable group purchasing organizations to report ownership and investment interests held by physicians or their immediate family members;

- U.S. price reporting laws, which require companies to calculate and report complex pricing metrics in an accurate and timely manner to government programs. Such laws may not only affect coverage, reimbursement, and pricing for our products, but can also result in civil penalties for late or incorrect reports;

- U.S. consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;

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

- certain state and other laws that require pharmaceutical companies to comply with the state standards or pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. government in addition to requiring pharmaceutical manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures;

- certain state and other laws that govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts; and

- analogous state and foreign laws and regulations, which may be broader in scope than their federal equivalents.

Numerous federal and state laws and regulations, including federal health information privacy laws, state data breach notification laws, state health information privacy laws and federal and state consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), that govern the collection, use, disclosure, and protection of health-related and other personal information could apply to our operations or the operations of our collaborators and third-party providers. In December 2023, the U.S. Department of Health and Human Services ("HHS") finalized its Health Data, Technology and Interoperability rule, establishing new standards for transparency, information exchange, and interoperability for health information technology. On February 25, 2025, the current administration issued an executive order requiring HHS to issue guidance and otherwise enforce regulations requiring meaningful price transparency and standardized, required disclosures aimed to allow patients to make well-informed healthcare decisions. California has enacted the California Consumer Privacy Act ("CCPA"). The CCPA gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing and receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. Additionally, the California Privacy Rights Act amended the CCPA to impose additional data protection obligations on companies doing business in California, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, opt outs for certain uses of sensitive data, and creation of a new California data protection agency authorized to issue substantive regulations. The majority of the provisions went into effect on January 1, 2023, and additional compliance investment and potential business process changes may be required. In the United States, states are constantly amending existing laws, requiring attention to frequently changing regulatory requirements.

Healthcare Reform

In the United States, there have been, and continue to be, proposals by the federal government, state governments, regulators and third-party payors to control or manage the increased costs of health care and, more generally, to reform the U.S. healthcare system. The pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. For example, in March 2010, the Affordable Care Act ("ACA") was enacted, which intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms, substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacts the U.S. pharmaceutical industry. Healthcare reforms that have been adopted, and that may be adopted in the future, could result in further reductions in coverage and levels of reimbursement for pharmaceutical products, increases in rebates payable under U.S. government rebate programs and additional downward pressure on pharmaceutical product prices.

There has been increasing legislative and enforcement interest in the United States with respect to drug and biologic pricing practices since the ACA was enacted. Several healthcare reform initiatives culminated in the enactment of the Inflation Reduction Act (the "IRA") in 2022, which, among other things, eliminated, beginning in 2025, the coverage gap under Medicare Part D by significantly lowering the enrollee maximum out-of-pocket costs and requiring manufacturers to subsidize, through a newly established manufacturer discount program, 10% of Part D enrollees' prescription costs for brand drugs and biologics below the out-of-pocket limit, and 20% once the out-of-pocket limit has been reached. The IRA also requires HHS to directly negotiate the selling price of a statutorily specified number of drugs and biologics each year that CMS reimburses under Medicare Part B and Part D. The negotiated price may not exceed a statutory ceiling price. Only high-expenditure single-source biologics that have been approved for at least 11 years (seven years for single-source drugs) are eligible to be selected by CMS for negotiation, with the negotiated price taking effect two years after the selection year. For 2026, the first year in which negotiated prices become effective, CMS selected 10 high-cost Medicare Part D products in 2023, negotiations began in 2024, and the negotiated maximum fair price for each product has been announced. These negotiations resulted in significant price reductions for the products from their 2023 list prices, ranging from 38% to 79%, with an average price reduction of 59.4%. In addition, CMS selected and announced the negotiated maximum fair price for 15 additional Medicare Part D drugs, which will become effective in 2027. For 2028, CMS has selected an additional 15 drugs, comprised of drugs covered under Medicare Part D and, for the first time, drugs payable under Medicare Part B. For 2029 and subsequent years, 20 Part B or D drugs will be selected. The negotiated prices have represented, and will continue to represent, a significant discount from average prices to wholesalers and direct purchasers. Currently, a drug or biologic that has an orphan drug designation for only one rare disease or condition will be excluded from the IRA's price negotiation requirements, but will lose that exclusion if it receives designations for more than one rare disease or condition, or if is approved for an indication that is not within that single designated rare disease or condition, unless such additional designation or such disqualifying approvals are withdrawn by the time CMS evaluates the drug for selection for negotiation. However, as a result of a statutory amendment enacted in July 2025, beginning with the 2028 negotiated price applicability year, a drug or biologic may be designated for more than one rare disease or condition and still be excluded from price negotiation, as long as the only approved indications are for such rare diseases or conditions. The IRA also imposes rebates on Medicare Part B and Part D drugs whose prices have increased at a rate greater than the rate of inflation, and, in 2024, CMS finalized regulations for the Medicare Part B and Part D inflation rebates. The IRA permits the Secretary of HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. Manufacturers that fail to comply with the IRA may be subject to various penalties, including civil monetary penalties.

These provisions may be subject to legal challenges. For example, the provisions related to the negotiation of selling prices of high-expenditure single-source drugs and biologics have been challenged in multiple lawsuits brought by pharmaceutical manufacturers. The outcome of these lawsuits is uncertain, and some IRA drug discount provisions have not been challenged in litigation. Thus, while it is unclear how the IRA will be implemented, it will likely have a significant impact on the pharmaceutical industry and the pricing of products. It is unclear what policies will be advanced with respect to IRA implementation and other drug pricing proposals.

In May 2025, the administration published an executive order regarding most favored nation ("MFN") drug pricing, which is sometimes referred to as "international reference pricing." This executive order directs the Secretary of HHS to communicate MFN price targets to pharmaceutical manufacturers and, if significant progress toward MFN pricing is not delivered, to propose a rulemaking plan to implement MFN pricing. Recently, on December 23, 2025, CMS issued proposed regulations to establish, under the Center for Medicare and Medicaid Innovation, two mandatory MFN pricing demonstration models under Medicare Part B and Part D. If these rules or other MFN pricing rules are finalized, they are likely to mandate reduced pricing of at least some of the drugs and biologics in the United States if they are also sold in comparator countries.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access, and marketing cost disclosure and transparency measures, and in some cases, designed to encourage importation from other countries and bulk purchasing.

Additional Regulations

In addition to the foregoing, state and federal laws regarding environmental protection and hazardous substances, including the U.S. Occupational Safety and Health Act, the U.S. Resource Conservancy and Recovery Act, and the U.S. Toxic Substances Control Act, all affect our business. These and other state and local 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.

Employee and Human Capital Resources

Workforce Demographics

As of February 27, 2026, we had 97 total employees, all of whom were full-time. The majority of our employees are located in Berkeley, California. Our employees are not represented by labor unions or covered by collective bargaining agreements. We believe that our employee morale is healthy and consider our relationship with our employees to be good; however, in July 2024 and in April 2025, we announced workforce reductions, which may have negatively impacted our relationship with employees.

Talent Acquisition, Development, and Total Rewards

We recognize that attracting, developing, and retaining talent at all levels is vital to our continued success. We have implemented a comprehensive talent strategy that motivates our employees to perform to the best of their abilities and to achieve our objectives. We are committed to providing a competitive and comprehensive total rewards program that includes market-aligned salaries, performance-based incentives, long-term equity grants, and comprehensive benefits, including health and wellness programs, retirement savings plan (401k), an employee stock purchase plan (ESPP), and paid time off. We invest in employee learning and development by identifying and providing training and development programs, tuition reimbursement, and cross-training in areas of interest beyond hired roles. Employees have access to ongoing learning opportunities to enhance their skills and advance their careers.

We understand the importance of goal setting and ongoing career development conversations. We require our managers and employees to play an active role in the performance management process. Our performance management process is designed to increase clarity and accountability for roles and responsibilities, strengthen communication, and build trust, all while championing personal and professional growth, learning, and success.

Great teamwork is a critical foundation for Caribou. Our peer-to-peer rewards and recognition program helps us maintain a culture of recognition and teamwork by offering various options for our employees and managers to recognize and reward colleagues across the organization. We plan to continue to refine our efforts related to optimizing our use of human capital, including improvements in the way we hire, develop, reward, and retain employees.

The Herd at Caribou

Our employees are our greatest asset, and we aim to create an inclusive and collaborative environment with the overall goal of engaging our workforce to support our current clinical product candidates and future business goals, while protecting the long-term interests of our stockholders. Our culture is built around our core values: we are driven by patient need, innovation is in our chRDNA, together we are stronger, and integrity and ethics guide our decision making. We have built a culture where employees are empowered, their ideas are taken seriously, and their contributions are recognized.

We at Caribou refer to ourselves as “the herd.” We encourage and value social interactions among the herd. We hold bi-monthly herd meetings in a hybrid on-site/videoconferencing format and periodically have all-employee on-site events to strengthen our culture, such as participating in San Francisco Bay clean-up events. We strive to build a culture that is driven by our mission to develop innovative, transformative therapies through novel genome editing for patients with devastating diseases.

We regularly conduct engagement surveys and use the feedback to enhance our workplace culture. Our well-being initiatives include mental health resources and flexible work arrangements to support our employees' overall health and productivity. We have established a culture advisory group comprised of cross-functional representatives from various geographic locations. Based on feedback from our culture advisory group, along with the results of employee surveys, we have focused on highlighting how our daily work connects to our corporate values, connecting teams to other functions, helping employees understand how decisions that impact them or their roles are made, ensuring leadership accessibility, and engaging our employees across multiple communication channels.

We expect all employees to observe the highest levels of business ethics while delivering the highest levels of performance. We encourage employees to speak up and raise questions and concerns promptly about any situation that may violate our Code of Business Conduct, Scientific and Data Integrity, and Ethics or any other corporate policy. We believe that it is beneficial for employees to raise concerns so that we may consider them carefully and address them appropriately. We seek to promote an environment that fosters honest communications about matters of conduct related to our business activities, whether that conduct occurs within our company or involves one of our third-party suppliers, service providers, or collaborators. We work diligently to make clear that management is prepared to address any reported violations and to ensure that it is known that any form of retaliation is prohibited. In addition, we have an easily accessible hotline available to employees wishing to report complaints anonymously.

Involvement in Our Community

Our headquarters are located in Berkeley, California, and many of our employees are alumni of local universities. Our employees are talented and passionate people who are committed to making a difference in our community and beyond. We provide each of our employees with eight hours of paid volunteer time each year, which can be used for participating in school activities, voter registrations, environmental activities, and the like. We strive to mitigate our impact on the environment where possible and pursue innovative ways to minimize our environmental footprint. The City of Berkeley requires companies with 10 or more employees to have a commuter benefits program in place, and we offer pre-tax commuter benefits to ride public transportation. Additionally, we provide bicycle vouchers to employees who bike to work and have bike repair tools on site as well as bike storage areas. Our employees have access to electric vehicle charging stations.

Workforce Health and Safety

Workplace safety is a priority for us. To maintain a safe and healthy workplace, we have implemented Environment, Health, and Safety ("EHS") initiatives that focus on key risk mitigation programs to identify, assess, and correct hazards. We also have a safety training program that is designed for employees to be assigned the appropriate training to understand how to safely perform their duties.

Information Available on the Internet

Investors and others should note that we announce material information to our investors using our investor relations website (cariboubio.com), our filings with the U.S. Securities and Exchange Commission ("SEC"), press releases, public conference calls, and webcasts. We use these channels to communicate with the public about our company, our business, our product candidates and other matters. Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, including exhibits, proxy and information statements and amendments to those reports filed or furnished pursuant to Sections 13(a) and 15(d) of the Exchange Act, are available on our website free of charge as soon as reasonably practicable after we electronically file the material with, or furnish it to, the SEC. The materials we file with or furnish to the SEC are also available at www.sec.gov.

Item 1A. Risk Factors.

Investing in shares of our common stock involves a high degree of risk. You should carefully consider the following risks and uncertainties, together with all of the other information contained in this Annual Report on Form 10-K, including our financial statements and related notes, before making an investment decision. These disclosures reflect our beliefs and opinions as to factors that could materially and adversely affect our company and its securities in the future. References to past events are provided by way of example only and are not intended to be a complete listing or a representation as to whether or not such factors have occurred in the past or their likelihood of occurring in the future. Furthermore, the risks described below are not the only ones facing us. The occurrence of any of the following risks, or of additional risks and uncertainties not presently known to us or that we currently believe to be immaterial, could materially and adversely affect our business, financial condition, results of operations and prospects, and reputation. In such case, the trading price of shares of our common stock could decline, and you may lose all or part of your investment. 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 a number of factors, including the risks described below. See Special Note Regarding Forward-Looking Statements in this Annual Report on Form 10-K.

Risks Relating to our Financial Position and Need for Additional Capital

We have incurred significant operating losses since our inception and anticipate that we will incur continued operating losses for the foreseeable future and we may not be able to achieve or sustain profitability.

We have incurred significant operating losses each year since our inception. For the years ended December 31, 2025, and 2024, we incurred net losses of $148.1 million and $149.1 million, respectively. As of December 31, 2025, we had an accumulated deficit of $596.5 million. In addition, we have not commercialized any products and have never generated any revenue from product sales. We have devoted almost all of our financial resources to research and development, including our preclinical and clinical development activities.

We expect to continue to incur significant expenses and operating losses over the next several years and for the foreseeable future as we seek to advance product candidates through clinical development, and seek regulatory approval and, if we receive approval from the FDA or foreign regulatory authorities, commercialize our products. Furthermore, the costs of advancing product candidates into each succeeding clinical phase with greater number of patients increase substantially over time and, if we advance vispa-cel into our planned pivotal clinical trial, we will incur significant expenses running a large, multicenter trial in the United States and foreign jurisdictions. The total costs to advance any of our product candidates to marketing approval in even a single jurisdiction is substantial. Our prior losses, combined with expected future losses, will continue to have an adverse effect on our stockholders' deficit and working capital. We anticipate that our expenses will increase substantially if and as we:

- progress our clinical trials for our vispa-cel and CB-011 product candidates, particularly as we advance our vispa-cel product candidate in our planned pivotal clinical trial;
- hire additional employees, as needed;
- acquire or in-license intellectual property, new technologies, and/or additional product candidates;
- expand, maintain, enforce, and defend our intellectual property estate;
- seek regulatory and marketing approvals for our vispa-cel or CB-011 product candidates if they successfully complete clinical trials;
- expand manufacturing capabilities and supply chain capacity for our vispa-cel and CB-011 product candidates;
- experience any delays, challenges or other issues associated with any of the above, including the failure of clinical trials meeting endpoints, the generation of clinical trial data subject to differing interpretations, or the occurrence of potential safety issues or other development or regulatory challenges;
- make royalty, milestone, or other payments under current, and any future, in-license or assignment agreements;
- establish a sales, marketing, and distribution infrastructure to commercialize any product candidates for which we obtain marketing approval; and

- continue to operate as a public company, including defending against any future securities class action litigation.

We are unable to predict the extent of any future losses or when we will become profitable, if at all. Even if we do become profitable, we may not be able to sustain or increase our profitability on a quarterly or annual basis.

We will need substantial additional financing to conduct our planned pivotal clinical trial for vispa-cel and to implement our operating plans. If we fail to obtain additional financing, we will be unable to complete the development and commercialization of our vispa-cel and/or CB-011 product candidates.

We will continue to need additional capital beyond the proceeds received from our initial public offering ("IPO"), follow-on public financing, at-the-market equity offering program, and other historical sources of proceeds. Because our allogeneic cell therapy product candidates are based on new technologies, they require extensive development. The costs to treat patients with our product candidates in clinical trials are significant. We expect to spend a substantial amount of capital in the clinical development and manufacture of our product candidates, particularly as we advance our CAR-T cell therapy product candidates through succeeding clinical phases with greater numbers of patients. We currently do not have sufficient funds to conduct our planned pivotal clinical trial for vispa-cel, and we will need to raise additional funds in order to do so. If we are unable to raise additional financing, we will be unable to initiate our planned pivotal clinical trial for vispa-cel or to develop CB-011 beyond dose expansion. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing, and distribution to the extent that we do not obtain commercialization partners who will bear the costs for such activities.

As of December 31, 2025, we had cash, cash equivalents, and marketable securities of $142.8 million. We expect our cash, cash equivalents, and marketable securities to be sufficient to fund our current operating plan through at least the next 12 months from the date our consolidated financial statements included in this Annual Report on Form 10-K are filed. Our expectation is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect.

Our future capital requirements will depend on, and could increase significantly as a result of, many factors, including:

- costs, progress, and results of clinical trials for our vispa-cel and CB-011 product candidates;
- potential delays in our clinical trials, whether current or planned, due to unforeseen events as well as other factors such as the economic or regulatory environment or pandemics or other public health crises;
- potential difficulties and delays in receiving regulatory clearances and/or approvals for our product candidates;
- costs to acquire or in-license technologies or other product candidates;
- expansion of our workforce or our facilities;
- costs of establishing and maintaining a supply chain for the development and manufacture of our product candidates;
- timing and outcome of regulatory review of our product candidates;
- our ability to establish and maintain collaborations on favorable terms;
- costs of fulfilling our contractual obligations to reimburse certain parties for costs incurred in connection with the prosecution and maintenance of licensed patent rights, including reimbursements owed to The Regents of the University of California;
- achievement of milestones that trigger payments under any of our current license and assignment agreements as well as under any additional agreements we enter into in the future;
- costs of preparing, filing, prosecuting, and maintaining our patent portfolio, including costs associated with administrative proceedings of patent offices;
- litigation costs in the event we seek to enforce our patents against third parties or if we are sued for infringement by third parties as well as for securities lawsuits;

- effects of competing technologies, success or failure of products similar to our product candidates, and market developments;
- costs of establishing or contracting for sales and marketing capabilities if we obtain regulatory approvals to market our product candidates; and
- costs of operating as a public company, including defending against any future class action securities litigation.

Changing circumstances may cause us to consume capital significantly faster than we currently anticipate, and we may need to spend more money than expected because of circumstances beyond our control. We may also need to raise additional capital sooner if we choose to expand programs, personnel, and facilities more rapidly than planned. In any event, we will require additional capital for the further development and commercialization of our product candidates, including potentially establishing our own internal manufacturing capabilities. Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates.

We cannot be certain that additional funding will be available when needed and on acceptable terms, or at all. If we are unable to obtain funding on a timely basis, we may be required to significantly delay initiation, curtail, or discontinue one or more of our product candidate clinical trials, or development and commercialization, or we may be unable to expand our operations or otherwise capitalize on our business opportunities, as desired. Any of the above could significantly harm our business, financial condition, results of operations, and prospects and cause the price of our common stock to decline.

Raising additional capital may cause dilution to our stockholders, restrict our operations, and/or require us to relinquish rights to our genome-editing technologies or product candidates.

Until such time, if ever, that we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings (including our at-the-market equity offering program), debt financings, new strategic collaborations, structured or other non-dilutive financings, licensing arrangements, and/or other sources. The terms of any financing may adversely affect the holdings or the rights of our stockholders and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our common stock to decline. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, licensing or assigning our intellectual property rights, declaring dividends, and possibly other restrictions.

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 and existing investors may be substantially diluted by those issuances and sales. The terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders and new investors could gain rights superior to those of our existing investors.

If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce, or terminate our product development or future commercialization efforts. Alternatively, we could be required to seek funding for our product candidates through collaborations or structured or other non-dilutive financings at an earlier stage than would otherwise be desirable or on terms that are less favorable than might otherwise be available. We might need to relinquish or license on unfavorable terms our rights to our product candidates in markets where we otherwise would seek to pursue development and commercialization ourselves, or to license our intellectual property to others who could develop products that will compete with our products. Any of these actions could have a material adverse effect on our business, financial condition, results of operations, and prospects.

We have a limited operating history, which may make it difficult to evaluate our technologies and product candidate development capabilities or to predict our future performance.

We are a clinical-stage biotechnology company formed in 2011, with no products approved for commercial sale, and we have not generated any revenues from product sales. Our operations to date have been limited to financing and staffing our company, developing our technologies, and evaluating our CAR-T cell therapy product candidates in phase 1 clinical trials. Our prospects must be considered in light of the uncertainties, risks, expenses, and difficulties frequently encountered by companies in their early stages of operations. We have not yet demonstrated an ability to obtain marketing approval, manufacture at commercial scale, or conduct sales and marketing activities for our product candidates, which are all necessary for successful product commercialization. Consequently, predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing cell therapy products. Our ability to generate product revenue or profits, which we do not expect to occur for many years, if ever, will depend heavily on the successful development and eventual commercialization of our product candidates. Unless we receive approval from the FDA or other regulatory authorities for our product candidates, we will not have product revenues. We may never be able to develop or commercialize a marketable cell therapy product.

We are early in our product development efforts. All of our programs will require clinical development, regulatory approval, manufacturing at commercial scale, distribution channels, a commercial organization, significant marketing efforts, and substantial investment before we generate any revenue from product sales. In addition, our product candidates must be approved for marketing by the FDA before we may commercialize our products in the United States and, if we wish to commercialize our products outside the United States, by foreign regulatory agencies.

Additionally, the rapidly evolving nature of the genome-editing and cell therapy fields may make it difficult to evaluate our technologies and product candidates as well as to predict our future performance. Our 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, known and unknown, that are frequently experienced by early-stage companies in rapidly evolving fields. As we advance our product candidates, we must continue to transition from a company with a research focus to a company capable of supporting clinical development and, if successful, commercial activities. We may not be successful in such transitions. If we do not address these risks successfully, our business will suffer. Similarly, we expect that our financial condition and operating results may fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. As a result, you should not rely upon the results of any quarterly or annual period as an indicator of future operating performance.

Risks Relating to our Business, Government Regulation, Technology, and Industry

Our CAR-T cell therapy product candidates are in clinical development and it will be many years before we commercialize a product candidate, if ever. If we are unable to advance our product candidates through clinical trials, obtain regulatory approval, and ultimately commercialize our product candidates, or if we experience significant delays in doing so, our business will be materially harmed.

We initially focused our research and development efforts on various CRISPR genome-editing technologies, including our chRDNA genome-editing technology, as well as identifying and developing our CAR-T cell product candidates. Our future success depends heavily on the successful clinical development of our vispa-cel and CB-011 product candidates. Our ability to generate product revenue, which we do not expect will occur for many years, if ever, will be a result of the successful development and eventual commercialization of these product candidates, which may never occur. These product candidates may have expected or unexpected adverse side effects or fail to demonstrate safety and efficacy. In certain cases, CROs and clinical trial sites may fail to conduct the clinical trials as planned, may fail to comply with applicable requirements, or may deviate from the clinical trial protocols. Furthermore, our vispa-cel and/or CB-011 product candidates may not receive regulatory approval or, if they do, they may not be accepted by the medical community or patients or may not be competitive with other products that become available. We currently have no product revenue and we may never be able to successfully develop or commercialize a marketable product.

We must submit an IND application to the FDA to initiate clinical trials in the United States. The filing of any future INDs for product candidates we may develop will be subject to nonclinical research, research-scale and clinical-scale manufacturing, exploration of possible other genome-editing systems, evaluation of potential targets, and other factors yet to be identified. In addition, commencing any new clinical trial is subject to review by the FDA based on the acceptability and sufficiency of our CMC, and nonclinical information provided to support our INDs. If the FDA or foreign regulatory authorities require us to complete additional nonclinical studies or we are required to satisfy other requests for additional data or information, our clinical trials may be delayed. Even after we receive and incorporate guidance from the FDA or foreign regulatory authorities, these regulatory authorities could disagree that we have satisfied all requirements to initiate our clinical trials or they may change their position on the acceptability of our trial design or the clinical endpoints selected. They could impose a clinical hold, which may require us to complete additional nonclinical studies or clinical trials. The FDA and foreign regulatory authorities may refuse to clear our INDs. The success of our product candidates will depend on several factors, including the following:

- sufficiency of our financial and other resources;
- acceptance of our chRDNA genome-editing technology;
- ability to develop and deploy armoring technologies so that our product candidates have a competitive edge;
- successful completion of any additional nonclinical studies;
- clearance of INDs to initiate clinical trials;
- successful enrollment in, and completion of, our clinical trials;
- data from our clinical trials that support an acceptable risk-benefit profile of our product candidates for our intended patient populations and indications and demonstrate acceptable safety and efficacy;
- establishment of agreements with CMOs for clinical and commercial supplies and scaling up of manufacturing processes and capabilities to support our clinical trials;
- successful development of our internal process development and transfer to larger-scale facilities;
- receipt of regulatory and marketing approvals from applicable regulatory authorities as well as receipt of nonpatent regulatory exclusivity for our product candidates;
- establishment, maintenance, enforcement, and defense of patent and trade secret protection and other intellectual property rights;
- not infringing, misappropriating, or otherwise violating third-party intellectual property rights;
- entry into collaborations to further the development of our product candidates or for the development of new product candidates;
- establishment of sales, marketing, and distribution capabilities for commercialization of our product candidates if approved, whether by us or in collaboration with third parties;
- identification and establishment of a stable supply chain that permits us to procure the necessary materials for our product candidates;
- legal and regulatory compliance by third parties that provide services to us or on our behalf, including but not limited to CMOs, suppliers, and contract research organizations (“CROs”), some of which may be subject to regulatory investigations;
- the ability of CROs and clinical trial sites to conduct our clinical trials;
- maintenance of a continued acceptable safety profile of products post-approval;
- acceptance of product candidates, if approved, by patients, the medical community, and third-party payors;
- effective competition with other therapies and treatment options, including but not limited to autologous CAR-T cell therapies, small molecules, and antibody treatment;

- establishment and maintenance of healthcare coverage and adequate reimbursement; and
- expanding indications and patient populations for our products post-approval.

Our product candidates are cell therapies generated by our novel CRISPR chRDNA genome-editing technology, which makes it difficult to predict the time and cost of developing these product candidates and obtaining regulatory approval. To date, no other products that use these chRDNA genome-editing technology have advanced into clinical trials or received marketing approval in the United States.

We are concentrating our development and manufacturing efforts on our allogeneic CAR-T cell therapies that are intended to treat patients with certain cancers. Before obtaining regulatory approval for the commercial sale of any of our product candidates, we must demonstrate through lengthy, complex, and expensive nonclinical studies and clinical trials that our product candidates are both safe and effective for their intended use. The clinical trial requirements of the FDA and other regulatory authorities, and the criteria these regulators use to determine the safety and efficacy of a product candidate, vary substantially according to the type, complexity, novelty, intended use, and target population of our product candidates. The outcome of nonclinical studies and clinical trials is inherently uncertain. Nonclinical results in animals may not be predictive of safety or efficacy in humans. Failure can occur at any time during the nonclinical study and clinical trial processes and because we have never successfully commercialized a product and our first product candidate is in an early stage of clinical development, there is a high risk of failure. We may never succeed in developing marketable products.

Approval processes by the FDA or other regulatory authorities for existing autologous anti-CD19 and anti-BCMA CAR-T cell therapies may not be indicative of what these regulatory authorities will require for approval of our allogeneic anti-CD19 CAR-T cell therapy or our other product candidates. Also, although we expect reduced variability in our allogeneic products candidates compared to autologous products, we do not have any clinical data supporting benefits of lower variability, and the use of healthy donor material may create separate variability challenges for us. Moreover, our product candidates may not perform successfully in clinical trials or may be associated with serious adverse events ("SAEs") that distinguish them from the autologous anti-CD19 and anti-BCMA CAR-T therapies that have previously been approved. For instance, allogeneic product candidates may result in GvHD, which is not experienced with autologous products. GvHD results when allogeneic T cells see the patient's normal tissue as foreign and attack and damage those cells. Even if we collect promising initial clinical data for our product candidates, longer-term data may reveal adverse events or responses that are not durable. Negative clinical outcomes would significantly impact our business.

In addition, approved autologous CAR-T therapies and those under development have shown frequent rates of cytokine release syndrome, neurotoxicity, serious infections, prolonged cytopenia, hypogammaglobulinemia, and other SAEs that have resulted in patient death. There may be similar adverse events for our allogeneic CAR-T cell therapy product candidates, including patient death. Moreover, patients eligible for allogeneic CAR-T cell therapies but ineligible for autologous CAR-T cell therapies due to aggressive cancer or an inability to wait for autologous CAR-T cell therapies may be at greater risk for complications and death from therapy. Our allogeneic CAR-T cell product candidates may also cause unique adverse events related to the differences between the donor and patients, such as GvHD or infusion reactions. Our product candidates may not be successful in limiting the risk of GvHD, exhaustion of the CAR-T cells, or premature rejection by a patient's immune system. If significant GvHD or other SAEs are observed with the administration of our product candidates, or if any of our product candidates are viewed as less safe or effective than autologous therapies or other allogeneic therapies, our ability to develop other allogeneic therapies may be adversely affected.

We use our CRISPR chRDNA genome-editing technology to generate our product candidates, and we believe our chRDNA guides significantly improve the specificity of CRISPR genome editing (e.g., by reducing the number of off-target events). CRISPR genome editing generally is relatively new; to date, only one cell therapy product using CRISPR-Cas9 genome editing has been approved in the United States although clinical trials of additional product candidates based on CRISPR-Cas9 and other genome-editing technologies are underway. As a result, the regulatory approval process for cell therapy product candidates such as ours is uncertain and may be more expensive and take longer than the approval process for product candidates based on better known or more extensively studied technologies. As such, it is difficult to accurately predict the developmental challenges we may face as we progress our product candidates through clinical trials. There may be long-term adverse effects from treatment with our product candidates resulting from the use of our chRDNA genome-editing technology that we cannot predict with the knowledge we have today. Also, animal models may not exist for some of the diseases we choose to pursue in the future, which may complicate and increase the cost of nonclinical research. As a result of these factors, it is difficult for us to predict the time and cost of our product candidate development, and we cannot predict whether the application of our chRDNA technology, or other genome-editing technologies we may use in the future, will result in the identification, development, nonclinical studies, and clinical trials to support regulatory approval of any future cell therapy product candidates. We cannot provide any assurance that any development problems we experience in the future related to our chRDNA technology will not cause significant delays or unanticipated costs, or that such development problems can be solved. We may not achieve the desired safety and efficacy of our product candidates. Also, we may not sufficiently improve genome-editing specificity and our genome editing may have off-target events. Moreover, we may not be able to achieve a high degree of on-target gene knockout and insertion efficiency in developing our product candidates. Any of these factors may prevent us from completing our clinical trials, delay or cause us to fail to meet our clinical trial endpoints, or lead us to fail to commercialize any of our cell therapy product candidates.

We may also experience delays in developing robust, reproducible, and scalable manufacturing processes and transferring those processes to CMOs, which may prevent us from completing our clinical trials or commercializing our products on a timely or profitable basis, if at all. Currently, we have only manufactured our CAR-T cell therapy product candidates for clinical trials.

Manufacturing our product candidates is complex and we could experience manufacturing problems during our clinical trials, which could delay or limit development and/or commercialization of our product candidates.

The manufacturing processes used to produce our cell therapy product candidates are complex, as our product candidates are new biologics. Several factors could cause production interruptions including facility contaminations; shortages or quality problems; contamination of healthy donor cells, chRDNA guides, Cas9 and Cas12a proteins, AAV6 viruses, and other materials used in the manufacturing of our product candidates; natural disasters, including pandemics and other public health crises; labor shortages and strikes; lack or loss of experienced clinical, quality control, process development, and manufacturing personnel; human error; or other disruptions in the operations of our suppliers and CMOs. We conduct process development activities at our facilities and we may experience personnel and supply shortages. Problems with our manufacturing process, even minor deviations from the normal process, could result in product defects or manufacturing failures that result in lot failures, product recalls, product liability claims, or insufficient inventory. We may encounter problems achieving adequate quantities and quality of clinical grade materials that meet FDA or other applicable standards or specifications with consistent and acceptable production yields and costs.

As our product candidates proceed through clinical trials to regulatory review, and potential marketing approval and commercialization, it is common that various aspects of our manufacturing methods will be altered along the way to optimize processes and results. Such changes carry the risk that intended objectives will not be achieved. If we make any such changes, our product candidates could perform differently and affect the results of clinical trials conducted with the altered materials. Such changes may also require additional testing as well as notification to or approval from the FDA or other regulatory authorities, which could delay completion of our clinical trials, require bridging clinical trials, require repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates, if any, and ultimately jeopardize commercialization.

If we receive marketing approval for a product candidate, the FDA and other regulatory authorities may require us to submit samples of any lot of any approved product together with the protocols showing the results of applicable tests at any time. Under some circumstances, the FDA or other regulatory authorities may require that we not distribute a lot until the relevant agency authorizes its release. Slight deviations in the manufacturing process, including those affecting quality attributes and stability, may result in unacceptable changes in the product that could result in lot failures or product recalls. Problems in our manufacturing processes could restrict our ability to meet market demand for our products. All these factors could be costly to us and otherwise harm our business, financial condition, results of operations, and prospects.

Our business is highly dependent on the success of our product candidates, which will require significant additional human clinical trials before we can seek regulatory approval and potentially commercialize our product candidates. If we are unable to advance our clinical trials and obtain regulatory approval for, and successfully commercialize, our product candidates for the treatment of patients in approved indications, or if we are substantially delayed in doing so, our business will be materially harmed.

Our business and future success depends on our ability to advance our product candidates through clinical trials, obtain regulatory approval for, and successfully commercialize, our product candidates. The failure of our product candidates in clinical trials, or the failure of other companies' allogeneic anti-CD19 CAR-T and allogeneic anti-BCMA CAR-T cell therapies, including for reasons due to safety, efficacy, or the durability of response, may impede our ability to develop our CAR-T cell therapy programs and product candidates and may significantly influence physicians' and regulatory authorities' opinions with regard to the viability of our allogeneic cell therapies, which could substantially impair our ability to commercialize our product candidates.

We are not currently researching and developing additional product candidates; if we choose to do so in the future, we may not be successful in our efforts to identify and successfully research and develop additional product candidates.

In the future, we may choose to identify and develop new product candidates, either internally or through acquisition from, or a partnership with, a third party. The process by which we identify product candidates may fail to yield successful product candidates for a number of reasons, including:

- we may not be able to assemble sufficient resources to identify or acquire additional product candidates;
- competitors may develop alternative therapies that render new product candidates obsolete or less attractive;
- product candidates we develop or acquire may be covered by third-party intellectual property rights;
- new product candidates may, on further study, be shown to have adverse side effects, toxicities, or other characteristics that indicate that they are unlikely to receive marketing approval or achieve market acceptance;
- new product candidates may not be safe or effective;
- the market for a new product candidate may change so that the continued development of that product candidate is no longer reasonable; and
- we may not be able to produce new product candidates in commercial quantities at an acceptable cost, or at all.

We have limited financial and managerial resources. We are currently focused on two allogeneic CAR-T cell therapy product candidates and, 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. Our resource allocation decisions may cause us to fail to timely capitalize on viable commercial products or profitable market opportunities. Our spending on current product candidates may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing, or structured or other non-dilutive financings when it would have been more advantageous for us to retain sole development and commercialization rights to that product candidate.

In the event that we are unable to continue to fund the clinical development of one or both of our product candidates, and/or if one or both of our clinical-stage product candidates is not clinically successful, does not receive regulatory approval, and/or is not commercially competitive, we currently do not have a research pipeline from which to generate new product candidates.

On July 16, 2024, we announced that we had discontinued preclinical research activities associated with our allogeneic CAR-NK platform and reduced our workforce by 21 positions, or approximately 12% of our workforce, primarily in the research group and, on April 24, 2025, we announced a strategic pipeline prioritization, including reduction of our workforce by 47 positions, or approximately 32% of our workforce, primarily in the preclinical research group. Additionally, as part of the strategic pipeline prioritization announced in April 2025, we disclosed that we had discontinued our AMpLify phase 1 clinical trial of CB-012. In the event that we are unable to continue to fund the clinical development of our vispa-cel and/or CB-011 product candidates, and/or one or both of our clinical-stage product candidates are not clinically successful, do not receive regulatory approval, and/or are not commercially competitive, we do not have any product candidates other than vispa-cel and CB-011 to advance into the clinic. Additionally, we do not currently have a scientific workforce to research and develop such new product candidates, and we would need to either reestablish a preclinical research and development workforce to internally develop additional product candidates or acquire one or more new product candidates from a third party, both of which would be time-consuming and costly. We cannot provide any assurance that we would be able to research and develop new product candidates, or acquire such new product candidates from a third party.

If we experience delays or difficulties enrolling patients in the clinical trials for our product candidates, our ability to advance our product candidates through clinical development and the regulatory process could be delayed or prevented.

The timely completion of clinical trials depends, among other things, on our ability to enroll a sufficient number of patients who remain in the trial until its conclusion. We may encounter delays in enrolling or be unable to enroll a sufficient number of patients to complete any of our clinical trials and, even if patients are enrolled, they may withdraw from our clinical trials before completion. For our current clinical trials, we have entered into contracts with CROs, as well as clinical trial agreements with the sites participating in our clinical trials. Patient selection and enrollment may be challenging; additionally, the protocols for our clinical trials specifically exclude patients with certain prior treatments as well as other conditions. Additionally, even after the FDA clears an IND for one of our product candidates, our clinical trials may not commence immediately if we are negotiating clinical trial agreements with clinical sites, conducting site initiation visits, or waiting for the sites to receive IRB approval. Due to competition from other clinical trials within the same therapeutic area at clinical sites, sites may drop out or take longer to start up and enroll trials. Thus, we may not treat the first patient in a clinical trials for several months, or even for a year, after IND clearance.

Our current and future clinical trials, will compete for enrollment of patients with other clinical trials for product candidates that are in the same cell therapeutic areas with the same or similar study populations as our product candidates. Our clinical trials will also compete for enrollment of patients with other clinical trials for product candidates based on non-cellular modalities, such as small molecules and antibodies, that are intended for the same or similar study populations as our product candidates. This competition will reduce the number and types of patients available to us because some patients who might opt to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Additionally, since the number of qualified and experienced clinical investigators for therapeutic areas is limited, some of our clinical trial sites may be also conducting clinical trials for some of our competitors, which may reduce the number of patients who are available for our clinical trials at that clinical trial site.

Our allogeneic CAR-T cell therapy product candidates can be administered not only in academic centers of excellence but also in community hospital settings; however, recruitment of community sites for participation in the trial may be challenging due to hesitancy to adopt a CAR-T cell therapy in a center that has not previously administered this type of therapy or to administer our clinical trial protocol. Moreover, because our product candidates represent a departure from more commonly used methods for cancer treatment, potential patients and their doctors may be inclined to use conventional therapies, such as chemotherapy, HSC transplantation, or autologous CAR-T cell therapies, rather than refer patients to our clinical trials. Additionally, because our cell therapy product candidates are edited with CRISPR chRDNA guides, our products may be perceived to have additional or greater safety risks. Patients eligible for allogeneic CAR-T cell therapies but ineligible for autologous CAR-T cell therapies may be difficult to treat due to advanced and aggressive cancers and may fail to experience improved outcomes and be at greater risk for complications and death from our product candidates. If patients are unwilling to participate in our cell therapy trials, the timeline for recruiting patients, conducting clinical trials, and obtaining regulatory approval of any of our product candidates may be delayed.

In addition, the enrollment of patients depends on many factors, including:

- severity or stage of the type of cancer under investigation;
- size of the patient population and process for identifying patients;
- design of the clinical trial protocol;
- regulatory hold on clinical trial recruitment because of unexpected safety events;
- availability of eligible prospective patients who are otherwise eligible patients for competitive clinical trials;
- availability and efficacy of approved alternative treatments for the disease under investigation;
- ability to obtain and maintain patient consent;
- risk that enrolled patients will drop out before completion of the trial;
- eligibility and exclusion criteria for the trial in question;
- perceived risks and benefits of our product candidates;
- perceived risks and benefits of genome-editing and cell therapies;
- perceived risks and benefits of participating in a clinical trial;
- efforts by clinical sites and investigators to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians;
- proximity and availability of clinical trial sites for prospective patients; and
- interruptions, delays, or staffing shortages resulting from pandemics or other public health crises.

Enrollment delays in our clinical trials may result in increased development costs for any product candidates we may develop, which may cause our stock price to decline and limit our ability to obtain additional financing. If we have difficulty enrolling a sufficient number of patients to conduct our clinical trials as planned, we may need to delay, limit, or terminate our current clinical trials, or future clinical trials, and postpone or forgo seeking marketing approval, any of which would have an adverse effect on our business, financial condition, results of operations, and prospects.

Clinical trials are expensive, time-consuming, and subject to uncertainty. Our clinical trials may not be conducted as planned or completed on schedule, if at all completed. Issues may arise that could suspend or terminate our clinical trials. A failure of one or more of our clinical trials may occur at any stage of testing, and our future clinical trials may not be successful.

Events that may prevent successful or timely completion of clinical development include:

- the FDA or comparable foreign regulatory authorities disagreeing as to the design or implementation of our clinical trials;
- delays or failure to obtain regulatory clearance to initiate our clinical trials, as well as delays or failures to obtain any necessary approvals by the clinical sites;
- delays, suspension, or termination of our clinical trials by the clinical sites;
- modification of clinical trial protocols;
- delays in reaching agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites, as well as possible future breaches of such agreements;
- failure to manufacture sufficient quantities of our product candidates for use in our clinical trials;

- failure by CMOs, suppliers, CROs, or clinical trial sites to comply with regulatory requirements and clinical trial protocols or to meet their contractual obligations to us in a timely manner, or at all;
- imposition of a temporary or permanent partial or full clinical hold by us, IRBs for the institutions at which such trials are being conducted, or by the FDA or other regulatory authorities for safety or other reasons, such as a result of a new safety finding in a clinical trial on a similar product by one of our competitors, that presents unreasonable risk to clinical trial participants;
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols;
- changes in the standard of care on which we developed our clinical development plan, which may require new or additional trials;
- the cost of clinical trials of our product candidates being greater than we anticipated;
- insufficient funding to continue clinical trials with our product candidates;
- the emergence of unforeseen safety issues or undesirable side effects;
- 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 development of our product candidates;
- inability to establish clinical trial endpoints that applicable regulatory authorities consider clinically meaningful, or, if we seek accelerated approval, that applicable regulatory authorities consider reasonably likely to predict clinical benefit;
- regulators withdrawing their approval of a product or imposing restrictions on its distribution; and
- interruptions, delays, or staffing shortages resulting from pandemics or other public health crises.

If (i) we are required to extend the duration of any clinical trials or to conduct additional nonclinical studies or clinical trials or other testing of our product candidates beyond those that we currently contemplate; (ii) we are unable to successfully complete additional nonclinical studies or clinical trials of our product candidates or other testing; (iii) the results of these trials, studies, or tests are negative or produce inconclusive results; (iv) there are safety concerns; or (v) we determine that the observed safety or efficacy profile would not be competitive in the marketplace, we may:

- abandon the development of one or more product candidates;
- incur unplanned costs;
- be delayed in obtaining marketing approval for our product candidates or not obtain marketing approval at all;
- obtain marketing approval in some jurisdictions and not in others;
- obtain marketing approval for indications or patient populations that are not as broad as we intended or designed;
- obtain marketing approval with labeling that includes significant use restrictions or safety warnings, including boxed warnings;
- be subject to additional post-marketing requirements; or
- have regulatory agencies remove the product from the market or we voluntarily withdraw the product from the market after obtaining marketing approval.

