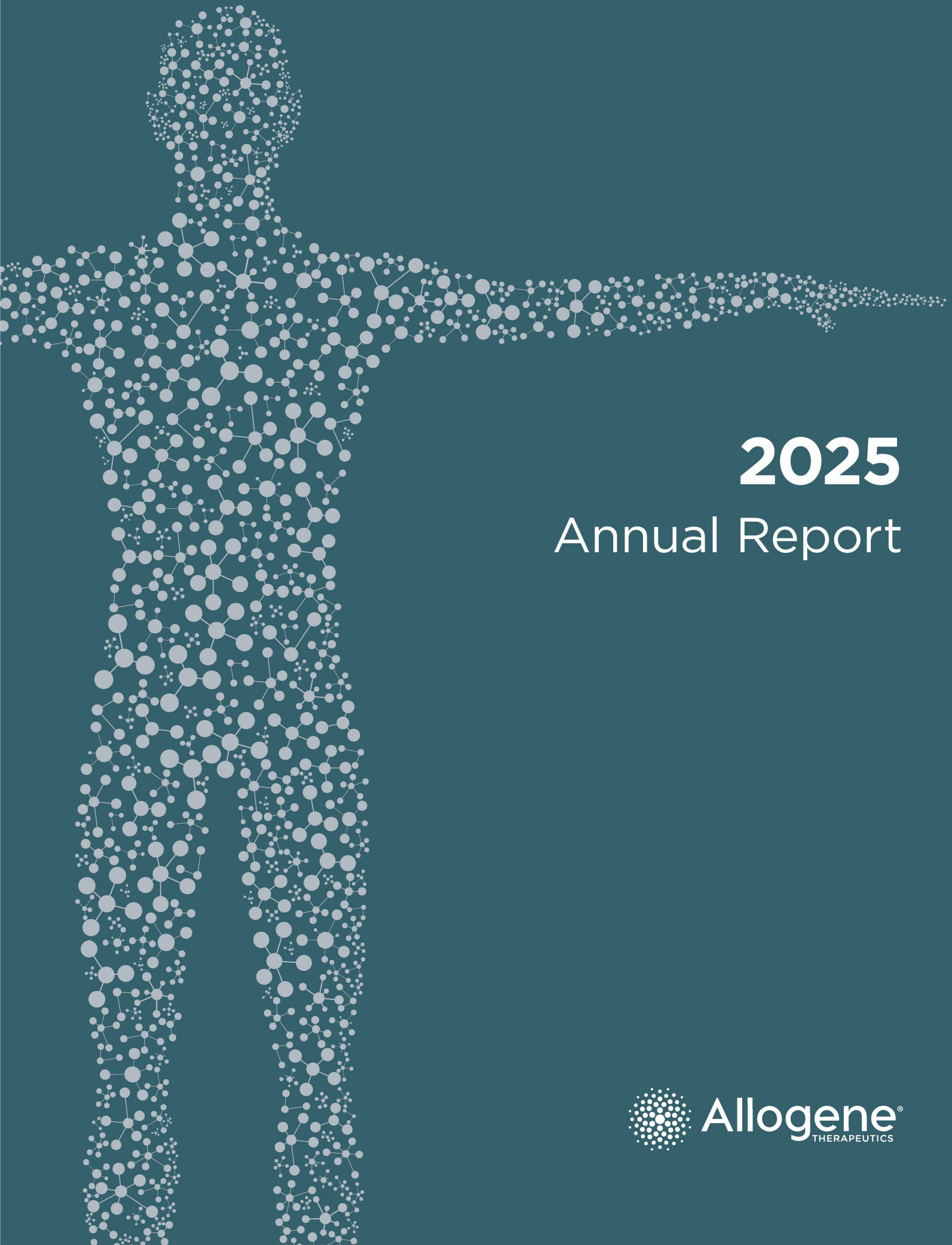


2025
Annual Report

Allogene® THERAPEUTICS

Message from Our President and CEO

Dear Fellow Stockholders,

As we reflect on 2024, I'm proud of the significant progress we made toward delivering on Allogene's mission to transform the future of cancer and autoimmune care through the ongoing development of our investigational allogeneic CAR T cell products. With a focused strategy, disciplined execution, and shared commitment across our team and Board, we achieved significant milestones across our clinical pipeline, strengthened our manufacturing capabilities, and enhanced our corporate governance - each an important component of long-term value.

During 2024, we significantly advanced our lead clinical development programs. We launched the pivotal Phase 2 ALPHA3 trial, positioning cema-cel as a component of first-line consolidation therapy for LBCL. This trial represents the opportunity to redefine the standard of care by reaching patients earlier, when disease burden is low and outcomes are potentially more favorable. We also received clearance of our investigational new drug (IND) application from the U.S. FDA for the RESOLUTION trial of ALLO-329 in autoimmune diseases, and earned RMAT designation for ALLO-316 in renal cell carcinoma. These advances reflect our leadership in the allogeneic CAR T field and the dedication of our team, none of which would be possible without your continued support.

We recognize that innovation alone is not enough. Building a sustainable company also means holding ourselves to high standards in governance, fiscal discipline, and stakeholder responsiveness. In 2024, we executed an active stockholder engagement program, including targeted outreach following our annual meeting. We appreciated the thoughtful feedback and, in response, implemented several enhancements to our executive compensation practices and disclosures. Our Board remains focused on aligning our governance structures with our evolving operational profile.

Looking ahead, we expect 2025 to be a defining year. With enrollment underway in the ALPHA3 trial and set to begin in the RESOLUTION trial, we are entering a period with the potential to transform how CAR T therapies are used in patient care, while laying the foundation for registration paths in multiple programs. As we do so, we remain grounded in our commitment to scientific excellence, integrity, and the patients we ultimately serve.

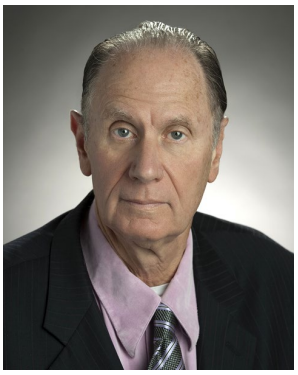
Thank you for your trust and support as we work to bring the next revolution in cell therapy to patients.

Sincerely,

David Chang, M.D., Ph.D.
President & Chief Executive Officer
Allogene Therapeutics, Inc.
April 29, 2025

IN MEMORIAM

David Bonderman (1942–2024)
Director, Allogene Therapeutics, Inc. (2018–2024)



The Board of Directors and executive leadership of Allogene Therapeutics, Inc. respectfully acknowledge the passing of David Bonderman, a founding member of our Board of Directors. Mr. Bonderman served with distinction from 2018 until his passing in 2024.

Mr. Bonderman brought to Allogene a unique combination of strategic insight, business acumen, and a deep commitment to innovation. His decades of experience as a global investor and leader in the private equity industry provided invaluable guidance during Allogene's formative years and throughout its evolution as a clinical-stage biotechnology company.