Our clinical trials may fail to adequately demonstrate the safety and efficacy of any of our product candidates and, if this happens, the development of our product candidates may be delayed or unsuccessful, which could prevent or delay regulatory approval and commercialization.

Our product candidates are in various stages of clinical development. If we encounter safety or efficacy problems in our ongoing or future studies, our developmental plans and business could be materially harmed. Product candidates in later stages of clinical trials may fail to show the desired safety profiles and efficacy results despite having progressed through initial clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of sufficient efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Based upon negative or inconclusive results, we may decide, or regulatory agencies may require us, to conduct additional clinical trials or nonclinical studies. In addition, data obtained from clinical trials are susceptible to varying interpretations, and regulatory agencies may not interpret our data as favorably as we do, which may delay, limit, or prevent regulatory approval. The design of a clinical trial can determine whether its results will support approval of our product candidates, and flaws in the design of a clinical trial may not be apparent until the clinical trial is well advanced. We have limited experience designing clinical trials and may be unable to design and execute a clinical trial that will support regulatory approval.

From time to time, we may publish initial, interim, or preliminary data from our clinical trials. Initial, interim, or preliminary data from clinical trials are subject to the risk that one or more of the clinical outcomes may materially and adversely change as patient enrollment continues, and additional and long-term patient data become available, including data respect to efficacy, duration of response, and/or safety. Additional clinical data may not support or may contradict the findings of the initial, interim, or preliminary data reported earlier. Initial, interim, or preliminary clinical trial data may be based on a limited number of patients and are subject to the risk that they will not ultimately be predictive of the safety and/or efficacy of the final product candidate. 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 evaluate all data at the time of publishing initial, interim, or preliminary data. These data also remain subject to audit and verification procedures that may result in the final data being materially different from the data we previously published. The information that we choose to disclose publicly regarding nonclinical studies or clinical trials is typically a summary of extensive information, and others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities, or otherwise regarding a particular product candidate or our product candidates generally. As a result, initial, interim, and preliminary data should be viewed with caution until the final data are available. Moreover, initial, interim, and preliminary data are subject to the risk that one or more of the clinical outcomes may materially and adversely change as more patient data become available when patients mature on study, dose levels change, patient enrollment continues, or, for final data, as other ongoing or future clinical trials with a product candidate further develop. Past results of clinical trials may not be predictive of future results. Unfavorable differences between initial, interim, or preliminary data and final data could significantly harm our business prospects and may cause the trading price of our common stock to decline significantly.

Because of these risks, our product candidates may fail or encounter difficulties in clinical trials. If we are unable to advance our product candidates through clinical trials to seek marketing approval, our business, financial condition, results of operations, and prospects will be materially harmed.

If our product candidates cause serious adverse events or undesirable side effects, including injury and death, or have other properties that could delay or prevent regulatory approval, our product candidates could have limited or no commercial potential.

Product candidates we develop may be associated with undesirable or unacceptable side effects, unexpected characteristics, or other SAEs, including death. Immunotherapy, and its method of action of harnessing the immune system, is powerful and could lead to serious side effects that we only discover in clinical trials. In addition to potential SAEs from the immune system or side effects caused by our product candidates currently in clinical trials, or any product candidate we may develop and advance into one or more clinical trials, the product candidate administration process and related procedures may also cause undesirable side effects. Patients who enroll in our current clinical trial undergo a lymphodepletion regimen, including administration of fludarabine and cyclophosphamide, which can lead to SAEs. Because these regimens will cause a transient and sometimes prolonged blood count suppression, patients have an increased risk of leukopenia, anemia, thrombocytopenia bleeding, or infection, which could ultimately lead to death. Although we educate clinical site personnel administering our cell therapy product candidates to understand the side effect profiles for our product candidates, inadequate recognition or management of the potential side effects of our product candidates could result in patient injury or death. If any undesirable or unacceptable side effects, unexpected characteristics, or other SAEs occur, our clinical trials could be suspended or terminated, and our business and reputation could suffer substantial harm.

We cannot provide any assurance that we will resolve any adverse event concerns related to any of our products to the satisfaction of the FDA or any regulatory agency in a timely manner or at all. If we are unable to demonstrate that such adverse events were caused by factors other than our product candidates, the FDA or other regulatory authorities could order us to cease further clinical trials of, or deny approval of, our product candidates. Even if we demonstrate that such SAEs are not product candidate-related, such occurrences could affect patient recruitment or the ability of enrolled patients to complete our clinical trials. Moreover, if we elect, or are required, to delay, suspend, or terminate any clinical trial of any of our product candidates, the commercial prospects of such product candidates may be harmed and our ability to generate product revenues from these product candidates may be delayed or eliminated. Any of these occurrences may harm our business, financial condition, results of operations, and prospects.

The FDA or other regulatory agencies may disagree with our regulatory plans and we may fail to obtain regulatory approval of our CAR-T cell therapy product candidates.

Although the FDA has found substantial evidence of effectiveness to support approval outside of the traditional phase 1, phase 2, and phase 3 framework for the approved autologous anti-CD19 and anti-BCMA CAR-T cell therapies, the general approach for FDA approval of a new biologic is for the sponsor to provide dispositive data from adequate and well-controlled clinical trials of the relevant biologic in the applicable patient population. Such clinical trials typically involve hundreds of patients, have significant costs, and take years to complete. We are in ongoing engagement with the FDA regarding the design of our pivotal trial for vispa-cel; however, we cannot provide any assurance that our proposed pivotal trial design will ultimately meet FDA requirements and/or recommendations or lead to regulatory approval. For example, in the event that the FDA requires us to conduct clinical trials with more patients than planned and/or to conduct clinical trials with designs or endpoints other than those we currently anticipate, we may not have the funding to enlarge or conduct such trials and we may not be able to raise sufficient funding to do so, which could delay or prevent commercialization of our product candidates. Additionally, the FDA may change its views and/or issue new guidance on aspects of clinical programs, including clinical trial designs, or the ability of trials as designed to support approval of a product candidate. Furthermore, we may experience changes in FDA personnel that alter the FDA's advice with respect to the development strategy of our vispa-cel and/or CB-011 product candidate. Changes in FDA leadership, personnel, policies, priorities, and regulations have affected our industry and may affect our product candidates. For example, FDA policies and practices concerning cell and gene therapies may change in a way that disparately impacts our product candidates. Additionally, decreases in FDA staff could lead to increases in newly hired, inexperienced staff with less expertise relevant in our industry and with our product candidates, which may negatively impact the review of our product candidate regulatory submissions and/or approval of our product candidates. If we are unable to effectively and efficiently resolve and comply with the inquiries and requests of the FDA or other comparable international regulatory authorities, the approval of our product candidates may be delayed, which would impact future commercialization of our product candidates.

In addition, the standard of care may change with the approval of new products in the same indications to which our cell therapy product candidates are directed. This may result in the FDA or other regulatory authorities requesting additional studies to show that our product candidate is comparable or superior to the new products.

Our clinical trial results may also not support marketing approval. In addition, our product candidates could fail to receive regulatory approval for many reasons, including:

- the FDA or other 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 or other regulatory authorities that our product candidates are safe and effective for their proposed indications;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or other regulatory authorities for approval, including due to heterogeneity of patient populations;
- we may be unable to demonstrate that the clinical and other benefits of our product candidates outweigh the safety risks;
- the data collected from clinical trials of our product candidates may not be sufficient to the satisfaction of the FDA or other regulatory authorities to support the submission of a BLA or a similar filing in a foreign jurisdiction or to support commercial reimbursement or reimbursement under publicly-funded health systems;
- new information or data indicating safety concerns with CAR-T cell therapies may result in the FDA or other regulatory authorities declining to approve or requiring additional clinical data for our product candidates;
- the FDA or other authorities will review our manufacturing processes and inspect our CMOs' facilities and may not approve our manufacturing processes or CMOs' facilities; and
- the approval policies or regulations of the FDA or other regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

Even if we comply with all FDA requests and requirements, we may still fail to obtain regulatory approval. We cannot be sure that we will ever obtain regulatory clearance for our product candidates. Failure to obtain FDA approval of our product candidates will severely undermine our business by leaving us without a commercially marketable product in the United States, and therefore without any source of revenues from product sales in the United States, until another product candidate can be developed or obtained and ultimately approved.

Changes at the FDA may hinder the agency's ability to hire and retain key leadership and other personnel, slow the time necessary for new product candidates to be reviewed and/or approved, or otherwise prevent these agencies from performing normal business functions on which our operations rely, which would adversely affect our business.

There continues to be substantial uncertainty regarding the requirements and policies of the FDA and other regulatory agencies with jurisdiction over our product candidates. We are reliant on regulators having the resources necessary to evaluate and approve our product candidates. Changes at the FDA may slow the time necessary for our product candidates to be reviewed and/or approved, which would adversely affect our business. For example, starting in January 2025, the current administration has reduced the number of federal employees, including those at the FDA, by establishing voluntary termination programs, position eliminations, or involuntary terminations. Decreases in FDA staffing could result in delays in the FDA's responsiveness or in its ability to review submissions or applications, issue regulations or guidance, or implement or enforce regulatory requirements in a timely fashion or at all. In the United States, there have been recent federal government shutdowns that halted the work of many federal agencies and their employees. For example, over the last several years, the U.S. government has shut down several times, and certain regulatory agencies, such as the FDA, had to furlough critical employees and stop critical activities. Any extended government shutdown or significant reductions of, or changes to, staffing and resources available to government agencies could result in reductions or delays of FDA's activities, including with respect to our ongoing clinical trials, the manufacturing of our product candidates, and regulatory review and approvals for our product candidates. There is currently substantial volatility and uncertainty surrounding the role and activities of federal regulatory agencies and their future, including potential workforce reductions. Although it is impossible to predict what governmental changes may occur, the impending uncertainty could present new challenges or potential opportunities as we navigate the clinical development and approval process for our product candidates. Any delay in obtaining, or inability to obtain, applicable regulatory approvals would delay or prevent commercialization of our products.

Even if we complete the necessary clinical trials, the regulatory approval process is expensive, time-consuming, and uncertain, and we may be unable to obtain the regulatory approvals necessary for the commercialization of our product candidates; furthermore, if there are delays in obtaining regulatory approvals, we may not be able to commercialize our products, may lose competitive lead time, and our ability to generate revenues will be materially impaired.

The process of obtaining marketing approvals, both in the United States and in other jurisdictions, is expensive, may take many years, 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. It is impossible to predict if or when any of our product candidates will prove to be safe and effective in humans or if we will receive regulatory approval for such product candidates. The risk of failure through the development process is high. Any product candidates we may develop, and the activities associated with their development and commercialization, including their manufacture, nonclinical and clinical development, safety, efficacy, recordkeeping, labeling, storage, advertising, promotion, sale, and distribution, are subject to comprehensive regulation by the FDA and other regulatory authorities.

Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate in a given jurisdiction. We have not received approval or authorization to market any 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 marketing approval or commercialization. We have not previously submitted a BLA to the FDA or made a similar submission to any foreign regulatory authority. A BLA must include extensive nonclinical and clinical data and supporting information to establish our product candidate's safety and efficacy for each desired indication. A BLA must also include significant information regarding the chemistry, manufacturing, and controls for our product. Any product candidates we develop 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 FDA and other regulatory authorities have substantial discretion in the approval process and may refuse to accept our BLA applications and decide that our data are insufficient and require additional nonclinical studies or clinical trials. The same may happen with review of our product candidates by foreign regulatory authorities. In addition, varying interpretations of the data obtained from nonclinical studies and clinical trials could delay, limit, or prevent marketing approval of our product candidates. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render our approved product not commercially viable. If we experience delays in obtaining approval or if we fail to obtain approval of any product candidates we may develop, the commercial prospects for those product candidates and our ability to generate revenues will be materially impaired and we may lose competitive lead time as similar products enter the market.

We expect the innovative nature of our product candidates to create further challenges in obtaining regulatory approval. For example, the FDA has limited experience with the development of allogeneic T cell therapies for cancer and other diseases. We may also request regulatory approval of future CAR-T cell therapy product candidates by target, regardless of cancer type or origin, which the FDA may have difficulty accepting if our clinical trials have only involved cancers of certain types or origins. The FDA may also require a panel of experts, referred to as an Advisory Committee, to deliberate on the adequacy of the safety and efficacy data. The opinion of an Advisory Committee, although not binding, may have a significant impact on our ability to obtain marketing approval of our product candidates based on our completed clinical trials, as the FDA often adheres to an Advisory Committee's recommendations. Accordingly, the regulatory approval pathway for our product candidates may be uncertain, complex, expensive, and lengthy, and approval may not be obtained.

The regulatory landscape that will govern our product candidates is uncertain; regulations relating to more established gene therapy and cell therapy products are still developing, and changes in regulatory requirements could result in delays or discontinuation of development of our product candidates or unexpected costs in obtaining regulatory approval.

Because we are developing CAR-T cell therapy product candidates that are unique biological entities, the regulatory requirements to which we will be subject 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. Gene therapy clinical trials are also subject to additional review and oversight by an IBC. Although the FDA decides whether individual gene therapy protocols may proceed, review processes and determinations of other reviewing bodies can impede or delay the initiation of a clinical trial, even if the FDA has reviewed the study and cleared its initiation. Conversely, the FDA can place an IND on clinical hold even if such other entities have provided a favorable review. In addition, regulatory agencies, including the FDA, develop and issue guidance documents with which we, in practice, must comply, even if the agencies state that the documents only represent the current thinking of the agencies and are not binding. These documents may provide additional guidance and recommendations regarding the testing, design, development, and manufacturing of cell therapy products. Failure to comply with such regulatory agency guidance could delay or prevent regulatory approval of our product candidates. The content of such guidance documents may change in the future, which could add to the cost, time, and resources that are required for completion of additional nonclinical studies, clinical trials, or regulatory approvals.

In June 2024, in *Loper Bright Enterprises v. Raimondo*, U.S. Supreme Court overruled the 1984 *Chevron USA v. National Resources Defense Council* doctrine, which gave deference to regulatory agencies' statutory interpretations in litigation against federal government agencies, such as the FDA, where the law is ambiguous. This landmark *Loper* decision may invite various stakeholders to bring lawsuits against the FDA to challenge longstanding decisions and policies of the FDA, including the FDA's statutory interpretations of market exclusivities and the "substantial evidence" requirements for regulatory approvals, which could undermine the FDA's authority, lead to uncertainty in the industry, and disrupt the FDA's normal operations.

There is currently substantial uncertainty regarding governmental agencies, including the implementation of laws, regulations, policies, and guidance, and personnel. Such uncertainties could adversely affect our business.

Currently, there is general uncertainty regarding many government agencies, such as the SEC, USPTO, DOJ, Federal Trade Commission ("FTC"), and Internal Revenue Service ("IRS"), as well as the FDA. New executive orders, regulations, policies, or guidance could adversely affect us or create a more challenging or costly environment to conduct business and to pursue the development of our product candidates. Moreover, recent reductions to the budgets of the National Institutes of Health ("NIH") for medical research could negatively impact the ability of facilities that rely on NIH funding to enroll and conduct clinical trials or could increase the costs to us of conducting clinical trials on our product candidates. We could be negatively impacted by future governmental orders, regulations, policies, or guidance, which could have a material adverse effect on us and our business. Additionally, court challenges to these changes may delay certainty around such executive orders, regulations, policies, guidance, and workforce reductions, and different courts may issue conflicting rulings.

If we are required by the FDA to obtain approval of a companion diagnostic in connection with approval of any of our product candidates, and we do not obtain, or face delays in obtaining, FDA approval of the companion diagnostic, we will not be able to commercialize our product candidates.

According to FDA guidance, if the FDA determines that a companion diagnostic is essential to the safe and effective use of a therapeutic product or new product indication, the FDA generally will not approve the therapeutic product or new therapeutic product indication if the companion diagnostic is not also approved or cleared for that indication. Depending on the data from our clinical trials, we may decide to use a diagnostic for our clinical trial enrollment process to help identify patients with characteristics that we believe will be most likely to benefit from our product candidates. If a satisfactory companion diagnostic is not commercially available in this situation, we may be required to develop or obtain the rights to such diagnostic, which would be subject to regulatory approval requirements. The process of obtaining or developing such a diagnostic is time consuming and costly and we may not be able to either develop such a diagnostic or receive appropriate and timely regulatory approval. Furthermore, the classification, approval, or clearance of a companion diagnostic as part of the therapeutic product's further labeling limits the approved use of the therapeutic product to only those patients who fit the criteria and indications that are reviewed and authorized by FDA.

We may not receive additional designations for expedited programs, such as priority review, RMAT designation, breakthrough therapy designation, or fast track designation, by the FDA for our allogeneic CAR-T cell therapies.

We may continue to apply for certain expedited programs in the United States, such as RMAT, breakthrough therapy, fast track, or priority review programs. The FDA granted RMAT designation for our vispa-cel product candidate for r/r LBCL as well as fast track designation for r/r B-NHL. Additionally, the FDA granted fast track designation for our CB-011 product candidate in r/r MM. Although obtaining each of these designations has specific and different criteria, these designations are reserved for therapeutic products that are intended for serious diseases, and each designation offers certain benefits to expedite the development, review, and potential approval of such therapeutic option, which may include rolling reviews, intensive guidance, or approval based on surrogate endpoint or an intermediate clinical endpoint that is reasonably likely to predict the clinical benefit of a biologic. However, we cannot provide any assurance that we will be able to obtain such designations in the future and, even with expedited designation, we may ultimately fail to obtain FDA approval for our product candidates on an expedited basis or at all, or the approved indication may be narrower than the indication covered by the designation.

We may continue to seek orphan drug designation for our allogeneic CAR-T cell therapy product candidates across various indications, but we may not be able to obtain such designations or to maintain the benefits associated with orphan drug designation, including potential exclusivity, which may cause our revenue, if any, to be reduced.

We may submit applications to FDA for additional orphan drug designation for our allogeneic CAR-T cell therapy product candidates in specific orphan indications in which there is a medically plausible basis for the use of these products. Under the Orphan Drug Act, the FDA may designate a drug or biologic as an orphan drug if it is intended to treat a rare disease or condition, defined as a patient population of fewer than 200,000 in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug or biologic will be recovered from sales in the United States.

Although we received orphan drug designation from the FDA for our vispa-cel product candidate in FL and for our CB-011 product candidate in the treatment of r/r MM, we may not be able to obtain additional designations for other indications as the FDA may decline future requests if it determines that our product candidates and the proposed indications do not meet the criteria for the orphan drug designation. Even if we obtain additional orphan drug designations, we may not be the first company to obtain FDA approval of a product for the orphan drug indication, in which case exclusive marketing rights would not be available to us, and approval of our product candidate would be blocked until expiration of the first company's orphan drug exclusivity for the indication for which we are seeking approval, unless we demonstrate that our product is clinically superior to the licensed product. In addition, 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, we are unable to ensure 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.

Our allogeneic CAR-T cell therapy product candidates will be regulated as biologics, and therefore may be subject to uncertainty regarding nonpatent regulatory exclusivity or maintaining regulatory approval.

Under the BPCIA, the FDA has the authority to review and approve biosimilar biologics, including the possible designation of a biosimilar as "interchangeable" based on its similarity to an approved biologic. An application for a biosimilar product cannot be approved by the FDA until 12 years after its reference product was first licensed under a BLA. We believe that our product candidates, if approved, should qualify for the 12-year period of exclusivity. However, some uncertainty over interpretation of the law remains, and there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our product candidates eligible for reference product exclusivity, potentially creating the opportunity for biosimilar competition sooner than anticipated. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of the reference products in a way that is similar to traditional generic substitution for drug products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing. In addition, critics of the 12-year exclusivity period in the biosimilar pathway law may continue to seek to shorten the data exclusivity period and/or to encourage the FDA to interpret narrowly the law's provisions regarding which new products receive data exclusivity. If the FDA or Congress were to make changes to the 12-year exclusivity period, this could expose us to biosimilar competition at an earlier time. There also have been, and may continue to be, legislative and regulatory efforts to promote competition through policies enabling easier generic and biosimilar approval and commercialization, including efforts to lower standards for demonstrating biosimilarity or interchangeability, eliminate the standard for interchangeability and declare by law that all biosimilars are de facto interchangeable with their reference products, limit patents that may be litigated and/or patent settlements, implement preferential reimbursement policies for biosimilars, and pass new laws requiring more disclosure in the FDA's Purple Book.

Even if we obtain marketing approvals for our product candidates, the terms of such approvals and ongoing regulation of our products could require substantial expenditure of resources and may limit how we manufacture and market our products, which could materially impair our ability to generate revenues. Any product candidate for which we obtain marketing approval could be subject to restrictions or withdrawal from the market, and we may be subject to substantial penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our products, when and if any of them are approved.

Even if we receive marketing approval for a product candidate, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval or contain requirements for costly post-marketing testing and studies to further assess the safety or efficacy of the product. The FDA also may place other conditions on our approval, including the requirement for a REMS to ensure the safe use of the product by reinforcing medication use behaviors and actions. If the FDA concludes a REMS is needed, we must submit a proposed REMS before our product candidate will be eligible to receive marketing approval. A REMS could include medication guides, physician communication plans, or other elements to ensure safe use, such as restricted distribution methods, patient registries, and other risk minimization tools. Certain REMS programs can significantly impact and restrict the marketability of our products, even if our products are approved.

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. If we are slow to address or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, which would adversely affect our business, prospects, and ability to achieve or sustain profitability. Any government investigation of alleged violations of law, including investigations of any of our suppliers or CMOs, could require us to expend significant time and resources in response and could generate negative publicity. Accordingly, we will need to continue to expend time, money, and effort on regulatory compliance activities. If we are not able to comply with post-approval regulatory requirements, we could have the marketing approval for our products withdrawn by regulatory authorities and our ability to market such products could be limited, which could adversely affect our ability to achieve or sustain profitability. Furthermore, the cost of compliance with post-approval regulations, including REMS, may have a negative effect on our business, financial condition, results of operations, and prospects.

The FDA and other regulatory authorities closely regulate the post-approval marketing and promotion of biologics to ensure that they are marketed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA and other regulatory authorities impose stringent restrictions on off-label promotion, and if we market our products for unapproved indications, we may be subject to enforcement action for off-label marketing by the FDA and other federal and state enforcement agencies, including the DOJ. Violation of the FDCA and other statutes, including the federal False Claims Act, relating to the promotion and advertising of prescription products, may also lead to investigations or allegations of violations of federal and state healthcare fraud and abuse laws and state consumer protection laws.

In addition, later discovery of previously unknown problems with our products or the manufacturing of our products, may cause:

- restrictions on our products or the manufacturing of our products;
- restrictions on the labeling or marketing of our products;
- restrictions on the exportation, distribution, or use of our products;
- requirements to conduct post-marketing clinical trials;
- receipt of warning or untitled letters;
- withdrawal of our products from the market;
- refusal to approve pending BLAs or BLA supplements that we submit;
- recall of our products;
- fines, restitution, or disgorgement of profits or revenue;
- suspension or withdrawal of marketing approvals;
- suspension of any ongoing clinical trials;
- product seizure; and
- injunctions or the imposition of civil or criminal penalties.

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

We may never obtain approval to commercialize our product candidates outside the United States, which could limit our ability to recognize the full market potential of our product candidates and could materially impair our ability to generate revenues.

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

Following the United Kingdom ("UK")'s exit from the EU in 2020 (commonly referred to as "Brexit"), the EU and the UK entered into the EU-UK Trade and Cooperation Agreement, which was entered into force permanently on May 1, 2021. The agreement provides details on how some aspects of the relationship between the UK and the EU regarding pharmaceutical products will operate; however, there are still many uncertainties. Since the regulatory framework in the UK covering pharmaceutical products is derived from EU directives and regulations, Brexit could materially impact the future regulatory requirements for product candidates and products in the UK as there is now potential for the UK regulations to diverge from the EU regulations. In the meantime, the Medicines and Healthcare products Regulatory Agency ("MHRA"), the medicines and medical devices regulator in the UK, has published detailed guidance for industry and organizations to follow as of January 1, 2021, which is updated as necessary. A number of new marketing authorization routes have been introduced post-Brexit under the UK Human Medicines Regulations 2012 (SI 2012/1916) to allow for quick recognition of products that are approved in the EU and to allow greater flexibility in the UK procedures (such as a "rolling review" that permits the submission of an application in modules). Since January 1, 2024, the MHRA is applying its new International Recognition Procedure ("IRP") to medicines approved in other jurisdictions (including by the FDA and EMA) that meet certain criteria to undergo a fast-tracked MHRA review to obtain and/or update a marketing authorization in the UK. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, may force us to restrict or delay efforts to seek regulatory approval in the UK for our product candidates, which could harm our business.

Negative public opinion and increased regulatory scrutiny of genetic research and therapies involving genome editing may damage public perception of our product candidates generated through genome editing or adversely affect our ability to conduct our business or obtain regulatory approvals for our product candidates.

The CRISPR chRDNA genome-editing technology that we use is novel, and public perception may be influenced by claims that CRISPR genome editing is unsafe, and therapeutic products generated through CRISPR genome editing may not gain the acceptance of the public or the medical community. In particular, our success will depend upon physicians specializing in our targeted diseases prescribing our product candidates, if approved for marketing, as treatments in lieu of, or in addition to, existing, more familiar treatments for which greater clinical data may be available. Any increase in negative perceptions of genome editing may result in fewer physicians prescribing our treatments or may reduce the willingness of patients to accept our products. In addition, given the nature of genome-edited and CAR-T cell therapies in general, governments may place import, export, or other restrictions in order to retain control or limit the use of such technologies. Increased negative public opinion or more restrictive government regulations, either in the United States or internationally, could have a negative effect on our business or financial condition and may delay or impair the commercialization of our product candidates or demand for such products.

In particular, CRISPR genome-editing technology is subject to public debate and heightened regulatory scrutiny due to ethical concerns relating to the potential application of genome-editing technology to human embryos or the human germline. We do not apply genome-editing technologies to human embryos or the human germline. In April 2016, a group of scientists reported on their attempts to edit the genome of human embryos to modify the gene for hemoglobin beta. This is the gene in which a mutation occurs in patients with the inherited blood disorder beta thalassemia. Although this research was purposefully conducted in embryos that were not viable, the work prompted calls for a moratorium or other types of restrictions on genome editing of human eggs, sperm, and embryos. Additionally, in November 2018, a researcher at the Southern University of Science and Technology in Shenzhen, China, reportedly claimed they had created the first human genome-edited babies, which was subsequently confirmed by Chinese authorities and was negatively received by the public, in particular by those in the scientific community. In the wake of the claim, the World Health Organization established a new advisory committee to create global governance and oversight standards for human genome editing. In 2021, the advisory committee published literature that provides a framework and recommendations for human genome editing, including human germline genome editing, while advising that it is premature to proceed with clinical application of germline human genome editing. The Alliance for Regenerative Medicine in Washington, D.C. has called for a voluntary moratorium on the use of genome-editing technologies, including CRISPR, in research that involves altering human embryos or human germline cells and has also released a bioethical framework of principles for the use of genome editing in therapeutic applications endorsed by a number of companies that use genome-editing technologies. Similarly, the NIH has announced that it would not fund any use of genome-editing technologies in human embryos, noting that there are multiple existing legislative and regulatory prohibitions against such work, including the Dickey-Wicker Amendment, which prohibits the use of appropriated funds for the creation of human embryos for research purposes or for research in which human embryos are destroyed. Recently, however, the *Wall Street Journal* reported on at least three companies that are planning to genome edit human embryos, in apparent violation of such prohibitions.

Although we do not use our CRISPR chRDNA genome-editing technology to edit human embryos or the human germline, such public debate about the use of genome-editing technologies in human embryos and heightened regulatory scrutiny could prevent or delay our development of our product candidates and, if approved, the market acceptance of our products. More restrictive government regulations or negative public opinion would have a negative effect on our business or financial condition. Adverse events in our clinical trials or those of our competitors or of academic researchers utilizing genome-editing technologies, even if not ultimately attributable to product candidates we may identify and develop, and the resulting publicity, could result in increased governmental regulation, unfavorable public perception, potential regulatory delays in the testing or approval of our product candidates, stricter labeling requirements for those product candidates that are approved, and a decrease in demand for any such product candidates.

We currently have no marketing and sales organization and as a company have no experience in marketing products. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our product candidates, we may not be able to generate product revenue.

To achieve commercial success for any approved product for which we retain sales and marketing responsibilities, we must develop and build a sales and marketing team or make arrangements with third parties to perform these services. There are risks involved with both establishing our own sales and marketing capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force is expensive and time consuming and could delay our product launch. We will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train, and retain marketing and sales personnel. If the commercial launch of our product for which we have recruited a sales force and established marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses, which may be costly and our investment will be lost if we cannot retain or reposition our sales and marketing personnel.

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

- our inability to recruit, hire, train, and retain adequate numbers of effective sales, marketing, customer service, medical affairs, and other support personnel;
- our inability to equip sales personnel with effective materials, including sales literature, to help them educate physicians and other healthcare providers regarding our product candidates and their approved indications;
- our inability to effectively manage a geographically dispersed sales and marketing team;
- the inability of medical affairs personnel to negotiate arrangements for reimbursement and other acceptance by payors;
- the inability to price our products at a sufficient price point to ensure an adequate and attractive level of profitability; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

If we are unable or decide not to establish internal sales, marketing, and distribution capabilities, we will need to enter into arrangements with third parties to perform sales, marketing, and distribution services. In such cases, our product revenue or the profitability to us from these revenue streams is likely to be lower than if we were to market and sell any product candidates that we develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell and market our product candidates or may be unable to do so on terms that are favorable to us. We likely will have little control over those third parties and they may fail to devote the necessary resources and attention to sell and market our product candidates effectively. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we may not be successful in commercializing our product candidates, and our business, financial condition, results of operations, and prospects will be materially adversely affected.

Our products may not gain market acceptance among physicians, patients, hospitals, cancer treatment centers, and others in the medical community, which could significantly harm our business, financial condition, results of operations, and prospects.

The use of CAR-T as potential cancer treatments is a recent development and may not become broadly accepted by physicians, patients, hospitals, cancer treatment centers, and others in the medical community. Ethical, social, and legal concerns about genome editing could result in the development of additional regulations restricting or prohibiting our products. Even with the requisite approvals from the FDA and other regulatory authorities internationally, the commercial success of our product candidates will depend, in significant part, on the acceptance of physicians, patients, and healthcare payors of products generated through genome editing in general, and our allogeneic CAR-T cell therapy product candidates in particular, as medically necessary, cost-effective, safe, and effective therapies. We expect physicians in the large bone marrow transplant centers to be particularly important to the market acceptance of our allogeneic CAR-T cell therapy product candidates and we may not be able to adequately educate them on the benefits and risks associated with the use of our product candidates to address concerns and foster acceptance, for many reasons. For example, certain of the product candidates that we may develop target a cell surface marker that may be present on cancer cells as well as non-cancerous cells. It is possible that our product candidates may kill these non-cancerous cells, which may result in unacceptable side effects, including death.

Additional factors will influence whether our product candidates are accepted in the market, including:

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

If our product candidates are approved but fail to achieve market acceptance among physicians, patients, hospitals, cancer 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 cell therapy products, genome-editing technologies, or other therapeutic approaches are introduced that are more favorably received than our products, are more cost effective, or render our products obsolete.

The market opportunities for our product candidates may be smaller than we currently believe and limited to those patients who are ineligible for or have failed prior treatment, which may adversely affect our business. Because the target patient populations of our product candidates are small, we must be able to successfully identify patients and capture a significant market share to achieve profitability and growth.

Our projections of both the number of patients who have the cancers we are targeting, as well as the subset of patients with these cancers 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. New studies may change the estimated incidence or prevalence of these cancers. The number of eligible patients may turn out to be lower than we 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. Given the small number of patients who have the eligibility criteria and diseases that we are or will be targeting, it is critical to our ability to become profitable that we successfully identify such patients. The effort to identify patients with diseases we seek to treat is in early stages, and we cannot accurately predict the number of patients for whom treatment might be possible. Additionally, the potentially addressable patient population for each of our product candidates may be limited or may not be amenable to treatment with our product candidates, and new patients may become increasingly difficult to identify or gain access to, which would adversely affect our business, financial condition, results of operations, and prospects. Even if we obtain significant market share for our product candidates, because the potential target populations are small, we may never achieve profitability without obtaining regulatory approval for additional indications.

Even if we are able to commercialize our product candidates, such products may be subject to unfavorable pricing regulations, third-party reimbursement practices, or healthcare reform initiatives, which could harm our business.

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

Because our current product candidates represent new approaches to the treatment of cancer, we cannot accurately estimate the potential revenue from our product candidates. Significant uncertainty exists as to the coverage and reimbursement status of any of our products for which we obtain regulatory approval. In the United States, although private third-party payors tend to follow Medicare practices, no uniform or consistent policy of coverage and reimbursement for drugs and biologics exists among third-party payors. Therefore, coverage and reimbursement for drugs and biologics can differ significantly from payor to payor as well as from state to state. Consequently, the coverage determination process is often a time-consuming and costly process that must be played out across many jurisdictions and different entities and that will require us to provide scientific, clinical, and health economics support for the use of our products compared to current alternatives and do so to each payor separately, and we cannot provide any assurance that coverage and adequate reimbursement will be obtained and in what time frame. Additionally, reimbursement coverage may be more limited than the indications for which our products are approved. The marketability of our products may suffer if government and other third-party payors fail to provide coverage and adequate reimbursement. Furthermore, 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 of our product candidates for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Moreover, eligibility for reimbursement does not imply that our product candidates will be paid for in all cases or at a rate that will cover our costs, including research, development, manufacture, sale, and distribution. Interim reimbursement levels for new products, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of our product candidate and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost products, and may be incorporated into existing payments for other services. Net prices for our product candidates may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of products from countries where our product candidates may be sold at lower prices than in the United States.

Third-party payors, whether domestic or foreign, governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory changes to healthcare systems that could impact our ability to sell our product candidates, if approved, profitably. There have been, and likely will continue to be, legislative and regulatory proposals at the federal and state levels directed at broadening the availability of, and containing or lowering the cost of, healthcare.

The implementation of cost containment measures that third-party payors and healthcare providers are instituting and any other healthcare reforms may prevent us from being able to generate, or may reduce, our revenues from the sale of our product candidates, if approved, and our products may not be profitable. Such reforms could have an adverse effect on anticipated revenue from products for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop product candidates. Even if our product candidates are successful in clinical trials and receive marketing approval, we cannot provide any assurance that we will be able to obtain and maintain third-party payor coverage or adequate reimbursement for our products in whole or in part.

Healthcare and other reform measures could hinder or prevent the commercial success of our product candidates, if approved.

Existing regulatory policies may change, and additional government regulations may be enacted that could prevent, limit, or delay regulatory approval of any future product candidates we may develop, or affect pricing and third-party payment for our product candidates, which could negatively affect our business, financial condition and prospects. In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in 2010, the ACA was enacted to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for health care and health insurance industries, impose new taxes and fees on the health industry, and impose additional health policy reforms.

Additionally, there has been increasing legislative and enforcement interest in the United States with respect to pharmaceutical pricing practices since the ACA was enacted. Several healthcare reform initiatives culminated in the enactment of the IRA in 2022, which, among other things, eliminated, beginning in 2025, the coverage gap under Medicare Part D by significantly lowering the enrollee maximum out-of-pocket costs and requiring manufacturers to subsidize, through a newly established manufacturer discount program, 10% of Part D enrollees' prescription costs for brand drugs below the out-of-pocket limit, and 20% once the out-of-pocket limit has been reached. The IRA also requires HHS to directly negotiate the selling price of a statutorily specified number of drugs and biologics each year that CMS reimburses under Medicare Part B and Part D. The negotiated price may not exceed a statutory ceiling price. Only high-expenditure single-source biologics that have been approved for at least 11 years (seven years for single-source drugs) are eligible to be selected by CMS for negotiation, with the negotiated price taking effect two years after the selection year. For 2026, the first year in which negotiated prices become effective, CMS selected 10 high-cost Medicare Part D products in 2023, negotiations began in 2024, and the negotiated maximum fair price for each product has been announced. These negotiations resulted in significant price reductions for the products from their 2023 list prices, ranging from 38% to 79%, with an average price reduction of 59.4%. In addition, CMS has selected and announced the negotiated maximum fair price for 15 additional Medicare Part D drugs which will become effective in 2027 for negotiated maximum fair pricing in 2027. For 2028, CMS has selected an additional 15 drugs comprised of drugs covered under Medicare Part D and, for the first time, drugs payable under Medicare Part B. For 2029 and subsequent years, 20 Part B or D drugs will be selected. The negotiated prices have represented, and will continue to represent, a significant discount from average prices to wholesalers and direct purchasers. The IRA also imposes rebates on Medicare Part B and Part D drugs whose prices have increased at a rate greater than the rate of inflation, and in 2024, CMS finalized regulations for the Medicare Part B and Part D inflation rebates. The IRA permits the Secretary of HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. Manufacturers that fail to comply with the IRA may be subject to various penalties, including civil monetary penalties.

These provisions may be subject to legal challenges. For example, the provisions related to the negotiation of selling prices of high-expenditure single-source drugs and biologics have been challenged in multiple lawsuits brought by pharmaceutical manufacturers. Although full economic effect of the IRA on our business and the pharmaceutical industry in general is unknown at this time, it will likely have a significant impact on the pharmaceutical industry and the pricing of our product candidates, if approved. Similarly, the adoption of restrictive price controls in new jurisdictions, more restrictive controls in existing jurisdictions, or the failure to obtain or maintain timely or adequate pricing could also reduce our profitability. We expect pricing pressures will continue globally.

The current administration is pursuing policies to reduce regulations and expenditures across government including at HHS, which include the FDA and CMS, and related agencies. For example, on May 12, 2025, an executive order was issued that, among other things, required HHS, within 30 days, to establish and communicate to drug manufacturers MFN price targets designed to bring drug prices for American patients in line with those in comparably developed nations. If significant progress towards MFN pricing is not achieved, the executive order requires HHS to propose a rulemaking to implement MFN pricing. Recently, on December 23, 2025, CMS issued proposed regulations to establish, under the Center for Medicare and Medicaid Innovation, two mandatory MFN demonstration models under Medicare Parts B and D, respectively. If these rules or other MFN pricing rules are finalized, they are likely to reduce prices of at least some drugs in the United States, if they are also sold in comparator countries. Even if we do not market our products in such countries, we will be indirectly affected if our products compete with products whose prices were reduced as a result of MFN pricing initiatives.

At the state level, legislatures are increasingly enacting legislation and implementing regulations designed to control pharmaceutical pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access, and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, the FDA issued a final rule in 2020 providing guidance for states to build and submit importation proposals for drugs from Canada, and the FDA authorized the first such plan in Florida in 2024, but implementation of Florida's plan has been extended until May 6, 2026. It is unclear how this program will be implemented, including which drugs will be chosen, and whether it will be subject to legal challenges in the United States or Canada. Other states have also submitted proposals that are pending review by the FDA.

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

We face significant competition from other biotechnology and pharmaceutical companies, which may result in other companies developing or commercializing products before, or more successfully than, we do, thus rendering our product candidates non-competitive or reducing the size of the market for our product candidates. Our operating results will suffer if we fail to compete effectively.

The biopharmaceutical industry, and the cell therapy and genome editing industries specifically, is characterized by intense competition and rapid innovation. Our potential competitors include major multi-national pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies, and universities and other research institutions. Furthermore, the field of cell and gene therapy faces increasing competition from entities outside of the United States, in particular from China due to a more flexible regulatory environment that facilitates faster translation of ideas to initial human clinical data. Many of our competitors have substantially greater financial, technical, and other resources, such as larger research and development staffs, established manufacturing capabilities and facilities, clinical trial expertise, and marketing organizations with well-established sales forces. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies that have greater resources. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated on our competitors. Competition may increase further as a result of advances in the commercial applicability of genome editing or other new technologies and greater availability of capital for investment in these industries. These competitors also compete with us in recruiting and retaining qualified clinical and management personnel and establishing clinical trial sites and patient enrollment for participation in clinical trials, as well as in acquiring technologies complementary to, or necessary for, our development programs. In addition, due to the intense research and development taking place in the genome-editing field, including by us and our competitors, the intellectual property landscape is in flux and highly competitive. There may be significant intellectual property-related litigation and proceedings relating to third-party intellectual property rights, as well as to intellectual property owned or controlled by us, in the future. Our commercial opportunities could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient to administer, have broader acceptance and higher rates of reimbursement by third-party payors, or are less expensive than any product candidates that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. Delays in the initiation and/or execution of our planned pivotal clinical trial for vispa-cel could result in us entering a more competitive market with vispa-cel, if approved, than what we have anticipated. Additionally, genome-editing technologies developed by our competitors may render our product candidates uneconomical or obsolete, and we may not be successful in marketing any product candidates we may develop against competitor products. The key competitive factors affecting the success of our product candidates are likely to be their efficacy, safety, and availability of reimbursement.

Our focus is on the development of cell therapies using our chRDNA genome-editing technology. Our allogeneic CAR-T cell therapy product candidates face significant competition from multiple companies developing allogeneic cell therapies and bispecific antibody therapies as well as developing and marketing autologous cell therapies. Autologous T cell therapies directed at CD19 have been commercialized by Novartis AG (Kymriah®), Kite Pharma, Inc., a Gilead Sciences, Inc. company (Yescarta®, Tecartus®), and Bristol-Myers Squibb Company (Breyanzi®). Autologous cell therapies directed at BCMA have been commercialized by Bristol-Myers Squibb Company (Abecma®) and Legend Biotech Corporation with their partner Johnson & Johnson (Carvykti®).

There are numerous preclinical- and clinical-stage allogeneic and autologous anti-CD19 and anti-BCMA CAR-T programs and product candidates, some of which will be competitive with our vispa-cel and CB-011 product candidates, respectively. Companies developing allogeneic T cell therapies include, but are not limited to, Allogene Therapeutics, Inc., Atara Biotherapeutics, Inc., AvenCell Therapuetics, Inc., Cellectis S.A., CRISPR Therapeutics AG, Fate Therapeutics, Inc., Gracell Biotechnologies (an AstraZeneca PLC company), Imugene Limited, Kite Pharma, Inc. (a Gilead Sciences, Inc. company), Legend Biotech Corporation, March Biosciences, Inc., F. Hoffman La-Roche Ltd (through its acquisition of Poseida Therapeutics, Inc.), and Sana Biotechnology, Inc. Companies developing additional autologous T cell therapies include, but are not limited to, AbelZeta Pharma Inc., Arcellx, Inc., Arsenal Biosciences, Inc., Astellas Pharma Inc., Autolus Therapeutics plc, AvenCell Therapeutics, Inc., Bristol-Myers Squibb Company, Cabaletta Bio, Inc., Eureka Therapeutics, Inc., Gracell Biotechnologies Inc., an AstraZeneca PLC company, Iovance Biotherapeutics, Inc., Johnson & Johnson, Kite Pharma, Inc. (a Gilead Sciences Inc. company), Kyverna Therapeutics, Inc., Legend Biotech Corporation, Lyell Immunopharma, Inc., March Biosciences, Inc., Miltenyi Biotec, Mustang Bio, Inc., Novartis AG, Precigen, Inc., Regeneron Pharmaceuticals, Inc. (through its acquisition of the 2seventy bio, Inc. research pipeline), F. Hoffman-La Roche Ltd (through its acquisition of Poseida Therapeutics, Inc.), TCR² Therapeutics Inc., Triumvira Immunologics Inc., and TScan Therapeutics, Inc. Additionally, multiple companies are developing other directly competitive technologies, such as small molecules, antibodies, bispecific antibodies, trispecific antibodies, and antibody-drug conjugates, and such companies include, but are not limited to, AbbVie Inc. (Epkinly®), F. Hoffman-La Roche Ltd (Columnvi® and Lunsumio®), Johnson & Johnson (Tecvayli® and Talvey®), Pfizer (Elrexfio®), and Regeneron Pharmaceuticals, Inc. (Lynozyfic®).

Compared to first-generation genome-editing approaches, our chRDNA genome-editing technology has shown improved specificity, a reduction in off-target edits and translocations and, when paired with Cas12a, an advanced capability to perform multiplexed edits, in particular multiplexed insertions. Although we believe that our novel technologies and intellectual property position offer competitive advantages, we face competition from multiple other genome-editing technologies and companies. Other companies developing CRISPR-based technologies include, among others, Arbor Biotechnologies, Inc., Beam Therapeutics Inc., CRISPR Therapeutics AG, Editas Medicine, Inc., Intellia Therapeutics, Inc., Mammoth Biosciences, Inc., Metagenomi Therapeutics, Inc., and Scribe Therapeutics, Inc. Companies developing other genome-editing technologies include, among others, Allogene Therapeutics, Inc., Cellectis S.A., Precision BioSciences, Inc., Prime Medicine, Inc., Sangamo Therapeutics, Inc., and Wave Life Sciences Ltd.

To become and remain profitable, we must continue to develop and eventually commercialize product candidates with significant market potential, which will require us to be successful in a range of challenging activities. These activities include completing clinical trials of our product candidates; obtaining marketing and reimbursement approval for these product candidates; manufacturing, marketing, and selling those products that are approved; and satisfying any post-marketing requirements. We may never succeed in any or all these activities and, even if we do, we may never generate revenues that are significant enough to achieve profitability. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the price of our common stock and could impair our ability to raise capital, maintain our development efforts, expand our business, or continue our operations. A decline in the price of our common stock also could cause stockholders to lose all or part of their investments.

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

Our business operations and current and future arrangements with clinical site investigators, healthcare professionals, consultants, third-party payors, patient organizations, and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we market, sell, and distribute our product candidates, if approved. Such laws include, but are not limited to, the U.S. Anti-Kickback Statute, U.S. civil and criminal false claims laws, the U.S. Beneficiary Inducement Statute, HIPAA, and state and local laws and regulations. Some of these laws may apply differently to, and may have different requirements for, and effects on, our business, rendering compliance complex and possibly burdensome. We cannot predict how future changes to these laws may impact our business.

Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices, including our relationships with physicians and other healthcare providers, may not comply with current or future statutes, regulations, agency guidance, 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 the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil, criminal, and administrative penalties; damages; fines; exclusion from government-funded healthcare programs, such as Medicare and Medicaid or similar programs in other jurisdictions; integrity oversight and reporting obligations to resolve allegations of non-compliance; disgorgement; individual imprisonment; contractual damages; reputational harm; diminished profits; and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to criminal, civil, or administrative sanctions, including exclusions from government-funded healthcare programs and imprisonment, which could affect our ability to operate our business. Furthermore, defending against any these actions can be costly, time-consuming, and may require significant personnel resources. Therefore, even if we are successful in defending against any actions that may be brought against us, our business may be impaired.

Our business activities will be subject to U.S. export control licensing requirements, as well as other U.S. and foreign trade regulations, sanctions laws, anti-corruption laws, and anti-money laundering laws and regulations including the Foreign Corrupt Practices Act, which could expose us to penalties.

We develop product candidates that may be subject to U.S. export control licensing requirements and foreign investment regulations. Export licensing policies vary, and we may be unable to collaborate with certain countries or, if our product candidates receive regulatory approval, make sales to certain customers as a result of applicable license requirements. We also may incur increased compliance program costs in connection with U.S. export controls, and the availability of future investments from certain countries may be limited as a result of the controlled nature of our product candidates.

If we expand our business internationally or collaborate globally, we will be required to make investments in compliance programs related to U.S. international trade laws, including the FCPA and similar anti-bribery or anti-corruption laws, regulations, and rules of other countries in which we may choose to operate. Anti-corruption laws are interpreted broadly.

Our business is heavily regulated and therefore involves significant interaction with public officials, including, potentially in the future, officials of non-U.S. governments. Additionally, in many other countries, the healthcare providers who prescribe pharmaceuticals are employed by their government, and the purchasers of pharmaceuticals are government entities; therefore, if our product candidates receive regulatory approval, our dealings with these prescribers and purchasers will be subject to regulation under the FCPA. We may engage third parties to sell our product candidates outside the United States if we receive regulatory approval in such jurisdictions for our product candidates. We may also have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. For these reasons, we may be required to expend resources related to training and compliance under FCPA and other anti-corruption laws. There is no certainty that all our employees, suppliers, CMOs, CROs, or other third parties providing services to us will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. We can be held liable for the corrupt or other illegal activities of our employees, consultants, and other collaborators, even if we do not explicitly authorize or have actual knowledge of these activities.

If we have international activities in the future, we may be required to invest in compliance programs and resources related to U.S. import and export regulations, anti-money laundering laws, and various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls.

Violations of these international trade laws and regulations could result in fines; criminal sanctions against us, our management, or other employees; the closing down of facilities, including those of our suppliers and CMOs; requirements to obtain export licenses; cessation of business activities in sanctioned countries; implementation of compliance programs; and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to seek regulatory approval for our product candidates and, if such approval is received, to sell our products in one or more jurisdictions. This could materially damage our reputation, our ability to attract and retain employees, and our business, financial condition, results of operations, and prospects.

We face potential liability related to the privacy of health information we may obtain from the patients in our clinical trials if we fail to comply with privacy laws.

Most healthcare providers are subject to privacy and security regulations promulgated under HIPAA, as amended by HITECH. We are not currently classified as a covered entity or business associate under HIPAA and thus are not subject to its requirements or penalties. Any person may be prosecuted under HIPAA's criminal provisions either directly or under aiding-and-abetting or conspiracy principles. Consequently, depending on the facts and circumstances, we could face substantial criminal penalties if we knowingly receive individually identifiable health information from a HIPAA-covered healthcare provider or research institution that has not satisfied HIPAA's requirements for disclosure of individually identifiable health information.

In addition, if we receive sensitive personally identifiable information, including health information, we may be subject to state laws requiring notification of affected individuals and state regulators if a breach of personal information occurs, which is a broader class of information than the health information protected by HIPAA. Some state health information privacy laws carry a private right of action in addition to regulatory enforcement actions that can be brought by state attorneys general.

We cannot provide any assurance that we, our CROs, our clinical trial sites, and our clinical trial principal investigators with access to personally identifiable and other sensitive or confidential information relating to the patients in our clinical trials will not breach contractual obligations, or that we or they will not experience data security breaches or attempts thereof. This could have a corresponding effect on our business, including putting us in breach of our obligations under federal and state privacy laws and regulations as discussed above, which could in turn adversely affect our business, financial condition, results of operations, and prospects. We cannot provide any assurance that our contractual measures and our own privacy and security-related safeguards will protect us from the risks associated with the third-party processing, storage, and transmission of such information.

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

The regulatory framework for the collection, use, safeguarding, sharing, transfer, and other processing of information worldwide is rapidly evolving and is likely to remain uncertain for the foreseeable future. Globally, many jurisdictions have established their own data security and privacy frameworks. In the United States, there are a broad variety of data protection laws that are either currently in place or under way and a wide range of enforcement agencies at both the state and federal levels have the authority to review companies for privacy and data security concerns based on general consumer protection laws. The FTC, and state attorneys general have been aggressive in reviewing privacy and data security protections for consumers. New laws also are being considered at both the state and federal levels. For example, the CCPA, which went into effect on January 1, 2020, provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. Many other states are considering similar legislation. A broad range of legislative measures also have been introduced at the federal level. There also is the threat of consumer class actions related to these laws and the overall protection of personal data.

Additionally, the CCPA was amended by the California Privacy Rights Act ("CPRA"), which significantly amends the CCPA and imposes additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It will also create a new California data protection agency authorized to issue substantive regulations, which could result in increased privacy and information security enforcement. The majority of the provisions went into effect on January 1, 2023, and additional compliance investment and potential business process changes may be required. Similar laws have passed in, or are being considered by, other states. Certain other states have enacted similar comprehensive privacy and security laws. The enactment of these laws in other states results in potentially conflicting requirements, which would make compliance challenging and costly.

The FTC and many state attorneys general continue to enforce federal and state consumer protection laws against companies for online collection, use, dissemination and security practices that appear to be unfair or deceptive. For example, according to the FTC, failing to take appropriate steps to keep consumers' personal information secure can constitute unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act. The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. We may also be subject to new state laws governing the privacy of consumer health data, including information concerning individual health conditions and treatment.

The data privacy laws in the EU have also been significantly reformed. The collection, use, disclosure, transfer, or other processing of personal data regarding individuals in the EU, including personal health data, is subject to the General Data Protection Regulation, (EU) 2016/679 (the "GDPR"). The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches, and taking certain measures when engaging third-party processors. The GDPR has expanded the definition of personal data to include coded data and requiring changes to informed consent practices and more detailed notices for clinical trial patients and investigators. In addition, the GDPR also imposes strict rules on the transfer of personal data to countries outside the EU, including the United States and, as a result, increases the scrutiny that clinical trial sites located in the European Economic Area ("EEA") should apply to transfers of personal data from such sites to countries that are considered to lack an adequate level of data protection, such as the United States unless such transfer is covered under the EU-US Data Privacy Framework. The GDPR also permits data protection authorities to require destruction of improperly gathered or used personal information or impose substantial fines for violations of the GDPR, which can be up to 4% of global revenues or €20 million, whichever is greater, and it also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. In addition, the GDPR provides that EU member states may make their own additional laws and regulations limiting the processing of personal data, including genetic, biometric, or health data.

Furthermore, since the UK is no longer part of the EU, its data protection regulatory regime is independent of the EU. From January 1, 2021, companies have had to comply with the GDPR and also the UK GDPR ("UK GDPR"), which, together with the amended UK Data Protection Act 2018, retains the GDPR in UK national law. The relationship between the UK and the EU in relation to certain aspects of data protection law remains unclear. In June 2021, the European Commission granted the UK an adequacy decision under the GDPR, permitting the free flow of personal data from the EU/EEA into the UK without additional safeguards. This adequacy decision was renewed in December 2025, although it remains subject to periodic review and could be revoked if the UK's data protection standards are deemed to have diverged materially from EU standards. In addition, the longer term economic, legal, political, regulatory, and social framework to be put in place between the UK and the EU has had, and may continue to have, a material and adverse effect on global economic conditions and the stability of global financial markets and may significantly reduce global market liquidity and restrict the ability of key market participants to operate in certain financial markets. Any of these factors could depress economic activity and restrict our access to capital, which could materially and adversely affect our business, financial condition, and results of operations.

Our use of artificial intelligence and challenges with properly managing its use could adversely affect our business.

We incorporate certain artificial intelligence ("AI") solutions into our business, and applications of AI may become more important in our operations over time. Although we scrutinize the AI platforms we use, there are significant risks involved in deploying AI. For example, any AI-related efforts, particularly those related to generative AI, could subject us to risks related to harmful content, inaccuracies, bias, discrimination, infringement of third-party intellectual property, or misappropriation, defamation, data privacy, cybersecurity, or sanctions and export controls, among others. AI's rapid development is the subject of evolving review by various U.S. and foreign governmental and regulatory agencies. The rapid evolution of AI may require us to apply resources 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 own 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. Further, bad actors around the world use increasingly sophisticated methods, including the use of AI, to engage in illegal activities involving the theft and misuse of confidential information and intellectual property. Any of these effects could damage our reputation, result in the loss of valuable intellectual property and confidential information, cause us to breach applicable laws and regulations, and adversely impact our business.

Risks Relating to Intellectual Property

If we do not possess the necessary intellectual property rights covering our CRISPR chRDNA genome-editing technology, our product candidates, or other proprietary technologies, we may not be able to block competitors or to compete effectively in the market.

Our industry is subject to rapid technological change and our success depends in large part on our ability to obtain and maintain intellectual property protection in the United States and other jurisdictions with respect to our CRISPR chRDNA genome-editing technology and product candidates. We rely upon a combination of patents, owned by us or in-licensed from third parties, and trade secrets to protect our technology and product candidates. We seek to protect our intellectual property by filing patent applications in the United States and in other jurisdictions related to our genome-editing technologies and product candidates that are important to our business. We also rely on know-how and continuing technological innovation to develop and maintain our competitive position. If we are unable to obtain or maintain intellectual property protection with respect to our CRISPR chRDNA genome-editing technology and product candidates, our business, financial condition, results of operations, and prospects will be materially harmed.

The strength of patents in the biotechnology and pharmaceutical fields generally, and the genome-editing field in particular, involves complex legal and scientific questions and can be uncertain. For example, the scope of patent protection that will be available to us in the United States is uncertain. Changes in either the patent laws or their interpretation may diminish our ability to protect our intellectual property; obtain, maintain, defend, and enforce our intellectual property rights; and, more generally, could affect the value of our intellectual property or narrow the scope of our owned or in-licensed patents. With respect to both owned and in-licensed intellectual property, we cannot predict whether the patent applications we and our licensors are currently pursuing will grant as patents, whether the claims of any granted patents will provide sufficient protection, or whether, if these patents are challenged by our competitors, they will be found to be invalid, unenforceable, or not infringed.

The patent prosecution process is expensive, time-consuming, and complex, and we or our licensors may not be able to file, prosecute, maintain, enforce, or license all necessary or desirable patents at a reasonable cost or in a timely manner or in all jurisdictions. It is also possible that we will fail to identify patentable aspects of our research and development in time to obtain patent protection before public disclosures are made. Although we may enter into non-disclosure or confidentiality agreements with parties who may have access to patentable aspects of our research and development, such as our employees, collaborators, CMOs, suppliers, consultants, CROs, clinical trial site investigators and personnel, and other third parties, any one of these parties may breach their confidentiality agreements and disclose innovations before we can file a patent application, thereby jeopardizing our ability to seek patent protection.

The USPTO requires compliance with various procedural, documentary, fee payment, and other similar provisions during the patent application process. The ultimate outcome of our pending patent applications is uncertain and the coverage claimed in a patent application can be significantly reduced before the patent is granted. Even as our patent applications, or those of our licensors, currently or in the future, grant as patents, they may not grant in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, dissuade companies from collaborating with us, or otherwise provide us with any competitive advantage. Periodic maintenance fees on granted patents are also required to be paid over the lifetime of the patent. Although an inadvertent lapse can, in many cases, be cured by payment of a late fee or by other means in accordance with applicable laws and regulations, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in the loss of patent rights. Noncompliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, nonpayment of fees, failure to properly legalize and submit formal documents, and the like. If we experience noncompliance events that cannot be corrected and we lose our patent rights, competitors could enter the market, which would have a material adverse effect on our business.

Composition of matter patents for biological and pharmaceutical products, such as CAR-based cell therapy products, often provide a strong form of intellectual property protection as such patents provide protection without specifying any particular method of use or manufacture. Methods of use patents can protect particular applications of a product or the manufacturing of a product; however, such method claims do not prevent a competitor from using a product that is identical to our product for an indication that is outside the scope of the patented method of use or making a product that is identical to our product using a different method of manufacturing. Our allogeneic CAR-T cell therapy product candidates do not contain our chRDNA genome-editing technology; rather, our chRDNA guides are used in manufacturing our CAR-T cell therapy product candidates. It is virtually impossible to determine whether a competitor has infringed our chRDNA patents in making their products. Thus, even if we obtain patent protection on certain aspects of our technologies, such protection may not be enough to block our competitors from entering the market.

Third-party claims of intellectual property infringement may prevent or delay our ability to commercialize our product candidates.

The fields of CAR-T cell therapies and genome editing are relatively new. Due to the widespread research and development that is taking place in these fields, including by us and our competitors, the intellectual property landscape is in flux and may remain uncertain for the foreseeable future. There may be significant litigation and administrative proceedings that could affect our genome-editing technologies and product candidates.

Our commercial success depends upon our ability to develop, manufacture, market, and sell product candidates that we may develop or license without infringing, misappropriating, or otherwise violating the intellectual property rights of third parties. The biotechnology and pharmaceutical industries are characterized by extensive litigation regarding patents and other intellectual property rights. Numerous U.S. and foreign granted patents and pending patent applications owned by third parties exist in the fields in which we are developing our product candidates. As industry, government, academia, and other biotechnology and pharmaceutical research expands and more patents are granted, the risk increases that our genome-editing technologies or product candidates may give rise to claims of infringement of the patent rights of others. Our genome-editing technologies, current and future product candidates, or the use or manufacture of such product candidates may currently or in the future infringe third-party patents. There may be third-party patents with claims to compositions, methods of manufacture, or methods of use or treatment that could cover our current or future product candidates. It is possible that we may fail to identify relevant third-party patents or applications. Furthermore, 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. Thus, although we have a substantial patent portfolio, we cannot be certain that we were the first to file any patent application related to our genome-editing technologies or product candidates. Furthermore, patent rights are granted jurisdiction-by-jurisdiction, and our freedom to practice certain genome-editing technologies, including our ability to research, develop, and commercialize our product candidates, may differ by country. Additionally, AI resources that are publicly available also present a risk that we may inadvertently obtain, incorporate, or use third-party intellectual property, thus possibly subjecting us to future litigation.

Numerous third-party U.S. and foreign granted patents and pending patent applications exist in the fields of cell therapy and CRISPR genome editing, including those relating to CAR and CAR-T cell therapy compositions, components (including specific co-stimulatory regions), and methods of use as well as those relating to CRISPR-Cas9 and CRISPR-Cas12a systems and methods of use. Our vispa-cel product candidate uses Cas9 chRDNAs to insert the CD19-specific CAR into the T cell genome and for an additional edit. Numerous third parties have intellectual property relating to RNA-guided Cas9 genome editing. See Risk Factors - *"Our ability to continue to receive licensing revenue and to enter into new licensing arrangements related to the foundational CRISPR-Cas9 intellectual property will be substantially impaired if such intellectual property is limited by administrative patent proceedings or other patent challenges,"* in Item 1A of this Annual Report on Form 10-K. Our CB-011 product candidate uses Cas12a chRDNAs to insert the CAR into the T cell genome and to make additional edits. We are aware of certain third-party patents relating to CRISPR-Cas12a genome-editing systems. There is ongoing patent litigation over various third-party CAR patents, and there is the potential that unexpired patents that survive that litigation could be asserted against us.

Third parties may assert that our product candidates infringe their patents, including those mentioned above. Under 35 U.S.C. § 271(e)(1), conducting clinical trials and other activities related to seeking regulatory approval in the United States for therapeutic products are generally not considered act of patent infringement, and similar exemptions are present in other countries. However, third parties may claim that certain of our activities are outside of the safe harbor provision because, for example, such activities are allegedly not reasonably related to the development and submission of information to the FDA for regulatory approval. Upon regulatory approval, third parties may assert infringement claims based on existing patents or patents that may be granted prior to our BLA, regardless of the merit of such claims. Even if we believe third-party intellectual property claims are without merit, a court may not find in our favor on questions of infringement, validity, enforceability, ownership, or priority. Patents in the United States by law enjoy a presumption of validity that can be rebutted only with evidence that is "clear and convincing," a heightened standard of proof. In order to successfully challenge the validity of any U.S. patent in federal court, we would need to overcome this presumption of validity, and we cannot provide any assurance that a court of competent jurisdiction would invalidate the patent. A court of competent jurisdiction could hold that these third-party patents are valid, enforceable, and infringed, which could materially and adversely affect our ability to commercialize our vispa-cel and/or CB-011 product candidates, if approved.

If any third-party patents were held by a court of competent jurisdiction to cover our genome-editing technology used in manufacturing our product candidates or any product candidate itself or its indication, the holders of those patents may be able to block our ability to commercialize the product candidate unless and until we obtained a license under the applicable patents, or the patents expire, or are held to be not infringed, unpatentable, invalid, or unenforceable. We may not be able to obtain a license to the blocking patents, or the terms of the license may not be commercially viable. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors and other third parties access to the same intellectual property licensed to us, and it could require us to make substantial upfront, milestone, and royalty payments. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, or at all, our ability to commercialize our product candidates may be blocked or delayed, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

We could also be forced, including by court order, to cease manufacturing and commercializing any infringing product candidates. In addition, we could be found liable for significant monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed the third-party patent. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar material adverse effect on our business, financial condition, results of operations, and prospects. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of our management time and resources from our business.

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

Filing, prosecuting, maintaining, enforcing, and defending patents on our genome-editing technologies and product candidates in countries outside the United States is expensive. Prosecution of patent applications is often a longer process and patents may grant at a later date, and with a shorter term, than in the United States. The requirements for patentability differ in certain jurisdictions and countries. Additionally, the patent laws of some countries do not afford intellectual property protection to the same extent as the laws of the United States. For example, unlike patent law in the United States, patent law in most European countries and many other jurisdictions precludes the patentability of methods of treatment and diagnosis of the human body. Other countries may impose substantial restrictions on the scope of claims, limiting patent protection to specifically disclosed embodiments. Consequently, we may not be able to prevent third parties from practicing our inventions in major markets outside the United States, or from selling or importing products into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and may export otherwise infringing products to jurisdictions where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent such competition. Moreover, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in intellectual property laws in various jurisdictions worldwide.

Many companies have encountered significant problems in enforcing and defending intellectual property rights in various jurisdictions globally. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our intellectual property rights generally. Proceedings to enforce our intellectual property rights in various jurisdictions globally could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put related patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we file, 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 against competitors.

Many jurisdictions have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties if they are not practicing the patented technology. In addition, some countries limit the enforceability of patents against third parties, including government agencies. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations, and prospects may be adversely affected. Patent protection must be maintained on a country-by-country basis, which is an expensive and time-consuming process with uncertain outcomes. Accordingly, we may choose not to seek patent protection in certain jurisdictions or countries, and we will not have the benefit of patent protection in such jurisdictions or countries.

We may be subject to claims challenging the inventorship of our patents and other intellectual property.

We may in the future be subject to claims that former employees, consultants, or other third parties have an interest in our patents or other intellectual property as an inventor, co-inventor, or owner of trade secrets. Although it is our policy to require our employees and consultants who may be involved in the conception or development of intellectual property to execute agreements assigning that intellectual property to us, we may be unsuccessful in executing such an agreement with each party who conceives or develops intellectual property that we regard as our own or such party may breach the assignment agreement. We may have disputes arise from conflicting obligations of consultants or others who are involved in developing our product candidates. Litigation may be necessary to obtain ownership or to defend against claims challenging inventorship. If we or our licensors fail in that litigation, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property. Such an outcome could have a material adverse effect on our business. Even if we or our licensors are successful in defending against those claims, litigation could result in substantial costs and be a distraction to our management and other employees, and the claims could have a material adverse effect on our business, financial condition, results of operations, and prospects.

The terms of our patents may not be sufficient to effectively protect our products and business, and the expiration of our patents may subject us to increased competition.

Although various extensions may be available, the term of a patent, and the protection it affords, is limited. In most countries including the United States, the natural expiration of a patent is generally 20 years after its first effective filing date. Even if patents covering our product candidates are obtained, once the patent term has expired for a product we may be open to competition from biosimilar or generic medications. In addition, although, upon issuance in the United States the term of a patent can be increased based on certain delays caused by the USPTO, this increase can be reduced or eliminated based on certain delays caused by us during patent prosecution or if terminal disclaimers are filed over other co-owned patents or patent applications to avoid rejections based on obviousness-type double patenting. If we do not have sufficient patent term to protect our products, our business, financial condition, results of operations, and prospects will be adversely affected.

We may not obtain patent term extension for any product candidates we develop.

Depending upon the timing, duration, and specifics of any FDA marketing approval of any product candidates we develop, our U.S. patents may be eligible for limited PTE under the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent extension term of up to five years as compensation for patent term lost during clinical trials and the FDA regulatory review process. A PTE cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended, and only a patent with claims covering the approved biologic, a method for its approved indication, or a method for manufacturing it may be extended. However, we may not be granted an extension because of, for example, failing to exercise due diligence during the clinical phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy the applicable requirements. Moreover, we may not receive PTE or we may receive less time than we requested. If we are unable to obtain PTE or if the term of any such PTE is less than we request, we will be unable to rely on our patent position to forestall the marketing of competing products following our patent expiration, and our business, financial condition, results of operations, and prospects could be materially harmed.

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

Patent reform legislation in the United States and other countries could increase the uncertainties around patent protection, costs, and the enforcement or defense of our patents, all of which could have a material adverse effect on our business, financial condition, results of operations, and prospects. For example, the 2011 Leahy-Smith America Invents Act included a number of significant changes to U.S. patent law. Such provisions affect the way patent applications are prosecuted, redefine prior art, and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. In addition, the Leahy-Smith America Invents Act transformed the U.S. patent system from a first-to-invent to a first-to-file system, effective on March 16, 2013. For small companies, such as ours, this means that we must file our patent applications earlier in our development process rather than relying on proving priority of invention and it is now easier and less costly for third parties to attack our patents, all of which could harm our business, financial condition, results of operations, and prospects.

There is uncertainty regarding the patentability of certain inventions in the biotechnology and pharmaceutical areas. Recent decisions by the U.S. Supreme Court have either narrowed the scope of patent protection available in certain circumstances or weakened the rights of patent owners in particular situations. For example, in *Association for Molecular Pathology v. Myriad Genetics, Inc*., the Supreme Court ruled that a "naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated," and invalidated Myriad Genetics' claims on isolated BRCA1 and BRCA2 genes. To the extent that our claims relate to naturally occurring antibodies or proteins, these may be deemed to be directed to natural products or to lack an inventive concept above and beyond an isolated natural product, and a court may decide the claims are invalid under the *Myriad* decision. Depending on future actions by Congress, the federal courts, the USPTO, and the relevant law-making bodies, as well as courts and patent offices in other countries, the laws and regulations governing patents could change in unpredictable ways that may weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future, which could have a material adverse effect on our existing patent portfolio and those of our licensors.

In Europe, a new unitary patent system took effect on June 1, 2023, which will significantly impact European patents, including those granted before the introduction of such a system. Under the unitary patent system, European patent applications will have the option, upon grant of a patent, of becoming a Unitary Patent, which will be subject to the jurisdiction of the Unitary Patent Court (the "UPC"). The UPC may present uncertainties for our ability to protect and enforce our patent rights against competitors in Europe. Although this new court was implemented to provide more certainty and efficiency to patent enforcement throughout Europe, it also provides our competitors with a new forum to use to centrally challenge our patents, rather than having to seek invalidity or non-infringement decisions on a country-by-country basis. It will be several years before the scope of patent rights that will be recognized by the UPC, and the strength of patent remedies that will be provided, is known.

We may be involved in lawsuits or other proceedings to enforce or protect our patents, the patents of our licensors, or our other intellectual property rights, which could be expensive, time-consuming, and unsuccessful.

Competitors may infringe our patents or our licensors' patents or challenge the validity of our or our licensors' patent rights. Even if our patents are unchallenged, they may not adequately prevent others from designing their products to avoid being covered by our claims. If the breadth or strength of protection provided by our patents and patent applications to our product candidates is threatened, it could dissuade companies from collaborating with us to develop, and threaten our or their ability to commercialize, our product candidates.

Litigation or other legal proceedings relating to intellectual property claims, with or without merit, is unpredictable and generally expensive and time-consuming and likely to divert significant resources from our core business, including distracting our management and personnel from their normal responsibilities, and generally harm our business. Additionally, a defendant could counterclaim that our patent is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Thus, suing a third party for patent infringement puts our patents at risk and we may choose not to take such actions, thus allowing a competitor to infringe our patents. Grounds for a validity challenge in a counterclaim could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, 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. Thus, a court may decide that one or more of our patents is not valid or is unenforceable or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated, held unenforceable, or interpreted narrowly and could put one or more of our pending patent applications at risk of not issuing, all of which could negatively impact our business. Even if we establish infringement in a legal proceeding against a third party, the court may decide not to grant an injunction against further infringing activity by the defendant and may only award money damages, which may or may not be an adequate remedy for us depending on the circumstances. Furthermore, because of the substantial amount of discovery required in connection with U.S. patent litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation.

Third parties may also raise similar claims of invalidity before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include inter partes review, ex parte reexamination, and post grant review in the United States, and equivalent proceedings in foreign jurisdictions, including opposition proceedings before the EPO. These proceedings could result in revocation or amendment to our patents, which potentially could result in our patents no longer protecting our genome-editing technologies or our product candidates. A loss of patent protection could have a material adverse impact on our business.

We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. We cannot provide any assurance that we will have sufficient financial or other resources for such litigation or proceedings, which may continue for several years. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing or misappropriating or successfully challenging our intellectual property rights. In addition, if securities analysts or investors perceive litigation results to be negative, it could have a substantial adverse effect on the price of our common stock. There could be public announcements of the results of litigation or patent challenge hearings, motions, or other interim proceedings or developments, which also could affect the price of our stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing, or distribution activities. Any of the foregoing could allow third parties to develop and commercialize competing technologies and products and have a material adverse impact on our business, financial condition, results of operations, and prospects.

Our product candidates are biologics, and as such, we may enter into a settlement agreement with a biosimilar manufacturer seeking to market a product highly similar to our product; such a settlement agreement may be reviewed by the Federal Trade Commission and such review could result in a fine or penalty and substantial expense.

The FTC reviews patent settlement agreements between biologics companies and biosimilar manufacturers to evaluate whether these agreements include, among other things, anti-competitive reverse payments that slow or defeat the introduction of lower-priced medicines, including biosimilars. If we are faced with an FTC challenge of a settlement agreement with a biosimilar manufacturer, such challenge could impact how or whether we settle the case and, even if we strongly disagree with the FTC's position, we could face a penalty or fine and substantial expense. Any litigation settlements we enter into with biosimilar manufacturers could also be challenged by third parties adversely affected by the settlement. These kinds of follow-on lawsuits, which may be class action suits, can be expensive and can continue over multiple years. If we were to face lawsuits of this nature, we may not be successful in defeating these claims and we may, therefore, be subject to large payment obligations, which we may not be able to satisfy in whole or in part.

Our rights to develop and commercialize our product candidates are subject to the terms and conditions of our licenses and assignments with third parties. If we fail to comply with our obligations under these agreements, we could lose intellectual property rights and be subject to litigation from our licensors or assignors.

We license, or have taken assignment to, patents related to certain of our product candidates and genome-editing technologies from third parties. These licenses and assignments typically impose obligations on us, including diligence and payment obligations. If we fail to comply with our obligations under these agreements, our licensors and assignors may have the right to terminate our agreements, in which case we would not be able to commercialize any product that is covered by the patent rights at issue. Additionally, we may be subject to litigation for breach of these agreements. Moreover, if disputes over intellectual property that we have licensed, or taken assignment of, prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the product candidates or technologies covered by such patents, which could have a material adverse effect on our business, financial conditions, results of operations, and prospects. In addition, intellectual property rights that we license in the future may include sublicenses under intellectual property owned by third parties, in some cases through multiple tiers. The actions of our licensors may therefore affect our rights to use our sublicensed intellectual property, even if we are in compliance with all of the obligations under our license agreements. Should our licensors or any of the upstream licensors fail to comply with their obligations under the agreements pursuant to which they obtain the rights that are sublicensed to us, or should those agreements be terminated or amended, our ability to develop and commercialize our product candidates may be materially harmed.

Our CRISPR chRDNA genome-editing patent family was developed under a three-year research collaboration between us and Pioneer, now Corteva Agriscience. Initially, this patent family was owned by Pioneer under the terms of the Pioneer Agreement with Pioneer (then a DuPont company), and Pioneer granted us an exclusive license to the chRDNA patent family in the fields of human and animal therapeutics and research tools as well as a non-exclusive license in certain other fields outside the Pioneer Exclusive Field. Through an amendment to the Pioneer Agreement, dated December 18, 2020, Pioneer assigned the chRDNA patent family to us in exchange for an upfront payment and potential future milestones. As part of this amendment, Pioneer also granted a covenant not to sue for our licensees of our chRDNA technology under certain other Pioneer intellectual property (to which we already have a license that, in this situation, we cannot sublicense to licensees of our chRDNA technology in the field of human therapeutics) that might cover our chRDNA genome-editing technology, provided that we make the required payments. Thus, if we do not make such payments, our licensees could be sued by Pioneer, which could result in our licensees suing us for breach of contract.

Additionally, under the Pioneer Agreement, we licensed certain Pioneer background CRISPR-Cas9 intellectual property, particularly a patent family owned by Vilnius University and exclusively licensed to Pioneer, that we have sublicensed to several third parties as part of our CRISPR-Cas9 out-licensing program. Although the Vilnius patent family does not cover our chRDNA genome-editing technology or product candidates, if we were to materially breach the Pioneer Agreement and not cure the breach, Pioneer could terminate the Pioneer Agreement, which would expose us to possible lawsuits from a number of our sublicensees to the Vilnius University patent family.

For our CB-011 product candidate, an allogeneic anti-BCMA CAR-T cell therapy, we took assignment of an anti-BCMA scFv from ProMab under the ProMab Agreement. Although we own the patent family that covers this scFv and its methods of use, if we materially breach, and do not cure, the ProMab Agreement, ProMab could terminate the ProMab Agreement and we would be required to immediately cease any and all manufacture, sale, offer for sale, use, import, or export of products comprising the anti-BCMA scFv (provided that, if our product is approved for commercial sale, we may sell any remaining existing inventory of such products for a short period of time). If this were to happen prior to regulatory approval, we would not be able to continue the development of CB-011 and, if this were to happen after regulatory approval, we would lose all future revenues from CB-011.

Thus, we are reliant upon the above licenses to and assignments of certain intellectual property from third parties that is important or necessary to the development of our genome-editing technologies and product candidates. In spite of our best efforts, our licensors or assignors might conclude that we have materially breached our license or assignment agreements, respectively, and might terminate these agreements, thereby removing our ability to develop and commercialize products and technology covered by the agreements. To the extent such third parties fail to meet their obligations under these agreements, which we are not in control of, we may lose the benefits of the agreements. If these agreements are terminated, or if the underlying patents fail to provide the intended exclusivity, competitors could have the freedom to seek regulatory approval of, and to market, products identical to ours. Any of these events could have a material adverse effect on our competitive position, business, financial condition, results of operations, and prospects.

Disputes may arise with the third parties from whom we license or take assignment of our intellectual property rights from for a variety of reasons, including:

- the scope of rights granted under the license or assignment agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe on, or derive from, intellectual property of the licensor that is not subject to the license or assignment agreement and is not covered by a covenant not to sue;
- the sublicensing of rights and the obligations to our licensors associated with sublicensing;
- our diligence obligations under license or assignment agreements and what activities satisfy those diligence obligations; and
- whether payments are due and when.

We may not be successful in obtaining or maintaining necessary rights to any future product candidates that we acquire through acquisitions or in-licenses.

Our future programs may involve additional product candidates that may require the use of intellectual rights held by third parties, and the growth of our business could depend, at least in part, on our ability to acquire or in-license these intellectual property rights. We may be unable to acquire or in-license intellectual property rights from third parties that we identify. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, which would harm our business. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In that case, we may be required to expend significant time and resources to develop or license other product candidates. We may need to cease development of a future product candidate covered by such third-party intellectual property rights.

The licensing and acquisition of third-party intellectual property rights is a competitive area, and companies that may be more established or have greater resources than we do may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider necessary or attractive in order to develop product candidates. More established companies may have a competitive advantage over us due to their size, cash resources, and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. We cannot provide any assurance that we will be able to successfully complete such negotiations and ultimately acquire the rights to the intellectual property surrounding the additional product candidates or new genome-editing or other technologies that we may seek to acquire. If we are unable to successfully obtain rights to required third party intellectual property rights, we may not be able to expand our product pipeline, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Our ability to continue to receive licensing revenue and to enter into new licensing arrangements related to the foundational CRISPR-Cas9 intellectual property will be substantially impaired if such intellectual property is limited by administrative patent proceedings or other patent challenges.

We have an exclusive license from UC and Vienna in all fields to the CVC IP, having as inventors Drs. Jennifer A. Doudna, Emmanuelle Charpentier, Martin Jinek, and Krzysztof Chylinski. We have entered into over 30 sublicenses, both exclusive and non-exclusive, to this CRISPR-Cas9 intellectual property in combination with licenses to our own Cas9 intellectual property (and sometimes in combination with a sublicense to the Vilnius Cas9 patent family we licensed from Pioneer) in a variety of fields (e.g., human therapeutics, animal therapeutics, agriculture, forestry, research reagents, transgenic animals, certain livestock targets, internal research, bioproduction, cell lines, and microbial applications, etc.). We are also required to share with UC/Vienna a percentage of sublicensing revenue we receive including cash and equity. These sublicense agreements are an important source of revenues for us while we are developing our own product candidates. Furthermore, we must reimburse UC/Vienna for the patent prosecution and maintenance costs associated with the CVC IP, which are substantial in light of all the disputes outlined below.

The CVC IP that we have exclusively licensed from UC/Vienna is co-owned with Dr. Charpentier, and Dr. Charpentier has not granted us any rights to the CVC IP, either directly or indirectly. On December 15, 2016, we entered into the IMA with UC, Vienna, Dr. Charpentier, CRISPR Therapeutics AG (the exclusive licensee of Dr. Charpentier in the field of human therapeutics), ERS Genomics Ltd (the exclusive licensee of Dr. Charpentier in all fields outside human therapeutics), and Intellia, our exclusive licensee in a defined field of human therapeutics. Under the IMA, the co-owners provided reciprocal worldwide cross-consents to each of the other co-owners' existing licensees and sublicensees as well as future licensees and sublicensees, with no accounting to the other owners. The IMA includes a number of other commitments and obligations with respect to supporting and managing the CVC IP, including a cost-sharing agreement. In the United States, each co-owner has the freedom to license and exploit the technology. As a result, although our license from UC/Vienna is exclusive, we do not have any rights from Dr. Charpentier and thus our license to the CVC IP from UC/Vienna is non-exclusive with respect to such co-owned rights. Furthermore, in the United States, each co-owner is required to be joined as a party to any claim or action we may wish to bring to enforce those patent rights. Although we have entered into the IMA, which provides for, among other things, notice of and coordination in the event of third-party infringement of the patent rights within the CVC IP, we cannot provide any assurance that all parties will cooperate in any future infringement. In addition, the parties to the IMA may dispute certain provisions and the resolution of any contract interpretation disagreement could increase what we believe to be our financial obligations to UC/Vienna.

The CVC IP is, and has been, the source of several disputes in the USPTO, the EPO, and other patent offices. At the time the CVC IP was first filed (May 25, 2012), the United States was under a first-to-invent patent system; thus, if two or more patent applications or one or more patents and one or more patent applications claimed the same invention, the USPTO would determine the inventorship. Specifically, the Broad Institute Inc. and Massachusetts Institute of Technology and, in some instances, the President and Fellows of Harvard College (individually and collectively, "Broad"), owns a patent family (having an earliest filing date of December 12, 2012) that includes granted patents in the United States and Europe that claim certain aspects of CRISPR-Cas9 systems to edit DNA in eukaryotic (i.e., plant and animal) cells, including human cells. In January 2016, the Patent Trial and Appeal Board ("PTAB") of the USPTO declared an interference (Interference No. 106,048, or the '048 interference) between one of the then-pending U.S. patent applications (now U.S. Patent No. 10,266,850) included in the CVC IP and 12 granted U.S. patents owned jointly by the Broad to determine which set of inventors invented first and, thus, was entitled to patents on the invention in the United States. The PTAB concluded at the end of the motions phase that the declared interference should be discontinued (and not progress to the priority phase) because the involved claim sets were considered patentably distinct from each other. Following appeal by the CVC group, in September 2018, the U.S. Court of Appeals for the Federal Circuit ("Federal Circuit"), affirmed the PTAB's decision to terminate the interference proceeding without determining which inventors actually invented the use of the CRISPR-Cas9 genome-editing technology in eukaryotic cells. In June 2019, the PTAB declared another interference (Interference No. 106,115, or the '115 interference) between 14 pending U.S. patent applications in the CVC IP and 13 patents and a patent application co-owned by the Broad. The Broad patents include those that were the subject of the '048 interference. In February 2022, the PTAB issued its decision that the Broad inventors were the first to invent the use of CRISPR-Cas9 genome editing in eukaryotic cells. The owners of the CVC IP appealed this decision to the Federal Circuit, which issued its decision on May 12, 2025, ruling that the PTAB incorrectly applied the legal standard for conception of the invention and remanded the case to the PTAB for further proceedings to reconsider the issue of conception in a manner consistent with the Federal Circuit's decision. The parties have completed briefing on the remand and are waiting for a decision from the PTAB.

In addition to the Broad, ToolGen, Inc., MilliporeSigma (a subsidiary of Merck KGaA), and Harvard University, each filed patent applications claiming CRISPR-Cas9-related inventions after the CVC IP was first filed (October 23, 2012 in the case of ToolGen patent family; December 6, 2012 in the case of the MilliporeSigma patent family; and December 17, 2012 in the case of the Harvard University patent family) and have each alleged that they invented one or more of the inventions claimed in the CVC IP before the CVC inventors did. In December 2020, the PTAB declared an interference (Interference No. 106,127, or the '127 interference) between a ToolGen patent application that claims certain aspects of CRISPR-Cas9 systems to edit DNA in eukaryotic cells, including human cells, and the same 14 pending U.S. patent applications in the CVC IP that are involved in the appeal of the '115 interference. The motions phase of this interference has concluded, and the priority phase is suspended until the remand from the Federal Circuit appeal in the '115 interference is decided. Additionally, the PTAB declared an interference (Interference No. 106,126) at the same time between the same ToolGen patent application and the Broad patents and patent application in the appeal of the '115 interference; the motions phase has concluded, and this interference is also suspended until the remand from the Federal Circuit appeal in the '115 interference is decided. In June 2021, the PTAB declared an interference (Interference No. 106,132 or the '132 interference) between a MilliporeSigma patent application that claims methods for using CRISPR-Cas9 systems to edit DNA in eukaryotic cells, including human cells, and the same 14 pending U.S. applications in the CVC IP that are involved in the '115 and '127 interferences. This interference completed the motions phase and is also suspended until at least the remand from the Federal Circuit appeal in the '115 interference is decided. Also in June 2021, the PTAB declared an interference (Interference No. 106,133) between the same MilliporeSigma patent application and the Broad patents and patent applications in the '115 and '126 interferences; the motions phase has concluded, and this interference is also suspended until at least the remand from the Federal Circuit appeal in the '115 interference is decided. We do not know the impact on these suspended interferences of a decision by the PTAB on remand from the Federal Circuit appeal in the '115 interference.