Mr. Bonderman was a strong advocate for the promise of allogeneic CAR T therapy, and his counsel played a significant role in advancing our mission to revolutionize cancer treatment. His dedication to the Company, sound judgment, and steady leadership made a lasting impact on Allogene and on all those who had the privilege of working with him.

We are deeply grateful for Mr. Bonderman's service and extend our heartfelt condolences to his family, friends, and colleagues.

Table of Contents

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

FORM 10-K

(Mark One)

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2024
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 001-38693

Allogene Therapeutics, Inc.
(Exact name of Registrant as specified in its Charter)

Delaware	**82-3562771**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

210 East Grand Avenue, South San Francisco, California 94080
(Address of principal executive offices including zip code)
Registrant's telephone number, including area code: (650) 457-2700

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 $0.001 Per Share	ALLO	The Nasdaq Stock Market LLC

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

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

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 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	☒	Small reporting company	☒
		Emerging growth company	☐

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

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

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

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

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant as of June 30, 2024 (the last business day of the registrant's most recently completed second fiscal quarter) was approximately $354 million based on the closing price of the registrant's common stock on June 28, 2024 of $2.33 per share, as reported by The Nasdaq Global Select Market.

The number of shares of Registrant's Common Stock outstanding as of March 7, 2025 was 217,264,738.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's Definitive Proxy Statement relating to the 2025 Annual Meeting of Stockholders, which will be filed with the Securities and Exchange Commission on or before April 30, 2025, are incorporated by reference into Part III of this Annual Report.

Table of Contents

Unless the context requires otherwise, references in this report to "Allogene," the "Company," "we," "us" and "our" refer to Allogene Therapeutics, Inc.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report contains forward-looking statements. The forward-looking statements are contained principally in the sections entitled "Business," "Risk Factors," and "Management's Discussion and Analysis of Financial Condition and Results of Operations". These statements relate to future events or to our future financial performance and involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Forward-looking statements include, but are not limited to, statements about:

- the success, cost, timing and potential indications of our product development activities and clinical trials;
- the timing of the initiation, enrollment and completion of planned clinical trials in the United States and foreign countries;
- our ability to obtain and maintain regulatory approval of our product candidates in any of the indications for which we plan to develop them, and any related restrictions, limitations, and/or warnings in the label of an approved product candidate;
- our ability to obtain funding for our operations, including funding necessary to complete the clinical trials of any of our product candidates;
- our ability and plans to research, develop, manufacture and commercialize our product candidates;
- our ability to attract and retain collaborators with development, regulatory and commercialization expertise;
- the size of the markets for our product candidates, and our ability to serve those markets;
- our ability to successfully commercialize our product candidates;
- the rate and degree of market acceptance of our product candidates;
- our ability to develop and maintain sales and marketing capabilities, whether alone or with potential future collaborators;
- regulatory developments in the United States and foreign countries;
- our ability to contract with and the performance of our and our collaborators' third-party suppliers and manufacturers;
- our ability to develop and successfully operate our own manufacturing facility;
- the success of competing therapies that are or become available;
- our ability to attract and retain key scientific or management personnel;
- the accuracy of our estimates regarding expenses, future revenues, capital requirements and needs for additional financing;
- our use of cash and other resources; and
- our expectations regarding our ability to obtain and maintain intellectual property protection for our product candidates and our ability to operate our business without infringing on the intellectual property rights of others.

In some cases, you can identify these statements by terms such as "anticipate," "believe," "could," "estimate," "expects," "intend," "may," "plan," "potential," "predict," "project," "should," "will," "would" or the negative of those terms, and similar expressions that convey uncertainty of future events or outcomes. These forward-looking statements reflect our management's beliefs and views with respect to future events and are based on estimates and assumptions as of the date of this report and are subject to risks and uncertainties. In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Annual Report, and while we believe such information forms a reasonable basis for such statements, such information may be

limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements. We discuss many of the risks associated with the forward-looking statements in this Annual Report in greater detail under the heading "Risk Factors." Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. Given these uncertainties, you should not place undue reliance on these forward-looking statements.

You should carefully read this Annual Report and the documents that we reference in this Annual Report and have filed as exhibits to this Annual Report completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of the forward-looking statements in this Annual Report by these cautionary statements.

Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in any forward-looking statements, whether as a result of new information, future events or otherwise.

Trademarks and Trade names

This Annual Report contains references to our trademarks and to trademarks belonging to other entities. Solely for convenience, trademarks and trade names referred to in this Annual Report, including logos, artwork and other visual displays, may appear without the ® or TM symbols, but such references are not intended to indicate, in any way, that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto. We do not intend our use or display of other companies' trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

RISK FACTOR SUMMARY

Below is a summary of the material factors that make an investment in our common stock speculative or risky. This summary does not address all of the risks that we face. Additional discussion of the risks summarized in this risk factor summary, and other risks that we face, can be found below under the heading "Risk Factors" under Item 1A of Part I of this Annual Report, and should be carefully considered, together with other information in this Annual Report before making investment decisions regarding our common stock.

Risks Related to Our Financial Position and Capital Needs

- We have incurred net losses in every period since our inception and anticipate that we will incur substantial net losses in the future.
- We will need substantial additional financing to develop our products and implement our operating plans. If we fail to obtain additional financing, we may be unable to complete the development and commercialization of our product candidates.
- We may fail to meet our publicly announced guidance or other expectations about our business, which would cause our stock price to decline.

Risks Related to Our Business and Industry

- Our product candidates are based on novel technologies, which makes it difficult to predict the time and cost of product candidate development and the likelihood of obtaining regulatory approval.
- Our business is highly dependent on the success of our lead product candidates. If we are unable to advance clinical development, obtain approval of and successfully commercialize our lead product candidates for the treatment of patients in approved indications, our business would be significantly harmed.
- Our product candidates may cause undesirable side effects or have other properties that have halted and could in the future halt their clinical development, prevent their regulatory approval, limit their commercial potential or result in significant negative consequences.
- Our clinical trials may fail to demonstrate the safety and efficacy of any of our product candidates, which would prevent or delay regulatory approval and commercialization.
- No CAR T therapy has been approved as a part of first-line consolidation strategy for the treatment of LBCL patients, which presents significant regulatory, commercial, and operational risks, and there is no assurance of success in this unproven setting.
- We may encounter substantial delays in our clinical trials, or may not be able to conduct our trials on the timelines we expect.
- If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.
- We may fail to successfully manufacture our product candidates, operate our own manufacturing facility, or obtain regulatory approval to utilize or commercialize from our manufacturing facility or at a CDMO, which could adversely affect our clinical trials and the commercial viability of our product candidates.
- We face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively.
- We are highly dependent on our key personnel, and if we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.
- Changes in funding for the FDA, the SEC and other government agencies including comparable foreign regulatory authorities could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal functions on which the operation of our business may rely, which could negatively impact our business.