Opposition and appeal proceedings in the EPO are ongoing against patents owned by the Broad, ToolGen, and MilliporeSigma as well as against the CVC IP. Additionally, invalidation trials or appeals thereof of the CVC IP are ongoing in China and India. Such proceedings are often lengthy and can lead to the revocation of a patent in its entirety, the maintenance of the patent as granted, or, depending upon the jurisdiction, the maintenance of a patent in amended form. These CVC IP will expire in 2033 without PTA or PTE.

In light of the uncertainty surrounding the CVC IP, certain third parties have negotiated royalty-stacking provisions in their sublicenses with us, whereby they can deduct from what they owe to us a certain percentage of royalties they pay to other parties with CRISPR-Cas9 patents (such as to the Broad). Furthermore, other third parties have adopted a "wait and see" approach and are not entering into license agreements with us or third parties until all the uncertainty surrounding inventorship and priority among the groups with CRISPR-Cas9 patents is resolved. If patents in the CVC IP are invalidated, certain of our sublicensees may wish to renegotiate their license agreements with us or may terminate for convenience. If this happens prior to commercialization of our own product candidates, we could lose a source of revenues while still remaining responsible for reimbursing UC for costs of prosecuting and maintaining the remaining CVC IP.

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

In addition to seeking patents for some of our technology and product candidates, we also rely on trade secrets and confidentiality agreements to protect our know-how that is not patentable, processes for which patents are difficult to enforce, and any other elements of our product discovery and development processes that involve confidential know-how, information, or technology that is not covered by patents. Trade secrets and know-how can be difficult to protect.

We seek to protect these trade secrets and other confidential information, in part, by entering into non-disclosure or confidentiality agreements with parties who have access to them, such as our employees, collaborators, CMOs, CROs, clinical trial site personnel and investigators, consultants, and other third parties. We also enter into confidentiality and invention assignment agreements with our employees and our agreements with consultants include invention assignment obligations. We seek to preserve the integrity and confidentiality of our data, know-how, and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. Although 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 breaches. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our confidential information will be effective. Our trade secrets and other confidential information may be inadvertently or illegally disclosed and competitors may gain access to our trade secrets.

Despite these efforts, any of these parties may breach agreements and disclose our confidential information, including our trade secrets, and we may not be able to obtain adequate remedies for any breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive, and time-consuming, and the outcome is unpredictable. In addition, some courts both within and outside the United States may be less willing or unwilling to protect confidential information, including trade secrets. If a competitor lawfully obtains or independently develops any of our trade secrets, we will have no right to prevent that competitor from using such information to compete with us, which could harm our competitive position. If we are unable to prevent unauthorized material disclosure of our intellectual property to third parties, or misappropriation of our intellectual property by third parties, we may not be able to establish or maintain a competitive advantage in our markets, which could materially adversely affect our business, operating results, financial condition, and prospects. Additionally, it is possible that our CRISPR chRDNA genome-editing technology, our trade secrets, and our know-how will over time be disseminated within the industry through the publication of journal articles and the movement of personnel from our company into academia or into other companies that may be our competitors.

Furthermore, others may independently discover our trade secrets or other confidential information. For example, the FDA, as part of its Transparency Initiative, is currently considering whether to make additional information publicly available on a routine basis, including information that we consider to be confidential, including trade secrets, and it is not clear at the present time how the FDA's disclosure policies may change in the future, if at all. 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 any of our trade secrets were to be disclosed to or independently developed by a competitor or other third party, our competitive position will be materially harmed.

Intellectual property rights do not necessarily address all potential competitive threats and may not adequately protect our business or permit us to maintain our competitive advantage.

The degree of future protection afforded by our intellectual property rights, whether through patents or trade secrets, 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, use, and sell cell therapy products that are similar to our product candidates without infringing our intellectual property rights;
- others may independently develop similar or alternative genome-editing technologies without infringing our intellectual property rights;
- we may not detect that a third-party is infringing our intellectual property rights;
- we may not develop additional patentable technologies;
- others may misappropriate our trade secrets, or independently develop or acquire our trade secrets lawfully; and
- our patents may have expired, whether or not PTE was granted.

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

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

If our trademarks are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected. Our unregistered trademarks may be challenged, infringed, circumvented, declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors may adopt trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our unregistered trademarks. Over the long term, if we are unable to successfully register our trademarks and establish name recognition based on our trademarks, then we may not be able to compete effectively and our business may be adversely affected. Our efforts to enforce or protect our trademarks, domain names, copyrights, or other intellectual property rights may be ineffective and could result in substantial costs and diversion of resources and could adversely impact our business, financial condition, results of operations, and prospects.

Risks Relating to our Relationships with Third Parties

We rely on third parties to supply the materials for, and the manufacturing of, our clinical product candidates, and, if such product candidates receive regulatory approval, we may continue our reliance on third parties for manufacturing our commercial products. Our continued success is subject to the performance of these third parties.

We currently do not have clinical-scale manufacturing capabilities, nor do we have any immediate plans to develop such capabilities; thus, we must rely on third-party CMOs to manufacture clinical supplies for our product candidates. We currently rely on five different CMOs to supply materials to additional CMOs that manufacture vispa-cel and CB-011 product candidates for our phase 1 clinical trials. We anticipate that we may need to engage other suppliers and CMOs for our clinical trials with our product candidates.

We receive the CRISPR chRDNA guides used for genome editing from one CMO, the Cas proteins (Cas9 in the case of vispa-cel and Cas12a in the case of CB-011) from another CMO, the virus used to insert the CAR into the T cell genome and the virus used to insert the B2M-HLA-E-peptide fusion into the T cell genome from another CMO located outside the United States, and our healthy donor cells from multiple sources. The CMO that supplies the virus receives plasmid from another supplier used in the manufacture of the viral material. Other CMOs use all of these materials to manufacture the CAR-T products. Coordination is essential to ensure that the various materials are received in time by the CMOs manufacturing the T cell products for us, and in the correct amounts, for manufacturing runs. The manufactured CAR-T products then undergo a series of release testing. We cannot provide any assurance that we will not experience supply or manufacturing issues in the future; particularly, given our reliance on single-source suppliers, some of which are small companies with limited resources and experience to support clinical, and ultimately commercial, products. We cannot ensure that these suppliers will remain in business, will not experience reductions in force, 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 purposes. 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 if we must switch to a new supplier or CMO. The time and effort to qualify a new supplier or CMO, including to meet any regulatory requirements for such qualification, could result in additional costs, diversion of resources, reduced manufacturing yields, or delays, any of which would negatively impact our operating results. Furthermore, 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, financial condition, results of operations, and prospects.

If our CMOs and suppliers cannot successfully manufacture materials that conform to our specifications and the strict regulatory requirements of the FDA or other regulatory authorities, they will not be able to secure or maintain regulatory approval for their manufacturing facilities. In addition, we have no direct control over the ability of our CMOs and suppliers to maintain adequate quality control, quality assurance, and corresponding maintenance of records and documents, or to hire and retain trained personnel. If the FDA or a foreign regulatory authority inspects these third-party facilities for compliance with regulations for the manufacture and testing of materials or product candidates and, if these facilities fail inspection and cannot adequately correct deficiencies, we may need to find alternative CMOs, which would significantly impact our ability to develop and obtain regulatory approval for our product candidates, and if approved, to market our products.

Any unfavorable government policies on international trade, such as export controls, capital controls or tariffs, new legislation or regulations, renegotiation of existing trade agreements, or any retaliatory trade actions due to recent or future trade tension, may impede, delay, limit, or increase the cost of manufacturing our CAR-T cell therapy product candidates, including recently imposed tariffs. Such events could result in a lack of supply for our clinical trials, which could harm our business.

In addition, if our CMOs and suppliers are unable to timely perform or have operations temporarily halted as a result of inspection or enforcement actions taken by the FDA or other regulatory authorities, or as a result of pandemics or other public health crises, we may experience manufacturing delays or delays in receiving healthy donor cells used in manufacturing our product candidates or may need to find alternative CMOs or suppliers, which in each case would significantly impact our ability to develop, obtain regulatory approval for, and market our product candidates, if approved. Our product candidates have not been manufactured for commercialization and we may not be able to achieve commercial manufacturing; additionally, we may be unable to create a product inventory necessary to satisfy demands for any of our product candidates following regulatory approval. As a result, we may never be able to develop a commercially viable product. We incorporated partial HLA matching in our ANTLER phase 1 clinical trial and we believe that we will be able to manufacture sufficient materials to support this effort; however, we cannot provide any assurance that we will be successful in manufacturing additional batches in a timely manner in order to supply our clinical trials.

In addition, our current reliance on a limited number of CMOs and suppliers exposes us to a variety of risks, each of which could delay our clinical trials, the approval, if any, of our product candidates by the FDA or foreign regulatory authorities, or the commercialization of our product candidates or result in higher costs or deprive us of potential product revenue. These risks include:

- our CMOs and suppliers may be unable to timely manufacture our product candidates or produce the quantity and quality required to meet our clinical, and commercial needs, if any;
- our CMOs and suppliers may not be able to execute our manufacturing procedures appropriately;
- our CMOs and suppliers have their own proprietary methods, which we may not have access to if we wish to, or are required to, switch CMOs or suppliers. Additionally, we may not own, or may have to share, the intellectual property rights to any improvements made by our CMOs in the manufacturing process for our product candidates;
- our CMOs and suppliers may not perform as agreed or may not remain in business for the time required to supply our clinical trials or to successfully manufacture, store, and distribute our commercial products;
- our CMOs and suppliers may experience reductions in force, and employees who are familiar with our product candidates and processes at such CMOs and suppliers may be impacted, resulting in employees who are not familiar with our product candidates and processes causing errors and/or delays;
- our CMOs and suppliers could breach or terminate their agreements with us;
- we face competition for supplies from other cell and gene therapy companies, which may make it difficult for us to secure materials or the testing of such materials on commercially reasonable terms or in a timely manner;
- our CMOs may fail to adequately store the various components received from our suppliers and any damage or loss of such materials could materially impact our ability to manufacture and supply our product candidates;
- our product candidates may be damaged or otherwise made unfit for use in clinical trials during shipments from our CMOs to clinical trial sites;
- we rely on third parties to perform release tests on our product candidates prior to delivery to clinical trial sites. If these tests are not appropriately done and test data are not reliable, patients could be put at risk of serious harm;
- we may be unable to identify additional CMOs or suppliers on acceptable terms or at all because the number of potential manufacturers is limited and the FDA or foreign regulatory authorities may have questions regarding any replacement CMO or supplier. This may require new testing and regulatory interactions. In addition, a new CMO would have to be educated in, or develop substantially equivalent processes for, production of our product candidates; and
- as a result of pandemics or other public health crises, our CMOs and suppliers may experience production delays and shutdowns.

Our CMO that supplies the virus we use to insert the CAR into our CAR-T product candidates and the virus to insert the B2M-HLA-E-peptide fusion into CB-011 is located outside the United States. To date, our virus CMO has not been audited by the FDA, but it has received the cGMP certification for the manufacture of recombinant viral vectors from an EU national regulatory authority. There are additional risks with using a non-U.S. vendor, including:

- economic weakness, including inflation, or political instability in particular non-U.S. economies and markets;
- difficulties in compliance with non-U.S. laws and regulations;
- changes in non-U.S. regulations and customs, tariffs, and trade barriers;
- changes in non-U.S. currency exchange rates and currency controls;
- trade protection measures, import, or export licensing requirements, or other restrictive actions by U.S. or non-U.S. governments;
- negative consequences from changes in tax laws;
- difficulties in managing international logistics and transportation;
- the CMO's potential unfamiliarity with FDA requirements when shipping into the United States; and
- workforce uncertainty in countries where labor unrest is more common than in the United States.

In addition, although we do not currently utilize Chinese CMOs, certain Chinese biotechnology companies may become subject to trade restrictions, sanctions, other regulatory requirements, or proposed legislation by the U.S. government, which could restrict or even prohibit our ability to work with such entities, thereby potentially disrupting the supply of material to us. For example, the BIOSECURE Act, which was recently signed into law in December 2025, prohibits U.S. federal agencies from entering into or renewing any contract with any entity that uses biotechnology equipment or services produced or provided by a "biotechnology company of concern" to perform that contract as well as authorize the U.S. government to name additional Chinese "biotechnology companies of concern." Although prior versions of the BIOSECURE Act explicitly named "biotechnology companies of concern," the revised version defines a "biotechnology company of concern" as an entity that is identified on the annual 1260H List of Chinese military companies (the "1260H List") issued by the U.S. Department of Defense, any entity designated by the U.S. government as such, and certain affiliates of the foregoing. In addition, the BIOSECURE Act provides a grandfathering period of five years for entities that are designated by the U.S. government; however, entities identified on the 1260H List are not eligible for such grandfathering period. None of our suppliers is currently designated on the 1260H List, but such list is subject to periodic updates by the U.S. government. It is possible for the legislation to be amended. If this law, or similar laws that are passed impact Chinese biotechnology manufacturing companies that may provide biotechnology equipment or services in the manufacture of our product candidates, we may be restricted in our ability to work with such Chinese biotechnology manufacturing companies to the extent we would contract with, or otherwise receive funding from, the U.S. government. As a result, we may need to seek alternative suppliers. Although we believe we will be able to identify and contract with such alternative suppliers, we cannot predict the terms of any such alternative arrangement nor what actions may ultimately be taken with respect to trade relations between the United States and China or other countries, what products and services may be subject to such actions, or what actions may be taken by China or the other countries in retaliation. In addition, any unfavorable government policies on international trade, such as export controls, capital controls or tariffs, new legislation or regulations, renegotiation of existing trade agreements, or any retaliatory trade actions due to recent or future trade tension, may impede, delay, limit, or increase the cost of manufacturing our product candidates. Such events could result in our clinical supply of our product candidates being interrupted or limited, which could harm our business.

For our allogeneic CAR-T product candidates, we rely on receiving safe and healthy donor material to manufacture our product candidates. Variation in quality of donor T cells, and potential challenges in procuring appropriate donor material, could impact the safety or efficacy of our product candidates, result in insufficient product supply, or cause us to be unable to initiate or continue clinical trials on the timelines we expect.

We are reliant on receiving healthy donor material to manufacture our product candidates. Healthy donor T cells vary in quality, and this variation requires us to release batches with the highest integrity based on specifications confirmed by regulatory authorities, which makes producing standardized product candidates more likely. However, this step may slow the development and commercialization pathway of those product candidates if releasable batches are not identified sufficiently rapidly. We and our CMOs have developed a screening process designed to enhance the quality and consistency of T cells used in the manufacture of our CAR-T cell product candidates, but our screening process may fail to identify suitable donor material and we may discover failures or issues impacting the safety or efficacy of our product candidates after production or during clinical trials. We may also have to develop new testing methods and update our specifications for new risks, such as screening for new viruses or developing additional screening for known viruses. We have strict specifications for donor material, which include specifications required by regulatory authorities as well as requirements for additional screening, for example, HLA matching and donor age and health. We have incorporated partial HLA matching and donor age restrictions (<30 years of age) in both our ANTLER phase 1 clinical trial and our CaMMouflage phase 1 clinical trial, and there may be other beneficial donor characteristics that could affect the efficacy and durability of our product candidates, which we may need to incorporate into our screening processes.

If we are unable to (i) identify and obtain donor material that satisfies specifications, (ii) agree with regulatory authorities on appropriate specifications, or (iii) address variability of donor T cells, there may be insufficient material or we may be unable to initiate or continue clinical trials on the timelines we expect, which could harm our reputation and adversely impact our business and prospects. Although our suppliers are currently able to provide us with donor material, if, in the future, our suppliers are unable to secure donor material due to pandemics or other public health crises or for any other reasons, we may no longer have sufficient donor material to manufacture our cell therapy product candidates. Additionally, our donor-derived product candidates may be subject to rapid recognition by a patient's immune system, thus limiting their potential efficacy.

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

We depend, and will continue to depend, on CROs, clinical trial sites and clinical trial principal investigators, contract laboratories, and other third parties to conduct our ongoing and future clinical trials. We will rely heavily on these third parties over the course of our clinical trials, and we control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the protocol and applicable legal, regulatory, and scientific standards and regulations, and our reliance on third parties does not relieve us of our regulatory responsibilities. We and these third parties are required to comply with cGCPs, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for the conduct of clinical trials on product candidates in clinical development. Regulatory authorities enforce cGCPs through periodic inspections and for-cause inspections of clinical trial principal investigators and trial sites. If we or any of these third parties fail to comply with applicable cGCPs or fail to enroll a sufficient number of patients, we may be required to conduct additional clinical trials to support our marketing applications, which would delay the regulatory approval process. Moreover, our business may be implicated if any of these third parties violates federal, state, or foreign fraud and abuse or false claims laws and regulations or healthcare privacy and security laws, or provide us or government agencies with inaccurate, misleading, or incomplete data.

Although we design the clinical trials for our product candidates, our CROs facilitate and monitor our clinical trials. As a result, many important aspects of our clinical development programs, including site and investigator selection, and the conduct and timing and monitoring of the study, are partly or completely outside our direct control. Our reliance on third parties to conduct and monitor the progress of clinical trials also results in less direct control over the collection, management, and quality of data developed through clinical trials than would be the case if we were relying entirely upon our own employees. Communicating with third parties can also be challenging, potentially leading to mistakes as well as difficulties in coordinating activities.

Any third parties conducting our clinical trials are not, and will not be, our employees and, except for remedies available to us under our agreements with these third parties, we cannot control whether they devote sufficient time and resources to our clinical trials. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug and biologic 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 deadlines, 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 if there are other difficulties with such third parties, such as staffing difficulties, changes in priorities, or financial distress, our clinical trials may be extended, delayed, or terminated.

Unauthorized access or manipulation of our clinical trial data in databases maintained or utilized by third parties may adversely affect the validity of the data from our clinical trials and, ultimately, our clinical trials. There have been instances in the biotechnology industry of clinical trial investigators acting improperly, including data fabrication and unauthorized manipulation of data. In addition, a growing number of cybersecurity incidents are being reported, during which certain organizations gain access to databases that contain clinical trial data and demand a ransom. In such instances, it may be difficult to determine whether the validity of our clinical trial data has been compromised, thereby jeopardizing the entire clinical trial. As a result, 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 will 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 timely enter into arrangements with alternative trial sites or CROs, or do so on commercially reasonable terms. Switching or adding clinical trial sites or CROs to conduct our clinical trials involves substantial cost and requires extensive management time, training, and focus. In addition, there is a natural transition lag when a new third party must learn about our product candidates and protocols, which can result in delays that may materially impact our ability to meet our desired clinical development timelines.

We also are required to register certain ongoing clinical trials and post the results of completed clinical trials on a U.S. government-sponsored database, www.ClinicalTrials.gov, within certain timeframes. Failure to do so can result in fines, adverse publicity, and civil and criminal sanctions. Our ANTLER phase 1 clinical trial for our vispa-cel product candidate and our ongoing CaMMouflage phase 1 clinical trial for our CB-011 product candidate are posted on www.ClinicalTrials.gov. For any violations of laws and regulations during the conduct of our clinical trials, we could be subject to warning letters or enforcement action that may include civil and other penalties, up to and including criminal prosecution.

We may form or seek new strategic collaborations in the future for the development and commercialization of one or more of our product candidates or for new product candidates. We may not be successful in those efforts and, even if we do enter into any collaborations, they may not be successful.

Our product candidate development programs and the potential commercialization of our product candidates will require substantial additional cash to fund expenses. To date, we have not partnered with a third party with respect to commercializing of any of our product candidates. We have entered into agreements with Pfizer with respect to certain information rights and rights of first negotiation with Pfizer regarding a BCMA Product Candidate, including our CB-011 product candidate, which rights will expire on June 29, 2026. In the future, we may choose to partner with third parties for one or more of our product candidates. If we are unable to negotiate and enter into partnerships, we may have to curtail the development of the product candidate for which we are seeking to collaborate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market, if approved, and generate product revenue.

If we decide to collaborate with pharmaceutical or biotechnology companies for the development and potential commercialization of any of our product candidates, or new product candidates, we may not be able to negotiate collaborations for such product candidates on a timely basis, on acceptable terms, or at all. We may also be restricted under existing agreements from entering into future collaborations. Collaborations are complex and time-consuming to negotiate and document. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the potential collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the potential collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by FDA or comparable regulatory authorities outside the United States, the potential market for the subject product candidate or candidates, the costs and complexities of manufacturing and delivering such product candidates to patients, the potential of competing biologics or other therapeutic approaches, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge, and industry and market conditions generally. The potential collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than one with us for our product candidate or for a new product candidate. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. Thus, we may face significant competition in seeking appropriate collaborators.

Furthermore, the terms of any collaborations or other arrangements that we may establish may not be favorable to us. Even if we are able to enter into a collaboration, the following are some of the risks associated with doing so:

- collaborators have significant discretion in determining the efforts and resources that they will apply to collaborations and may not devote sufficient resources to the development, manufacturing, marketing, or sale of collaboration products;
- collaborators may not pursue development and commercialization of any product candidates we may develop or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborator's strategic focus or available funding, or external factors such as an acquisition that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials, or require further development of a product candidate for clinical testing;
- collaborators may adopt alternative technologies, which could decrease the marketability of our product candidates and genome-editing technologies;
- collaborators may independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours, that may result in the withdrawal of the collaborator support for our collaboration product candidates;
- collaborators with marketing and distribution rights to one or more products may not commit sufficient resources to the marketing and distribution of our product candidates;
- collaborators may not properly obtain, maintain, enforce, or defend our intellectual property if we grant such rights or may use our intellectual property in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or expose us to potential litigation;
- we may lose certain valuable rights under circumstances identified in our collaborations, including if we undergo a change in control;
- disputes may arise between our collaborator and us that may cause the collaborator to act in a manner adverse to us and could result in the delay or termination of the development or commercialization of our product candidates or that result in costly litigation or arbitration that diverts our management's attention and resources;
- collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner, if at all. For example, if a collaborator were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program under such collaboration could be delayed, diminished, or terminated; and

- collaboration agreements may be terminated and, if terminated, it may be more difficult for us to find a suitable replacement collaborator or attract new collaborators, resulting in a need for additional capital to pursue further development or commercialization of the applicable product candidates we may develop.

We may not realize the benefits of acquired assets or other strategic transactions.

We evaluate various strategic transactions on an ongoing basis. We may acquire other businesses, products or product candidates, intellectual property, or technologies as well as pursue joint ventures or investments in complementary businesses. The success of any future strategic transaction depends on various risks and uncertainties, 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's time and focus from operating our business to management of new strategic collaborations or joint ventures or acquisition integration challenges;
- increases in our expenses and reductions in our cash available for operations and other uses;
- disruption in or termination of 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.

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, and regulatory risks associated with specific countries.

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. We could also incur losses resulting from undiscovered liabilities that are not covered by the indemnification we may obtain from the seller.

If we in-license product candidates or products or acquire businesses, we may not be able to realize the benefit of those 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 the transaction. 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 Relating to Employee Matters, Managing Growth, and Other Risks Relating to our Business

Our future success depends on our ability to retain our executive officers and to attract, retain, and motivate qualified personnel.

We are highly dependent upon our executive officers, particularly our president and chief executive officer, Rachel E. Haurwitz, Ph.D., as well as other members of our senior management team. Although we have entered into employment agreements with all our executive officers, each of them may terminate their employment with us at any time, which could result in disruption to our business while we find, negotiate with, and hire an executive officer to serve in the same function or while we reorganize our departmental reporting structures.

All our non-officer employees are "at will," which means that any of our employees could leave our employment at any time, with or without notice. Our corporate headquarters are in Berkeley, California. The San Francisco Bay Area is headquarters to many other biopharmaceutical companies and many academic and research institutions. Competition for skilled personnel in our industry is intense and may limit our ability to hire and retain highly qualified personnel on acceptable terms, if at all. Many of the biotechnology companies and research institutions that we compete against for qualified personnel and consultants have greater financial and other resources, different risk profiles, and a longer history in the industry than we do.

Recruiting and retaining qualified development, manufacturing, regulatory, and clinical personnel is critical to our success. Our success also depends on our ability to continue to attract, retain, and motivate entry-level, mid-level, and senior personnel. We may not be able to attract and retain these personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies, as well as academic and research institutions, for similar personnel. If we are unable to continue to attract and retain high-quality personnel and consultants, the rate and success at which we can discover and develop product candidates and operate our business will be limited. To induce employees to remain at our company, in addition to salary and cash incentives, we provide equity awards that vest over time, the value of which may be significantly affected by movements in our stock price that are beyond our control and may be insufficient to counteract more lucrative offers from other companies.

Since the COVID pandemic, many of our employees work remotely or on a hybrid work schedule. This may lead to employees not feeling as connected to our company and thus more inclined to pursue other opportunities. Additionally, on July 16, 2024, we announced that we had discontinued preclinical research activities associated with our allogeneic CAR-NK platform and reduced our workforce by 21 positions, or approximately 12% of our workforce, primarily in the research group and, on April 24, 2025, we announced a strategic pipeline prioritization, including reduction of our workforce by 47 positions, or approximately 32% of our workforce, primarily in the preclinical research group. These reductions in force, as well as any others we may need to implement in the future, may have a detrimental impact on company culture and employee morale, which may hurt our ability to retain employees.

We rely on consultants and advisors, including our co-founders and SAB, to assist us in formulating our development and commercialization strategy. Our consultants and advisors, including Drs. Jennifer A. Doudna and Martin Jinek, who are among our founders and who are pioneers in CRISPR genome-editing technology, are not employed by us, are employed by employers other than us, and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us.

The inability to recruit or retain certain executive officers, key employees, consultants, or advisors may impede the progress of our development and commercialization objectives and have a material adverse effect on our business, intellectual property, financial condition, results of operations, and prospects.

We must continue developing and expanding our company, and we may encounter difficulties in managing this development and expansion, which could disrupt our operations.

As of February 27, 2026, we had 97 full-time employees, and we expect to continue to increase our number of employees and the scope of our operations in 2026 and beyond as we seek to advance development, and if successful, commercialization, of our product candidates. To manage our anticipated development and expansion, we must continue to implement and improve our managerial, operational, and financial systems; expand our facilities; and continue to recruit and train additional qualified personnel. Current and future growth imposes significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining, motivating, and integrating additional employees;
- managing our internal development efforts effectively, including clinical trials and FDA or foreign regulatory authority review for our product candidates, while complying with our contractual obligations to third parties; and
- improving our operational, financial and management controls, reporting systems, and procedures.

Also, our management may need to divert a disproportionate amount of its attention away from their day-to-day activities and devote a substantial amount of time to managing these expansion activities. Due to our limited resources, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. This may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees, and reduced productivity among our remaining employees. The physical expansion of our operations may lead to significant costs and may divert financial resources from other projects, such as the development of our product candidates. If our management is unable to effectively manage this expansion, our expenses may increase more than expected, our ability to generate or increase our revenue could be reduced, and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize our product candidates, if approved, and compete effectively will depend, in part, on our ability to effectively manage the continuing development and expansion of our company.

Our internal computer systems, or those of third parties with which we interact, may fail or suffer security breaches, which could result in a material disruption of the development of our product candidates, compromise sensitive information related to our business, or prevent us from accessing critical information, potentially exposing us to liability or otherwise adversely affecting our business.

Our internal computer systems, and those of third parties with which we interact, including our clinical sites, governmental agencies, CMOs, suppliers, CROs, clinical sites, and the like, are vulnerable to damage from computer viruses, ransomware, malware, data corruption, cyber-based attacks, phishing attacks, unauthorized access, natural disasters, terrorism, war, and telecommunication and electrical failures. Attacks on information technology systems are increasing in their frequency, levels of persistence, sophistication and intensity, and they are being conducted by increasingly sophisticated and organized groups and individuals with a wide range of motives and expertise. The prevalent use of mobile devices and unauthorized applications also increases the risk of data security incidents. Additionally, remote work has become more common and has increased risks to our information technology systems and data, as more of our employees utilize network connections, computers, and devices outside our premises or network, including working at home, while in transit, and in public locations. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may also experience security breaches that may remain undetected for an extended period. Even if identified, we may be unable to adequately investigate or remediate incidents or breaches due to attackers increasingly using tools and techniques that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence.

Although we have not experienced any such material system failure, accident, or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a disruption of our product candidate development and our business operations, whether due to a loss of our trade secrets or other confidential information or other similar disruptions. For example, the loss of clinical trial data from our current or future 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 breach were to result in the theft, loss, or destruction of intellectual property, data, or other misappropriation of assets; financial loss; or otherwise compromise our confidential information, including trade secrets, and disrupt our operations, our competitive position could be harmed, and the further development and commercialization of our product candidates could be delayed, any of which could materially adversely affect our business, financial condition, results of operations, and growth prospects.

We could be subject to risks caused by misappropriation, misuse, leakage, falsification, or intentional or accidental release or loss of information maintained in the information systems and networks of our company, our third-party service providers and vendors, and clinical sites, including personal information of our employees and, potentially, our clinical trial patients, and company and vendor confidential data. In addition, third parties may attempt to penetrate our systems or those of our vendors or fraudulently induce our personnel or the personnel of our vendors to disclose sensitive information to gain access to data and systems. We may experience threats to our data and systems, including malicious codes and viruses, phishing, and other cyberattacks. The number and complexity of these threats continue to increase over time. If a material breach of our information technology systems or those of our vendors occurs, the market perception of the effectiveness of our security measures could be harmed and our reputation and credibility could be damaged. We could be required to expend significant amounts of money and other resources to repair or replace information systems or networks.

In addition, we could be subject to regulatory actions or claims made by individuals and groups in litigation involving privacy issues related to data collection and use practices and other data privacy laws and regulations, including claims for misuse or inappropriate disclosure of data, as well as unfair or deceptive practices. Although we develop and maintain systems and controls designed to prevent these events from occurring, and we have a process to identify and mitigate threats, the development and maintenance of these systems, controls, and processes is costly and requires ongoing monitoring and updating as technologies change and efforts to overcome security measures become increasingly sophisticated.

Moreover, despite our efforts, the possibility of these events occurring cannot be eliminated entirely. As we outsource more of our information systems to vendors, engage in more electronic transactions with clinical sites and collaborators, 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. In addition, we cannot provide any assurance that our internal information technology systems, or those of third parties with which we conduct business, will be sufficient to protect us against breakdowns, service disruption, data deterioration, or loss in the event of a system malfunction, or prevent data from being stolen or corrupted in the event of a cyberattack, security breach, industrial espionage attacks, or insider threat attacks, which could result in financial, legal, business, or reputational harm.

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

We are exposed to the risk of fraud or other misconduct by our employees, clinical trial principal investigators, and consultants. Misconduct by these parties could include intentional failures to comply with FDA regulations or the regulations applicable in other jurisdictions, to provide accurate information to the FDA and other regulatory authorities, to comply with healthcare fraud and abuse laws and regulations in the United States and in other jurisdictions, to report financial information or data accurately, or to disclose unauthorized activities to us. Such misconduct could involve the improper use of information obtained in the course of clinical trials or interactions with the FDA or other regulatory authorities, which could result in regulatory sanctions and cause serious harm to our reputation. We may also be subject to federal, state, and foreign laws governing the privacy and security of identifiable patient information. If our operations are found to be in violation of any of these laws that apply to us, we may be subject to significant administrative, civil, and criminal penalties. If we commercialize our products, sales, marketing, and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing, and other abusive practices. These laws and regulations restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs, and other business arrangements.

We have adopted a Code of Business Conduct, Scientific and Data Integrity, and Ethics that is applicable to all of our employees, but it is not always possible to identify and deter employee misconduct. The precautions we take to detect and prevent misconduct may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from government investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. Additionally, we are subject to the risk that a person could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, financial condition, results of operations, and prospects, including the imposition of administrative, civil, and criminal penalties; damages; monetary fines; contractual damages; reputational harm; and curtailment of our operations, any of which could adversely affect our business, financial condition, results of operations, and prospects.

We may be subject to claims that our employees, consultants, or third parties performing services for us have wrongfully used or disclosed confidential information of third parties.

Many of our employees were previously, and our consultants are or were previously, employed at universities or research institutions, or at other biotechnology or pharmaceutical companies. Although we try to ensure that our employees, consultants, and third parties performing services for us do not use the confidential information of former employers or other companies in their work for us, we may be subject to claims that we or these individuals have used or disclosed confidential information or intellectual property, including trade secrets, of any such individual's current or former employer or other third party. 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 our management and employees.

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 harm our business; additionally, our business could be shut down until we are in compliance with those laws and regulations.

We are subject to numerous federal, state, and local environmental, health, and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment, and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We contract with third parties for the disposal of these materials and wastes. We will not be able to eliminate the risk of contamination or injury from these materials. If contamination or injury results from any use by us of hazardous materials, we could be held liable for any resulting damages. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with these laws and regulations. In addition, we may incur substantial costs to comply with current or future environmental, health, and safety laws and regulations. These current or future laws and regulations may impair our product candidate development efforts.

Moreover, there is increasing stakeholder pressure on companies to diligence environmental, social, and governance matters in the supply chain. Negative publicity regarding production methods, alleged practices, or workplace or related conditions of any of our CMOs, suppliers, CROs, clinical sites, or third parties who perform services for us could adversely affect our reputation. We could be forced to locate alternatives, which could increase our costs and result in delayed supply of components for, and manufacturing of, our product candidates, or other disruptions to our operations.

Our insurance policies are expensive and only protect us from some business risks, which may leave us exposed to certain uninsured liabilities.

Although we have obtained product liability insurance coverage for our clinical trials, it may not be adequate to cover all expenses or liabilities that we may incur. Furthermore, we anticipate that we will need to increase our insurance coverage if we successfully commercialize any product candidate. Product insurance coverage is increasingly expensive, and we may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. Once, and if, we obtain marketing approval for a product candidate, we intend to acquire product liability insurance coverage for our commercial products; however, we may be unable to obtain such product liability insurance on commercially reasonable terms or in adequate amounts. Our insurance policies may also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. Additionally, 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. Many of our license agreements require us to indemnify our licensors or licensees against certain third-party claims; we may not have insurance for those indemnifications or our insurance may be inadequate should any claim arise.

As a public company, it is expensive for us to maintain and, in the future, increase our levels of director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our cash position and results of operations. As a result, it may be more difficult for us to attract and retain qualified people to serve on our board of directors, our board committees, or as executive officers.

Product liability lawsuits against us could cause us to incur substantial liabilities and could limit commercialization of any product candidates that we may develop.

We will face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and will face an even greater risk if such product candidates receive marketing approval and are sold commercially. 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 claims that our product candidates caused injuries, we could incur substantial liabilities. Even a successful defense would require significant financial and management resources. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates that we may develop;
- injury to our reputation and significant negative media attention;

- withdrawal of clinical trial patients;
- significant costs to defend any related product liability litigation;
- initiation of investigations by regulators;
- diversion of our management's time and resources;
- substantial monetary awards to clinical trial patients;
- product recalls, withdrawals, or labeling, marketing, or promotional restrictions;
- exhaustion of any available insurance and our capital resources;
- loss of revenue;
- the inability to commercialize any product candidates that we may develop; and
- a decline in our stock price.

As a public company, we are obligated to develop and maintain proper and effective internal controls over financial reporting, and any failure to maintain the adequacy of these internal controls may adversely affect investor confidence in our company and, as a result, the value of our common stock.

We are required, pursuant to Section 404 of the Sarbanes-Oxley Act of 2002 ("Sarbanes-Oxley Act"), to furnish a report by management on, among other things, the effectiveness of our internal controls over financial reporting. This assessment includes disclosure of any material weaknesses identified by our management in our internal controls over financial reporting. In addition, our independent registered public accounting firm will be required to attest to the effectiveness of our internal controls over financial reporting in our first annual report required to be filed with the SEC following the date we are no longer an emerging growth company if we are not a non-accelerated filer at such time.

If we or our independent registered public accounting firm determines we have a material weakness in our internal controls over financial reporting, investors could lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by the SEC or other regulatory authorities. Internal control deficiencies could also result in a restatement of our financial results in the future. Failure to remedy any material weakness or significant deficiency in our internal controls over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

Our effective tax rate may fluctuate, and we may incur obligations in tax jurisdictions in excess of amounts accrued on our financial statements.

In addition to federal income tax, we are subject to taxation in various state and local tax jurisdictions. As a result, our effective tax rate is derived from a combination of applicable tax rates in the locations in which we operate. In preparing our financial statements, we estimate the amount of tax, if any, that will become payable in each jurisdiction using enacted tax rates as of the balance sheet date. Nevertheless, our effective tax rate may change from year to year due to numerous factors, including changes in the mix of our profitability, if any, from jurisdiction to jurisdiction, the results of examinations and audits of our tax filings, our inability to secure or sustain acceptable agreements with tax authorities, and changes in tax laws. In particular, new income or other tax laws or regulations could be enacted at any time, which could adversely affect our business operations and financial performance. Furthermore, existing tax laws and regulations could be interpreted, modified, or applied adversely to us. The U.S. government may enact additional significant changes to the taxation of business entities, and we are currently unable to predict whether such changes will occur and what the ultimate impact of any such changes would be; thus, we cannot provide any assurance that such changes will not adversely affect our business.

Recently, on July 4, 2025, the U.S. government enacted The One Big Beautiful Bill Act (the "OBBBA"), which includes a broad range of tax reform provisions, including the allowance of immediate expensing of qualifying domestic research and development expenses and permanent extensions of certain provisions within the Tax Cuts and Jobs Act of 2017 ("TCJA"). We have evaluated the impact of the guidance provided to date and determined that there is no material impact to our financial statements for the year ended December 31, 2025. We will continue to address and evaluate the impact of changes in tax laws and legislation as such changes could affect our income tax payable and deferred tax assets and liabilities.

Our ability to use our net operating loss ("NOL") carryforwards and certain other tax attributes may be limited.

We have generated, and expect to continue to generate in the future, significant federal and state NOL carryforwards that are available to offset taxable income in future years, if any. We have also generated, and expect to continue to generate in the future, significant federal and state research and development tax credit carryforwards, and, beginning in 2022, we began to generate orphan drug credit carryforwards that are available to potentially offset federal and state income taxes, respectively, in future years, if any.

Under the TCJA, as modified by the Coronavirus Aid, Relief and Economic Security Act ("CARES Act"), our federal NOLs incurred in taxable years beginning after December 31, 2017 may be carried forward indefinitely but are limited to 80% of our taxable income. It is uncertain if and to what extent various states will conform to the NOL changes contained in the TCJA and the CARES Act. Federal research and development credit and orphan drug credit carryforwards may only be carried forward for 20 years and therefore could expire unused. As a result, they may be unavailable to offset future taxes.

In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended ("Tax Code"), and corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a greater than 50 percentage point change, by value, in its equity ownership by certain stockholders over a rolling three-year period, the corporation's ability to use its pre-change NOL carryforwards and other pre-change tax attributes (such as research and development tax credits) to offset its post-change income or taxes may be limited. We have experienced prior ownership changes in 2014, 2016, and 2021. We do not expect any permanent limitations on our tax attributes. We have recorded a full valuation allowance for deferred tax assets, including NOLs and tax credits as of December 31, 2025. The issuance of common stock in the future, or shifts in the ownership of our common stock among certain stockholders, either separately or in combination, over time may result in a limitation under Sections 382 and 383 of the Tax Code. In addition, at the state level, there may be periods during which the use of NOL carryforwards is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. If an ownership change occurs and we earn taxable income in future years, the limitation on our ability to use our NOLs and other tax attribute carryforwards could adversely affect our future operating results by increasing our future income tax liabilities. See Note 12 to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K for additional information.

Pandemics or other public health crises may adversely impact our business, financial condition, and results of operations, including our clinical trials, and may cause substantial disruption in the financial markets and adversely impact economies worldwide.

We may experience disruptions related to pandemics or other public health crises that could severely impact our business, clinical trials, and commercialization activities, including:

- halting or suspending enrollment in our clinical trials;
- delays or difficulties in enrolling and retaining patients in our clinical trials;
- interruption of key clinical trial activities, such as clinical trial site data monitoring and efficacy, safety and translational data collection, and processing and analyses, due to limitations on travel imposed or recommended by federal, state, or local governments, employers and others or interruption of clinical trial subject visits, which may impact the collection and integrity of subject data and clinical trial endpoints;
- requirements to change the ways in which our clinical trials are conducted due to governmental regulations as part of a response to pandemics or other public health crises, which may result in unexpected costs, delays, or discontinuation of our clinical trials altogether;
- increased adverse events and deaths in our clinical trials due to pandemic-related infections;

- increased rates of patients withdrawing from our clinical trials following enrollment as a result of contracting certain diseases or being forced to quarantine due to other public health crises;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- interruption or delays in the operations of the FDA and comparable foreign regulatory agencies and necessary interactions with such regulatory agencies due to limitations in employee resources, limitations on travel, forced furlough of government employees, or diversion of resources, which would impact review and approval timelines;
- interruption of, or delays in receiving, supplies of components for our product candidates from our suppliers, including the supply of healthy donor cells, and delays or suspension in manufacturing by our CMOs due to staffing shortages, production slowdowns or stoppages, and disruptions in delivery systems, or due to prioritization of production for pandemic-related therapies or vaccines;
- limitations on employee resources that would otherwise be focused on advancing our business, including because of sickness of employees or their families, including our executive officers and other key employees, the desire of employees to avoid contact with large groups of people, an increased reliance on working from home, or mass transit disruptions; and
- significant disruptions and volatility in the financial markets.

The extent to which pandemics or other public health crises may impact our business and clinical trials, productivity of our employees, supply chains, and access to capital or business development activities will depend on future developments, which are highly uncertain at this time. To the extent pandemics or other public health crisis adversely affects our business, financial condition, results of operations, and prospects, it may also have the effect of amplifying many of the other risks described in this "Risk Factors" section, such as those relating to the timing and results of our current and future clinical trials and our financing needs.

Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.

In addition to the business disruptions caused by public health crises or potential cybersecurity attacks, our operations, and those of our CMOs, suppliers, CROs, and clinical trial sites, could be subject to disruptions, including those caused by earthquakes, power shortages or outages, telecommunications failures, water shortages or outages, floods, hurricanes, typhoons, fires, extreme weather conditions, epidemics and pandemics, and other natural or man-made disasters or business interruptions. The occurrence of any of these business disruptions could seriously harm our business, financial condition, results of operations, and prospects, and increase our costs and expenses. Our ability to manufacture our product candidates could be disrupted if our operations or those of our CMOs, suppliers, CROs, or clinical trial sites are affected by a natural or man-made disaster or other business interruption. Our corporate headquarters are located in California near major earthquake faults and fire zones. The ultimate impact on us and our general infrastructure of being located near major earthquake faults and fire zones and being consolidated in certain geographical areas is unknown, but our business, financial condition, results of operations, and prospects could suffer in the event of a major earthquake, fire, or other natural disaster.

Furthermore, we interact with the FDA and other federal, state, and regulatory agencies, and lack of funding for such agencies or temporary shutdowns can affect our operations. Over the last several years, 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 government employees and stop critical activities. 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; statutory, regulatory, and policy changes; and public health crises. Average review times at the agency have fluctuated in recent years as a result. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions for our product candidates, which could have a material adverse effect on our business.

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 bank failures and market-wide liquidity problems. For example, on March 10, 2023, Silicon Valley Bank ("SVB") was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation ("FDIC") as receiver. Similarly, on March 12, 2023, Signature Bank and Silvergate Capital Corp. were each put into receivership. The Federal Reserve Board subsequently announced that account holders would be made whole; however, it is uncertain whether the U.S. Department of Treasury, FDIC, and Federal Reserve Board will provide access to uninsured funds in the future in the event of the closure of other banks or financial institutions, or that they would do so in a timely fashion. Although we have not experienced any adverse impact to our liquidity or to our current and projected business operations, financial condition, or results of operations as a result of the matters relating to these banks, uncertainty remains over liquidity concerns in the broader financial services industry, and our industry as a whole may be adversely impacted in ways that we cannot predict at this time. As of December 31, 2025, substantially all our cash on deposit was maintained at four financial institutions in the United States, and our current deposits are in excess of federally insured limits. If further failures in financial institutions where we hold deposits occur, we could experience additional risk. Any loss or limitation on our cash, cash equivalents, or marketable securities would adversely affect our business. In addition, if any of the third parties on which we rely to conduct our clinical trials are unable to access funds pursuant to a failure at a financial institution, the ability for such party to fulfill its obligations to us could be adversely affected.

Although we assess our banking relationships as we believe necessary or appropriate, our access to cash in amounts adequate to finance our current and projected future business operations could be significantly impaired by factors that affect the financial institutions with which we have banking relationships. These factors could include, among others, events such as liquidity constraints or failures, the ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, disruptions or instability in the financial services industry or financial markets, or concerns or negative expectations about the prospects for companies in the financial services industry. These factors could also include factors involving financial markets or the financial services industry generally. The results of events or concerns that involve one or more of these factors could include a variety of material and adverse impacts on our current and projected business operations and our financial condition and results of operations. These could include, but may not be limited to, delayed access to deposits or other financial assets or the uninsured loss of deposits or other financial assets, termination of cash management arrangements, and/or delays in accessing or actual loss of funds subject to cash management arrangements.

In addition, widespread investor concerns regarding the U.S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all. Any decline in available funding or access to our cash and liquidity resources could, among other risks, adversely impact our ability to meet our operating expenses, financial obligations or fulfill our other obligations, result in breaches of our financial and/or contractual obligations or result in violations of federal or state wage and hour laws. Any of these impacts, or any other impacts resulting from the factors described above or other related or similar factors not described above, could have material adverse impacts on our liquidity and our current and/or projected business operations and financial condition and results of operations.

We maintain our cash at financial institutions, often in balances that exceed federally insured limits.

We maintain the majority of our cash and cash equivalents in accounts at four banking institutions in the United States that we believe are of high quality. Cash held in these accounts often exceed the FDIC insurance limits. If such banking institutions were to fail, we could lose all or a portion of amounts held in excess of such insurance limitations. As noted above, the FDIC took control of certain banks. In the event of failure of any of the financial institutions where we maintain our cash and cash equivalents, we cannot provide any assurance that we would be able to access uninsured funds in a timely manner or at all. Any inability to access or delay in accessing these funds could adversely affect our business and financial position.

Unfavorable global economic conditions could adversely affect our business, financial condition, or results of operations.

Our business, financial condition, results of operations, or prospects could be adversely affected by general conditions in the global economy and in the global financial markets. A severe or prolonged economic downturn, including as a result of pandemics or other public health crises, the ongoing war between Russia and Ukraine, conflicts in the Middle East, including the recent hostilities involving Iran, tension between China and Taiwan, geopolitical tensions in Europe, South America, and elsewhere, interest rate fluctuations, rising inflation, recession, or other global financial, geopolitical crises or macroeconomic factors, could result in a variety of risks to our business, including weakened demand for our product candidates, if approved, or our ability to raise additional capital when needed on acceptable terms, if at all. Recent global events such as 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 product candidates may be negatively affected. A significant worsening of global economic conditions could precipitate or materially amplify the other risks described herein. Furthermore, the range of actions taken to date, as well as those that may occur in the future, around tariffs and trade and the associated uncertainty of how such actions may be implemented, may have adverse effects on the global economic environment and could also amplify such other risks. Global conflicts or a weak or declining economy may increase the likelihood disruptions of our clinical trials or manufacturing and supply of our product candidates. Additionally, any supply disruptions could make it more difficult for us to find favorable pricing and reliable sources for the materials we need, which would increase pressure on our costs and increase the risk that we may be unable to acquire the necessary materials to successfully manufacture our product candidates. Current capital market conditions, including the impact of inflation, have increased borrowing rates and can be expected to significantly increase the cost of capital as compared to prior periods and could also affect 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 CMOs to manufacture clinical trial materials for our product candidates. Furthermore, we currently conduct some clinical trials outside of the United States, and unfavorable global conditions could affect these trials. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which such conditions could adversely impact our business.

Risks Relating to Ownership of our Common Stock

The market price of our common stock has been, and may continue to be, volatile, and our investors may suffer substantial losses if the price of our common stock drops significantly.

Due to the volatility of the market price for our common stock, investors may suffer substantial losses if the price drops significantly. Some of the factors that may cause the market price of our common stock to fluctuate include:

- the timing and results of our clinical trials;
- delay, failure, or discontinuation of any of our product candidates;
- results of nonclinical studies, clinical trials, or regulatory approvals of product candidates of our competitors, or announcements about new research programs or product candidates of our competitors;
- adverse regulatory decisions, including failure to receive regulatory approval of one or more of our product candidates;
- unanticipated or serious safety concerns related to our product candidates;
- developments or changing views regarding the use of biologics, including those that involve genome editing;
- commencement or termination of collaborations;
- regulatory or legal developments in the United States and other countries;
- assertions that our product candidates infringe third-party patents;
- invalidity challenges to our intellectual property, including intellectual property that we have in-licensed;
- manufacturing delays and delays caused by supply chain issues;

- acceptance or lack of acceptance of allogeneic CAR-T cell therapies as compared with autologous CAR-T cell therapies and perceptions that allogeneic CAR-T cell therapies do not maintain a durable response;
- inability to obtain and maintain collaboration partners;
- the recruitment and retention of key personnel;
- the level of expenses related to any of our product candidates, including clinical trials;
- the results of our efforts to develop additional product candidates or technologies;
- actual or anticipated changes in estimates as to financial results, development timelines, or recommendations by securities analysts;
- announcements, expectations, or structures of additional financing efforts;
- significant lawsuits, including contract disputes with our licensors, licensees, assignors, assignees, suppliers, CMOs, CROs, clinical sites, or securities class action litigation;
- sales of our common stock by us, our insiders, or other stockholders;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic and political conditions such as recessions, inflationary pressures, interest rates, fuel prices, elections, drug and biologic pricing policies, international currency fluctuations, acts of war or terrorism, geopolitical events, and public health crises; and
- the other factors described in this "Risk Factors" section.

We may not remain in compliance with the continued listing requirements of Nasdaq, and, if we are not able to remain in compliance, our common stock will be subject to delisting.

Our common stock is currently listed for trading on the Nasdaq Global Select Market under the symbol "CRBU." The continued listing of our common stock on Nasdaq is subject to our compliance with a number of listing standards. On May 7, 2025, we received a letter from the Listing Qualifications Staff ("Staff") of The Nasdaq Stock Market LLC notifying us that, for the prior 30 consecutive business days, the bid price for our shares of common stock had closed below $1.00 per share, which is the minimum bid price required to maintain continued listing on the Nasdaq Global Select Market under Nasdaq Listing Rule 5450(a)(1) ("Minimum Bid Price Rule"). On June 18, 2025, we received a written notice ("Compliance Notice") from the Staff notifying us that, from June 3, 2025, to June 17, 2025, the closing bid price of the our common stock had been $1.00 per share or greater and, accordingly, we had regained compliance the Minimum Bid Price Rule.

We cannot provide any assurance that, in the future, we will remain in compliance with the Minimum Bid Price Rule, and the bid price of our shares of common stock may again close below $1.00 per share for 30 consecutive business days. In such event, we will have 180 calendar days to regain compliance as long as we have not implemented a reverse stock split within the one-year period before we fail to be in compliance with the Minimum Bid Price Rule. To regain compliance during a compliance period, the closing bid price of our common stock must be at least $1.00 per share for a minimum of 10 consecutive business days during this 180-calendar day period, at which time the Staff will provide written notification to us that our stock complies with the Minimum Bid Price Rule, unless the Staff exercises its discretion to extend this 10-business day period pursuant to Nasdaq Listing Rule 5810(c)(3)(H).

We cannot provide any assurance that our common stock will regain compliance with the Minimum Bid Price Rule by any compliance deadline. Even if the market price per post-reverse stock split share of our common stock remains in excess of $1.00 per share, we may be delisted due to a failure to meet other continued listing requirements, including Nasdaq requirements related to the minimum number of shares that must be in the public float, the minimum market value of the public float, and the minimum number of market makers, among others. If we are unable to satisfy the Nasdaq criteria for continued listing, our common stock would be subject to delisting. A delisting of our common stock could negatively impact us by, among other things, (i) reducing the liquidity and market price of our common stock; (ii) reducing the number of investors willing to hold or acquire our common stock, which could negatively impact our ability to raise equity financing; (iii) decreasing the amount of news and analyst coverage of us; (iv) limiting our ability to issue additional securities or obtain additional financing in the future; (v) limiting the number of shares we could sell under a registration statement to offer and sell freely tradable securities, thereby reducing the amount of capital we could raise in the public capital markets; and (vi) impairing our ability to provide equity incentives to our employees. In addition, delisting from Nasdaq may negatively impact our reputation and, consequently, our business. If this happens, we cannot provide any assurance that we will be able to regain compliance with the applicable Nasdaq Global Select listing requirements, or, if our listing is transferred to the Nasdaq Capital Market, that we will meet the continued listing requirement for the market value of publicly held shares and all other initial listing standards of the Nasdaq Capital Market, with the exception of the Minimum Bid Price Rule.

Our stockholders have approved an amendment to our amended and restated certificate of incorporation to effect a reverse stock split at the discretion of our board of directors. We cannot provide any assurance that a reverse stock split, if implemented, will increase our stock price for a sustained period or will cause our stock to maintain compliance with Nasdaq continued listing requirements.

At our 2025 Annual Meeting of Stockholders held on June 12, 2025, our stockholders approved a proposal to adopt an amendment to our amended and restated certificate of incorporation to effect a reverse stock split at a ratio ranging from any whole number between 1-for-5 and 1-for-50 inclusive ("Split Ratio Range"), as determined by our board of directors in its discretion, subject to our board of directors' authority to abandon such amendment. Our board of directors has the sole authority to elect, at any time on or prior to June 12, 2026, whether or not to effect a reverse stock split. Our board of directors could decide to implement a reverse stock split for a variety of business reasons, including but not limited to, regaining compliance with Nasdaq continued listing requirements in the event we are not in compliance with the Minimum Bid Price Rule; increasing the marketability of our common stock since investors, brokerage firms, and market makers consider low-priced stocks as unduly speculative in nature, in part due to the trading volatility often associated with stocks below certain prices, and, as a matter of policy, avoid investment and trading in such stocks; decreasing price volatility as currently small changes in the price of our common stock result in relatively large percentage changes in the stock price; and, providing more authorized shares available for issuance in capital-raising transactions by reducing the number of issued and outstanding shares. If a reverse stock split is implemented, we expect that a reverse stock split will increase the market price of our common stock. However, the effect of a reverse stock split on the market price of our common stock cannot be predicted with any certainty, and the history of similar reverse stock splits for companies in like circumstances is varied, particularly since some investors may view a reverse stock split negatively. It is possible that the per share price of our common stock after a reverse stock split will not rise in proportion to the reduction in the number of shares of our common stock outstanding resulting from the reverse stock split, and the reverse stock split may not result in a per share price that would attract brokers and investors who do not trade in lower-priced stocks. Even if a reverse stock split is implemented, the market price of our common stock may decrease due to factors unrelated to the reverse stock split. The market price of our common stock may also be based on other factors that may be unrelated to the number of shares outstanding, including the timing and content of disclosures about our clinical trials for our product candidates. If a reverse stock split is effected and the trading price of our common stock declines, the percentage decline as an absolute number and as a percentage of our overall market capitalization may be greater than would occur in the absence of the reverse stock split. Even if we implement a reverse stock split, we cannot provide any assurance that we will maintain compliance with the Minimum Bid Price Rule, or otherwise be in compliance with other applicable Nasdaq listing rules.

Moreover, under a recent change in Nasdaq rules, if we effect a reverse stock split and we fail to be in compliance with the Minimum Bid Price Rule within one year of that previous reverse stock split, we would not be eligible for any 180-day compliance period and we may be subject to immediate delisting. Nasdaq's position is that this applies to a company even if the company was in compliance with the Minimum Bid Price Rule at the time of its prior reverse stock split. Accordingly, if we effect a reverse stock split, whether for the purpose of regaining compliance with the Minimum Bid Price Rule or other business reasons, and subsequently the closing bid price of our common stock drops below $1.00 long enough to no longer be in compliance with the Minimum Bid Price Rule within one year of a previous reverse stock split, we may suffer immediate delisting without an opportunity to regain compliance.

The effective increase in the number of authorized shares of our common stock as a result of a reverse stock split may result in dilution to existing stockholders from future issuances of shares.

Under the stockholder proposal approved at our 2025 Annual Meeting, if a reverse stock split is implemented, it would not change the total authorized number of shares of our common stock, which would remain at 300,000,000 authorized shares of common stock and 10,000,000 authorized shares of preferred stock. However, the reduction in the issued and outstanding shares would, in effect, provide more authorized shares available for future issuance. These additional shares would be available for issuance from time to time for corporate purposes such as issuances of common stock in connection with capital-raising transactions and acquisitions of other companies or assets, as well as for issuance upon conversion or exercise of securities such as convertible debt, warrants, or options convertible into, or exercisable for, common stock. Although we believe that the availability of the additional shares will provide us with flexibility to meet business needs as they arise, to take advantage of favorable opportunities, and to respond effectively in a changing corporate environment, if we issue additional shares for any of these purposes, the aggregate ownership interest of our current stockholders, and the interest of each existing stockholder, would be diluted, possibly substantially. In the past, we have conducted public and private offerings of our securities, and we will require additional capital to develop our product candidates and fund our operations. As a result, it is foreseeable that we will seek to issue additional shares of common stock in connection with capital raising activities or any of the other activities described above, which would result in dilution of the interests of existing stockholders.

We may be subject to securities class action litigation, and our officers and directors may be subject to shareholder derivative lawsuits, which will result in substantial costs and a diversion of management's attention and resources, which could harm our business.

Securities class action litigation is often been brought against a company following a decline in the market price of its securities, and, in the past, we have had such securities class action litigation brought against us as well as shareholder derivative complaints filed against our directors and certain of our current and former officers relating to securities class action litigation. In the future, we may face additional securities class action litigation, and our officers and directors may be subject to shareholder derivative suits. This risk is especially relevant for us because biotechnology and pharmaceutical companies have experienced significant stock price volatility in recent years, and we expect to experience continued stock price volatility. We cannot provide any assurance that we will be able to have such lawsuits dismissed or, if not, that we will be able to settle the cases. Defending against future litigation could result in substantial costs and a diversion of management’s attention and resources, which could harm our business.

If securities analysts do not publish research or reports about our business or if they publish negative evaluations of our stock, the price of our stock could decline.

We currently have coverage by several biotechnology research analysts. If any of those analysts discontinue coverage, we could lose visibility in the market for our stock, which in turn could cause our stock price to decline. If one or more of the analysts covering our business downgrade or adjust the price target as part of their evaluations of our stock, the price of our stock could decline.

We are an “emerging growth company” under the JOBS ACT and a “smaller reporting company” and the reduced disclosure requirements and exemptions from certain governance requirements applicable to emerging growth companies and smaller reporting companies may make our common stock less attractive to investors.

We are an “emerging growth company,” as defined in the JOBS Act, and may remain an emerging growth company until the last day of our fiscal year following the fifth anniversary of the closing of our IPO (i.e., December 31, 2026). For as long as we remain an emerging growth company, we are permitted and plan to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act; not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board (“PCAOB”) regarding mandatory audit firm rotation or a supplement to the auditor’s report providing additional information about the audit and the financial statements; reduced disclosure obligations regarding executive compensation; and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. As a result, the information we provide stockholders will be different than the information that is available with respect to some other public companies.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that we (i) are no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, our consolidated financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

We are also a "smaller reporting company," as defined by applicable rules of the SEC. Even after we no longer qualify as an emerging growth company, we may still qualify as a smaller reporting company and would be permitted to continue to take advantage of many of the same reporting exemptions, including the exemption from the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act as long as we do not otherwise also qualify as an "accelerated filer" or "large accelerated filer" for SEC reporting purposes, and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. In addition, as a smaller reporting company, we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Reports on Form 10-K.

We cannot predict if investors will find our common stock less attractive if we rely on emerging growth company or smaller reporting company exemptions. If some investors determine that our common stock is less attractive, there may be a less active trading market for our common stock and our stock price may be more volatile.

We have incurred, and will continue to incur, increased costs as a result of operating as a public company, and our management will continue to devote substantial time to compliance initiatives and corporate governance practices.

As a public company, we have and will continue to incur legal, accounting, and other expenses that we did not incur as a private company. The Dodd-Frank Wall Street Reform and Consumer Protection Act, the Sarbanes-Oxley Act, the listing requirements of Nasdaq, and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. We have had to hire additional accounting, finance, legal, and other personnel in connection with our efforts to comply with the requirements of being, a public company. Our management and other personnel devote a substantial amount of time toward maintaining compliance with these requirements. These requirements have increased our legal and financial compliance costs and have made some activities more time-consuming and costly. Operating as a public company also makes it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain coverage. This may make it more difficult for us to attract and retain qualified people to serve on our board of directors or as executive officers.

As a public company, we are subject to Section 404 of the Sarbanes-Oxley Act and the related rules of the SEC, which generally require our management and independent registered public accounting firm to report on the effectiveness of our internal control over financial reporting. However, for so long as we remain an emerging growth company as defined in the JOBS Act or a smaller reporting company, we intend to take advantage of certain exemptions from various reporting requirements that are applicable to public companies that are not emerging growth companies or smaller reporting companies, including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404. Once we are no longer either an emerging growth company or a smaller reporting company or, if prior to such date, we opt to no longer take advantage of the applicable exemption, we will be required to include an opinion from our independent registered public accounting firm on the effectiveness of our internal control over financial reporting.

During the course of our review and testing, we may identify deficiencies and be unable to remediate them before we must provide the required reports. Furthermore, if we identify any material weaknesses, we may not detect errors on a timely basis and our financial statements may be materially misstated. We or our independent registered public accounting firm may not be able to conclude on an ongoing basis that we have effective internal control over financial reporting, which could materially and adversely affect our business, financial condition, results of operations, and prospects; cause investors to lose confidence in our reported financial information; and cause the trading price of our stock to fall. In addition, as a public company we are required to file accurate and timely quarterly and annual reports with the SEC under the Exchange Act. In order to report our results of operations and financial statements on an accurate and timely basis, we depend in part on third parties to provide timely and accurate notice of their costs to us. Any failure to report our financial results on an accurate and timely basis could result in sanctions, lawsuits, delisting of our shares from Nasdaq, or other adverse consequences that would materially and adversely affect our business, financial condition, results of operations, and prospects.

We do not expect to pay any dividends for the foreseeable future. Investors may never obtain a return on their investment.

You should not rely on an investment in our common stock to provide dividend income. We do not anticipate that we will pay any dividends to holders of our common stock in the foreseeable future. Instead, we plan to retain any earnings to maintain and expand our existing operations. In addition, any future credit facility may contain terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock. Accordingly, investors must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any return on their investment. As a result, investors seeking cash dividends should not invest in our common stock.

Provisions in our amended and restated certificate of incorporation, our amended and restated bylaws, and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders. These provisions may prevent attempts by our stockholders to replace or remove our current management.

Our amended and restated certificate of incorporation, amended and restated bylaws, and Delaware law contain provisions that may have the effect of discouraging, delaying, or preventing a change in control of us or changes in our management that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. Our amended and restated certificate of incorporation and bylaws include provisions that:

- authorize "blank check" preferred stock, which could be issued by our board of directors without stockholder approval and may contain voting, liquidation, dividend, and other rights superior to our common stock;
- established a classified board of directors whose members serve staggered three-year terms;
- specify that special meetings of our stockholders can be called only by our board of directors, the chair of our board, or our chief executive officer;
- prohibit stockholder action by written consent;
- establish an advance notice procedure for stockholder matters to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to our board of directors;
- provide that vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum;
- provide that our directors may be removed only for cause;
- expressly authorized our board of directors to make, alter, amend, or repeal our amended and restated bylaws; and
- require supermajority votes of the holders of our common stock to amend our amended and restated bylaws and specified provisions of our amended and restated certificate of incorporation.

These provisions, alone or together, could delay or prevent hostile takeovers and changes in control or changes in our management. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock.

In addition, because we are incorporated in the State of Delaware, we are governed by the provisions of Section 203 of the General Corporation Law of the State of Delaware, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

Any provision of our amended and restated certificate of incorporation, amended and restated bylaws, or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock, and could also affect the price that some investors are willing to pay for our common stock.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware and the federal district courts will be the exclusive forums for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, executive officers, or employees.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for the following types of actions or proceedings under Delaware statutory or common law:

- any derivative claim or action or proceeding brought on our behalf;
- any claim or action asserting a breach of fiduciary duty or aiding and abetting a breach of fiduciary duty;
- any claim or action against us arising under the Delaware General Corporation Law, our amended and restated certificate of incorporation, or our amended and restated bylaws; and
- any action asserting a claim against us that is governed by the internal-affairs doctrine.

This provision would not apply to suits brought to enforce a duty or liability created by the Securities Act or the Exchange Act. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated certificate of incorporation further provides that the federal district courts will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. This exclusive federal forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, executive officers, or other employees, which may discourage lawsuits against us and our directors, executive officers, and other employees.

Although the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive federal forum provisions. In March 2023, a putative class action lawsuit was filed in Superior Court of the State of California for the County of Alameda against our company and certain of our officers and current and former members of our board of directors, *Lowry v. Caribou Biosciences, Inc., et al.*, case number T23-1084 ("Lowry Case"), for alleged violations of Sections 11 and 15 of the Securities Act. In February 2024, the California state court granted our motion to dismiss on the grounds that our amended and restated certification of incorporation mandates that Securities Act claims against us be brought in federal court. Although we were successful in the Lowry Case and we will vigorously assert the validity and enforceability of our exclusive federal forum provision in any future litigation in other jurisdictions, this may require significant additional costs associated with resolving the action, and we cannot provide any assurance that the federal forum provision will be enforced by a court in the future or in other jurisdictions.

Item 1B. Unresolved Staff Comments.

Not applicable.

Item 1C. Cybersecurity.

Cybersecurity Risk Management and Strategy

We recognize the importance of assessing, identifying, and managing material risks associated with cybersecurity threats, as such term is defined in Item 106(a) of Regulation S-K. These risks include operational risks, intellectual property or trade secret theft, improper disclosure of confidential information, fraud, extortion, harm to employees or third parties with which we do business, and violation of data privacy or security laws.

Identifying and assessing cybersecurity risk is integrated into our overall risk management systems and processes. Cybersecurity risks related to our business, technical operations, privacy, and compliance issues are identified and addressed through a multi-faceted approach including third-party assessments, internal information technology ("IT") audits, and IT security reviews. To defend, detect, and respond to cybersecurity incidents, we perform cybersecurity reviews of systems and applications; audits of applicable data policies; regular vulnerability assessments and penetration testing using external third-party tools to test security control; security incident and event management; continuous monitoring, and threat intelligence gathering; conduct employee training; and implement appropriate changes.

We also leverage third-party expertise to audit and test our cybersecurity program. These include periodic reviews of cybersecurity threats and related controls, including reviews of periodic penetration tests conducted by independent third parties. We have implemented processes to manage the cybersecurity risks associated with our use of third-party service providers. This includes proactive monitoring of third-party service providers' security protocols, risk questionnaires for new technology vendors, and other processes to minimize risks associated with our third-party providers.

Security events and data incidents are evaluated, ranked by severity, and prioritized for response and remediation. Incidents are evaluated to determine materiality as well as operational and business impact, and reviewed for privacy impact.

Our risk management program also assesses third-party risks, and we perform third-party risk management to identify and mitigate risks from third parties such as vendors and suppliers. Cybersecurity risks are evaluated when determining the selection and oversight of applicable third-party service providers and potential fourth-party risks when handling and/or processing our confidential information and data. In addition to new vendor onboarding, we perform risk management during third-party cybersecurity compromise incidents to identify and mitigate risks to us from third parties.

We do not believe that there are currently any risks from known cybersecurity threats that have materially affected or are reasonably likely to materially affect us, including our business strategy, results of operations, or financial condition. For additional information regarding risks we face, see Risk Factors - *"Our internal computer systems, or those of third parties with which we interact, may fail or suffer security breaches, which could result in a material disruption of the development of our product candidates, compromise sensitive information related to our business, or prevent us from accessing critical information, potentially exposing us to liability or otherwise adversely affecting our business,*" in Item 1A of this Annual Report on Form 10-K.

Cybersecurity Governance

Cybersecurity is an important part of our risk management processes and an area of focus for our board of directors and management. The board's audit committee is responsible for the oversight of risks from cybersecurity threats and receives updates on a quarterly basis from management, including representatives from our IT, finance, and legal departments regarding matters of cybersecurity. These updates include existing and new cybersecurity risks, status on how management is addressing and/or mitigating those risks, cybersecurity and data privacy incidents (if any) and status on key information security initiatives. Our board members also engage in ad hoc conversations with management on cybersecurity-related news events and updates to our cybersecurity risk management and strategy programs.

Our day-to-day cybersecurity risk management and strategy processes are overseen by representatives from our IT, finance, and legal departments. Such individuals have an average of over 20 years of prior work experience in various roles involving IT security, auditing, compliance, data protection, privacy, risk management, systems, and programming. These individuals are informed about and monitor the prevention, mitigation, detection, and remediation of cybersecurity incidents through their management of, and participation in, our cybersecurity risk management and strategy processes, and report to the audit committee on any appropriate items.

Item 2. Properties.

Our corporate headquarters are located in Berkeley, California, where we lease approximately 71,735 square feet of laboratory and office space under two leases. These leases expire in July 2032 and March 2033. We have the ability to extend these leases for an additional five years each. See Note 8 to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K for additional information.

We believe that our existing facilities are adequate for our near-term needs and that suitable additional facilities will be available in the future if and when needed.

Item 3. Legal Proceedings.

From time to time, we may become involved in litigation arising in the ordinary course of business. Regardless of the outcome, litigation can have a material adverse effect on us due to defense and settlement costs, diversion of our management resources, and other factors.

On December 24, 2024, a putative class action lawsuit was filed in the U.S. District Court for the Northern District of California against our company and certain of our current and former officers, *Saylor v. Caribou Biosciences, Inc., et al.,* case number 3:24-cv-09413 ("Saylor Case"). The alleged class period was July 14, 2023, to July 16, 2024. The Saylor Case complaint challenged disclosures regarding our business, operations, and prospects, specifically with respect to the alleged safety, efficacy, and durability of vispa-cel, the clinical results and commercial prospects for vispa-cel, and our financial statements, in alleged violation of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended ("Exchange Act"). On April 15, 2025, the lead plaintiff filed a motion to voluntarily dismiss the lawsuit and, on April 27, 2025, the court granted the motion, dismissing the lawsuit without prejudice.

On March 3, 2025, a shareholder derivative complaint was filed in the U.S. District Court for the Northern District of California against our directors and certain of our current and former officers, *Moisio, derivatively on behalf of Caribou Biosciences, Inc. v. Haurwitz, et al,* case number 4:25-cv-02199 ("First Derivative Case"), alleging, among other things, that the named directors and officers breached their fiduciary duties by causing our company to make the disclosures being challenged in the Saylor Case and seeking unspecified monetary damages from our company as well as that we make certain changes to our corporate governance. On March 11, 2025, a second shareholder derivative complaint was filed in the U.S. District Court for the Northern District of California against the same defendants as in the First Derivative Case, *Allen, derivatively on behalf of Caribou Biosciences, Inc. v. Braunstein, et al.*, case number 4:25-cv-02463 ("Second Derivative Case"), with the same allegations. On April 1, 2025, the First Derivative Case and the Second Derivative Case were deemed related and assigned to the same judge and, on April 7, 2025, the First Derivative Case and the Second Derivative Case were consolidated into a single action, *In re Caribou Biosciences, Inc. Derivative Litigation*, lead case number 4:25-cv-02199 ("Consolidated Derivative Action"). The plaintiffs in the Consolidated Derivative Action filed an amended complaint on July 7, 2025. The amended complaint largely tracked the claims from the original complaints, but it also challenged additional disclosures as false or misleading. On August 21, 2025, the defendants filed a motion to dismiss the complaint. On October 16, 2025, the parties filed a stipulation to voluntarily dismiss the lawsuit without prejudice, which the court granted on October 17, 2025.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

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

Market Information

Our common stock is traded on the Nasdaq Global Select Market under the symbol "CRBU."

Holders

As of February 27, 2026, we had 34 holders of record of our common stock. This number does not include beneficial owners whose shares were held in street name by banks, brokers, and other financial institutions.

Dividend Policy

We have not declared or paid cash dividends on our capital stock since our inception. We intend to retain future earnings, if any, to finance the operation and expansion of our business and do not anticipate paying any cash dividends to holders of common stock in the foreseeable future.

Securities authorized for issuance under equity compensation plans

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

Recent Sales of Unregistered Securities

We had no sales of unregistered equity securities during the period covered by this Annual Report that were not previously reported in a Current Report on Form 8-K (or on Form 10-Q in lieu of Form 8-K).

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

Item 6. [Reserved]

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

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and the related notes included in this Annual Report on Form 10-K. This discussion and analysis contain forward-looking statements, including statements regarding our intentions, plans, projections and expectations for our business. Forward-looking statements are based upon current beliefs, plans and expectations related to future events and our future financial performance and are subject to risks, uncertainties and assumptions. Our actual results and the timing of certain events could differ materially from those described in or implied by these forward-looking statements as a result of various factors, including those set forth the "Risk Factors" section in Part I, Item 1A of this Annual Report on Form 10-K. See also the Special Note Regarding Forward-Looking Statements section of this Annual Report on Form 10-K.

We are a clinical-stage **C**lustered **R**egularly **I**nterspaced **S**hort **P**alindromic **R**epeats ("CRISPR") genome-editing biopharmaceutical company dedicated to developing transformative therapies for patients with devastating diseases. Our genome-editing platform is based on our novel chRDNA (**C**RISPR **h**ybrid **R**NA-**DNA**, or "chRDNA," pronounced "chardonnay") genome-editing technology, which enables more precise genome editing of allogeneic cell therapies.

Our allogeneic chimeric antigen receptor ("CAR") -T ("CAR-T") cell therapy product candidates are manufactured in advance with cells from healthy donors, with the goal of enabling broad patient access, rapid patient treatment, and increased manufacturing scale. Our allogeneic CAR-T cell therapy product candidates in clinical development are directed at established cell surface targets against which autologous CAR-T cell therapeutics have already demonstrated clinical proof of concept, CD19 and B cell maturation antigen ("BCMA"). We use our chRDNA technology to armor our cell therapy product candidates through genome-editing strategies, such as checkpoint disruption and immune cloaking, to enhance allogeneic CAR-T cell therapy activity against hematologic malignancies.

We are advancing two clinical-stage allogeneic CAR-T cell therapy product candidates for the treatment of patients with hematologic malignancies:

- Vispacabtagene regedleucel ("vispa-cel," formerly CB-010): an allogeneic anti-CD19 CAR-T cell therapy that has been evaluated in patients with relapsed or refractory B cell non-Hodgkin lymphoma ("r/r B-NHL") in our ANTLER phase 1 clinical trial
- CB-011: an allogeneic anti-BCMA CAR-T cell therapy that is being evaluated in patients with relapsed or refractory multiple myeloma ("r/r MM") in our CaMMouflage phase 1 clinical trial

Since our founding in 2011, we have devoted substantially all of our resources to organizing and staffing, business planning, raising capital, expanding our genome-editing platform technologies, developing our product candidates and building our pipeline, creating and maintaining our intellectual property portfolio, and establishing arrangements with third parties for the manufacture, testing, and clinical trial evaluations of our product candidates. We do not have any products approved for commercial sale and have not generated any revenue from product sales. We have incurred operating losses since commencement of our operations.

To date, we have primarily funded our operations through proceeds from the sales of our capital stock, revenue from our license and collaboration agreements, and proceeds from the sale of shares of Intellia Therapeutics, Inc. ("Intellia") common stock.

Our net losses for the years ended December 31, 2025, and 2024 were $148.1 million and $149.1 million, respectively. We had an accumulated deficit of $596.5 million as of December 31, 2025. Our net losses and operating losses may fluctuate from quarter to quarter and year to year depending primarily on the timing of expenses associated with our clinical trials and nonclinical studies and our other research and development expenses. We anticipate that our expenses will increase substantially as we:

- progress our clinical trials for our vispa-cel and CB-011 cell therapy product candidates, particularly as we advance vispa-cel in our planned pivotal clinical trial;
- hire additional personnel, as needed;
- acquire or in-license intellectual property, new technologies, and/or additional product candidates;
- expand, maintain, enforce, and defend our intellectual property portfolio;

- seek regulatory and marketing approvals for our vispa-cel and CB-011 product candidates if our clinical trials are successful;
- expand manufacturing capabilities and supply chain capacity for our vispa-cel and CB-011 product candidates;
- experience any delays, challenges, or other issues associated with any of the above, including the failure of clinical trials meeting endpoints, generation of clinical trial data subject to differing interpretations, or the occurrence of potential safety issues or other development or regulatory challenges;
- make royalty, milestone, or other payments under current, and any future, in-license or assignment agreements with third parties;
- establish a sales, marketing, and distribution infrastructure to commercialize any product candidates for which we obtain marketing approval; and
- continue to operate as a public company, including defending against any future class action securities litigation.

We do not own or operate any manufacturing facilities. We use multiple contract manufacturing organizations ("CMOs") to individually manufacture, under current good manufacturing processes, our chRDNA guides, Cas9 and Cas12a proteins, plasmids, and adeno-associated virus serotype 6 ("AAV6") vectors used in the manufacture of our cell therapy product candidates as well as the CAR-T cell therapy product candidates themselves. We expect to continue to rely on our CMOs for manufacturing our clinical trial materials, and most of these CMOs have capabilities for commercial manufacturing. Additionally, we may decide to build our own manufacturing facility in the future to provide greater flexibility and control over our clinical or commercial manufacturing needs.

Because of the numerous risks and uncertainties associated with therapeutic product development, we may never achieve profitability and, unless and until we are able to develop and commercialize our product candidates, we will need to continue to raise additional capital. Until such time, if ever, that we can generate significant revenue from product sales, we expect to finance our operations through equity offerings (including our at-the-market equity offering program), debt financings, new strategic collaborations, structured or other non-dilutive financings, licensing arrangements, and/or other sources. We cannot provide any assurance that we will be successful in obtaining an adequate level of financing to support our business plans as needed on acceptable terms, or at all. If we raise additional funds through collaborations, new strategic collaborations, structured or other non-dilutive financings, or licensing arrangements with third parties, we may have to relinquish valuable rights to our intellectual property, future revenue streams, or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise capital as and when needed or on attractive terms, we may have to significantly delay, reduce, or discontinue the development and commercialization of our product candidates or scale back or terminate our pursuit of new in-licenses and acquisitions.

Components of Results of Operations

Licensing and Collaboration Revenue

We have not generated any revenue from product sales to date and do not expect to generate any revenue from the sale of products in the foreseeable future. We cannot predict if, when, or to what extent we will generate revenue from the commercialization and sale of our product candidates if we succeed in obtaining regulatory approval for these product candidates.

To date, all of our revenue consists of licensing and collaboration revenue earned from collaboration and/or licensing agreements entered into with third parties, including related parties. Under these agreements, we license rights to certain intellectual property controlled by us. The terms of these arrangements typically include payments to us of one or more of the following: nonrefundable, upfront license fees or exclusivity fees; annual maintenance fees; regulatory and/or commercial milestone payments; research and development payments; and royalties on the net sales of products and/or services. Each of these payments results in licensing and collaboration revenue. Revenue under such licensing and collaboration agreements was $11.2 million and $10.0 million for the years ended December 31, 2025, and 2024, respectively. See Notes 5 and 7 to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K for additional information.

For the foreseeable future, we expect substantially all our revenue will be generated from licensing and collaboration agreements.

Operating Expenses

Research and Development Expenses

Our research and development expenses consist of internal and external expenses incurred in connection with the development of our product candidates and our genome-editing platform technologies, and our in-licensing, assignment, and other third-party agreements.

External costs include:

- costs associated with acquiring technology and intellectual property licenses that have no alternative future uses, sublicensing revenues, and milestones;
- costs incurred in connection with the clinical development and manufacturing of our product candidates, including under agreements with CMOs, suppliers, contract research organizations ("CROs"), and clinical sites; and
- other research and development costs, including lab supplies, and consulting services.

Internal costs include:

- personnel-related costs, including salaries, benefits, and stock-based compensation expense, for our research and development personnel; and
- allocated facilities and other overhead expenses, including expenses for rent, facilities maintenance, and depreciation.

We expense research and development costs as incurred. Costs of certain activities are recognized based on an evaluation of the progress to completion of specific tasks. However, payments made prior to the receipt of goods or services that will be used or rendered for future research and development activities are deferred and capitalized as prepaid expenses and other current assets on our consolidated balance sheets. The capitalized amounts are recognized as expenses as the goods are delivered or as related services are performed. We separately track certain external costs on a program-by-program basis; however, we do not track costs that are deployed across our programs. We do not allocate internal costs as several of our departments support our programs and our payroll and other personnel expenses are not tracked on a program-by-program basis.

Clinical development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect that our research and development expenses will increase substantially for the foreseeable future as we continue to implement our business strategy; advance our product candidates through clinical trials; conduct translational research to support our product candidates; seek regulatory approvals for our product candidates that successfully complete clinical trials; and hire additional personnel to support our clinical development efforts.

The successful development of our CAR-T product candidates is highly uncertain. Accordingly, at this time, we cannot reasonably estimate or know the nature, timing, and costs of the efforts that will be necessary to complete the development of our product candidates. We are also unable to predict when, if ever, we will generate revenue and material net cash inflows from the commercialization and sale of any of our product candidates for which we may obtain marketing approval. We may never succeed in achieving regulatory approval for any of our product candidates. The duration, costs, and timing of clinical trials, and development of our product candidates will depend on a variety of factors, including:

- sufficiency of our financial and other resources;
- acceptance of our CRISPR chRDNA genome-editing technology;
- ability to develop differentiating features so that our products have a competitive edge;
- establishment, maintenance, enforcement, and defense of our patents and other intellectual property rights;

- our ability to not infringe, misappropriate, or otherwise violate third-party intellectual property rights;
- successful enrollment in, and completion of, our clinical trials of our product candidates;
- data from our clinical trials that support an acceptable risk-benefit profile of our product candidates for the intended patient populations and that demonstrate safety and efficacy;
- entry into collaborations to further the development of our product candidates;
- successful development of our internal process development and transfer to CMOs;
- establishment and maintenance of agreements with CMOs and suppliers for clinical and commercial supplies and scaling up manufacturing processes and capabilities to support our clinical trials;
- receipt of timely responses and marketing approvals from applicable regulatory authorities;
- grant of nonpatent regulatory exclusivity for our product candidates;
- establishment of sales, marketing, and distribution capabilities necessary for commercialization of our product candidates if approved, whether by us or in collaboration with third parties;
- maintenance of a continued acceptable safety profile of our products post-approval;
- acceptance of our product candidates, if approved by the applicable regulatory authorities, by patients, the medical community, and third-party payors;
- ability of our products to compete with other therapies and treatment options;
- establishment and maintenance of healthcare coverage and adequate reimbursement; and
- expanded indications and patient populations for our products.

The following table summarizes our research and development expenses for the periods indicated:

	Year Ended December 31,		
	2025	2024	Change
	(in thousands)		
External costs:			
Expenses related to licenses, sublicensing revenue, and milestones	$ 2,720	$ 4,828	$ (2,108)
Services provided by CROs, CMOs, and third parties that conduct preclinical studies and clinical trials on our behalf	46,183	49,261	(3,078)
Other research and development expenses	14,799	23,560	(8,761)
Total external costs	63,702	77,649	(13,947)
Internal costs:			
Personnel-related expenses	33,983	39,531	(5,548)
Facilities and other allocated expenses	11,754	12,973	(1,219)
Total internal costs	45,737	52,504	(6,767)
Total research and development expenses	$ 109,439	$ 130,153	$ (20,714)

General and Administrative Expenses

Our general and administrative expenses consist primarily of personnel-related costs, intellectual property costs, consulting costs, and allocated overhead, including rent, equipment depreciation, and utilities. Personnel-related costs consist of salaries, benefits, and stock-based compensation expense for our general and administrative personnel. Intellectual property costs include expenses for filing, prosecuting, and maintaining patents and patent applications, including certain patents and patent applications that we license from third parties. We are entitled to receive reimbursement from third parties of a portion of the costs for filing, prosecuting, and maintaining certain patents and patent applications. We accrue for these reimbursements as the respective expenses are incurred and classify such reimbursements as a reduction of general and administrative expenses. During each of the years ended December 31, 2025, and 2024, we recorded $1.2 million of patent cost reimbursements as a reduction to general and administrative expenses.

We expect that our general and administrative expenses will increase in the future if our clinical trials are successful and if we prepare for potential commercialization of our product candidates, to support the growth and operations of a public company with late-stage clinical programs and potential commercial products.

Impairment Charges

Impairment charges consist of charges related to the strategic pipeline prioritization with workforce and cost reduction initiatives announced on April 24, 2025, and include impairment of our leasehold improvements, right of use assets, and lab equipment. See Note 15 to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K for additional information.

Other (Expense) Income

Other (expense) income consists primarily of impairment of an equity investment, interest income earned on cash and marketable securities and the change in fair value of the Memorial Sloan Kettering Cancer Center ("MSKCC") success payments liability under the now-terminated Exclusive License Agreement, dated November 13, 2020, with MSKCC (as amended, "MSKCC Agreement").