Risks Related to the Development of Our Product Candidates

- Our engineered allogeneic T cell product candidates represent a novel approach to cancer treatment and treatment of autoimmune diseases, which creates significant challenges for us.
- Gene-editing is a relatively new technology, and if we are unable to use this technology in our intended product candidates, our revenue opportunities will be materially limited.

- We are heavily reliant on our partners, Cellectis and Servier, for access to TALEN gene editing technology for the manufacturing and development of our oncology product candidates.
- We are heavily reliant on our partner, Foresight Diagnostics, for access to their CLARITY™ MRD test for identifying eligible patients for our ALPHA3 trial.

Risks Related to Our Reliance on 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 meet expected deadlines, we may not be able to obtain regulatory approval of or commercialize our product candidates.

Risks Related to Government Regulation

- The FDA and other comparable foreign regulatory approval processes are lengthy and time-consuming, and we may experience significant delays in the clinical development and regulatory approval of our product candidates.
- The FDA or comparable foreign regulatory authorities may disagree with our regulatory plan and we may fail to obtain regulatory approval of our CAR T cell product candidates.
- If we, or our collaborators, are required by the FDA, or comparable foreign regulatory authorities, to obtain approval (or clearance, or certification) of a companion diagnostic device in connection with approval of one of our product candidates, and we, or our collaborators, do not obtain, or face delays in obtaining, approval (or clearance, or certification) of a companion diagnostic device, we will not be able to commercialize the product candidate, and our ability to generate revenue will be materially impaired.

Risks Related to Our Intellectual Property

- We depend on intellectual property licensed from third parties and termination of any of these licenses could result in the loss of significant rights, which would harm our business.
- If our efforts to protect the proprietary nature of the intellectual property related to our technologies are not adequate, we may not be able to compete effectively in our market.

Risks Related to Ownership of Our Common Stock

- The price of our stock has been and may continue to be volatile, and you could lose all or part of your investment.

PART I

Item 1. Business

Overview

We are a clinical stage immuno-oncology company pioneering the development of genetically engineered allogeneic T cell product candidates for the treatment of cancer and autoimmune diseases. We are developing a pipeline of "off-the-shelf" T cell product candidates that are designed to target and kill cancer cells in patients or eliminate pathogenic autoreactive cells in patients with autoimmune disorders. Our engineered T cells are allogeneic, meaning they are derived from healthy donors for intended use in any patient, rather than from an individual patient for that patient's use, as in the case of autologous T cells. We believe this key difference will enable us to deliver readily available treatments faster, more reliably, at greater scale, and to more patients.

Last year we executed our 2024 Platform Vision, which we believe will redefine the future of chimeric antigen receptor (CAR) T therapy by leveraging the unique attributes of allogeneic CAR T products. In furtherance of that vision, we continue to focus on three core programs:

1. *Large B-Cell Lymphoma (LBCL)*: Potentially groundbreaking ALPHA3 Trial that we believe may leapfrog other CAR T's and embed cemacabtagene ansegedleucel (cema-cel, previously ALLO-501A) in first line (1L) LBCL treatment in community cancer centers where most newly diagnosed patients seek care.

2. *Autoimmune Disease (AID)*: ALLO-329, our next-generation CD19 Dagger® program, focuses on scalability and reduced or chemotherapy-free lymphodepletion, positioning allogeneic CAR T to potentially transform autoimmune management and meet the demand of the market.

3. *Renal Cell Carcinoma (RCC)*: TRAVERSE trial with ALLO-316 seeks to advance scientific innovation underlying the Dagger® technology to optimize CAR T cell expansion and persistence, thereby maximizing the potential of allogeneic CAR T in solid tumors while mitigating treatment-associated inflammatory response.

Our allogeneic approach involves engineering healthy donor T cells, which we believe will allow for the creation of an inventory of off-the-shelf products that can be delivered to a larger portion of eligible patients throughout the world. These potential benefits led our Executive Chair, Arie Belldegrun, M.D., who was previously the Chair and Chief Executive Officer at Kite Pharma (Kite, now a Gilead company), and our President and Chief Executive Officer, David Chang, M.D., Ph.D., previously Chief Medical Officer and Executive Vice President of Research and Development at Kite, to found our company with the driving purpose of accelerating the development of allogeneic CAR T cell therapies.

Although we are currently focusing on our three core development programs noted above, we continue to have a deep pipeline to further the research and development of allogeneic CAR T cell product candidates in both hematological malignancies and solid tumors. We believe our technology platform combined with our management team's experience in immuno-oncology and specifically in CAR T cell therapy will help drive the rapid development and, if approved, the commercialization of potentially curative therapies for patients with aggressive cancer or who suffer from autoimmune diseases.

Our Approach

Our allogeneic CAR T cell development strategy has four key pillars: (1) engineering product candidates to minimize the risk of graft-versus-host disease (GvHD), a condition where allogeneic T cells can recognize the patient's normal tissue as foreign and cause damage, (2) creating a window of persistence that may enable allogeneic T cells to expand and eradicate cancer cells in patients or pathogenic autoreactive cells in patients, (3) building a leading manufacturing platform to enable consistent and high quality production and (4) leveraging next generation technologies to improve the functionality of allogeneic CAR T cells.

For our oncology programs we use Cellectis, S.A. (Cellectis), TALEN® gene-editing technology to limit the risk of GvHD by engineering T cells to lack functional T cell receptors (TCRs), thereby preventing them from recognizing a patient's normal tissue as foreign. With the goal of enhancing the expansion and persistence of our engineered allogeneic T cells, we use TALEN® technology to inactivate the CD52 gene in donor T cells and an anti-CD52 monoclonal antibody to deplete CD52 expressing T cells in patients while sparing the therapeutic allogeneic T cells. We believe this enables a window of persistence for the infused allogeneic T cells to actively target and destroy cancer cells. We are also developing ALLO-647, our own anti-CD52 monoclonal antibody, which is designed to be used prior to infusing our other product candidates as part of a

lymphodepletion regimen. Our off-the-shelf approach is dependent on state-of-the-art manufacturing processes, and we believe we have built a technical operations organization with fully integrated in-house expertise in clinical and commercial engineered T cell manufacturing.