Results of Operations

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

The following table summarizes our results of operations for the periods indicated:

	Years Ended December 31,		Change
	2025	2024	$
		(in thousands)	
Licensing and collaboration revenue	$ 11,159	$ 9,994	$ 1,165
Operating expenses:			
Research and development	109,439	130,153	(20,714)
General and administrative	37,914	46,457	(8,543)
Impairment charges	12,150	—	12,150
Total operating expenses	159,503	176,610	(17,107)
Loss from operations	(148,344)	(166,616)	18,272
Other (expense) income			
Impairment of equity investment	(9,158)	—	(9,158)
Other income, net	8,827	17,502	(8,675)
Total other (expense) income	(331)	17,502	(17,833)
Net loss before benefit from income taxes	(148,675)	(149,114)	439
Benefit from income taxes	(550)	(9)	(541)
Net loss	$ (148,125)	$ (149,105)	$ 980

Licensing and Collaboration Revenue

The following table summarizes our revenue by licensee for the years ended December 31, 2025, and 2024:

	Years Ended December 31,		
	2025	2024	Change
		(in thousands)	
Pfizer, related party[1]	2,487	2,487	—
Edge, related party	—	1,623	(1,623)
Other licensees	8,672	5,884	2,788
Total licensing revenue	$ 11,159	$ 9,994	$ 1,165

[1]Pfizer ceased to be a related party as of December 31, 2025.

Licensing and collaboration revenue increased by $1.2 million to $11.2 million for the year ended December 31, 2025, from $10.0 million for the year ended December 31, 2024. This increase is primarily due to a $2.8 million increase related to other licensees, which was partially offset by a $1.6 million decrease in revenue related to the issuance of additional shares of convertible preferred stock received as consideration to us under the Exclusive License Agreement for Veterinary Therapeutics (as amended, "Edge chRDNA License Agreement") with Edge Animal Health ("Edge") in the year ended December 31, 2024.

Research and Development Expenses

Research and development expenses decreased by $20.7 million to $109.4 million for the year ended December 31, 2025 from $130.2 million for the year ended December 31, 2024. This decrease was primarily due to (i) a decrease of $8.8 million in other research and development expenses primarily related to the reduction in workforce and strategic pipeline prioritization, (ii) a decrease of $5.5 million in personnel-related expenses related to the reduction in workforce and strategic pipeline prioritization, (iii) a net decrease of $3.1 million in external CMO and CRO activities, driven by a decrease of (a) $3.5 million due to timing of CMO activities, and an increase of (b) $0.4 million in CRO activities for our clinical trials, (iv) a decrease of $2.1 million in expenses related to licenses, sublicensing revenue, and milestones, and (v) a decrease of $1.2 million in other facilities and allocated expenses.

General and Administrative Expenses

General and administrative expenses decreased by $8.5 million to $37.9 million for the year ended December 31, 2025, from $46.5 million for the year ended December 31, 2024. This decrease was primarily related to a decrease of $4.7 million in legal expenses, including $3.9 million related to the accrual of a securities class action litigation settlement expense in 2024 and a decrease of $3.3 million in personnel-related expenses related to the reduction in workforce and strategic pipeline prioritization.

Impairment Charges

Impairment charges consist of charges related to the strategic pipeline prioritization with workforce and cost reduction initiatives announced on April 24, 2025, and include impairment of our leasehold improvements, right of use assets, and lab equipment. See Note 15 to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K for additional information.

Other (Expense) Income

Total other (expense) income decreased by $17.8 million for the year ended December 31, 2025, as compared to the year ended December 31, 2024.

Impairment of equity investment was $9.2 million related to our equity investment in Edge for the year ended December 31, 2025, compared to zero for the year ended December 31, 2024. See Note 3 to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K for additional information.

Other income, net decreased by $8.7 million for the year ended December 31, 2025, compared to December 31, 2024. This decrease was primarily related to a $7.2 million decrease in interest income earned from marketable securities and a $1.4 million decrease in gain recognized related to the change in the fair value of the MSKCC success payments liability.

Benefit From Income Taxes

An income tax benefit of $0.6 million was recognized for the year ended December 31, 2025, which was primarily related to deferred federal and state taxes. An income tax benefit of less than $0.1 million was recognized for the year ended December 31, 2024, which was primarily related to deferred state taxes.

Liquidity, Capital Resources, and Capital Requirements

Sources of Liquidity

Since our inception through December 31, 2025, we have raised an aggregate net proceeds of $849.0 million to fund our operations through our initial public offering ("IPO"); sales of convertible preferred stock; a follow-on public offering; proceeds from our licensing, licensing and collaboration, service, and patent assignment agreements, including sales of Intellia stock; private placements; at-the-market equity offerings; and government grants.

As of December 31, 2025, we had cash, cash equivalents, and marketable securities of $142.8 million.

Shelf Registration Statements

On August 9, 2022, we filed a universal shelf registration statement on Form S-3 ("2022 Shelf Registration Statement") with the SEC, which allowed us to sell, from time to time, up to $400.0 million of common stock, preferred stock, debt securities, warrants, rights, or units comprised of any combination thereof (including the $100.0 million of common stock reserved under the 2022 Shelf Registration Statement for our at-the-market equity offering program described below).

On May 8, 2025, in anticipation of the expiration of the 2022 Shelf Registration Statement on August 16, 2025, we filed a new shelf registration statement on Form S-3 ("2025 Shelf Registration Statement"), which was declared effective by the SEC on May 14, 2025. Upon the effectiveness of the 2025 Shelf Registration Statement, the offering of securities under the 2022 Shelf Registration Statement was deemed terminated. Pursuant to the 2025 Shelf Registration Statement, we may, from time to time, sell up to $300.0 million of common stock, preferred stock, debt securities, warrants, rights, or units comprised of any combination thereof (including the $100.0 million of common stock reserved under the 2025 Shelf Registration Statement for our at-the-market equity offering program described below). As of December 31, 2025, we had $295.7 million available for sale under the 2025 Shelf Registration Statement.

At-the-Market Equity Offering Program

On August 9, 2022, we entered into an at-the-market Open Market Sale Agreement℠ ("ATM Sales Agreement") with Jefferies LLC ("Jefferies"), pursuant to which, on the terms and subject to the conditions and limitations set forth in the ATM Sales Agreement, from time to time, we could have issued and sold, through Jefferies, acting as sales agent, up to $100.0 million of our shares of common stock under the 2022 Shelf Registration Statement. Under the ATM Sales Agreement and the 2022 Shelf Registration Statement, we issued and sold an aggregate of 3,588,696 shares of our common stock at an average price per share of $4.71 for aggregate gross proceeds of $16.9 million ($16.2 million net of offering expenses).

With the effectiveness of the 2025 Shelf Registration Statement, we refreshed our at-the-market equity offering program under the ATM Sales Agreement. We may, from time to time, sell and issue shares of our common stock, through Jefferies as sales agent under the ATM Sales Agreement, having an aggregate offering price of up to $100.0 million in gross proceeds under the 2025 Shelf Registration Statement, by any method permitted by law deemed to be an "at the market offering" as defined in Rule 415(a)(4) of the Securities Act of 1933, as amended ("Securities Act"). Jefferies has agreed to use commercially reasonable efforts consistent with its normal sales and trading practices to sell shares from time to time, based on our instructions (including any price or size limits or other customary parameters or conditions we may impose).

During the year ended December 31, 2025, we sold 1,644,228 shares of our common stock, in a series of sales, at an average price of $2.60 per share, in accordance with the ATM Sales Agreement and the 2025 Shelf Registration Statement for aggregate gross proceeds of $4.3 million ($4.1 million net of offering expenses).

During the year ended December 31, 2024, we sold 3,420,061 shares of our common stock, in a series of sales, at an average price of $4.58 per share, in accordance with the ATM Sales Agreement and the 2022 Shelf Registration Statement for aggregate gross proceeds of $15.7 million ($15.2 million net of offering expenses).

As of December 31, 2025, $95.7 million of shares of our common stock remained available for sale under the 2025 Shelf Registration Statement pursuant to the ATM Sales Agreement.

Funding Requirements

We expect that our existing cash, cash equivalents, and marketable securities will be sufficient to fund our current operating plan for at least the next 12 months from the date this Annual Report on Form 10-K is filed. We have based these estimates on our current assumptions, which may require future adjustments based on our ongoing business decisions.

We will continue to be dependent on equity financing, debt financing, collaboration and licensing arrangements, and/or other forms of capital raises, including structured or other non-dilutive financings, to fund operating expenses, including to fully fund our planned pivotal trial for vispa-cel, at least until we are able to generate significant positive cash flows from our operations. We have no current ongoing material financing commitments, such as lines of credit or guarantees, that are expected to affect our liquidity over the next five years, except for our lease commitments and payments under certain of our license agreements as described in Notes 4 and Note 9, respectively, to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

Our primary use of cash is to fund operating expenses and research and development expenses, which primarily consist of expenditures related to clinical trials. 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 accounts payable, accrued expenses, and prepaid expenses.

Our future funding requirements will depend on many factors, including the following:

- the initiation, progress, timing, costs, and results of clinical trials for our product candidates;
- the clinical development plans we establish for these product candidates;
- the outcome, timing, and cost of meeting regulatory requirements established by the FDA and other comparable foreign regulatory authorities;
- potential impact of reductions in government spending and personnel;
- whether we enter into any collaboration agreements and the terms of any such agreements;
- the cost of filing and prosecuting our patent applications, and maintaining and enforcing our patents and other intellectual property rights;
- the cost of defending intellectual property disputes, including patent infringement actions brought by third parties against our products after we receive regulatory approval;
- the effect of competing technological and market developments;
- the cost and timing of completion of commercial-scale outsourced manufacturing activities or the cost and timing of completion of clinical-scale and commercial-scale internal manufacturing activities;
- the cost of establishing sales, marketing, and distribution capabilities for any product candidates for which we may receive regulatory approval in regions where we choose to commercialize our products;
- the amount of revenue, if any, received from commercial sales of our product candidates, should any of our product candidates receive marketing approval;

- the achievement of milestones or occurrence of other developments that trigger payments by or to third parties;
- our implementation of various computerized informational systems and efforts to enhance operational systems;
- the impact of public health crises or geopolitical events on our clinical development or operations;
- the impact of inflationary pressures and tariffs on the cost of our operations; and
- the costs of operating as a public company, including defending against any future class action securities litigation and shareholder derivative lawsuits.

Furthermore, our operating plans may change, and we expect to need additional funds to meet operational needs and capital requirements for our clinical trials and development of our product candidates.

Because of the numerous risks and uncertainties associated with therapeutic product development, we may never achieve profitability and, unless and until we are able to develop and commercialize our product candidates, we will need to continue to raise additional capital. Until we can generate significant revenue from product sales, if ever, we expect to finance our operations through equity offerings (including our at-the-market equity offering program), debt financings, new collaborations, structured or other non-dilutive financings, licensing arrangements, and/or other sources. We cannot provide any assurance that we will be successful in obtaining an adequate level of financing to support our business plans as needed on acceptable terms, or at all. If we raise additional funds through new strategic collaborations or licensing arrangements with third parties, we may have to relinquish valuable rights to our intellectual property, future revenue streams, or product candidates or grant licenses on terms that may not be favorable to us. Disruptions and volatility in the global and domestic capital markets resulting from heightened inflation, tariffs, capital market volatility, interest rate and currency rate fluctuations, artificial intelligence ("AI"), political and geopolitical tensions, government agency changes, any potential economic slowdown or recession, including trade wars or civil or political unrest (such as the ongoing war between Ukraine and Russia, conflicts in the Middle East, including the recent hostilities involving Iran, tension between China and Taiwan, geopolitical tensions in Europe, South America, and elsewhere) may increase the cost of capital and limit our ability to access capital. If we are unable to raise capital as and when needed or on attractive terms, we may have to significantly delay, reduce, or discontinue the development and commercialization of our product candidates or scale back or terminate our pursuit of new in-licenses and acquisitions.

Contractual Obligations and Commitments

We enter into contracts in the normal course of business with suppliers, CMOs, CROs, clinical trial sites, licensors, assignors, and the like. These agreements provide for termination at the request of either party generally with less than one-year's notice and, therefore, we believe that our non-cancelable obligations under these agreements are not material. Some of these agreements include contingent payments that will become payable if and when we achieve certain development, regulatory, clinical, and/or commercial milestones. As of December 31, 2025, the satisfaction and timing of such contingent payments is uncertain and is not reasonably estimable.

We have milestones, royalties, and/or other payments due to third parties under our existing license and assignment agreements. See Note 9 to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K. We cannot estimate when such payments will be due and none of these events is probable as of December 31, 2025.

Leases

We have two operating lease agreements for our laboratory and office space. As of December 31, 2025, we had lease payment obligations totaling $43.8 million, of which $4.8 million is due within 12 months.

Strategic Investment

On June 29, 2023, we entered into a Securities Purchase Agreement ("Securities Purchase Agreement") with Pfizer, Inc. ("Pfizer") pursuant to which we, in a private placement transaction, agreed to issue and sell to Pfizer 4,690,431 shares of our common stock, par value $0.0001 per share, at a purchase price of $5.33 per share, for aggregate gross proceeds of approximately $25.0 million ("Pfizer Investment"). The issuance and sale of the shares to Pfizer closed on June 30, 2023. We granted certain registration rights to Pfizer under the Securities Purchase Agreement covering the resale of the shares. Unless otherwise agreed by Pfizer, we have agreed to use the proceeds from the Pfizer Investment solely in connection with (i) the development program for our allogeneic anti-BCMA CAR-T cell therapy product candidate (CB-011) that is being evaluated in our CaMMouflage phase 1 clinical trial and/or (ii) any other single-targeted anti-BCMA CAR-T cell therapy using an anti-BCMA single-chain variable fragment ("scFv") owned or controlled by us (collectively, cell therapies described in clauses (i) and (ii) are referred to as a "BCMA Product Candidate"), for 36 months expiring on June 29, 2026.

On June 29, 2023, in connection with the Pfizer Investment, we and Pfizer also entered into an Information Rights Agreement, having a 36-month term and expiring on June 29, 2026. Under the Information Rights Agreement, we granted Pfizer a 30-calendar day right of first negotiation ("ROFN") if we commence or engage with any third party with respect to a potential grant of rights to develop and/or commercialize a BCMA Product Candidate, including, without limitation, a license agreement, a co-promotion/co-commercialization agreement, a profit share agreement, a joint venture agreement, or an asset sale agreement (a "Grant of Program Rights"). If we and Pfizer do not reach an agreement with respect to a Grant of Program Rights within the 30-day period, then we may pursue negotiations and enter into an agreement with any third party. If we and such third party do not reach agreement on the Grant of Program Rights within a specified time period, Pfizer's right of first negotiation will be reinstated. Under the Information Rights Agreement, we also granted Pfizer the right to designate one representative to serve on our scientific advisory board ("SAB"). Through an information sharing committee, we provide calendar quarter updates to Pfizer regarding the development program for a BCMA Product Candidate. Additionally, we agreed to provide Pfizer access to any preclinical or interim or final clinical data (including raw data) and results generated as part of the development program for a BCMA Product Candidate at the same time that we provide such data to a third party (other than to our service providers or the FDA or other regulatory authorities), subject to certain confidentiality exceptions.

Cash Flows

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

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

	Years Ended December 31,		
	2025	2024	Change
	(in thousands)		
Cash used in operating activities	$ (110,992)	$ (138,200)	$ 27,208
Cash provided by investing activities	102,238	86,607	15,631
Cash provided by financing activities	4,821	16,724	(11,903)
Net decrease in cash, and cash equivalents, and restricted cash	$ (3,933)	$ (34,869)	$ 30,936

Cash Used in Operating Activities

Net cash used in operating activities was $111.0 million for the year ended December 31, 2025, compared to $138.2 million for the year ended December 31, 2024. This decrease was due to (i) changes in the components of net loss primarily related to (a) increase in non-cash charges primarily for impairment charges and impairment of equity investment incurred for the year ended December 31, 2025, and (b) decreases in research and development expenses and general and administrative expenses; and (ii) an increase in net changes in our operating assets and liabilities primarily related to increases in net changes in other assets, prepaid expenses and other current assets, and accounts payable partially offset by a decrease in net changes of accrued expenses and other current liabilities.

Cash Provided by Investing Activities

Net cash provided by investing activities was $102.2 million for the year ended December 31, 2025, compared to $86.6 million for the year ended December 31, 2024. The increase was primarily driven by lower cash utilized for purchases of marketable securities; partially offset by a decrease in proceeds from maturities of marketable securities.

Cash Provided by Financing Activities

Net cash provided by financing activities was $4.8 million for the year ended December 31, 2025, compared to $16.7 million for the year ended December 31, 2024. The decrease was primarily driven by lower proceeds from the issuance of common stock under the ATM Sales Agreement during the year ended December 31, 2025, compared to proceeds from the issuance of common stock under the ATM Sales Agreement during the year ended December 31, 2024.

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 U.S. generally accepted accounting principles ("U.S. 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 our consolidated financial statements, as well as the reported expenses incurred during the reporting periods. These estimates and assumptions are monitored and analyzed by us for changes in facts and circumstances, and material changes in these estimates and assumptions could occur in the future. 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. Changes in estimates are reflected in reported results for the period in which they become known. Actual results may differ from these estimates under different assumptions or conditions.

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

Revenue Recognition

We recognize revenue when a licensee or assignee, or a customer, obtains control of the promised goods or services (e.g., an intellectual property license), in an amount that reflects the consideration that we have received or expect to receive in exchange for those goods or services.

We apply judgment to determine whether agreements are within the scope of revenue for customers or other accounting guidance at an agreement's effective date. Our revenues are primarily derived through our license agreements and license and collaboration agreements. The terms of these types of agreements may include (i) licenses for our technology, (ii) research and development services, and (iii) services or obligations in connection with participation in research or governance committees. Payments to us under these arrangements typically include one or more of the following: nonrefundable upfront license or exclusivity fees; annual maintenance fees; regulatory and/or commercial milestone payments; research and development payments; and royalties on the net sales of licensed products and/or services.

We assess whether the promises in our arrangements with customers are considered as distinct performance obligations that should be accounted for separately. Judgment is required to determine whether the license to intellectual property is distinct from the research and development services or participation on steering committees.

If the license to intellectual property controlled by us is determined to be distinct from the other performance obligations identified in the arrangement, we recognize revenues allocated to the license at the point in time when the license is transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that are combined with other promises, we utilize our judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue. We evaluate the measure of progress each reporting period and, if necessary, adjust the measure of performance and related revenue recognition.

Certain of our license agreements have two performance obligations: a license and a material right for annual license renewals. Such license agreements require payments of non-refundable annual license fees by the licensees (referred to as maintenance fees in the license agreements), which are accounted for as material rights for license renewals. We recognize revenue when the license is delivered and the term commences. Revenue for the material right for license renewals is recognized at the point in time the annual license fee is paid by the licensee and the renewal period begins.

Our collaboration and license agreements may include contingent milestone payments. Such milestone payments are typically payable when the collaboration partner or licensee achieves certain predetermined clinical, regulatory, and/or commercial milestones. Milestone payments that are not within our or the licensee's control, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. At each reporting date, we re-evaluate whether the milestones are considered probable of being achieved and estimate the amount to be included in the transaction price by using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price in such period of determination.

Our collaboration and license agreements may also include contingent payments related to sales-based milestones. Sales-based milestones are typically payable when annual sales of a covered product reach specified levels. Sales-based milestones are recognized at the later of when the associated performance obligation has been satisfied or when the sales occur. Unlike other contingency payments, such as regulatory milestones, sales-based milestones are not included in the transaction price based on estimates at the inception of the contract, but rather, are included when the sales or usage occur.

Accrued Research and Development Expenses

As part of the process of preparing our financial statements, we are required to estimate and accrue expenses. Research and development expenses are expensed as incurred. Research and development expenses include those for certain payroll and personnel; laboratory supplies; consulting; manufacturing; external clinical; and allocated overhead, including rent, equipment depreciation, and utilities.

We record accrued liabilities for estimated costs of research and development activities conducted by third-party CMOs, CROs, and other third-party service providers. We accrue for these costs based on factors such as estimates of the work completed and in accordance with service agreements established with these third-party service providers.

We make significant judgments and estimates in determining the accrual balance in each reporting period. As actual costs become known, we adjust our accruals. Although we do not expect our estimates to be materially different than the actual amounts incurred, the estimates for the status and timing of services performed relative to the actual status and timing of services performed may vary and could result in us reporting amounts that are too high or too low in any one period. Our accrual is dependent, in part, upon the receipt of timely and accurate reporting from CROs, CMOs, and other third-party service providers. Variations in the assumptions used to estimate accruals including, but not limited to, the number of patients enrolled, the rate of patient enrollment and the actual services performed, may vary from our estimates, resulting in adjustments to clinical trial and manufacturing expenses in future periods. Changes in these estimates that result in material changes to our accruals could materially affect our financial condition and results of operations. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual or prepaid expense accordingly.

Impairment of Long-Lived Assets

We review long-lived assets for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. In order to determine if assets have been impaired, assets are grouped and tested at the lowest level for which identifiable independent cash flows are available. An impairment loss is recognized when the sum of projected undiscounted cash flows is less than the carrying value of the asset group. The measurement of the impairment loss to be recognized is based on the difference between the fair value and the carrying value of the asset group. Fair value may be determined using a market approach or income approach.

For asset groups where impairment is triggered, we use discounted cash flow models (an income approach) to estimate the fair values of the asset groups. The significant assumptions used in the discounted cash flow models include projected sublease income over the remaining lease terms, expected downtime prior to the commencement of executed or future subleases, and discount rates that reflect a market participant's assumptions in valuing the asset groups. Changes in these assumptions used could materially affect our financial condition and results of operations.

Recently Issued Accounting Pronouncements

See Note 2 to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K for more information regarding recently issued accounting pronouncements.

Emerging Growth Company and Smaller Reporting Company Status

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012 Act ("JOBS Act") and may remain an emerging growth company until the last day of our fiscal year following the fifth anniversary of the closing of our IPO *(*i.e., December 31, 2026). Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. We have elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that we (i) are no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, our consolidated financial statements may not be comparable to those of companies that comply with the new or revised accounting pronouncements as of public company effective dates.

We expect to use the extended transition period for any other new or revised accounting standards during the period in which we remain an emerging growth company.

We are also a "smaller reporting company." If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company, we may choose to present only the two most recent fiscal years of audited consolidated financial statements in our Annual Report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

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

We had cash, cash equivalents, and marketable securities of $142.8 million and $249.4 million as of December 31, 2025, and December 31, 2024, respectively, consisting of cash, money market funds, government securities, commercial paper, and U.S. Treasury bills.

We do not enter into investments for trading or speculative purposes and have not used any derivative financial instruments to manage our interest rate risk exposure. A hypothetical 10% change in interest rates during any of the periods presented would not have had a material impact on our consolidated financial statements. We have not been exposed to, nor do we anticipate being exposed to, material risks due to changes in interest rates.

We do not have any foreign currency. Inflation generally affects us by increasing our cost of labor, manufacturing, and clinical trial costs. We do not believe that inflation had a material effect on our results of operations during the year ended December 31, 2025.

Item 8. Financial Statements and Supplementary Data.

The financial statements required to be filed by this item are appended at the end of this Annual Report on Form 10-K beginning on page F-1 and is incorporated herein by reference. An index of those financial statements is found in Part IV, Item 15, Exhibits, Financial Statement Schedules, of this Annual Report on Form 10-K.

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

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

We have established disclosure controls and procedures designed to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms and is accumulated and communicated to management, including the principal executive officer (our president and chief executive officer) and principal financial officer (our chief financial officer), to allow timely decisions regarding required disclosure.

Our management, under the supervision and with the participation of our president and chief executive officer and chief financial officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of the end of the period covered by this Annual Report on Form 10-K.

Management recognizes that any disclosure controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives. Our disclosure controls and procedures have been designed to provide reasonable assurance of achieving their objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs. Based on such evaluation, our president and chief executive officer (principal executive officer) and our chief financial officer (principal financial officer) have concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of December 31, 2025.

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. 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 for external purposes in accordance with U.S. GAAP. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of 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 or procedures may deteriorate.

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2025, based on the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in its 2013 Internal Control - Integrated Framework. Based on this assessment, our management has concluded that our internal control over financial reporting was effective as of December 31, 2025.

Attestation Report of the Registered Public Accounting Firm

Our independent registered accounting firm is not required to opine on the effectiveness of our internal control over financial reporting pursuant to Section 404 of Sarbanes-Oxley Act of 2002 until we are no longer either an "emerging growth company" as defined in the JOBS Act or a smaller reporting company as defined by Rule 12b-2 of the Exchange Act that does not otherwise also qualify as an "accelerated filer" or "large accelerated filer" for SEC reporting purposes.

Changes in Internal Control

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

Item 9B. Other Information.

(b) Rule 10b5-1 Trading Arrangements

During the quarter ended December 31, 2025, no director or Section 16 officer adopted or terminated any "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement" (in each case, as defined in Item 408 of Regulation S-K).

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

Not applicable.

PART III

Certain information required by Part III is incorporated by reference herein to our definitive proxy statement for our 2026 Annual Meeting of Stockholders ("2026 Proxy Statement") pursuant to Regulation 14A of the Securities Exchange Act of 1934, as amended ("Exchange Act"), which we intend to file not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

Item 10. Directors, Executive Officers, and Corporate Governance.

The information required by this item of Form 10-K will be included under the caption "Board of Directors and Corporate Governance" and subsections thereof, including "—Nominees for Election as Class II Directors," "—Directors Continuing in Office," "—Family Relationships," "—Classified Board of Directors," and "—Board Committees—Audit Committee" and under the caption "Executive Officers" in our 2026 Proxy Statement and is incorporated by reference herein.

We have adopted a written Code of Business Conduct, Scientific and Data Integrity, and Ethics ("Code of Conduct") that applies to all of our employees, consultants, and directors. A current copy of the Code of Conduct is available on the Corporate Governance section of our website, cariboubio.com. The audit committee of our board of directors is responsible for overseeing the Code of Conduct and must approve any waivers of the Code of Conduct for our executive officers and directors. We expect that any amendments to the Code of Conduct, or any waivers of its requirements with respect to our executive officers and directors, will be disclosed on our website at the address indicated above. Our website and the information contained therein or connected thereto shall not be deemed to be incorporated into this Annual Report on Form 10-K. We have included our website address as an inactive textual reference only. We will provide to any person, without charge, a copy of the Code of Conduct. Any such request should be directed to Caribou Biosciences, Inc., 2929 7th Street, Suite 105, Berkeley, CA 94710, Attn: Chief Legal Officer and Corporate Secretary, telephone: 510-982-6030.

We have adopted an insider trading policy that governs the purchase, sale, and/or other dispositions of our securities by all of our employees, consultants, contractors, officers, and directors, as well as by our company. The insider trading policy is designed to promote compliance with insider trading laws. A copy of our insider trading policy is filed as Exhibit 19.1 to this Annual Report on Form 10-K.

Item 11. Executive Compensation.

The information required by this item of Form 10-K will be included under the caption "Executive and Director Compensation" in our 2026 Proxy Statement and is incorporated by reference herein.

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

The information required by this item of Form 10-K will be included under the captions "Security Ownership of Certain Beneficial Owners and Management" and "Securities Authorized for Issuance Under Equity Compensation Plans" in our 2026 Proxy Statement and is incorporated by reference herein.

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

The information required by this item of Form 10-K will be included under the captions "Certain Relationships and Related Party Transactions" and "Board of Directors and Corporate Governance—Director Independence" in our 2026 Proxy Statement and is incorporated by reference herein.

Item 14. Principal Accounting Fees and Services.

The information required by this item of Form 10-K will be included under the caption "Ratification of Selection of Independent Registered Public Accounting Firm" in our 2026 Proxy Statement and is incorporated by reference herein.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a) The following documents are included in this Annual Report on Form 10-K:

1. The following Report and Consolidated Financial Statements of our company are included in this Annual Report on Form 10-K:

Report of Independent Registered Public Accounting Firm (PCAOB ID No. 34)

Consolidated Balance Sheets

Consolidated Statements of Operations and Comprehensive Loss

Consolidated Statements of Stockholders' Equity

Consolidated Statements of Cash Flows

Notes to Consolidated Financial Statements

See Index to Consolidated Financial Statements on page F-1 of this Annual Report on Form 10-K, incorporated into this item by reference.

2. All financial schedules have been omitted because the required information is either presented in our consolidated financial statements or the notes thereto or is not applicable or required.

3. 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.

Not applicable.

EXHIBIT INDEX

Exhibit Number	Exhibit Description
3.1	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. 001-40631), filed with the SEC on July 28, 2021)
3.2	Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K (File No. 001-40631), filed with the SEC on July 28, 2021)
4.1	Description of Common Stock (incorporated by reference to Exhibit 4.1 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2021 (File No. 001-40631), filed with the SEC on March 21, 2022)
10.1†	Sale and Assignment Agreement, dated January 31, 2020, by and between the Registrant and ProMab Biotechnologies, Inc. (incorporated by reference to Exhibit 10.3 to the Registration Statement on Form S-1 filed with the SEC on July 1, 2021 (File No.: 333-257604) (the "Form S-1"))
10.2†	Amendment No. 1 to Sale and Assignment Agreement, dated October 20, 2020, by and between the Registrant and ProMab Biotechnologies, Inc. (incorporated by reference to Exhibit 10.4 to the Form S-1)
10.3†	Amendment No. 2 to Sale and Assignment Agreement, dated December 15, 2020, by and between the Registrant and ProMab Biotechnologies, Inc. (incorporated by reference to Exhibit 10.5 to the Form S-1)
10.4	Amendment No. 3 to Sale and Assignment Agreement, dated May 5, 2020, by and between the Registrant and ProMab Biotechnologies, Inc. (incorporated by reference to Exhibit 10.6 to the Form S-1)

10.5†	Amended and Restated Collaboration and License Agreement, dated July 13, 2015, by and between the Registrant and Pioneer Hi-Bred International, Inc. (incorporated by reference to Exhibit 10.7 to the Form S-1)
10.6†	Amendment No. 1 to Amended and Restated Collaboration and License Agreement, dated January 21, 2016, by and between the Registrant and Pioneer Hi-Bred International, Inc. (incorporated by reference to Exhibit 10.8 to the Form S-1)
10.7†	Amendment No. 2 to Amended and Restated Collaboration and License Agreement, dated July 18, 2016, by and between the Registrant and Pioneer Hi-Bred International, Inc. (incorporated by reference to Exhibit 10.9 to the Form S-1)
10.8†	Amendment No. 3 to Amended and Restated Collaboration and License Agreement, dated March 13, 2017, by and between the Registrant and Pioneer Hi-Bred International, Inc. (incorporated by reference to Exhibit 10.10 to the Form S-1)
10.9†	Amendment No. 4 to Amended and Restated Collaboration and License Agreement, dated June 26, 2017, by and between the Registrant and Pioneer Hi-Bred International, Inc. (incorporated by reference to Exhibit 10.11 to the Form S-1)
10.10†	Amendment No. 5 to Amended and Restated Collaboration and License Agreement, dated May 25, 2018, by and between the Registrant and Pioneer Hi-Bred International, Inc. (incorporated by reference to Exhibit 10.12 to the Form S-1)
10.11†	Amendment No. 6 to Amended and Restated Collaboration and License Agreement, dated June 2, 2019, by and between the Registrant and Pioneer Hi-Bred International, Inc. (incorporated by reference to Exhibit 10.13 to the Form S-1)
10.12†	Amendment No. 7 to Amended and Restated Collaboration and License Agreement, dated December 18, 2020, by and between the Registrant and Pioneer Hi-Bred International, Inc. (incorporated by reference to Exhibit 10.14 to the Form S-1)
10.13†	Amendment No. 8 to Amended and Restated Collaboration and License Agreement, dated December 18, 2020, by and between the Registrant and Pioneer Hi-Bred International, Inc. (incorporated by reference to Exhibit 10.15 to the Form S-1)
10.14†	License Agreement, dated July 16, 2014, by and between the Registrant and Intellia, LLC (incorporated by reference to Exhibit 10.16 to the Form S-1)
10.15†	Amendment No. 1 to the License Agreement, dated February 2, 2016, by and between the Registrant and Intellia Therapeutics, Inc. as successor in interest to Intellia, LLC (incorporated by reference to Exhibit 10.17 to the Form S-1)
10.16†	Addendum to License Agreement, dated February 2, 2016, by and between the Registrant and Intellia Therapeutics, Inc. as successor in interest to Intellia, LLC (incorporated by reference to Exhibit 10.18 to the Form S-1)
10.17†	Leaseback Agreement, dated June 16, 2021, by and between the Registrant and Intellia Therapeutics, Inc. (incorporated by reference to Exhibit 10.19 to Amendment No. 1 to the Registration Statement on Form S-1 filed with the SEC on July 19, 2021 (File No. 333-257604) ("Amendment No. 1 to the Form S-1")
10.18†	Consent to Assignments, Licensing and Common Ownership and Invention Management Agreement for a Programmable DNA Restriction Enzyme for Genome Editing, dated December 15, 2016, by and among the Registrant and the other parties thereto (incorporated by reference to Exhibit 10.20 to the Form S-1)
10.19†	Exclusive License Agreement, dated April 16, 2013, by and among the Registrant, The Regents of the University of California, and the University of Vienna (incorporated by reference to Exhibit 10.21 to the Form S-1)
10.20†	Amendment No. 1 to the Exclusive License Agreement, dated April 16, 2013, by and among the Registrant, The Regents of the University of California, and the University of Vienna (incorporated by reference to Exhibit 10.22 to the Form S-1)
10.21†	Amendment No. 2 to the Exclusive License Agreement, dated April 17, 2013, by and among the Registrant, The Regents of the University of California, and the University of Vienna (incorporated by reference to Exhibit 10.23 to the Form S-1)

10.22†	Amendment No. 3 to the Exclusive License Agreement, dated April 16, 2021, by and among the Registrant, The Regents of the University of California, and the University of Vienna (incorporated by reference to Exhibit 10.24 to the Form S-1)
10.23†	Amendment No. 4 to the Exclusive License Agreement, dated February 14, 2025, by and among the Registrant, The Regents of the University of California, and the University of Vienna (incorporated by reference to Exhibit 10.25 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2024 (File No. 001-40631), filed with the SEC on March 10, 2025)
10.24†	Memorandum of Understanding, dated March 14, 2019, by and among the Registrant, the University of Vienna, and the Regents of the University of California (incorporated by reference to Exhibit 10.25 to the Form S-1)
10.25	Amended and Restated Office/Laboratory Lease, dated March 31, 2021, by and between the Registrant and 2929 Seventh St., LLC (incorporated by reference to Exhibit 10.26 to the Form S-1)
10.26	First Amendment, dated January 11, 2022, to Amended and Restated Office/Laboratory Lease by and between Registrant and 2929 Seventh St., LLC (incorporated by reference to Exhibit 10.27 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2021 (File No. 001-40631), filed with the SEC on March 21, 2022)
10.27*	Second Amendment, dated December 15, 2025, to Amended and Restated Office/Laboratory Lease by and between Registrant and 2929 Seventh St., LLC
10.28	Office/Laboratory Lease between the Registrant and 7th Street Property III General Partnership, having a commencement date of January 13, 2022 (incorporated by reference to Exhibit 10.1 to the Form 8-K (File No. 001-40631) filed with the SEC on January 19, 2022)
10.29	Rider 1 to Office/Laboratory Lease between the Registrant and 7th Street Property III General Partnership, effective as of the lease commencement date of January 13, 2022 (incorporated by reference to Exhibit 10.29 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2021 (File No. 001-40631), filed with the SEC on March 21, 2022)
10.30+	Officer Employment Agreement by and between the Registrant and Rachel E. Haurwitz, Ph.D., dated July 27, 2021 (incorporated by reference to Exhibit 10.1 to the Form 8-K (File No. 001-40631), filed with the SEC on July 28, 2021)
10.31+	Officer Employment Agreement by and between the Registrant and Barbara G. McClung, J.D., dated July 27, 2021 (incorporated by reference to Exhibit 10.3 to the Form 8-K (File No. 001-40631), filed with the SEC on July 28, 2021)
10.32+	Officer Employment Agreement by and between the Registrant and Steven B. Kanner, Ph.D., dated July 27, 2021 (incorporated by reference to Exhibit 10.2 to the Form 8-K (File No. 001-40631), filed with the SEC on July 28, 2021)
10.33+	Amendment to the Officer Employment Agreement, dated July 27, 2021, by and between the Registrant and Steven B. Kanner, Ph.D. (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the period ended June 30, 2024 (File No. 001-40631), filed with the SEC on August 6, 2024)
10.34+	Advisory Consulting Agreement by and between the Registrant and Steven B. Kanner, Ph.D., effective as of July 1, 2025 (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q for the three months ended March 31, 2025 (File No. 001-40631), filed with the SEC on May 8, 2025)
10.35+	Officer Employment Agreement by and between the Registrant and Ruhi Khan, dated November 8, 2021 (incorporated by reference to Exhibit 10.39 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2021 (File No. 001-40631), filed with the SEC on March 21, 2022)
10.36+	Officer Employment Agreement by and between the Registrant and Tim Kelly, dated January 1, 2024 (incorporated by reference to Exhibit 10.55 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2023 (File No. 001-40631), filed with the SEC on March 11, 2024)
10.37+	Officer Employment Agreement by and between the Registrant and Tina Albertson, M.D., Ph.D., dated August 12, 2024 (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q for the period ended September 30, 2024 (File No. 001-40631), filed with the SEC on November 6, 2024)
10.38+	Officer Employment Agreement by and between the Registrant and Sriram Ryali, dated January 2, 2025 (incorporated by reference to Exhibit 10.51 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2025 (File No. 001-40631), filed with the SEC on March 10, 2025)

10.39+	2013 Equity Incentive Plan (as originally adopted) (incorporated by reference to Exhibit 99.1 to the Registration Statement on Form S-8 filed with the SEC on July 26, 2021 (File No.: 333-258173) (the "Form S-8"))
10.40+	2013 Equity Incentive Plan (as amended May 12, 2016) (incorporated by reference to Exhibit 99.2 to the Form S-8)
10.41+	2013 Equity Incentive Plan of the Registrant, as amended and restated April 3, 2019 and as amended March 1, 2021 (incorporated by reference to Exhibit 10.41 to Amendment No. 1 to the Form S-1)
10.42+	Amendment to 2013 Equity Incentive Plan (effective December 9, 2021) (incorporated by reference to Exhibit 10.46 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2021 (File No.: 001-40631), filed with the SEC on March 21, 2022)
10.43+	Form of Stock Option Agreement under the 2013 Equity Incentive Plan (as originally adopted and as amended May 12, 2016) (incorporated by reference to Exhibit 99.4 to the Form S-8)
10.44+	Form of Stock Option Agreement under the 2013 Equity Incentive Plan, as amended and restated April 3, 2019 (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the period ended September 30, 2021 (File No.: 001-40631), filed with the SEC on November 11, 2021)
10.45+	2021 Equity Incentive Plan of the Registrant (incorporated by reference to Exhibit 99.6 of the Form S-8)
10.46+	Form of Employee Stock Option Agreement under the 2021 Equity Incentive Plan of the Registrant (incorporated by reference to Exhibit 10.50 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2021 (File No.: 001-40631), filed with the SEC on March 21, 2022)
10.47+	Form of Non-Employee Director Stock Option Agreement under the 2021 Equity Incentive Plan of the Registrant (incorporated by reference to Exhibit 10.51 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2021 (File No.: 001-40631), filed with the SEC on March 21, 2022)
10.48+	Form of Restricted Stock Unit Award Grant Notice and Restricted Stock Unit Award Agreement under the 2021 Equity Incentive Plan of the Registrant (incorporated by reference to Exhibit 10.52 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2021 (File No.: 001-40631), filed with the SEC on March 21, 2022)
10.49+	Form of Restricted Stock Unit Award Grant Notice and Restricted Stock Unit Award Agreement under the 2021 Equity Incentive Plan of the Registrant (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the period ended September 30, 2022 (File No.: 001-40631), filed with the SEC on November 8, 2022)
10.50+	Form of Performance Stock Unit Award Grant Notice and Performance Stock Unit Award Agreement under the 2021 Equity Incentive Plan of the Registrant (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q for the period ended September 30, 2022 (File No.: 001-40631), filed with the SEC on November 8, 2022)
10.51+	Form of Performance-Based Stock Option Agreement under the 2021 Equity Incentive Plan of the Registrant (incorporated by reference to Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q for the period ended September 30, 2025 (File No.: 001-40631), filed with the SEC on November 12, 2025)
10.52+	2021 Employee Stock Purchase Plan (incorporated by reference to Exhibit 99.7 to the Form S-8)
10.53	Form of Indemnification Agreement between the Registrant and its directors and officers (incorporated by reference to Exhibit 10.50 to the Form S-1)
10.54	Open Market Sale Agreement[SM], dated August 9, 2022, by and between the Registrant and Jefferies LLC (incorporated by reference to Exhibit 1.2 to the Company's Registration Statement on Form S-3 (File No. 333-266712) filed with the SEC on August 9, 2022)
10.55	Securities Purchase Agreement, dated June 29, 2023, by and between the Registrant and Pfizer, Inc. (incorporated by reference to Exhibit 10.1 to the Form 8-K filed with the SEC on July 6, 2023)
19.1	Insider Trading Policy (incorporated by reference to Exhibit 19.1 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2024 (File No.: 001-440631), filed with the SEC on March 10, 2025)
21.1*	List of Subsidiaries of the Registrant

23.1*	Consent of Deloitte & Touche LLP
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Exchange Act, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Exchange Act, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1#	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2#	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
97.1	Clawback Policy (incorporated by reference to Exhibit 97.1 of the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2023 (File No. 001-40631), filed with the SEC on March 11, 2024)
101.INS*	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101)

* Indicates filed herewith
+ Indicates management contract or compensatory plan
† Indicates certain portions of this document that constitute confidential information have been redacted in accordance with Regulation S-K, Item 601(b)(10)
# This certification is being furnished solely to accompany this Annual Report on Form 10-K pursuant to 18 U.S.C. Section 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended ("Exchange Act"), or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference into any filing of the Registrant under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

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 Annual Report on Form 10-K (this "Report") to be signed on its behalf by the undersigned, thereunto duly authorized.

CARIBOU BIOSCIENCES, INC.

Date: March 5, 2026

By: /s/ Rachel E. Haurwitz
Rachel E. Haurwitz
President and Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Report 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/ Rachel E. Haurwitz **Rachel E. Haurwitz**	President and Chief Executive Officer (*Principal Executive Officer*); Director	March 5, 2026
/s/ Sriram Ryali **Sriram Ryali**	Chief Financial Officer (*Principal Financial Officer & Principal Accounting Officer*)	March 5, 2026
/s/ Scott Braunstein **Scott Braunstein**	Director	March 5, 2026
/s/ Andrew Guggenhime **Andrew Guggenhime**	Director	March 5, 2026
/s/ Dara Richardson-Heron **Dara Richardson-Heron**	Director	March 5, 2026
/s/ David Johnson **David Johnson**	Director	March 5, 2026
/s/ Natalie R. Sacks **Natalie R. Sacks**	Director	March 5, 2026
/s/ Nancy Whiting **Nancy Whiting**	Director	March 5, 2026
/s/ Ran Zheng **Ran Zheng**	Director	March 5, 2026

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the stockholders and the Board of Directors of Caribou Biosciences, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Caribou Biosciences, Inc. and subsidiaries (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 "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2025 and 2024, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2025, in conformity with accounting principles generally accepted in the United States of America.

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.

/s/ Deloitte & Touche LLP

San Francisco, California

March 5, 2026

We have served as the Company's auditor since 2016.

CARIBOU BIOSCIENCES, INC. AND ITS SUBSIDIARIES
Consolidated Balance Sheets
(in thousands, except share and per share amounts)

	December 31, 2025	December 31, 2024
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 12,360	$ 16,293
Marketable securities, short-term	126,980	193,244
Accounts receivable	69	265
Contract assets	1,006	1,158
Other receivables	1,904	1,828
Prepaid expenses and other current assets	2,913	6,589
Total current assets	145,232	219,377
NON-CURRENT ASSETS		
Investments in equity securities	—	9,276
Marketable securities, long-term	3,505	39,849
Property and equipment, net	6,760	19,281
Operating lease, right of use assets	17,670	20,009
Other assets	2,200	5,521
TOTAL ASSETS	$ 175,367	$ 313,313
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 5,783	$ 2,476
Accrued expenses and other current liabilities	16,535	23,620
Operating lease liabilities, current	1,201	1,426
Deferred revenue ($0 and $2,487 from related party as of December 31, 2025, and December 31, 2024, respectively)	1,895	3,129
Total current liabilities	25,414	30,651
LONG-TERM LIABILITIES		
Deferred revenue, net of current portion ($0 and $1,243 from related party as of December 31, 2025, and December 31, 2024, respectively)	1,752	3,317
MSKCC success payments liability	—	785
Operating lease liabilities, non-current	26,026	25,061
Deferred tax liabilities	—	548
Total liabilities	53,192	60,362
COMMITMENTS AND CONTINGENCIES (Note 9)		
STOCKHOLDERS' EQUITY		
Common stock, par value $0.0001 per share, 300,000,000 shares authorized at December 31, 2025, and December 31, 2024; 95,143,690 and 92,378,577 shares issued and outstanding at December 31, 2025, and December 31, 2024, respectively	9	9
Additional paid-in-capital	718,578	701,077
Accumulated other comprehensive income	103	255
Accumulated deficit	(596,515)	(448,390)
Total stockholders' equity	122,175	252,951
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 175,367	$ 313,313

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

CARIBOU BIOSCIENCES, INC. AND ITS SUBSIDIARIES
Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except share and per share amounts)

	Years Ended December 31,	
	2025	2024
Licensing and collaboration revenue (including $2,487 and $4,110 for years ended December 31, 2025, and December 31, 2024, respectively, from related parties)	$ 11,159	$ 9,994
Operating expenses:		
Research and development	109,439	130,153
General and administrative	37,914	46,457
Impairment charges	12,150	—
Total operating expenses	159,503	176,610
Loss from operations	(148,344)	(166,616)
Other (expense) income		
Impairment of equity investment	(9,158)	—
Other income, net	8,827	17,502
Total other (expense) income	(331)	17,502
Net loss before benefit from income taxes	(148,675)	(149,114)
Benefit from income taxes	(550)	(9)
Net loss	(148,125)	(149,105)
Other comprehensive (loss) income		
Net unrealized (loss) gain on available-for-sale marketable securities, net of tax	(152)	225
Net comprehensive loss	$ (148,277)	$ (148,880)
Net loss per share, basic and diluted	$ (1.59)	$ (1.65)
Weighted-average common shares outstanding, basic and diluted	93,389,283	90,317,925

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

CARIBOU BIOSCIENCES, INC. AND ITS SUBSIDIARIES
Consolidated Statements of Stockholders' Equity
(in thousands, except share amounts)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
BALANCE—December 31, 2023	88,448,948	$ 8	$ 667,648	$ 30	$ (299,285)	$ 368,401
Issuances of common stock under ESPP	261,178	—	914	—	—	914
Issuances of common stock on exercises of options	182,217	—	618	—	—	618
Issuances of common stock upon vesting of RSUs	66,173	—	—	—	—	—
Issuances of common stock in connection with ATM offering, net of offering expenses	3,420,061	1	15,191	—	—	15,192
Stock-based compensation expense	—	—	16,706	—	—	16,706
Other comprehensive income	—	—	—	225	—	225
Net loss	—	—	—	—	(149,105)	(149,105)
BALANCE—December 31, 2024	92,378,577	$ 9	$ 701,077	$ 255	$ (448,390)	$ 252,951
Issuances of common stock under ESPP	637,396	—	745	—	—	745
Issuances of common stock on exercises of options	15,000	—	6	—	—	6
Issuances of common stock upon vesting of RSUs	468,489	—	—	—	—	—
Issuances of common stock in connection with ATM offering, net of offering expenses	1,644,228	—	4,070	—	—	4,070
Stock-based compensation expense	—	—	12,680	—	—	12,680
Other comprehensive loss	—	—	—	(152)	—	(152)
Net loss	—	—	—	—	(148,125)	(148,125)
BALANCE—December 31, 2025	95,143,690	$ 9	$ 718,578	$ 103	$ (596,515)	$ 122,175

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

CARIBOU BIOSCIENCES, INC. AND ITS SUBSIDIARIES
Consolidated Statements of Cash Flows
(in thousands)

	Years Ended December 31,	
	2025	2024
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (148,125)	$ (149,105)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	3,645	3,927
Gain on disposal of fixed assets	(25)	(9)
Non-cash consideration for licensing and collaboration revenue	(9)	(1,634)
Change in fair value of equity securities	99	111
Stock-based compensation expense	12,680	16,706
Change in fair value of MSKCC success payments liability	(785)	(2,154)
Acquired in-process research and development	—	1,625
Accretion of discounts on investments in marketable securities, net	(1,140)	(4,726)
Impairment charges	12,150	—
Impairment of equity investment	9,158	—
Non-cash lease expense	1,844	2,173
Changes in operating assets and liabilities:		
Accounts receivable	196	(117)
Contract assets	152	267
Other receivables	(76)	458
Prepaid expenses and other current assets	3,675	(433)
Other assets	3,350	(3,935)
Accounts payable	3,254	(354)
Accrued expenses and other current liabilities	(6,340)	2,134
Deferred revenue, current and long-term	(2,798)	(2,503)
Operating lease liabilities	(1,349)	(621)
Deferred tax liabilities	(548)	(10)
Net cash used in operating activities	(110,992)	(138,200)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Proceeds from maturities of marketable securities	252,830	397,492
Purchases of marketable securities	(149,233)	(304,393)
Purchases of property and equipment	(1,359)	(4,880)
Proceeds from sale of property and equipment	—	13
Payments to acquire in-process research and development	—	(1,625)
Net cash provided by investing activities	102,238	86,607
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from exercise of stock options	6	618
Proceeds from issuances of common stock under ESPP	745	914
Proceeds from issuances of common stock related to ATM, net of offering expenses	4,070	15,192
Net cash provided by financing activities	4,821	16,724
NET DECREASE IN CASH, CASH EQUIVALENTS, AND RESTRICTED CASH	(3,933)	(34,869)
CASH, CASH EQUIVALENTS, AND RESTRICTED CASH — BEGINNING OF PERIOD	16,339	51,208
CASH, CASH EQUIVALENTS, AND RESTRICTED CASH — END OF PERIOD	$ 12,406	$ 16,339
RECONCILIATION OF CASH, CASH EQUIVALENTS, AND RESTRICTED CASH		
Cash and cash equivalents	$ 12,360	$ 16,293
Restricted cash	46	46
CASH, CASH EQUIVALENTS, AND RESTRICTED CASH ON THE BALANCE SHEET	$ 12,406	$ 16,339
SUPPLEMENTAL SCHEDULE OF NON-CASH INVESTING AND FINANCING ACTIVITIES:		
Purchases of property and equipment included in accounts payable and accrued expenses	$ 60	$ 754
Right-of-use-assets recognized due to lease remeasurement	$ 2,089	$ —

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

CARIBOU BIOSCIENCES, INC. AND ITS SUBSIDIARIES
Notes to Consolidated Financial Statements

1. Description of the Business, Organization, and Liquidity

Business and Organization

Caribou Biosciences, Inc. ("Company" or "we") is a clinical-stage **C**lustered **R**egularly **I**nterspaced **S**hort **P**alindromic **R**epeats ("CRISPR") genome-editing biopharmaceutical company dedicated to developing transformative therapies for patients with devastating diseases. Our genome-editing platform is based on our novel chRDNA (**C**RISPR **h**ybrid **R**NA-**DNA**, or "chRDNA," pronounced "chardonnay") genome-editing technology, which enables more precise genome editing of allogeneic cell therapies. Our allogeneic, or off-the-shelf, chimeric antigen receptor ("CAR")-T ("CAR-T") cell therapy candidates are manufactured in advance with cells from healthy donors, with the goal of enabling broad patient access, rapid patient treatment, and increased manufacturing scale. We use our chRDNA technology to armor our allogeneic CAR-T cell therapy product candidates through genome-editing strategies, such as checkpoint disruption and immune cloaking, to enhance activity against hematologic malignancies.

We incorporated in October 2011 as a Delaware corporation and are headquartered in Berkeley, California. We have four wholly owned subsidiaries: Antler Holdco, LLC, incorporated in Delaware in April 2019; Microbe Holdco, LLC, incorporated in Delaware in June 2020; Arboreal Holdco, LLC, incorporated in Delaware in November 2020; and Biloba Holdco, LLC, incorporated in Delaware in April 2021. Our wholly owned subsidiaries hold interests in our equity investments and do not have operating activities.

Liquidity

We have incurred operating losses and negative cash flows from operations since our inception and we had an accumulated deficit of $596.5 million as of December 31, 2025. During the year ended December 31, 2025, we incurred a net loss of $148.1 million and used $111.0 million of cash in operating activities. We expect to continue to incur substantial losses, and our ability to achieve and sustain profitability will depend on the successful development, regulatory approval, and commercialization of our product candidates and on our ability to generate sufficient revenue to support our cost structure. We may never achieve profitability and, unless and until we do, we will need to continue to raise additional capital. Our management expects that existing cash, cash equivalents, and marketable securities of $142.8 million as of December 31, 2025, will be sufficient to fund our current operating plan for at least the next 12 months from the date our consolidated financial statements included in this Annual Report on Form 10-K are filed.

2. Summary of Significant Accounting Policies

Basis of Presentation and Principles of Consolidation

Our consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States ("U.S. GAAP") and include our accounts and the accounts of our wholly owned subsidiaries. All intercompany accounts and transactions are eliminated in consolidation. Certain prior period amounts in our consolidated financial statements have been reclassified to conform to current period presentation.

Use of Estimates

The preparation of consolidated financial statements in conformity with U.S. GAAP requires our management to make estimates and assumptions that affect the reported amounts of assets and liabilities; the disclosure of contingent assets and liabilities at the date of our consolidated financial statements; and the reported amounts of revenue, income, and expenses for the applicable reporting period. On an ongoing basis, we evaluate our estimates and assumptions, including those related to revenue recognition, impairment of long-lived assets, stock-based compensation expense, accrued research and development expenses, and income taxes. Our management evaluates its estimates and assumptions on an ongoing basis using historical experience and various other assumptions that they believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ materially from those estimates.

Segments

Operating segments are defined as components of an entity about which separate discrete information is available for evaluation by the chief operating decision maker ("CODM") in deciding how to allocate resources and in assessing performance. The CODM is our president and chief executive officer. We view our operations as, and manage our business in, one operating segment, which is the business of developing allogeneic CAR-T cell therapies (see Note 14, "Segment Information").

Concentrations of Credit Risk and Other Uncertainties

Financial instruments that potentially subject us to concentration of credit risk consist of cash and cash equivalents, accounts receivable, contract assets, other receivables, and investments in marketable securities and equity securities. Substantially all our cash and cash equivalents are deposited in accounts at four financial institutions, and our account balances exceed federally insured limits. We mitigate the risks by investing only in high-grade instruments, limiting our exposure to any single issuer, and we monitor the ongoing creditworthiness of these financial institutions and issuers.

Licensees that represent 10% or more of our revenue and accounts receivable and contract assets were as follows:

	Revenue		Accounts Receivable and Contract Assets	
	Years Ended December 31,		As of December 31,	
	2025	2024	2025	2024
Licensee A	19.5 %	26.6 %	54.5 %	49.3 %
Licensee B	22.3 %	24.9 %	*	*
Licensee C	*	16.2 %	*	*
Licensee D	21.5 %	*	*	*
Licensee E	*	*	11.8 %	*
Total	63.3 %	67.7 %	66.3 %	49.3 %

*Less than 10%

We monitor economic conditions to identify facts or circumstances that may indicate if any of our accounts receivable are not collectible or if contract assets should be impaired. No allowance for credit losses or contract asset impairment was recorded as of December 31, 2025, or 2024.

Revenue Recognition

We determine whether agreements are within the scope of Accounting Standard Codification ("ASC") Topic 606, Revenue from Contracts with Customers ("ASC 606") or other topics at the effective date of an agreement. For agreements that are determined to be within the scope of ASC 606, revenue is recognized when a licensee, or customer, obtains control of promised goods or services (e.g., an intellectual property license). The amount of revenue recognized reflects the consideration that we expect to be entitled to receive in exchange for these goods and services. To achieve this core principle, we apply the following five steps (i) identify the contract with the customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when or as we satisfy a performance obligation.

Our revenues are primarily derived through license and/or license and collaboration agreements. The terms of these types of agreements may include (i) licenses for our technology, (ii) research and development services, and (iii) services or obligations in connection with our participation in research or governance committees. Payments to us under these arrangements typically include one or more of the following: nonrefundable upfront license fees, maintenance fees, milestones, and other contingent payments to us for the achievement of defined collaboration objectives and certain nonclinical, clinical, regulatory, and sales-based events, as well as royalties on sales of any commercialized products.

We assess whether the promises in our contracts with third parties are considered distinct performance obligations that should be accounted for separately. Judgment is required to determine whether a license to our intellectual property is distinct from research and development services or participation on research or governance committees.

If a license to intellectual property controlled by us is determined to be distinct from the other performance obligations identified in the agreement, we recognize revenues allocated to the license at the point in time when the license is transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that are combined with other promises, we utilize our judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue. We evaluate the measure of progress using the input method for each reporting period and, if necessary, adjust the measure of performance and related revenue recognition.

Certain of our license agreements include contingent milestone payments. Such milestone payments are typically payable when the collaborator or licensee achieves certain predetermined clinical, regulatory, and/or commercial milestones. Milestone payments that are not within our control or the control of the licensee, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. At each reporting date, we reevaluate whether the milestones are considered probable of being reached, and we estimate the amount to be included in the transaction price by using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price in such period of determination.

Our license and/or collaboration and license agreements may also include contingent payments related to sales-based milestones. Sales-based milestones are typically payable when annual sales of a covered product reach specified levels. Sales-based milestones are recognized at the later of when the associated performance obligation has been satisfied or when the sales occur. Unlike other contingency payments, such as regulatory milestones, sales-based milestones are not included in the transaction price based on estimates at the inception of the contract, but rather, are included when the sales or usage occur. We use the sales-based royalty exception because the license is a predominant item to which sales-based royalties relate.

Certain of our license agreements have two performance obligations: a license and a material right for annual license renewals. Such license agreements require payments of non-refundable annual license fees by the licensee (referred to as maintenance fees in the license agreements), which are accounted for as material rights for license renewals. We recognize revenue when the license is delivered and the term commences. Revenue for the material right for license renewals is recognized at the point in time that the annual license fee is paid by the licensee and the renewal period begins.

Payments received under third-party contracts are recorded as deferred revenue upon receipt or when due and may require deferral of revenue recognition to a future period until we satisfy our performance obligations under these contracts. We record contract assets when payment is due under third-party contracts conditioned on future performance or the occurrence of other events. Amounts payable to us are recorded as accounts receivable if invoiced and if our right to consideration is unconditional.

Fair Value Measurements

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability (see Note 3, “Fair Value Measurements and Fair Value of Financial Instruments”).

Cash and Cash Equivalents

We consider all highly liquid investments purchased with an original maturity of three months or less to be cash equivalents. As of December 31, 2025, cash and cash equivalents consisted of cash, money market funds, and commercial paper. As of December 31, 2024, cash and cash equivalents consisted of cash, money market funds, government securities, commercial paper, and U.S. Treasury bills.

Restricted Cash

We define restricted cash as cash and cash equivalents that cannot be withdrawn or used for general operating activities. Our restricted cash consists of a letter of credit with a financial institution related to one of our workers’ compensation insurance policies. As of December 31, 2025, and 2024, we had less than $0.1 million of restricted cash, which was recorded in other assets in our consolidated balance sheets.

Marketable Securities

Our short-term and long-term marketable securities are available for sale securities and consist of U.S. Treasury bills, commercial paper, U.S. government agency bonds, and corporate debt securities. We classify those securities that mature in more than 12 months as long-term investments in our consolidated balance sheets. We record at estimated fair value based on quoted market prices or observable market inputs of almost identical assets, with the unrealized holding gains or losses recorded in other comprehensive (loss) income in our consolidated statements of operations and comprehensive loss. The amortized cost of securities is adjusted for amortization of premiums and accretion of discounts to maturity, which are both recorded to interest income in our consolidated statements of operations and comprehensive loss. When the fair value of a debt security declines below its amortized cost basis, any portion of that decline attributable to credit losses, to the extent expected to be nonrecoverable before the sale of the security, is recognized in our statement of operations. When the fair value of a debt security declines below its amortized cost basis due to changes in interest rates, such amounts are recorded in other comprehensive (loss) income, and are recognized in our statements of operations only if we sell or intend to sell the security before recovery of its cost basis.

Investments in Equity Securities

We may receive as consideration under our license agreements equity securities of private or public companies (an "investee"). If we determine that we do not have control over these investees under either the Variable Interest Entity ("VIE") or voting models, we then determine if we have an ability to exercise significant influence via voting interests, board of director representation, or other business relationships. If we conclude that we do not have an ability to exercise significant influence over an investee, we account for our investment at fair value and may elect to account for an equity security without a readily determinable fair value using a measurement alternative. This measurement alternative allows us to measure the equity investment at its cost minus impairment, if any, plus or minus changes resulting from observable price changes in orderly transactions for the identical or a similar investment of the same issuer. If we determine that we do have control over these companies under either voting or VIE models, we consolidate them in our consolidated financial statements.

As of December 31, 2024, investments in equity securities, long-term, consisted primarily of our investment in the preferred stock of a private company, related party (see Note 7, "Related Party Transactions"). We concluded that our shares of the private company's preferred stock are not in substance common stock and, since these securities do not have readily determinable fair value, we account for our investment in the private company's preferred stock using the measurement alternative method. During the second quarter of 2025, we determined that impairment indicators existed, and the fair value of our shares of the private company's preferred stock was zero, as a result, as of June 30, 2025, the preferred stock was fully impaired and no balance remained. We recorded an impairment expense of $9.2 million for the year ended December 31, 2025.

Property and Equipment

Property and equipment are recorded at cost, net of accumulated depreciation and amortization. Property and equipment are depreciated using the straight-line method over the estimated useful lives of the assets.

Computer equipment	3 years
Furniture and office equipment	5 years
Lab equipment	5 years
Leasehold improvements	Shorter of remaining lease term or estimated useful life

Upon retirement or sale of the assets, the cost and related accumulated depreciation and amortization are removed from the balance sheet and the resulting gain or loss is recorded in the statements of operations. Repairs and maintenance are expensed as incurred.

Impairment of Long-Lived Assets

We evaluate the carrying amount of our long-lived assets whenever events or changes in circumstances indicate that the assets may not be recoverable. An impairment loss is recognized when estimated future cash flows expected to result from the use of the asset and its eventual disposition is less than the carrying amount of the asset. During the second quarter of 2025, we identified certain triggering events, such as significant changes in our current and expected use of leased office and lab space and lab equipment. We determined that these asset groups were impaired and recorded an impairment expense of $12.2 million for the year ended December 31, 2025 (see Note 15, "Restructuring Charge").

Leases

Under Financial Accounting Standards Board ("FASB") Accounting Standards Update ("ASU") No. 2016-02, Leases (Topic 842) and its associated amendments, we determine if an arrangement is a lease at inception. In addition, we determine whether a lease meets the classification criteria of a finance or operating lease at the lease commencement date considering whether: (i) the lease transfers ownership of the underlying asset to the lessee at the end of the lease term; (ii) the lease grants the lessee an option to purchase the underlying asset that the lessee is reasonably certain to exercise; (iii) the lease term is for a major part of the remaining economic life of the underlying asset; (iv) the present value of the sum of the lease payments and residual value guaranteed by the lessee equals or exceeds substantially all of the fair value of the underlying asset; and (v) the underlying asset is such a specialized nature that it is expected to have no alternative use to the lessor at the end of the lease term. As of December 31, 2025, our leases consisted of real estate operating leases and we did not have any finance leases.

Operating leases are included in Operating lease right-of-use assets; Operating lease liabilities, current; and Operating lease liabilities, non-current in our consolidated balance sheets. Right-of-use assets represent our right to use the underlying assets for the lease term and lease liabilities represent our obligation to make lease payments arising from the leases. Operating lease right-of-use assets and liabilities are recognized at the lease commencement date based on the present value of lease payments over the lease term. In determining the present value of lease payments, if the rate implicit in the lease is not readily determinable, we use our incremental borrowing rate based on the information available at the lease commencement date. We determine the incremental borrowing rate based on an analysis of corporate bond yields with a credit rating similar to ours. The determination of our incremental borrowing rate requires management judgment, including development of a synthetic credit rating and cost of debt, as we currently do not carry any debt. We believe that the estimates used in determining the incremental borrowing rate are reasonable based upon facts and circumstances. Applying different judgments to the same facts and circumstances could yield a different incremental borrowing rate. The operating lease right-of-use assets also include adjustments for prepayments, accrued lease payments, and lease incentives. Right-of-use assets and lease liabilities may include options to extend or terminate leases if it is reasonably certain that we will exercise such options. If significant events, changes in circumstances, or other events indicate that the lease term or other inputs have changes, we would reassess lease classification, remeasure the lease liabilities using revised inputs as of the reassessment date, and adjust the operating lease right-of-use assets. Lease payments which are fixed and determinable are amortized as rent and lease expense on a straight-line basis over the expected lease term. Variable lease costs, such as common area maintenance charges and other operating costs, are expensed as incurred. Lease agreements that include lease and non-lease components are accounted for as a single lease component. Lease agreements with non-cancelable terms of less than 12 months are not recorded on our balance sheets.

Accrued Research and Development Expenses

Research and development expenses are expensed as incurred. Research and development expenses include those for certain payroll and personnel; laboratory supplies; consulting; manufacturing; external clinical; and allocated overhead, including rent, equipment depreciation, and utilities.

We record accrued liabilities for estimated costs of our research and development activities conducted by third-party service providers. We record the estimated costs of research and development activities based upon the estimated amount of services provided but not yet invoiced and include these costs in accrued liabilities in our consolidated balance sheets and within research and development expenses in our consolidated statements of operations and comprehensive loss. We accrue for these costs based on factors such as estimates of the work completed and in accordance with the third-party service agreements. If we do not identify costs that have begun to be incurred or if we underestimate or overestimate the level of services performed or the costs of these services, actual expenses could differ from our estimates. To date, we have not experienced any material differences between accrued costs and actual costs incurred.

We make payments in connection with clinical trials to contract manufacturing organizations ("CMOs") that manufacture the material for our product candidates and to contract research organizations ("CROs") and clinical trial sites that conduct and manage our clinical trials. The financial terms of these contracts are subject to negotiation, which vary by contract and may result in payments that do not match the periods over which materials or services are provided. Generally, these agreements set forth the scope of work to be performed at a fixed fee, unit price or on a time and materials basis. In the event we make advance payments for goods or services that will be used or rendered for future research and development activities, the payments are deferred and capitalized as a prepaid expense and recognized as expense as the goods are received or the related services are rendered. These payments are evaluated for current or long-term classification based on when they are expected to be realized.

Acquisition of In-Process Research and Development Assets

We measure and recognize acquired in-process research and development assets, which include licenses, know-how, patents, and transaction fees, based on the cost to acquire the assets and the consideration that is allocated to the items based on a relative fair value methodology. Goodwill is not recognized in asset acquisitions. If acquired in-process technology is determined to not have an alternative future use, the cost is charged to research and development expenses at the acquisition date.

Patent Costs

We expense patent costs as incurred for filing, prosecuting, and maintaining patents and patent applications, including certain of the patents and patent applications that we license from third parties. We classify these costs as general and administrative expenses in our consolidated statements of operations and comprehensive loss. In addition, we are entitled to receive reimbursement from third parties for a portion of the filing, prosecution, and maintenance costs for certain patents and patent applications. We accrue for these reimbursements as the respective expenses are incurred, and we classify such reimbursements as a reduction of general and administrative expenses. During the years ended December 31, 2025, and 2024, we incurred gross patent costs of $3.6 million and $3.8 million, respectively. During each of the years ended December 31, 2025, and 2024, we recorded $1.2 million of patent cost reimbursements as a credit to general and administrative expenses.

Stock-Based Compensation Expense

Stock-based compensation expense related to awards to employees is measured at the grant date based on the fair value of the award. We determine the grant-date fair value of the options using the Black-Scholes option-pricing model. The fair value of restricted stock units ("RSUs"), performance-based RSUs ("PSUs"), and performance-based stock options ("PBSOs") awards is determined based on the number of units granted and the closing price of our common stock as of the grant-date. For options and RSUs, the fair value of the award that is ultimately expected to vest is recognized as expense on a straight-line basis over the requisite service period of the awards, which is generally the vesting period. For performance-based awards, expense is recognized over the related vesting period once the conditions for achievement of the milestones are probable. All awards are adjusted for pre-vesting forfeitures in the period in which the forfeitures occur.

We use the Black-Scholes valuation model as the method for determining the estimated fair value of stock options and stock purchases under our 2021 Employee Stock Purchase Plan ("ESPP") with the following assumptions:

Fair Market Value of Common Stock — The fair market value of our common stock is based on its closing price on Nasdaq as reported on the date of the stock option grant.

Expected Term — Expected term represents the period that our stock-based awards are expected to be outstanding and is determined using the simplified method, which represents the average of the contractual term of the stock option and its weighted-average vesting period. The expected term for our stock purchases under our ESPP is the offering period.

Expected Volatility — Expected volatility is estimated based on the average historical volatilities of common stock of comparable publicly traded entities within the life sciences industry over a period equal to the expected term of the stock option grants, as we do not have sufficient trading history for our common stock. Comparable companies are chosen based on their size, stage in the life cycle, or area of specialty. We will continue to apply this process for stock options and ESPP stock purchases until enough historical information regarding the volatility of our stock price becomes available.

Expected Dividends — Expected dividends are zero as we have never paid dividends on our common stock and have no plans to do so for the foreseeable future.

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

Income Taxes

We account for income taxes using the asset and liability method. We recognize deferred tax assets and liabilities for the expected future tax consequences of events that have been included in our consolidated financial statements or tax returns. Deferred tax assets and liabilities are determined based on the difference between our consolidated financial statements and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Valuation allowances are provided if, based upon the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized. Tax benefits related to uncertain tax positions are recognized when it is more likely than not that a tax position will be sustained during an audit. Interest and penalties related to unrecognized tax benefits are included within the provision for income tax.

Other Income, net

We recognize fees earned from sources not considered to be within the normal course of business in other income within the statements of operations and comprehensive loss. During the years ended December 31, 2025, and 2024, we recognized $8.0 million and $15.3 million, respectively, of interest income from our short-term and long-term marketable securities.

Comprehensive Loss

Comprehensive loss is composed of net loss and other comprehensive (loss) income. Other comprehensive (loss) income consists of unrealized gains and losses on available-for-sale marketable securities.

Net Loss Per Share

Basic net loss per share is computed by dividing the net loss by the weighted-average number of common shares outstanding during the period, without consideration of potential dilutive securities. Diluted net loss per share is computed by dividing the net loss by the sum of the weighted-average number of common shares outstanding during the period plus the dilutive effects of potentially dilutive securities outstanding during the period. Potentially dilutive securities include common stock options, shares committed under ESPP and RSUs issued and outstanding. For all periods presented, diluted net loss per share is the same as basic net loss per share since the effect of including potential common shares is anti-dilutive.

Recently Adopted Accounting Pronouncements

From time to time, new accounting pronouncements are issued by FASB or other standard-setting bodies and adopted are by us as of the specified effective date.

In December 2023, the FASB issued ASU 2023-09 - Income Taxes (Topic 740): Improvements to Income Tax Disclosures. This ASU requires public entities, on an annual basis, to provide disclosure of specific categories in the tax rate reconciliation, as well as disclosure of income taxes paid disaggregated by jurisdiction. ASU 2023-09 is effective for fiscal years beginning after December 15, 2024, with early adoption permitted. We have adopted ASU 2023-09 on a prospective basis for the fiscal year 2025. The impact of ASU 2023-09 resulted in additional disclosures in the notes to our consolidated financial statements (see Note 12, “Income Taxes”).

Recently Issued Accounting Pronouncements Not Yet Adopted

In November 2024, the FASB issued ASU No. 2024-03 - Income Statement - Reporting Comprehensive Income - Expense Disaggregation (Subtopic 220-40): Disaggregation of Income Statement Expenses. The amendments in ASU 2024-03 require a public business entity to disclose specific information about certain costs and expenses in the notes to its financial statements for interim and annual reporting periods. The objective of the disclosure requirements is to provide disaggregated information about a public business entity's expenses to help investors (i) better understand the entity's performance, (ii) better assess the entity's prospects for future cash flows, and (iii) compare an entity's performance over time and with that of other entities. ASU 2024-03 is effective for fiscal years beginning after December 15, 2026, and for interim periods within fiscal years beginning after December 15, 2027, with early adoption permitted. We are currently evaluating the impact of the adoption of ASU 2024-03.

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

In December 2025, the FASB issued ASU 2025-11 - Interim Reporting (Topic 270): Narrow-Scope Improvements. The amendments in ASU 2025-11 provide clarifications intended to improve the consistency and usability of interim disclosure requirements, including a comprehensive listing of required interim disclosures and a new disclosure principle for reporting material events occurring after the most recent annual financial reporting period. ASU 2025-11 is effective for fiscal years beginning after December 15, 2027, and interim periods within those fiscal years, with early adoption permitted. We are currently evaluating the impact of the adoption of ASU 2025-11.

Emerging Growth Company and Smaller Reporting Company Status

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012 Act ("JOBS" Act"), and may remain an emerging growth company until the last day of our fiscal year following the fifth anniversary of the closing of our initial public offering ("IPO") (i.e., December 31, 2026). Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. We have elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that we (i) are no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, our consolidated financial statements may not be comparable to those of companies that comply with the new or revised accounting pronouncements as of public company effective dates.

We expect to use the extended transition period for any other new or revised accounting standards during the period in which we remain an emerging growth company. We have early adopted certain accounting standards because the JOBS Act does not preclude an emerging growth company from adopting a new or revised accounting standard earlier than the time that such standard applies to private companies to the extent early adoption is allowed by the accounting standard.

We are also a "smaller reporting company." If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company, we may choose to present only the two most recent fiscal years of audited consolidated financial statements in our Annual Report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

3. Fair Value Measurements and Fair Value of Financial Instruments

We classify fair value-based measurements using a three-level hierarchy that prioritizes the inputs used to measure fair value. This hierarchy requires entities to maximize the use of observable inputs and minimize the use of unobservable inputs. The three levels of inputs used to measure fair value are as follows: Level 1, quoted market prices (unadjusted) in active markets for identical assets or liabilities; Level 2, observable inputs other than quoted market prices included in Level 1, such as quoted market prices for markets that are not active or other inputs that are observable or can be corroborated by observable market data; and 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, including certain pricing models, discounted cash flow methodologies and similar techniques that use significant unobservable inputs. Changes in the ability to observe valuation inputs may result in a reclassification of levels of certain securities within the fair value hierarchy. We recognize transfers into and out of levels within the fair value hierarchy in the period in which the actual event or change in circumstances that caused the transfer occurs. No such transfers occurred during the years ended December 31, 2025, and 2024.

Recurring Measurements

The following table sets forth our financial instruments that were measured at fair value on a recurring basis by level within the fair value hierarchy (in thousands):

	Fair Value Measurements as of December 31, 2025			
	Total	Level 1	Level 2	Level 3
Assets:				
U.S. Treasury bills	$ 86,964	$ 86,964	$ —	$ —
U.S. government agency bonds	28,717	—	28,717	—
Money market fund investments (included in cash and cash equivalents)	11,361	11,361	—	—
Corporate debt securities	8,663	—	8,663	—
Commercial paper ($999 included in cash and cash equivalents)	7,140	—	7,140	—
Total fair value of assets	$ 142,845	$ 98,325	$ 44,520	$ —

	Fair Value Measurements as of December 31, 2024			
	Total	Level 1	Level 2	Level 3
Assets:				
U.S. Treasury bills ($1,293 included in cash and cash equivalents)	$ 169,615	$ 169,615	$ —	$ —
U.S. government agency bonds ($1,993 included in cash and cash equivalents)	33,482	—	33,482	—
Commercial paper ($1,499 included in cash and cash equivalents)	26,283	—	26,283	—
Money market fund investments (included in cash and cash equivalents)	11,508	11,508	—	—
Corporate debt securities	8,498	—	8,498	—
Total fair value of assets	$ 249,386	$ 181,123	$ 68,263	$ —
Liabilities:				
MSKCC success payments liability	$ 785	$ —	$ —	$ 785
Total fair value of liabilities	$ 785	$ —	$ —	$ 785

The fair value and amortized cost of cash equivalents and available-for-sale marketable securities by major security type as of December 31, 2025, and 2024 are presented in the following tables (in thousands):

	As of December 31, 2025			
	Amortized Cost Basis	Unrealized Gains	Unrealized Losses	Estimated Fair Value
U.S. Treasury bills	$ 86,872	$ 92	$ —	$ 86,964
U.S. government agency bonds	28,707	12	(2)	28,717
Money market fund investments (included in cash equivalents)	11,361	—	—	11,361
Corporate debt securities	8,663	2	(2)	8,663
Commercial paper ($999 included in cash and cash equivalents)	7,139	1	—	7,140
Total cash equivalents and marketable securities	$ 142,742	$ 107	$ (4)	$ 142,845

Classified as:	
Cash and cash equivalents	$ 12,360
Marketable securities, short-term	126,980
Marketable securities, long-term	3,505
Total cash equivalents and marketable securities	$ 142,845

	As of December 31, 2024			
	Amortized Cost Basis	Unrealized Gains	Unrealized Losses	Estimated Fair Value
U.S. Treasury bills ($1,293 included in cash and cash equivalents)	$ 169,414	$ 268	$ (67)	$ 169,615
U.S. government agency bonds ($1,993 included in cash and cash equivalents)	33,440	53	(11)	33,482
Commercial paper ($1,499 included in cash equivalents)	26,274	11	(2)	26,283
Money market fund investments (included in cash equivalents)	11,508	—	—	11,508
Corporate debt securities	8,495	3	—	8,498
Total cash equivalents and marketable securities	$ 249,131	$ 335	$ (80)	$ 249,386

Classified as:	
Cash and cash equivalents	$ 16,293
Marketable securities, short-term	193,244
Marketable securities, long-term	39,849
Total cash equivalents and marketable securities	$ 249,386

We reviewed each of our marketable securities as of December 31, 2025, and 2024, and concluded that any decline in fair value was not related to credit losses and is recoverable. Accordingly, no allowance for credit losses was recorded and the unrealized losses are reported as a component of accumulated other comprehensive income.

The following table presents the fair value of available-for-sale marketable securities by contractual maturities (in thousands):

	December 31, 2025
Due in less than one year	126,980
Due in one to five years	3,505
Total	$ 130,485

On May 13, 2025, we provided notice of termination to Memorial Sloan Kettering Cancer Center ("MSKCC") of the Exclusive License Agreement, dated November 13, 2020, (as amended, "MSKCC Agreement") with MSKCC Agreement, which termination was effective on August 11, 2025, due to the prior discontinuation of the AMpLify phase 1 clinical trial for our CB-012 product candidate, an allogeneic anti-C-type lectin-like molecule-1 ("CLL-1") CAR-T cell therapy for the treatment of relapsed or refractory acute myeloid leukemia ("r/r AML"). Under the now-terminated MSKCC Agreement, MSKCC was entitled to certain success payments if our common stock fair value would have increased by certain multiples of increasing value based on a comparison of the fair value of our common stock to $5.1914 per share, adjusted for any future stock splits (the "Initial Share Price"), during a specified time period. The relevant time period commenced on February 13, 2024, when the first patient was dosed with CB-012 in our AMpLify phase 1 clinical trial, and would have ended upon the earlier of the third anniversary from the approval of our biologics license application ("BLA") by the FDA or 10 years from February 13, 2024.

The following table summarizes the amounts of the MSKCC success payments that would have been due:

Multiple of Initial Share Price giving rise to a success payment	5x	10x	15x
MSKCC success payments (in millions)	$ 10.0	$ 10.0	$ 15.0

The MSKCC success payments liability under the now-terminated MSKCC Agreement had been carried at fair value and changes were recognized as expense or income as part of other income. During the second quarter of 2025, we re-measured the fair value of the MSKCC success payments liability, updating inputs, such as the probability of achieving a multiple of a defined initial share price and the expected term, to reflect the pending termination of the MSKCC Agreement, and we estimated the fair value to be zero.

The following table sets forth a summary of the changes in the fair value of our Level 3 financial liability (in thousands):

	MSKCC Success Payments Liability
Balance at December 31, 2023	$ 2,939
Change in fair value	(2,154)
Balance at December 31, 2024	$ 785
Change in fair value	(785)
Balance at December 31, 2025	$ —

Nonrecurring Measurements

On May 15, 2020, we entered into an Exclusive License Agreement for Veterinary Therapeutics (as amended, "Edge chRDNA License Agreement") with Edge Animal Health ("Edge"), a related party private company, under which we granted Edge an exclusive worldwide license to our Cas9 and Cas12a chRDNA intellectual property and know-how in a defined field of veterinary therapeutics. As consideration for this license agreement, we received 7,500,000 shares of convertible preferred stock ("Edge Stock") with an estimated fair value of $7.5 million, which was based on the price per share paid for similar shares by another investor, and which was an arm's length transaction. In June 2024, we received 1,623,275 additional shares of convertible preferred stock pursuant to anti-dilution rights of the Edge chRDNA License Agreement with an estimated fair value of $1.6 million, based on management's best estimate and judgment. We elected to apply the measurement alternative under Accounting Standards Codification ("ASC") Topic 321, Investments - Equity Securities ("ASC 321") for an equity security without a readily determinable fair value. Accordingly, this investment is carried at its cost minus impairment, if any, and is classified within Level 3 of the fair value hierarchy. If we identify observable price changes in orderly transactions for this investment or a similar investment, we will measure the investment at fair value as of the date that the observable transactions or events occurred.

As part of the preparation of our prior quarter financial statements, we assessed potential indicators of impairment of our Edge Stock. As part of our assessment, we considered Edge's planned operating cash flow requirements, available capital to fund those requirements, and ability to secure additional capital if needed as indicators of impairment. During the second quarter of 2025, we determined that impairment indicators existed, and the fair value of our Edge Stock was zero; as a result, as of June 30, 2025, our Edge Stock was fully impaired and no balance remained. We recorded an impairment expense of $9.2 million as "impairment of equity investment" in our consolidated statements of operations and comprehensive loss for the year ended December 31, 2025. This impairment expense was recorded as a reduction to the investment balance within investments in equity securities in our consolidated balance sheets as of December 31, 2025.

4. Significant Agreements

The Regents of the University of California and the University of Vienna

We entered into an Exclusive License Agreement, dated April 16, 2013 (as amended, "UC/Vienna Agreement") with The Regents of the University of California ("UC") and the University of Vienna ("Vienna") (together, "UC/Vienna") wherein UC/Vienna granted us an exclusive worldwide license, with the right to sublicense, in all fields to the foundational CRISPR-Cas9 patent family co-owned by UC, Vienna, and Dr. Emmanuelle Charpentier ("CVC IP"). Dr. Charpentier has not granted us any rights, either directly or indirectly. The UC/Vienna Agreement continues until the last-to-expire patent or last-to-be-abandoned patent application within the CVC IP; provided, however, that UC/Vienna may terminate the UC/Vienna Agreement upon the occurrence of certain events and we may terminate the UC/Vienna Agreement at our sole discretion upon written notice. Without patent term adjustment ("PTA") or patent term extension ("PTE"), the CVC IP will expire in 2033. For products and services sold by us that are covered by the CVC IP, we will owe low- to mid-single-digit percent royalties on net sales, subject to a minimum annual royalty. Prior to the time that we are selling products, we owe UC/Vienna an annual license maintenance fee. We will owe UC/Vienna up to $3.1 million in certain regulatory and clinical milestone payments in the field of human therapeutics and diagnostics for products that are covered by the CVC IP. Additionally, we pay UC/Vienna a specified percentage of sublicensing revenue, including cash and equity, we receive from sublicensing the CVC IP, subject to certain exceptions. If we include intellectual property owned or controlled by us in a sublicense to the CVC IP, we pay UC/Vienna a low double-digit percentage of sublicensing revenues received under the sublicense. If we do not include intellectual property owned or controlled by us in a sublicense to the CVC IP, we pay UC/Vienna 50% of sublicensing revenues received under the sublicense. To date, we have entered into over 30 sublicensing agreements in a variety of fields such as human therapeutics, animal therapeutics, agriculture, forestry, research reagents, transgenic animals, certain livestock targets, internal research, bioproduction, cell lines, and microbial applications that include the CVC IP as well as other Cas9 intellectual property owned or controlled by us. We are obligated to reimburse UC for its prosecution and maintenance costs of the CVC IP.

For the years ended December 31, 2025, and 2024, we incurred $1.7 million and $1.1 million, respectively, for payments we owe to UC related to sublicensing revenues, which we recorded in research and development expenses in our consolidated statements of operations and comprehensive loss.

For the years ended December 31, 2025, and 2024, we reimbursed UC $1.8 million and $1.7 million, respectively, for prosecution and maintenance costs of the CVC IP, which were recorded in general and administrative expenses in our consolidated statements of operations and comprehensive loss.

On December 15, 2016, we entered into a Consent to Assignments, Licensing and Common Ownership and Invention Management Agreement ("IMA") relating to the CVC IP. Under the IMA, CRISPR Therapeutics AG reimburses us 50% of the amounts we reimburse UC for patent prosecution and maintenance costs of the CVC IP. For each of the years ended December 31, 2025, and 2024, CRISPR Therapeutics AG reimbursed us $0.9 million, which we recorded as reductions of general and administrative expenses in our consolidated statements of operations and comprehensive loss.

Intellia Therapeutics, Inc.

On July 16, 2014, we entered into a License Agreement (as amended, "Intellia License Agreement") with Intellia, LLC, to which Intellia Therapeutics, Inc. ("Intellia") is a successor in interest. Under the Intellia License Agreement, we granted Intellia an exclusive worldwide license, with the right to sublicense, to certain CRISPR-Cas9 technology for a defined field of human therapeutics. Intellia granted us an exclusive worldwide license, with the right to sublicense, to certain of its CRISPR-Cas9 technology for all fields outside of the defined field of human therapeutics. Under the Intellia License Agreement, each party is responsible for 30% of the other party's expenses for prosecution and maintenance of the licensed intellectual property.