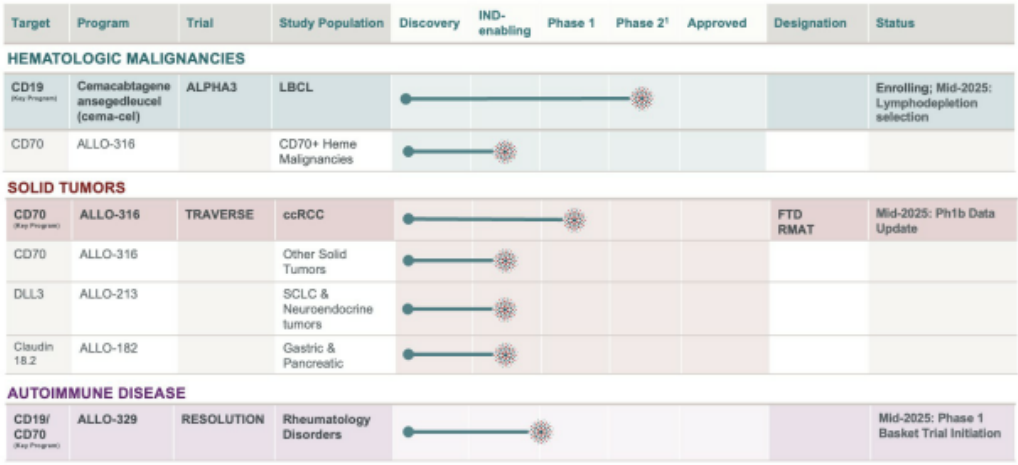
For our lead autoimmune program, we have a non-exclusive license with Arbor Biotechnologies relating to a CRISPR-based gene-editing technology for the development of allogeneic T cell product candidates directed against various targets, including CD19 and CD70 both of which ALLO-329 targets.

We have built our own current good manufacturing practices (cGMP) manufacturing facility in Newark, California, that we call Cell Forge 1 (CF1). We are currently utilizing CF1 for clinical manufacturing of our product candidates.

Finally, we plan to leverage next generation technologies to develop more potent product candidates and to develop product candidates to overcome premature rejection of allogeneic CAR T cells by the patient's immune system. We believe next generation technologies will also allow us to further develop allogeneic T cell therapies for the treatment of solid tumors, which to date have been difficult to treat because of, among other factors, the lack of validated targets and tumor microenvironments that can impair the activity of T cells.

Our Pipeline

We are currently developing a pipeline of multiple allogeneic CAR T cell product candidates utilizing protein engineering, gene editing, gene insertion and advanced proprietary T cell manufacturing technologies. Our most advanced product candidate, cemacabtagene ansegedleucel, referred to as cema-cel (previously ALLO-501A), is an engineered allogeneic CAR T cell product candidate that targets CD19, a protein expressed on the cell surface of B cells and a validated target for B cell driven hematological malignancies. We are currently focused on developing cema-cel for LBCL. Our pipeline also includes ALLO-316 and ALLO-329. ALLO-316 is an engineered allogeneic CAR T cell product candidate that targets CD70, which is highly expressed in RCC and is selectively expressed in several other cancers thereby creating the potential for ALLO-316 to be developed across a variety of both hematologic malignancies and solid tumors. We are currently focused on developing ALLO-316 for RCC. ALLO-329, an engineered allogeneic CAR T cell product candidate that targets both CD19 and CD70, is in development for the treatment of systemic lupus erythematosus (SLE), idiopathic inflammatory myopathies (IIM), and systemic sclerosis (SSc). We have additional product candidates, but we have deprioritized these programs to allow us to focus on cema-cel, ALLO-316 and ALLO-329. Our pipeline is represented in the diagram below.



[1]Phase 2 designed to be registrational

Our lead product candidates include:

- *Cemacabtagene ansegedleucel (cema-cel).* We are enrolling a pivotal Phase 2 clinical trial (ALPHA3) for cema-cel as part of a 1L treatment plan for newly diagnosed and treated LBCL patients who are likely to relapse and need further therapy. The design of the ALPHA3 1L consolidation trial builds upon the results demonstrated in the Phase 1 ALPHA2 trial and leverages an investigational diagnostic test developed by Foresight Diagnostics, Inc. (Foresight Diagnostics) that we believe will identify patients who have achieved remission by standard disease assessment but who have minimal residual disease (MRD) at the completion of 1L chemoimmunotherapy. The ALPHA3 trial is designed to study the impact of treating MRD positive patients with cema-cel. The study will randomize

approximately 240 patients who achieve a complete response or partial response to 1L therapy, but who are MRD positive. Patients will be randomized to receive either consolidation with cema-cel or the current standard of care, which is observation. The study design, which has event free survival (EFS) as its primary endpoint, initially includes two lymphodepletion arms:

- FCA: standard fludarabine and cyclophosphamide plus ALLO-647
- FC: standard fludarabine and cyclophosphamide without ALLO-647

One of these lymphodepletion arms will be discontinued following a planned interim analysis designed to identify the most appropriate regimen for this patient population. An initial safety and futility interim analysis will occur once 12 patients in each arm have been enrolled and followed for MRD conversion. If both treatment arms perform better than the control arm according to the futility criteria, but neither treatment arm shows a trend toward superiority relative to the other in this interim analysis, additional patients may be enrolled and analyzed before we select the final lymphodepletion regimen. The selection of the lymphodepletion regimen is anticipated around mid-2025, depending on the interim analyses results and overall trial progress.

- ALLO-316. We have completed enrollment in a Phase 1 clinical trial (TRAVERSE) of ALLO-316, an allogeneic CAR T cell product candidate targeting CD70, in adult patients with advanced or metastatic RCC. We presented interim results from the TRAVERSE trial at the International Kidney Cancer Symposium (IKCS) and The Society for Immunotherapy of Cancer's (SITC) Annual Meeting in November 2024. See "-Product Pipeline and Development Strategy-Anti-CD70 Development Program-Results from the Phase 1 ALLO-316 TRAVERSE Trial" for information regarding the results. In October 2024, we announced that we received Regenerative Medicine Advanced Therapy (RMAT) designation for ALLO-316 for adult patients with advanced or metastatic RCC. The RMAT designation was based on Phase 1 clinical data from the TRAVERSE trial indicating the potential of ALLO-316 to address the unmet need for patients with difficult-to-treat RCC who have failed multiple standard RCC therapies, including an immune checkpoint inhibitor and a VEGF-targeting therapy. Once we have obtained additional follow-up data on the enrolled patients, we plan to engage with FDA to establish the next steps for this development program.

- ALLO-329. Following the clearance of an IND in January 2025, we plan to initiate a Phase 1 clinical trial (the RESOLUTION trial) of ALLO-329, an allogeneic CAR T cell product candidate targeting both CD19 and CD70, in adult patients with systemic lupus erythematosus, including lupus nephritis, idiopathic inflammatory myopathies, and systemic sclerosis in mid-2025. Inclusion of an anti-CD70 CAR in ALLO-329 incorporates the Dagger® technology, which is designed to reduce or eliminate the need for standard chemotherapy by preventing premature rejection while targeting CD19+ B-cells and CD70+ activated T-cells, both of which play a role in autoimmune diseases. The RESOLUTION trial will include two distinct lymphodepletion arms: one using a dose of cyclophosphamide alone which is used by rheumatologists, and another that eliminates lymphodepletion entirely.

- *Other Product Candidates:* While we have additional programs in our pipeline, our development priorities are focused on cema-cel (1L Consolidation in LBCL), ALLO-316, and ALLO-329. We will explore opportunities to partner with collaborators on product candidates across our pipeline.

Our History and Team

We believe we have established a leadership position in allogeneic CAR T cell therapy. In April 2018, we acquired certain assets from Pfizer Inc. (Pfizer), including strategic license and collaboration agreements and other intellectual property related to the development and administration of allogeneic CAR T cells for the treatment of cancer. We have an Exclusive License and Collaboration Agreement (the Servier Agreement) with Les Laboratoires Servier SAS and Institut de Recherches Internationales Servier SAS (collectively, Servier) to develop and commercialize cema-cel, and certain additional product candidates, and we hold the commercial rights to these product candidates in the United States, the European Union, and the United Kingdom. The Servier Agreement gives us access to Cellectis' TALEN® gene-editing technology for cema-cel. We also have an exclusive worldwide oncology license from Cellectis to use its TALEN® gene-editing technology for the development of allogeneic T cell product candidates directed against 15 different cancer antigens, including CD70 which ALLO-316 targets. We also have a non-exclusive license with Arbor Biotechnologies relating to a CRISPR-based gene-editing technology for the development of allogeneic T cell product candidates in the field of autoimmune diseases directed against various targets, including CD19 and CD70, both of which ALLO-329 targets.

Our world-class management team has significant experience in immuno-oncology and in progressing products from early-stage research to clinical trials, and ultimately to regulatory approval and commercialization. In particular, both Dr. Belldegrun and Dr. Chang led the development and approval of Yescarta® at Kite. Additionally, our Executive Vice President of Research and Development and Chief Medical Officer, Dr. Zachary Roberts, was also instrumental in the development and execution of the clinical trials of Yescarta® across multiple indications.

Our Strategy

Our goal is to maintain and build upon our leadership position in allogeneic CAR T cell therapy. We plan to rapidly develop and, if approved, commercialize allogeneic CAR T cell products for the treatment of cancer and autoimmune disease that can be delivered faster, more reliably, and at greater scale than autologous T cell therapies. We believe achieving this goal could result in allogeneic CAR T therapy becoming a standard of care in cancer and autoimmune disease treatments and enable us to make potentially curative products more readily accessible to more patients throughout the world. Key elements of our strategy include:

- ***Repositioning our allogeneic CAR T product as the only CAR T to be part of a first-line (1L) consolidation approach.*** We seek to redefine the future of CAR T by potentially repositioning our allogeneic CAR T product as the only CAR T to be part of a first line (1L) treatment plan for newly diagnosed and treated LBCL patients who are likely to relapse and need further therapy. The design of the ALPHA3 1L consolidation trial builds upon the results demonstrated in the Phase 1 ALPHA2 trial and leverages an investigational diagnostic test developed by Foresight Diagnostics to identify patients who have MRD at the completion of 1L chemoimmunotherapy for treatment with cema-cel. The ALPHA3 trial was initiated in June 2024 and now has 40 sites activated and screening for patients with MRD. An interim analysis is anticipated around mid-2025 depending on the analyses and overall trial progress, and based thereon, the lymphodepletion regimen for the remainder of the trial will be selected.

- ***Expand our allogeneic CAR T platform into the treatment of autoimmune disease (AID).*** We are currently developing a next-generation product candidate, ALLO-329, which is an engineered allogeneic CAR T cell product candidate that targets CD19 and CD70. ALLO-329 incorporates our Dagger® technology. In January 2025, we announced that the FDA has cleared our IND for a rheumatology basket study of ALLO-329, our RESOLUTION trial. Incorporation of the Dagger® technology into an "off-the-shelf" CD19 product for use in AID is designed to reduce or eliminate the need for standard chemotherapy while targeting CD19+ B-cells and CD70+ activated T-cells, both of which play a role in AID. Initiation of the RESOLUTION trial is targeted for mid-2025 with initial proof-of-concept data available anticipated around year-end 2025.

- ***Build state-of-the-art gene engineering and cell manufacturing capabilities.*** Manufacturing allogeneic T cell product candidates involves a series of complex and precise steps. We believe a critical component to our success will be to leverage and expand our proprietary manufacturing know-how, expertise and capacity. For instance, for our lead product candidate, cema-cel, we were able to identify and select a manufacturing process that was associated with robust clinical performance in Phase 1. We believe establishing our own fully integrated manufacturing operations and infrastructure will allow us to continuously improve the manufacturing process, limit our reliance on contract development and manufacturing organizations (CDMOs) and more rapidly advance the commercialization of any of our product candidates that receive regulatory approval.

- ***Expand into solid tumor indications with high unmet need and leverage next generation technologies to advance our platform.*** We plan to continue to advance the research and development of ALLO-316, which targets CD70, for the treatment of clear cell renal cell carcinoma (ccRCC) as part of our TRAVERSE trial. We are investigating next-generation technologies incorporated in the design of ALLO-316 which seek to better control rejection of allogeneic CAR T cells by the patient's immune system. Such technologies include our Dagger® technology that utilizes an anti-CD70 CAR to kill alloreactive host T cells. We continually survey the scientific and industry landscape for opportunities to license, partner or acquire technologies that may help us advance current or new cell therapies for the benefit of patients.

Allogeneic CAR T Cell Therapy

Engineered T Cell Therapies

T cells are a type of white blood cell and are involved in both sensing and killing infected or abnormal cells, including cancer cells, as well as coordinating the activation of other cells in an immune response. Engineered T cell therapy is a type of immunotherapy treatment whereby human T cells are removed from the body and engineered to express CARs which, when infused into a patient, may allow the recognition and destruction of cancer cells in a targeted manner.

Chimeric Antigen Receptors (CARs)

CARs are engineered molecules that, when present on the surface of a T cell, enable the T cell to recognize specific proteins or antigens that are present on the surface of other cells. More than one type of CAR can be included in a CAR T cell,

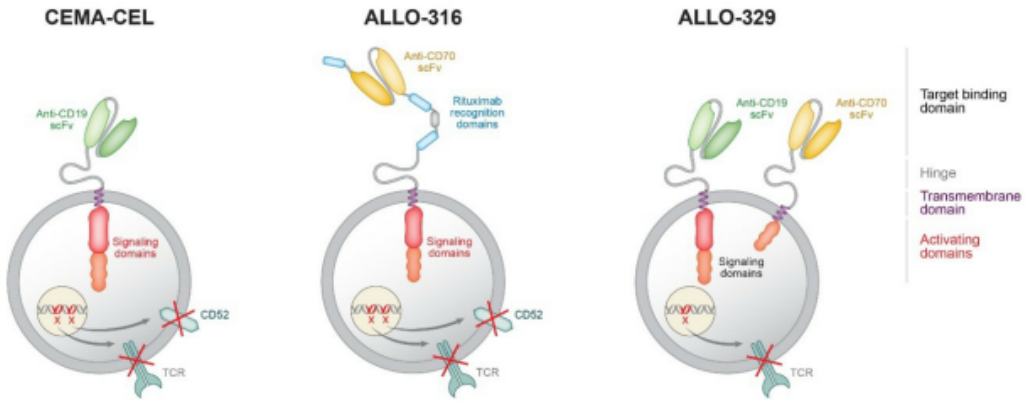
imparting multi-antigen targeting capability. The CAR molecule(s) in our product candidates are comprised of a single chain protein that contains the following elements:

- *Target Binding Domain:* At one end of the CAR is a target binding domain that is specific to a target antigen. This domain extends out onto the surface of the engineered T cell, where it can recognize the target antigens. The target binding domain consists of a single-chain variable fragment (scFv) of an antibody comprising variable domains of heavy and light chains joined by a short linker.