During the years ended December 31, 2025, and 2024, we recognized $0.2 million and $0.3 million, respectively, of expenses in reimbursable patent prosecution and maintenance costs, which were recorded as general and administrative expenses in our consolidated statements of operations and comprehensive loss. During the years ended December 31, 2025, and 2024, Intellia reimbursed us $0.4 million and $0.3 million, respectively (including reimbursement for a portion of the patent prosecution and maintenance costs of the CVC IP paid to UC), which were recorded as reductions of general and administrative expenses in our consolidated statements of operations and comprehensive loss. The term of the Intellia License Agreement continues for the life of the licensed patents and patent applications; provided, however, either party may terminate the agreement upon the occurrence of certain events.

On June 16, 2021, we entered into a leaseback agreement with Intellia ("Leaseback Agreement"). Pursuant to the Leaseback Agreement, in exchange for Intellia's grant to us of an exclusive license to certain intellectual property relating to CRISPR-Cas9, including Cas9 chRDNAs, for use solely in the manufacture of our vispacabtagene regedleucel ("vispa-cel," formerly CB-010) product candidate, we paid Intellia an upfront cash payment of $1.0 million and we will owe up to $23.0 million in potential future regulatory and sales milestones. Additionally, we will owe Intellia low- to mid- single-digit percent royalties on net sales of our vispa-cel product candidate until the expiration, abandonment, or invalidation of the last patent within the intellectual property relating to CRISPR-Cas9, including that relating to Cas9 chRDNAs (i.e., 2036, without PTA or PTE).

Pioneer Hi-Bred International, Inc. (now Corteva Agriscience)

On July 13, 2015, we and Pioneer Hi-Bred International, Inc. ("Pioneer") (now Corteva Agriscience), then a DuPont company ("DuPont"), entered into an Amended and Restated Collaboration and License Agreement (as amended, "Pioneer Agreement"). Under the terms of the Pioneer Agreement, we and Pioneer cross licensed CRISPR intellectual property portfolios. Pioneer granted us an exclusive worldwide license, with the right to sublicense, to its CRISPR intellectual property in the field of research tools, as well as a non-exclusive worldwide license to such intellectual property in human and animal therapeutics, industrial biotechnology, certain agriculture segments, and other fields; and we granted Pioneer an exclusive worldwide license, with the right to sublicense, to our CRISPR intellectual property, including the CVC IP, in a defined field of agriculture relating to specified row crops, as well as a non-exclusive worldwide license to the intellectual property in other agricultural applications, industrial biotechnology, nutrition and health, and other fields. The Pioneer Agreement continues until the expiration, abandonment, or invalidation of the last patent or patent application within the licensed intellectual property; provided, however, that the parties may terminate the Pioneer Agreement by mutual consent or either party may unilaterally terminate the Pioneer Agreement in the event of an uncured breach of a payment obligation, bankruptcy, or failure to maintain or own licensed intellectual property by the other party if the non-breaching party is materially adversely affected by the failure. We are obligated to pay low-single-digit percent royalties to Pioneer for the sales of our products in the research tools field as well as certain sublicensing revenues in that field. We are eligible to receive milestone payments from Pioneer if certain regulatory and commercial milestones are met related to specified row crops, for a total of up to $22.4 million, as well as to receive low-single-digit percent royalties for sales of defined agricultural products and certain sublicensing revenues in that field. Initially, Pioneer owned the patents and patent applications developed under the collaboration, including the chRDNA patent family, and granted us an exclusive license to these patents and patent applications in the fields of research tools and therapeutics.

In December 2020, we and Pioneer entered into an amendment to the Pioneer Agreement under which Pioneer assigned to us the chRDNA patent family developed under the research collaboration, and we paid Pioneer an upfront payment of $0.5 million. In addition to the upfront payment, we are now obligated to pay all patent prosecution and maintenance costs for the chRDNA patent family; up to $2.8 million in regulatory milestone payments and up to $20.0 million in sales milestones for any therapeutic products that are covered by the chRDNA patent family; and a low-single-digit percentage of licensing revenue we receive for licensing the chRDNA patent family in the therapeutic field after December 2020. During the years ended December 31, 2025, and 2024, we did not recognize any expense or income related to the Pioneer Agreement

5. Revenue

Disaggregation of Revenue

We disaggregate revenue by geographical market based on the location of research and development activities of our licensees and collaborators. The following table is a summary of revenue by geographic location for the years ended December 31, 2025, and 2024, (in thousands):

	Years Ended December 31,	
	2025	2024
United States	$ 9,478	$ 9,270
Rest of world	1,681	724
Total	$ 11,159	$ 9,994

During the year ended December 31, 2025, we recognized $8.7 million of revenue related to performance obligations satisfied at a point in time, and we recognized $2.5 million of revenue related to performance obligations satisfied over time.

During the year ended December 31, 2024, we recognized $7.5 million of revenue related to performance obligations satisfied at a point in time, and we recognized $2.5 million of revenue related to performance obligations satisfied over time.

Contract Balances

Accounts receivable relate to our right to consideration for performance obligations completed (or partially completed) for which we have an unconditional right to consideration. Our accounts receivable balances represent amounts that we billed to our licensees with invoices outstanding as of the end of a reporting period.

Contract assets are rights to consideration in exchange for a license that we have granted to a licensee when the right is conditional on something other than the passage of time. Our contract asset balances represent royalties and milestone payments from our other license agreements that are unbilled as of the end of a reporting period.

Contract liabilities consist of deferred revenue and relate to amounts invoiced to, or advance consideration received from, licensees that precede our satisfaction of the associated performance obligations. As of December 31, 2025, and 2024, our deferred revenue balance primarily resulted from the upfront payment received relating to our performance obligation to Pfizer, Inc. (“Pfizer”). The remaining deferred revenue relates to upfront payments received under license agreements that also include nonrefundable annual license fees, which are accounted for as material rights for license renewals and are recognized at the point in time when annual license fees are paid by the licensees and the renewal periods begin.

The following table presents changes in our contract assets and liabilities during the year ended December 31, 2025 (in thousands):

	Balance as of December 31, 2024	Additions	Deductions	Balance as of December 31, 2025
Accounts receivable	$ 265	$ 8,497	$ (8,693)	$ 69
Contract assets:				
Unbilled accounts receivable	$ 1,158	$ 3,427	$ (3,579)	$ 1,006
Contract liabilities:				
Deferred revenue, current and long-term	$ 6,446	$ 1,540	$ (4,339)	$ 3,647

Deferred revenue decreased during the year ended December 31, 2025, primarily due to the recognition of deferred revenue related to the satisfaction of our performance obligation to Pfizer (see Note 7, “Related Party Transactions”).

During the years ended December 31, 2025, and 2024, we recognized $2.8 million and $2.9 million of revenue, respectively, which was included in the opening contract liabilities balances at the beginning of the respective periods.

Transaction Prices Allocated to Remaining Performance Obligations

Remaining performance obligations represent in aggregate the amount of a transaction price that has been allocated to performance obligations not delivered as of the end of a reporting period. The value of transaction prices allocated to remaining unsatisfied performance obligations as of December 31, 2025, and 2024, were approximately $3.6 million and $6.4 million, respectively. We expect to recognize approximately $1.9 million of remaining performance obligations as revenue in the next 12 months from December 31, 2025 and to recognize the remainder thereafter.

Capitalized Contract Acquisition Costs and Fulfillment Costs

We did not incur any expenses to obtain our existing contracts, and costs to fulfill those contracts do not generate or enhance our resources. As such, no costs to obtain or fulfill a contract have been capitalized in any period.

6. Balance Sheet Items

Property and equipment, net, consisted of the following (in thousands):

	December 31, 2025	December 31, 2024
Lab equipment	$ 15,636	$ 19,054
Leasehold improvements	3,057	11,518
Computer equipment	897	897
Furniture and office equipment	697	697
Total property and equipment	20,287	32,166
Less accumulated depreciation and amortization	(13,527)	(12,885)
Property and equipment, net	$ 6,760	$ 19,281

Depreciation and amortization expenses related to property and equipment were $3.6 million and $3.9 million, for the years ended December 31, 2025, and 2024, respectively.

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

	December 31, 2025	December 31, 2024
Accrued employee compensation and related expenses	$ 7,745	$ 8,560
Accrued research and development expenses	6,109	12,020
Accrued expenses related to sublicensing revenues	992	592
Accrued patent expenses	873	769
Other	816	1,679
Total	$ 16,535	$ 23,620

7. Related Party Transactions

Edge Animal Health

As consideration for the Edge chRDNA License Agreement, Edge issued to us 7,500,000 shares of convertible preferred stock with an estimated fair value of $7.5 million, which was the price paid for similar shares by another investor, and which was an arm's length transaction. This represents a material voting interest in Edge and entitles us to hold one of the four board of director seats. As of December 31, 2025, we had appointed one of the four Edge directors. We concluded that Edge is a variable interest entity and that we are not its primary beneficiary based on our representation on its board of directors. As Edge's convertible preferred stock is not in substance common stock, we recorded this investment using the measurement alternative.

In June 2024, we received additional shares of convertible preferred stock pursuant to anti-dilution rights associated with the Edge chRDNA License Agreement with Edge. Edge issued 1,623,275 shares of convertible preferred stock to us with an estimated fair value of $1.6 million, based on management's best estimate and judgment. The Edge chRDNA License Agreement is a contract with a customer under ASC 606. We did not recognize any revenue in connection with the Edge chRDNA License Agreement in 2025. We recognized $1.6 million as revenue during the year ended December 31, 2024. The carrying value of the Edge investment was $9.2 million as of December 31, 2024, respectively. As of June 30, 2025, our investment in Edge was deemed impaired, resulting in a zero balance as of December 31, 2025 (see Note 3, "Fair Value Measurements").

Pfizer Investment

On June 29, 2023, we entered into a Securities Purchase Agreement ("Securities Purchase Agreement") with Pfizer, pursuant to which we, in a private placement transaction, issued and sold to Pfizer 4,690,431 shares of our common stock, par value $0.0001 per share, at a purchase price of $5.33 per share, for aggregate gross proceeds of approximately $25.0 million ("Pfizer Investment"). The issuance and sale of the shares to Pfizer closed on June 30, 2023. We granted certain registration rights to Pfizer under the Securities Purchase Agreement covering the resale of the shares. Unless otherwise agreed by Pfizer, we agreed to use the proceeds from the Pfizer Investment solely in connection with (i) the development program for our allogeneic anti-BCMA CAR-T cell therapy known as CB-011 that is being evaluated in our CaMMouflage phase 1 clinical trial and/or (ii) any other single-targeted anti-BCMA CAR-T cell therapy using an anti-BCMA scFv owned or controlled by us (collectively, cell therapies described in clauses (i) and (ii) are referred to as a "BCMA Product Candidate"), for 36 months expiring on June 29, 2026.

On June 29, 2023, in connection with the Pfizer Investment, we and Pfizer also entered into an Information Rights Agreement, having a 36-month term and expiring on June 29, 2026. Under the Information Rights Agreement, we granted Pfizer a thirty (30)-calendar day right of first negotiation ("ROFN") if we commence or engage with any third party with respect to a potential grant of rights to develop and/or commercialize a BCMA Product Candidate, including, without limitation, a license agreement, a co-promotion/co-commercialization agreement, a profit share agreement, a joint venture agreement, or an asset sale agreement (a "Grant of Program Rights"). If we and Pfizer do not reach an agreement with respect to a Grant of Program Rights within the 30-day period, then we may pursue negotiations and enter into an agreement with any third party. If we and such third party do not reach agreement on the Grant of Program Rights within a specified time period, Pfizer's right of first negotiation will be reinstated. Under the Information Rights Agreement, we also agreed to grant Pfizer the right to designate one representative to serve on our scientific advisory board ("SAB"). Through an information sharing committee, we provide calendar quarter updates to Pfizer regarding the development program for a BCMA Product Candidate. Additionally, we agreed to provide Pfizer access to any preclinical or interim or final clinical data (including raw data) and results generated as part of the development program for a BCMA Product Candidate at the same time that we provide such data to a third party (other than to our service providers or the FDA or other regulatory authorities), subject to certain confidentiality exceptions.

We recorded the issuance of our common stock at its estimated fair value of $17.5 million, which reflects a discount for the lack of marketability of the shares. The remaining $7.5 million of the aggregate purchase price was allocated to the Information Rights Agreement, which represented a contract with a customer under ASC 606. We concluded that the information sharing committee represents the only performance obligation under the Information Rights Agreement. The ROFN does not provide Pfizer with a material right and is therefore not a performance obligation.

We recognize revenue over time as the measure of progress which we believe best depicts our obligations to Pfizer. The information sharing committee will meet quarterly over the 36-month term of the Information Rights Agreement, which results in recognition of the transaction price over the 36-month term.

During each of the years ended December 31, 2025 and December 31, 2024, we recognized $2.5 million of revenue from Pfizer. As of December 31, 2025, Pfizer ceased to be a related party. As of December 31, 2024, there was approximately $3.7 million of related party deferred revenue ($2.5 million included in current liabilities and $1.2 million included in long-term liabilities) related to our performance obligation to Pfizer.

8. Leases

Operating Lease Obligations

We lease laboratory and office space under two noncancellable operating agreements. In March 2021, we entered into a ten-year lease agreement, which superseded and replaced our prior lease, as amended, for our corporate headquarters and the new lease included additional office and laboratory space located within the same building in Berkeley, California. This lease agreement contains a renewal option for an additional term of five years. In addition to base rent, we pay our share of operating expenses and taxes. On December 15, 2025, we entered into an amendment to the ten-year lease agreement under which we extended the term of the majority of the space covered by our lease by an additional 24 months to expire on March 31, 2033, in exchange for deferral of a certain amount of base rent from January 1, 2026, through December 31, 2027.

In January 2022, we entered into a ten-and-a-half-year lease agreement for approximately 10,000 square feet of office and laboratory space in Berkeley, California, near our current corporate headquarters. In connection with signing this lease, we paid a deposit in the amount of $0.4 million to the lessor, and we will receive a total of $1.8 million in tenant improvement allowances. This lease agreement contains an escalation clause for increased base rent over the term and a renewal option for an additional term of five years. In addition to base rent, we pay our share of operating expenses and taxes. The leasehold improvements constructed are presented under property and equipment on our consolidated balance sheets and are depreciated on a straight-line basis over the shorter of remaining lease term or estimated useful life.

As a result of the previously announced strategic pipeline prioritization during the second quarter of 2025, we identified certain triggering events, such as significant changes in our current and expected use of leased office and lab space (see Note 15, “Restructuring Charge”). We determined these asset groups were impaired and recognized impairment charges totaling $2.6 million related to the right of use asset associated with the underlying leased properties.

The components of lease costs, which are included in our statements of operations and comprehensive loss, were as follows (in thousands):

	Years Ended December 31,	
	2025	2024
Operating lease cost[(1)]	$ 7,628	$ 7,679
Short-term lease cost	277	250
Total lease cost	$ 7,905	$ 7,929

[(1)]Includes $2.8 million and $2.5 million of variable lease cost related to operating expenses and taxes for each of the years ended December 31, 2025, and 2024, respectively.

Supplemental information related to our leases was as follows (in thousands):

	Years Ended December 31,	
	2025	2024
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	$ 4,310	$ 3,522

The following table summarizes the weighted-average remaining lease term and weighted-average discount rate for our corporate laboratory and office leases:

	Years Ended December 31,	
	2025	2024
Weighted-average remaining lease term (years)	7.1	6.5
Weighted-average discount rate	13.8 %	11.3 %

The following table summarizes a maturity analysis of our operating lease liabilities showing the aggregate lease payments as of December 31, 2025:

Year ending December 31:	(in thousands)
2026	$ 4,842
2027	5,014
2028	6,513
2029	6,728
2030	6,950
Thereafter	13,768
Total future undiscounted lease payments	43,815
Less imputed interest	(16,588)
Total discounted lease payments	27,227
Less current portion of lease liability	(1,201)
Noncurrent portion of lease liability	$ 26,026

9. Commitments and Contingencies

Research, Manufacturing, and License Agreements

We enter into various agreements in the ordinary course of business, such as those with CMOs, suppliers, CROs, clinical trial sites, licensors, assignors, and the like. These agreements provide for termination by either party in certain circumstances, generally with less than one-year notice and are, therefore, cancellable contracts and, if cancelled, are not anticipated to have a material effect on our consolidated financial condition, results of operations, or cash flows. Some of these agreements include contingent payments that will become payable if and when certain development, regulatory, clinical, and/or commercial milestones are achieved by us. As of December 31, 2025, satisfaction and timing of such contingent payments are uncertain and thus cannot be reasonably estimated.

Guarantees and Indemnifications

In the ordinary course of business, we enter into agreements that contain a variety of representations and warranties and provide for certain indemnifications by us. Our exposure under these agreements is unknown because claims may be made against us in the future. As of December 31, 2025, and 2024, we did not have any material indemnification claims that were probable or reasonably possible, and consequently, we have not recorded related liabilities.

Litigation

From time to time, we may become involved in litigation arising in the ordinary course of business. We record a liability for such litigation when it is probable that future losses will be incurred and if such losses can be reasonably estimated. Significant judgment by us is required to determine both probability and the estimated amount.

On December 24, 2024, a putative class action lawsuit was filed in the U.S. District Court for the Northern District of California against our company and certain of our current and former officers, *Saylor v. Caribou Biosciences, Inc., et al.,* case number 3:24-cv-09413 (“Saylor Case”). The alleged class period was July 14, 2023, to July 16, 2024. The Saylor Case complaint challenged disclosures regarding our company’s business, operations, and prospects, specifically with respect to the alleged safety, efficacy, and durability of vispa-cel, the clinical results and commercial prospects for vispa-cel, and our financial statements, in alleged violation of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended (“Exchange Act”). On April 15, 2025, the lead plaintiff filed a motion to voluntarily dismiss the lawsuit and, on April 27, 2025, the court granted the motion, dismissing the lawsuit without prejudice.

On March 3, 2025, a shareholder derivative complaint was filed in the U.S. District Court for the Northern District of California against our directors and certain of our current and former officers, *Moisio, derivatively on behalf of Caribou Biosciences, Inc. v. Haurwitz, et al.,* case number 4:25-cv-02199 ("First Derivative Case"), alleging, among other things, that the named directors and officers breached their fiduciary duties by causing our company to make the disclosures being challenged in the Saylor Case and seeking unspecified monetary damages from our company as well as that we make certain changes to our corporate governance. On March 11, 2025, a second shareholder derivative complaint was filed in the U.S. District Court for the Northern District of California against the same defendants as in the First Derivative Case, *Allen, derivatively on behalf of Caribou Biosciences, Inc. v. Braunstein, et al.,* case number 4:25-cv-02463 ("Second Derivative Case"), with the same allegations. On April 1, 2025, the First Derivative Case and the Second Derivative Case were deemed related and assigned to the same judge and, on April 7, 2025, the First Derivative Case and the Second Derivative Case were consolidated into a single action, *In re Caribou Biosciences, Inc. Derivative Litigatio*n, lead case number 4:25-cv-02199 ("Consolidated Derivative Action"). The plaintiffs in the Consolidated Derivative Action filed an amended complaint on July 7, 2025. The amended complaint largely tracked the claims from the original complaints, but it also challenged additional disclosures as false or misleading. On August 21, 2025, the defendants filed a motion to dismiss the complaint. On October 16, 2025, the parties filed a stipulation to voluntarily dismiss the lawsuit without prejudice, which the court granted on October 17, 2025.

10. Common Stock

Shares of common stock reserved for future issuances consisted of the following:

	As of December 31, 2025	As of December 31, 2024
Stock options, issued and outstanding	12,511,072	10,782,103
Shares of common stock, authorized for future issuances	9,192,963	7,618,931
Shares committed under ESPP	2,426,055	2,139,666
Unvested RSUs and PSUs	2,173,234	1,297,327
Total shares of common stock reserved for future issuances	26,303,324	21,838,027

Shelf Registration Statements

On August 9, 2022, we filed a universal shelf registration statement on Form S-3 ("2022 Shelf Registration Statement") with the U.S. Securities and Exchange Commission ("SEC"), which allowed us to sell, from time to time, up to $400.0 million of common stock, preferred stock, debt securities, warrants, rights, or units comprised of any combination thereof (including the $100.0 million of common stock reserved under the 2022 Shelf Registration Statement for our at-the-market equity offering program described below).

On May 8, 2025, in anticipation of the expiration of the 2022 Shelf Registration Statement on August 16, 2025, we filed a new shelf registration statement on Form S-3 ("2025 Shelf Registration Statement"), which was declared effective by the SEC on May 14, 2025. Upon the effectiveness of the 2025 Shelf Registration Statement, the offering of securities under the 2022 Shelf Registration Statement was deemed terminated. Pursuant to the 2025 Shelf Registration Statement, we may, from time to time, sell up to $300.0 million of common stock, preferred stock, debt securities, warrants, rights, or units comprised of any combination thereof (including the $100.0 million of common stock reserved under the 2025 Shelf Registration Statement for our at-the-market equity offering program described below). As of December 31, 2025, we had $295.7 million available for sale under the 2025 Shelf Registration Statement.

At-the-market Equity Offering Program

On August 9, 2022, we entered into an at-the-market Open Market Sale Agreement℠ ("ATM Sales Agreement") with Jefferies LLC ("Jefferies"), pursuant to which, through Jefferies as sales agent, from time to time, we could have issued and sold shares of our common stock having an aggregate offering price of up to $100.0 million in gross proceeds under the 2022 Shelf Registration Statement.

With the effectiveness of the 2025 Shelf Registration Statement, we refreshed our at-the-market equity offering program under the ATM Sales Agreement. We may, from time to time, sell and issue shares of our common stock, through Jefferies as sales agent under the ATM Sales Agreement, having an aggregate offering price of up to $100.0 million in gross proceeds under the 2025 Shelf Registration Statement.

During the year ended December 31, 2025, we sold 1,644,228 shares of our common stock, in a series of sales, at an average price of $2.60 per share, in accordance with the ATM Sales Agreement and the 2025 Shelf Registration Statement for aggregate gross proceeds of $4.3 million ($4.1 million net of offering expenses).

During the year ended December 31, 2024, we sold 3,420,061 shares of our common stock, in a series of sales, at an average price of $4.58 per share, in accordance with the ATM Sales Agreement and the 2022 Shelf Registration Statement for aggregate gross proceeds of $15.7 million ($15.2 million net of offering expenses).

As of December 31, 2025, $95.7 million of shares of our common stock remained available for sale under the 2025 Shelf Registration Statement pursuant to the ATM Sales Agreement.

11. Stock-Based Compensation

Equity Incentive Plans

In July 2021, our board of directors adopted and our stockholders approved the 2021 Equity Incentive Plan ("2021 Plan") that became effective on July 22, 2021. We reserved 5,200,000 shares of common stock for issuance under the 2021 Plan. In addition, 934,562 shares available for issuance under the 2013 Equity Incentive Plan, adopted in 2013 and amended and restated in 2019, were transferred into the 2021 Plan. In addition, any shares subject to awards under the 2013 Plan that terminate, expire, or lapse for any reason without the delivery of shares, or are reacquired or withheld (or not issued) to satisfy a tax withholding obligation or the purchase or exercise price, will be added to the 2021 Plan. The 2021 Plan also provides that the number of shares initially reserved and available for issuance will automatically increase each January 1, beginning on January 1, 2022 and ending on January 1, 2031, by an amount equal to the lesser of (i) 5% of the shares of common stock outstanding on the last day of the immediately preceding fiscal year and (ii) such smaller number of shares of stock as determined by our board of directors. No more than 56,000,000 shares of stock may be issued upon the exercise of incentive stock options under the 2021 Plan. Options under the 2021 Plan may be granted for periods of up to 10 years at exercise prices no less than the fair market value of our common stock on the date of grant; provided, however, that the exercise price of an incentive stock option granted to a 10% stockholder may not be less than 110% of the fair market value of the shares on the date of grant and such option may not be exercisable after the expiration of five years from the date of grant. The grant date fair market value of all awards made under the 2021 Plan and all cash compensation paid by us to any non-employee director for services as a director in any fiscal year may not exceed $750,000, increased to $1,000,000 in the fiscal year of their initial service as a non-employee director. As of December 31, 2025, we had 9,192,963 shares available for issuance under the 2021 Plan.

Stock Options

The following table summarizes stock option activity, including PBSOs, under our equity incentive plans for the year ended December 31, 2025:

	Stock Options and PBSOs	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (in thousands) [1]
Outstanding at December 31, 2023	9,410,404	$ 8.03	8.0	$ 6,432
Options granted	3,593,852	$ 5.90		
Options exercised	(182,217)	$ 3.39		
Options cancelled or forfeited	(2,039,936)	$ 7.61		
Outstanding at December 31, 2024	10,782,103	$ 7.47	7.7	$ 18
Options granted	4,645,853	$ 1.59		
Options exercised	(15,000)	$ 0.40		
Options cancelled or forfeited	(2,901,884)	$ 6.65		
Outstanding at December 31, 2025	12,511,072	$ 5.49	7.6	$ 466
Exercisable at December 31, 2025	6,565,291	$ 7.69	6.5	$ 45
Vested and expected to vest at December 31, 2025	12,511,072	$ 5.49	7.6	$ 466

(1) The aggregate intrinsic value is calculated as the difference between the stock option exercise price and the estimated fair value of the underlying common stock at the end of each reporting period referenced above.

Grant Date Fair Value of Stock Options

During the year ended December 31, 2025, we granted 3,553,688 stock options under the 2021 Plan to employees with a weighted-average grant date fair value of $1.08.

During the year ended December 31, 2024, we granted 3,593,852 stock options under the 2021 Plan to employees with a weighted-average grant date fair value of $4.04.

We estimated the fair value of each employee stock option award on the grant date using the Black-Scholes option-pricing model based on the following assumptions:

	Years Ended December 31,	
	2025	2024
Volatility	86.1% to 89.9%	75.3% to 75.9%
Expected term (in years)	5.0 to 6.0	5.0 to 6.0
Risk-free interest rate	3.8% to 4.6%	3.7% to 4.5%
Expected dividend yield	0.0%	0.0%

As of December 31, 2025, there was $10.4 million of unrecognized stock-based compensation expense related to employee stock options that is expected to be recognized over a weighted-average period of 2.4 years.

Grant Date Fair Value of PBSOs

On July 21, 2025, we granted 1,092,165 PBSOs under the 2021 Plan to each of our officers with a weighted average grant date fair value of $1.00 per PBSO. We estimated the fair value of each PBSO on the grant date using the Black-Scholes option-pricing model based on a volatility of 88.7%, expected term of 1.9 years, risk-free interest rate of 3.9%, and expected dividend yield of 0.0%. Vesting of the PBSOs is conditioned on achievement of certain clinical development milestones during a two-year performance period ending June 30, 2027, and contingent on each executive officer's continued employment on the vesting dates. As of December 31, 2025, there were 1,092,165 PBSOs outstanding with a weighted average grant date fair value of $1.00. As of December 31, 2025, we have concluded that it is not yet deemed probable, as required by ASC Topic 718 Compensation - Stock Compensation, that the clinical milestones will be achieved, and as such, no stock-based compensation expense has been recorded for PBSOs. As of December 31, 2025, there was $1.1 million of unrecognized stock-based compensation expense related to PBSOs, which will be recognized if the conditions for achievement of the milestones are probable.

Restricted Stock Units

During the year ended December 31, 2025, we granted 1,943,585 RSUs and no PSUs under the 2021 Plan. A summary of the status of and change in unvested RSUs and PSUs as of December 31, 2025 was as follows:

	Number of Shares Underlying Outstanding RSUs and PSUs	Weighted-Average Grant Date Fair Value per RSU and PSU
Unvested, January 1, 2024	205,357	$ 8.49
Granted	1,410,242	5.53
Vested	(66,173)	10.07
Forfeited	(252,099)	7.60
Unvested, December 31, 2024	1,297,327	$ 5.37
Granted	1,943,585	1.65
Vested	(468,489)	5.01
Forfeited	(599,189)	3.12
Unvested, December 31, 2025	2,173,234	$ 2.74

On August 22, 2022, we granted PSUs to our executive officers, which would have vested contingent upon the achievement of a clinical milestone for our vispa-cel product candidate during a performance period ending December 31, 2024, and the executive officer's continued employment during the performance period. As of December 31, 2024, the clinical milestone was not met and none of these PSUs had vested. No stock-based compensation expense was recorded on these awards. There were no PSUs outstanding as of December 31, 2025.

As of December 31, 2025, the total unrecognized stock-based compensation expense related to unvested RSUs was $4.5 million, which is expected to be recognized over the remaining weighted-average vesting period of 2.5 years.

Employee Stock Purchase Plan

In July 2021, our board of directors adopted and our stockholders approved the ESPP, which became effective on July 22, 2021. The ESPP is intended to qualify as an employee stock purchase plan under Section 423 of the Internal Revenue Code of 1986, as amended ("Tax Code"). We reserved 511,000 shares of our common stock for employee purchases under the ESPP. The number of shares of common stock reserved for issuance under the ESPP will be automatically increased each January 1, beginning on January 1, 2022 and ending on January 1, 2031 by an amount equal to the lesser of (i) 1.00% of the shares of common stock outstanding on the last day of the immediately preceding fiscal year and (ii) such smaller number of shares of stock as determined by our board of directors; provided that the maximum number of shares that may be issued under the ESPP is 10,000,000 shares. The ESPP allows an eligible employee to purchase shares of our common stock at a discount through payroll deductions of up to 15% of the employee's eligible compensation. At the end of each purchase period, employees are able to purchase shares at 85% of the lower of the fair market value of our common stock at the beginning of the offering period or at the end of each applicable offering period. We issued 1,106,141 shares of common stock under the ESPP as of December 31, 2025. We recorded $0.4 million in accrued liabilities related to contributions withheld as of December 31, 2025, and 2024.

Stock-Based Compensation Expense

We recorded stock-based compensation expense related to employee equity-based awards grants as follows (in thousands):

	Years Ended December 31,	
	2025	2024
Research and development	$ 5,406	$ 6,920
General and administrative	7,274	9,786
Total	$ 12,680	$ 16,706

The above stock-based compensation expense related to the following equity-based awards (in thousands):

	Years Ended December 31,	
	2025	2024
Stock options	$ 10,208	$ 14,193
RSUs	1,988	2,091
ESPP	484	422
Total	$ 12,680	$ 16,706

12. Income Taxes

We reported pre-tax book losses in the United States of $148.7 million and $149.1 million for the years ended December 31, 2025, and 2024, respectively.

For the years ended December 31, 2025, and 2024, our benefit from income taxes consisted of the following (in thousands):

Years	2025	2024
Current income taxes		
Federal	$ —	$ —
State	1	1
Total current income tax expense	1	1
Deferred income taxes:		
Federal	(385)	67
State	(166)	(77)
Total deferred income tax (benefit) expense	(551)	(10)
Total income tax (benefit) expense	$ (550)	$ (9)

We adopted ASU 2023-09 on a prospective basis beginning with the year ended December 31, 2025. The following table presents required disclosure pursuant to ASU 2023-09 and reconciles the U.S. federal statutory tax rate to our actual global effective tax rate for the year ended December 31, 2025 (in thousands):

	Amount	Rate
U.S. federal statutory tax rate	$ (31,221)	21.0 %
State & local income taxes, net of federal income tax effect*	(693)	0.5 %
Tax credits		
Federal research and development credits	(7,570)	5.1 %
Changes in prior year credits	58	— %
Changes in valuation allowances	34,619	(23.3)%
Changes in unrecognized tax benefits	2,029	(1.4)%
Other adjustments		
Other non-deductible expenses	2,228	(1.5)%
Effective tax rate	$ (550)	0.4 %

*State taxes in California represent the majority (greater than 50%) of the tax effect in this category.

The following table presents the required disclosures prior to our adoption of ASU 2023-09 and reconciles the U.S. federal statutory income tax rate to the actual global effective income tax rate for the year ended December 31, 2024:

Years	2024
Federal income tax benefit at statutory rate	(21 %)
State taxes, net of federal benefit	(8 %)
Change in valuation allowance, federal	27 %
Change in valuation allowance, state	7 %
Stock-based compensation	1 %
Research and development tax credits, net of reserves	(5 %)
Return to provision, federal	(2 %)
Change in rates	1 %
Effective income tax rate	— %

Our effective tax rate differs from the U.S. federal statutory rate primarily due to tax credits, state income taxes, changes in valuation allowances, and nondeductible expenses. The rate was reduced by federal and state research and development credits generated during the year and by adjustments to prior-year credit carryforwards. State income taxes, net of the federal benefit, primarily reflect an increase in the valuation allowance on certain state deferred tax assets, with only immaterial state minimum taxes recognized during the year for California, Connecticut, and Wisconsin.

Deferred income taxes reflect the net tax 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 following table presents significant components of our deferred tax assets and liabilities as of December 31, 2025, and 2024 (in thousands):

	2025	2024
Deferred tax assets:		
NOL and tax attributes	$ 142,818	$ 81,619
Accrued expenses and reserve	1,684	1,800
Deferred revenue and expenses	801	1,402
State income taxes	7	7
Capitalized license and patent costs	869	1,089
Capitalized research and development cost	30,557	56,865
Lease liabilities	6,571	6,090
Stock-based compensation	6,639	5,976
Investments in equity securities	37	—
Fixed assets	1,206	—
Total deferred tax assets	191,189	154,848
Valuation allowance	(186,924)	(147,313)
Net deferred tax assets	4,265	7,535
Deferred tax liabilities:		
Investments in equity securities	—	(2,107)
Lease right of use assets	(4,265)	(4,600)
Fixed assets	—	(1,376)
Total deferred tax liabilities	(4,265)	(8,083)
Net deferred tax assets (liabilities)	$ —	$ (548)

We have evaluated the positive and negative evidence in determining the realizability of our net deferred tax assets. As of December 31, 2025, our deferred tax assets were primarily the result of historical federal and state net operating loss ("NOL") and tax credits, capitalized research costs, stock-based compensation expense, and the net of lease right of use assets and liabilities. As of December 31, 2025, a valuation allowance of $186.9 million was recorded against our deferred tax assets. As of December 31, 2024, a valuation allowance of $147.3 million was recorded against our deferred tax assets.

As of December 31, 2025, we had federal NOL carryforwards of $381.8 million, which do not expire. As of December 31, 2025, we had state NOL carryforwards of $297.9 million, which may be available to offset future state income, and which expire at various years beginning with 2036.

As of December 31, 2025, we generated federal research and development tax credit and orphan drug tax credit carryforwards of $35.5 million, which will begin to expire in 2037. As of December 31, 2025, we had state research and development tax credit carryforwards of $13.9 million, which do not expire.

Under Section 382 of the Tax Code, the ability to utilize NOL carryforwards or other tax attributes, such as research and development tax credit and orphan drug tax credit, in any taxable year may be limited if we have experienced an "ownership change." Generally, a Section 382 ownership change occurs if there is a cumulative increase of more than 50 percentage points in the stock ownership of one or more stockholders or groups of stockholders who own at least 5% of a corporation's stock within a specified testing period. Similar rules may apply under state tax laws. As a result of our analysis, we believe that there have been three ownership changes under Section 382; however, none of our state NOL and research and development tax credit carryforwards is currently expected to expire unused. We may experience ownership changes as a result of future financing or other changes in our stock ownership.

A reconciliation of the beginning and ending amount of unrecognized tax benefits is as follows (in thousands):

	Years Ended December 31,	
	2025	2024
Balance at the beginning of the year	$ 8,009	$ 4,093
Increases related to current year tax positions	2,059	2,654
Increases related to prior year tax positions	305	1,298
Decreases related to prior year tax positions	(339)	(36)
Balance at the end of year	$ 10,034	$ 8,009

We recognize interest and penalties related to uncertain tax positions in income tax expense. As of December 31, 2025, and 2024, we had no accrued interest or penalties related to uncertain tax positions and no amounts have been recognized in our consolidated statements of operations and comprehensive loss.

We file our federal and state income tax returns with varying statutes of limitations. Our tax years from 2014 through 2025 will remain open to examination due to the carryover of the unused NOLs and tax credits. There are no ongoing examinations by taxing authorities at this time.

The following table shows the change in deferred tax valuation allowance for the periods indicated:

	2025	2024
Beginning balance, January 1	$ 147,313	$ 96,166
Change charged to expense	39,611	51,147
Ending balance, December 31	$ 186,924	$ 147,313

Previously, the Tax Cuts and Jobs Act of 2017 ("TCJA") eliminated the ability to deduct research and development expenditures in the year incurred, requiring capitalization and amortization under Section 174 of the Tax Code Section. On July 4, 2025, the U.S. government enacted the One Big Beautiful Bill Act ("OBBBA"), which includes broad tax reform provisions that extend and modify key elements of the TCJA. Notably, the new legislation now allows an option for the immediate expensing of domestic research and development expenditures, beginning with 2025. The OBBBA also includes favorable modifications to international tax provisions, including changes to the Global Intangible Low-Taxed Income regime and enhancements to the Foreign-Derived Deduction Eligible Income deduction that will become effective for taxable years beginning after December 31, 2025.

13. Net Loss Per Share

The following table sets forth the computation of the basic and diluted net loss per share (in thousands, except share and per share amounts):

	Years Ended December 31,	
	2025	2024
Numerator:		
Net loss	$ (148,125)	$ (149,105)
Denominator:		
Weighted-average common shares outstanding used to compute net loss per share, basic and diluted	93,389,283	90,317,925
Net loss per share, basic and diluted	$ (1.59)	$ (1.65)

Because we were in a net loss position for all periods presented, basic net loss per share is the same as diluted net loss per share for all periods, as the inclusion of all common stock equivalents outstanding would have been anti-dilutive. Potentially dilutive securities that were not included in the diluted per share calculations because they would be anti-dilutive were as follows:

	As of December 31, 2025	As of December 31, 2024
Stock options outstanding	12,511,072	10,782,103
RSUs issued and outstanding	2,173,234	1,297,327
Shares committed under ESPP	356,910	304,434
	15,041,216	12,383,864

14. Segment Information

We operate and manage our business as one reportable segment and one operating segment, which is the business of developing allogeneic CAR-T cell therapies. Our CODM assesses performance for the segment and decides how to allocate resources based on consolidated net loss that is also reported on our consolidated statements of operations. The measure of segment assets is reported on our consolidated balance sheets as total consolidated assets. All our material long-lived assets are located in the United States. Our CODM uses consolidated net loss to evaluate our spending and monitor our budget versus actual results to assess performance of the segment and to allocate resources across our company. Factors used in determining the reportable segment include the nature of our operating activities, our company's organizational and reporting structures, and the type of information reviewed by our CODM to allocate resources and evaluate financial performance.

The following table presents reportable segment profit and loss, including significant expense categories, attributable to our reportable segment for the periods indicated:

	Years Ended December 31,	
	2025	2024
Licensing and collaboration revenue	$ 11,159	$ 9,994
Less:		
Research and development:		
External costs	63,702	77,649
Internal costs[1]	37,099	42,120
Total research and development	100,801	119,769
General and administrative[2]	30,252	36,217
Other segment items[3]	37,058	18,461
Other income, net	(8,827)	(15,348)
Segment and consolidated net loss	$ (148,125)	$ (149,105)

[1]Research and development internal costs for the years ended December 31, 2025, and 2024, exclude $5.4 million and $6.9 million of stock-based compensation expense, respectively, and $3.2 million and $3.5 million of depreciation and amortization expense, respectively.

[2]General and administrative expense for the years ended December 31, 2025, and 2024, exclude $7.3 million and $9.8 million of stock-based compensation expense, respectively, and $0.4 million and $0.5 million of depreciation and amortization expense, respectively.

[3]Other segment items for the year ended December 31, 2025, include impairment charges, impairment of equity investment, stock-based compensation expense, depreciation and amortization, and benefit from income taxes. Other segment items for the year ended December 31, 2024, include stock-based compensation expense, change in fair value of the MSKCC success payments liability, depreciation and amortization, and benefit from income taxes.

15. Restructuring Charge

Severance and Wind Down Costs

On April 24, 2025, we announced the discontinuation of preclinical research and two clinical programs: our GALLOP phase 1 clinical trial evaluating vispa-cel in patients with lupus prior to dosing the first patient, and our AMpLify phase 1 clinical trial evaluating CB-012, as additional data would be needed to advance this program. Additionally, we announced that our workforce was reduced by 47 employees, or approximately 32% of our workforce. As a result, we recorded cash severance costs, benefits, and transition support services expenses of $1.8 million for the year ended December 31, 2025, which we recorded as research and development expenses or general and administrative expenses in our consolidated statements of operations and comprehensive loss. For the year ended December 31, 2025, we recorded wind down costs of $0.4 million, as research and development expenses in our consolidated statements of operations and comprehensive loss related to the discontinuation of our GALLOP and AMpLify phase 1 clinical trials.

Impairment Charges

As part of the preparation of the financial statements for each reporting period, we review our long-lived assets for impairment indicators. As a result of the previously announced strategic pipeline prioritization during the second quarter of 2025, we identified certain triggering events, such as significant changes in our current and expected use of leased office and lab space and lab equipment. We determined the asset groups based on the lowest level of identifiable cash flows under our strategic pipeline prioritization and assessed the impairment for each of the asset groups.

We have reduced the usage of our leased office and lab space, and we may sublease the unused space under one or both of our leases. The leasehold improvements, right of use assets, and lab equipment related to the leased office and lab spaces were assessed as a single asset group and determined to not be recoverable. Accordingly, for the second quarter of 2025, we concluded that this asset group is impaired. For asset groups where impairment is triggered, we use discounted cash flow models (an income approach) with Level 3 inputs to estimate the fair values of the asset groups. The significant assumptions used in the discounted cash flow models include projected sublease income over the remaining lease terms, expected downtime prior to the commencement of executed or future subleases, and discount rates that reflect a market participant's assumptions in valuing the asset groups. As a result, we recognized impairment charges totaling $10.0 million for the second quarter of 2025, of which $7.4 million and $2.6 million, respectively, were related to the tenant improvements and right of use asset associated with the underlying leased properties.

We also identified certain laboratory equipment that we no longer plan to use. This asset group, consisting of laboratory equipment that would no longer be used going forward, was also determined to not be recoverable. As a result, this asset group was deemed impaired, resulting in a $2.2 million impairment charge for the second quarter of 2025. The fair value of the lab equipment is classified as Level 3 in the fair value hierarchy due to the use of unobservable inputs utilized, such as estimates provided by third-party vendors.

The following table summarizes the restructuring and impairment costs recognized in our consolidated statements of operations and comprehensive loss for the year ended December 31, 2025:

	Severance Related Expenses	Wind Down Costs	Impairment Charges	Total
Research and development	$ 1,478	$ 438	$ —	$ 1,916
General and administrative	360	—	—	360
Impairment charges	—	—	12,150	12,150
Total	$ 1,838	$ 438	$ 12,150	$ 14,426

Our strategic pipeline prioritization was substantially completed in the second quarter of 2025, and we currently do not expect to record additional material charges.