- *Transmembrane Domain and Hinge:* This middle portion of the CAR links the scFv target binding domain to the activating elements inside the cell. This transmembrane domain "anchors" the CAR in the cell's membrane. In addition, the transmembrane domain may also interact with other transmembrane proteins that enhance CAR function. The hinge domain, which extends to the exterior of the cell, connects the transmembrane domain to scFv and provides structural flexibility to facilitate optimal binding of scFv to the target antigen on the cancer cell's surface.

- *Activating Domains:* The other end of transmembrane domain, inside the T cell, is connected to one or more signaling domains responsible for activating the T cell when the CAR binds to the target cell. The CD3 zeta domain delivers an essential primary signal within the T cell, and the 41BB domain delivers an additional, co-stimulatory signal. Together, these signals trigger T cell activation, resulting in proliferation of the CAR T cells and killing of the cancer cell. In addition, activated CAR T cells stimulate the local secretion of cytokines and other molecules that can recruit and activate additional immune cells to potentiate killing of the cancer cells.

In addition to the domains described above, in ALLO-316, we have included rituximab recognition domains to potentially serve to identify and/or eliminate ALLO-316 cells using rituximab. The figure below shows the constructs that support our lead product candidates in clinical development: cema-cel, ALLO-316 and ALLO-329.



Allogeneic CAR T Cell Products: The Next Revolution

There are two primary approaches to engineered T cell therapy: autologous and allogeneic. Autologous therapies use engineered T cells derived from the individual patient, while allogeneic products use engineered T cells derived from unrelated healthy donors. While the autologous approach has been revolutionary, demonstrating compelling efficacy in many patients, it is burdened by the following key limitations:

- ***Lengthy Delivery Time***. Due to the individualized manufacturing process, patients may wait weeks to months to be treated with their engineered cells. As a result, in the registrational trials for Yescarta® and Kymriah®, up to 31% of intended patients ultimately did not receive treatment primarily due to complications from the underlying disease prior to delivery of therapy or as a result of manufacturing failures. In addition, certain patients being treated with autologous therapies have sometimes required bridging therapy as they wait for the manufacture of their T cells, however, bridging therapy to control disease may increase some cumulative or synergistic toxicities for the patients. Other rapidly progressing patients may not be considered candidates for autologous CAR T given lengthy waiting times and limited manufacturing slots. Each of these autologous CAR T challenges creates inherent limitations to the uptake of autologous CAR T therapies. As discussed in more detail below, these limitations become increasingly prohibitive in diseases where time is of the essence as is the case in 1L consolidation, making autologous CAR T therapy unsuitable for such use.

- ***Variable Potency***. In some cases, patients may have T cells that have been damaged or weakened due to prior chemotherapy or hematopoietic stem-cell transplant. Compromised T cells may not proliferate well during manufacturing or may produce cells with insufficient potency that cannot be used for patient treatment, resulting in manufacturing failures, or that can show poor expansion and activity in patients. In addition, the individualized nature of autologous manufacturing, together with the variability in patients' T cells, may lead to variable potency of manufactured T cells, and this variability may cause unpredictable treatment outcomes.

- ***Manufacturing Failures***. Autologous cell manufacturing sometimes encounters production failures. This can mean that a patient never receives treatment, as additional patient starting material may not be available or the patient may no longer be eligible due to advanced disease. Furthermore, retreatment can be difficult due to a limited supply of usable patient starting material.

- ***Complex Logistics***. The delivery of autologous T cell therapy is complicated due to the individualized nature of manufacturing, which allows only one patient to be treated from each manufacturing run and requires dedicated infrastructure to maintain a strict chain of custody and chain of identity of patient-by-patient material collection, manufacturing and delivery. The complex logistics add significant cost to the process and limit the ability to scale. Additionally, the collection of T cells through leukapheresis from each individual patient results in a time consuming and costly step in the autologous process. In part due to these logistics, autologous treatment is currently only available at select centers.

Allogeneic engineered T cells are manufactured in a similar manner as autologous, but our manufacturing has two key differences: (1) our allogeneic T cells are derived from healthy donors, not cancer patients, and (2) our allogeneic T cells are genetically engineered to minimize the risk of GvHD and enable a window of persistence in the patient.

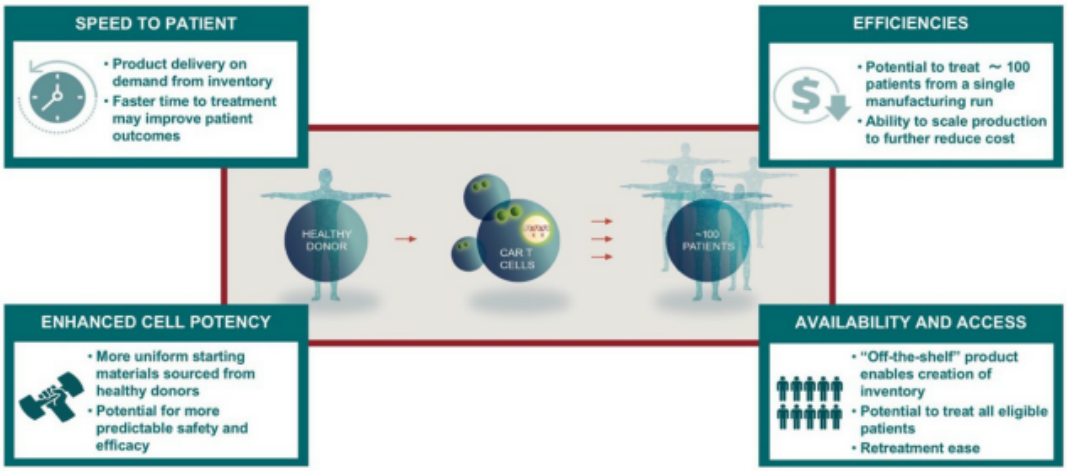
Our approach is designed to provide the same intended curative outcome as autologous therapy, while offering the following potential key advantages:

- ***Availability and Access***. Starting with T cells from a healthy donor, we believe that at scale we can manufacture approximately 100 doses or more of allogeneic CAR T product per manufacturing run that could be used in any eligible patient. Because our allogeneic product candidates are designed to be frozen and available off-the-shelf, they are expected to be readily shipped and administered to patients.

- ***Speed to Patient***. Many patients with aggressive or rapidly progressing cancer may not have multiple weeks to wait for autologous CAR T treatment. Our allogeneic approach has the potential to create off-the-shelf product inventory, which could enable dosing of patients within days of a decision to treat. This would represent a significant reduction in patient wait time, potentially obviating the need for any bridging therapy and allowing the treatment of patients who are either too sick, or their disease progresses too quickly for them to wait for their autologous CAR T cells to be manufactured, thus potentially improving patient outcomes. In addition, as we seek to incorporate our investigational allogeneic CAR T product into a 1L consolidation strategy, the speed to patient becomes even more important. Once it is determined that a patient is MRD positive following standard 1L treatment, published results of front-line chemotherapy outcomes suggest that the patient is very likely to progress, and some patients may do so very quickly (i.e., within a matter of weeks after completing 1L therapy). Furthermore, data suggests that patients who have low burden of disease when they receive CAR T cells tend to have better safety and efficacy outcomes, including lower rates of cytokine release syndrome (CRS) and more durable remissions. As a result, we believe that autologous CAR T therapy is far less suitable for treating MRD positive patients as part of a 1L consolidation strategy given the lengthy lead time for the autologous individualized manufacturing process, which would not allow for rapid CAR T treatment before disease progression and while the disease burden remains low.

- ***Enhanced Cell Consistency and Potency***. Our manufacturing process produces therapies from selected, screened and tested healthy donors. Healthy donor T cells are potentially superior for engineered cellular therapy as compared to T cells from patients who have undergone prior chemotherapy or hematopoietic stem-cell transplant, which can damage or weaken T cells. In addition, greater consistency of the product may yield more predictable treatment outcomes.

- ***Streamlined Manufacturing***. We have built an efficient and scalable manufacturing process and organization. The allogeneic CAR T approach utilizes healthy donor T cells which we believe provides enhanced scalability, and an off-the-shelf capability that can potentially reduce the costs to the overall healthcare system as it does not require bridging therapy, leukapheresis and complex logistics.



Manufacturing Allogeneic T Cells

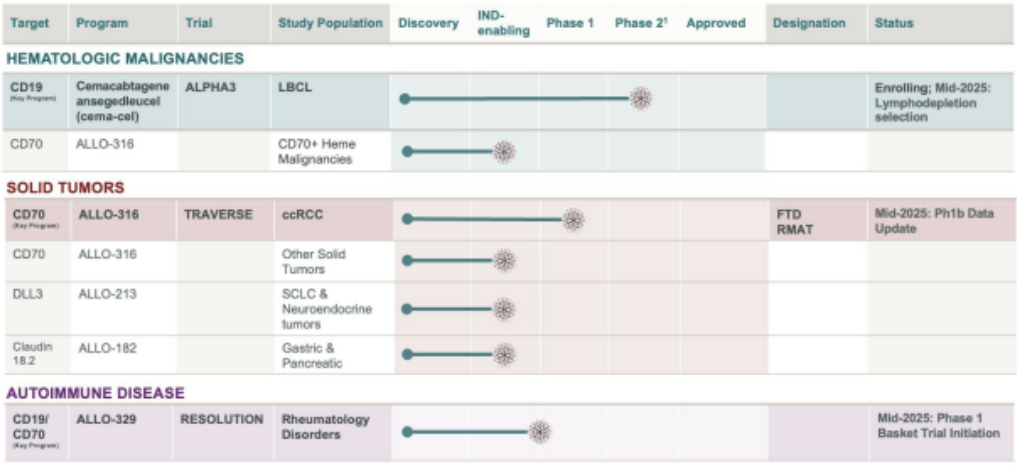
There are similarities as well as key differences between the processes for allogeneic and autologous CAR T cell manufacturing. The three primary steps to creating our engineered allogeneic CAR T cells are: (1) collection and transduction, (2) gene editing, and (3) purification, formulation, and storage. We start with collecting white blood cells from a healthy donor, which are subsequently stimulated to proliferate and transduced with a viral vector to integrate the CAR sequence into the T cell genome. The CAR sequence directs the expression of CAR proteins on the cell surface that allows the transduced T cells to recognize and bind to a target molecule, for example a target that is present on cancer cells or pathogenic autoreactive immune cells. Next, we use gene editing tools to edit the T cell genome to inactivate TCRα, and in the case of our oncology products, to also inactivate CD52. Inactivation of TCRα and CD52 is intended to reduce the risk of GvHD and enable the use of ALLO-647, a proprietary CD52 monoclonal antibody, as part of lymphodepletion to allow the allogeneic T cells to expand and persist in patients, respectively. For oncology products the transduction and genetic editing steps are separate, but for our autoimmune disease product candidate, ALLO-329, the steps are combined and utilize different gene editing technology. Furthermore, ALLO-329 does not incorporate the CD52 knockout utilized in oncology products. Finally, the edited T cells are cultured for several days to increase the cell number, harvested and purified. The purified T cells are formulated in a cryopreservation media and filled into closed, stoppered vials prior to controlled-rate freezing and long-term storage in the vapor phase of liquid nitrogen. This inventory is securely stored and then shipped to treatment facilities, as needed.

Product Pipeline and Development Strategy

Using our proprietary allogeneic CAR T cell platform, we are researching and developing multiple product candidates for the treatment of blood cancers, solid tumors and autoimmune diseases. Our product candidates are allogeneic T cells engineered to be used as off-the-shelf treatments for any patient with a particular cancer type or autoimmune disease. Each product candidate bears specific engineered attributes, and targets a selected antigen expressed on tumor cells or pathogenic autoreactive immune cells.

Our product pipeline is represented in the chart below:

Table of Contents



[1]Phase 2 designed to be registrational

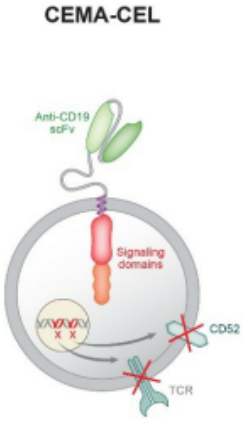
Anti-CD19 Oncology Development Program

CD19 is an antigen expressed on the surface of B cells, including on B cells that are malignant. B cells are considered non-essential tissue, as they are not absolutely required for patient survival. We believe CD19 is a validated target for the treatment of B cell leukemias and lymphomas. Multiple autologous anti-CD19 CAR T therapies have shown promising results and have been approved by the FDA as therapies in multiple blood cancers, including relapsed/refractory (R/R) LBCL, as further described below under "-Competition".

Historically, under our Servier Agreement, we have worked with Servier to develop several CD19 product candidates, including UCART19, ALLO-501 and cema-cel. On September 15, 2022, Servier sent us a notice of discontinuation of its involvement in the development of all CD19 Products pursuant to the Servier Agreement. On May 10, 2024, the we entered into an Amendment and Settlement Agreement (the Servier Amendment) with Servier which restructures our relationship under the Servier Agreement. Under the Servier Amendment the parties agreed that co-development performed by the Company and Servier under the Servier Agreement, including co-development relating to CD19 Products, ceased as of December 15, 2022.

UCART19 was our first CD19 product candidate, and Servier led its manufacturing and clinical development. UCART19 was manufactured to express a CAR that is designed to target CD19 and gene edited to lack TCRα and CD52 to minimize the risk of GvHD and enable use of anti-CD52 monoclonal antibodies to create a window of CAR T cell persistence in the patient. In addition, UCART19 cells were engineered to express a small protein on the cell surface called RQR8, which consists of two rituximab recognition domains. This allowed for recognition and elimination of the CAR T cells by rituximab if silencing of CAR T cell activity is desired. Servier sponsored two Phase 1 clinical trials of UCART19 in patients with R/R CD19 positive B-cell acute lymphoblastic leukemia (ALL), both of which were completed in 2020. Patients from both studies are continuing the long-term follow-up as planned.

We have been, and continue to be, responsible for the manufacture and clinical development of ALLO-501 and cema-cel. ALLO-501 is identical to UCART19 in molecular design, however several modifications were introduced by us to the manufacturing process for ALLO-501. These modifications are designed to facilitate more efficient manufacturing scale-up for the larger patient population targeted by ALLO-501. Like UCART19, ALLO-501 also co-expresses a small protein on the cell surface called RQR8, which consists of two rituximab recognition domains. This is intended to allow for destruction of the CAR T by rituximab. Prior treatment with rituximab is typical for patients with Non-Hodgkin Lymphoma (NHL) and, depending on the lag time between the rituximab administration and the CAR T infusion, prior administration of rituximab may interfere with any CAR T that includes RQR8. As a result, we have removed RQR8 in cema-cel, which is illustrated below, to facilitate treatment of patients who were recently treated with rituximab.



Lead Target Indication: Non-Hodgkin Lymphoma (NHL)

NHL is a hematologic cancer originating from malignant lymphocytes. It is the most common hematological malignancy in the United States, with 80,620 new cases estimated to be diagnosed and 20,140 deaths estimated in 2024, according to the American Cancer Society. Over 60 NHL subtypes have been identified, and each subtype represents different neoplastic lymphoid cells (T, B or NK cells) that have arrested at different stages of differentiation. According to the American Cancer Society, B-cell lymphomas make up approximately 85% of NHL cases in the United States.

B-cell NHL itself represents a group of different neoplasms that not only differ in pathology, but also response to therapy and prognosis. NHL can be rapidly growing (aggressive), such as LBCLs, or it can be slow growing, or indolent, such as follicular lymphoma (FL).

The R-CHOP chemotherapy combination (rituximab, cyclophosphamide, doxorubicin, vincristine, and prednisone) introduced in the early 2000s remains the standard of care for newly diagnosed LBCL, and can yield five-year survival rates of 55-60%. Unfortunately, approximately 30% of LBCL patients relapse or have treatment-refractory disease and require second-line therapy. Subsequent therapy for fit patients is commonly high-dose therapy followed by autologous stem-cell therapy or autologous anti-CD19 CAR T therapy. Two previous randomized controlled trials evaluated anti-CD19 CAR T cell therapies, Yescarta® and Breyanzi® compared to high dose chemotherapy followed by autologous stem cell rescue. Yescarta® and Breyanzi® improved event-free-survival versus stem cell transplant (8.3 months vs. 2.0 months and 10.1 months vs. 2.3 months, respectively). A retrospective analysis of patients with R/R LBCL, who were not treated with autologous CAR T therapy, found that outcomes in this population are poor, with an objective response rate of 26% (complete response (CR): 7%, partial response: 18%) and median overall survival of 6.3 months.

Autologous CAR T therapy has made significant advances in addressing R/R NHL, and has moved to earlier lines of therapy, as further described below under - "Competition".

Results from the Phase 1 ALLO-501 ALPHA Trial and the Phase 1 cema-cel ALPHA2 Trial

On February 13, 2025, we announced long-term follow up data from the Phase 1 ALPHA trial of ALLO-501 and from the Phase 1 ALPHA2 trial of cema-cel in R/R LBCL which was published in the Journal of Clinical Oncology. The ALPHA/ALPHA2 studies were single-arm, multicenter, open-label, Phase 1 trials. As of the data cutoff date (September 26, 2024), 33 CD19 CAR T-naive patients with R/R LBCL were treated in ALPHA/ALPHA2 with cema-cel/ALLO-501 manufactured with the process selected for use in pivotal studies.

The overall Response Rate (ORR) and Complete Response (CR) rate in the ALPHA/ALPHA2 trials were comparable with those observed in patients with R/R LBCL after two or more lines of systemic therapy who received treatment with approved autologous CD19 CAR T cell products. All treatment regimens studied demonstrated clinical benefit. The selected Phase 2 regimen (fludarabine/cyclophosphamide lymphodepletion with 90 mg of ALLO-647 (FCA90) followed by a single dose of CAR+ cells) yielded the highest ORR and CR of 67% and 58%, respectively. Five of 12 patients in this group achieved CR that lasted at least 6 months.

	Patients Treated with Phase 2 Regimen (n=12)
Overall Response Rate (ORR), n (%)	**8 (67)**
Complete Response (CR), n (%)	**7 (58)**
6 Month CR Rate, n (%)	**5 (42)**

Patients who achieved a CR had excellent outcomes with a median DOR, PFS (progression free survival) and OS of 23.1 months, 24 months, and not reached, respectively. For patients receiving the selected Phase 2 regimen, median DOR was 23.1 months and median OS was not reached.

The safety profile, including incidence of cytopenias and infections, was manageable and consistent with that of approved autologous CD19 CAR T cell therapies. There were no dose-limiting toxicities, graft-versus-host disease (GvHD), immune effector cell-associated neurotoxicity syndrome (ICANS), or high-grade cytokine release syndrome (CRS). The most common any-grade treatment emergent adverse events (TEAE) (≥25%) were neutropenia (85%), anemia (67%), thrombocytopenia (58%), infusion-related reactions (IRRs; 58%), fatigue (52%), and pyrexia (49%), nausea (39%), lymphopenia (36%), hypotension (36%), peripheral edema (33%), decreased white blood cell count (30%), CMV reactivation (30%), decreased appetite (30%), chills (30%), and hypoxia (27%).

The median time to start of treatment was two days from study enrollment. In contrast, autologous CAR T cell products require wait times often longer than 1 month despite incremental advancements in manufacturing and supply chains.

A growing body of evidence indicates that treatment with CAR T at times when the disease burden is low leads to improved safety and efficacy outcomes and this study reported similar findings. Among patients with baseline tumor burden <1000 mm² or normal serum lactate dehydrogenase (LDH), a blood test that indicates disease activity, the CR rate was 100% (6/6) and 82% (9/11), respectively. These CR rates in this subpopulation support cema-cel as a promising therapeutic option in patients with minimum residual disease (MRD), the population currently being studied in the ALPHA3 trial.

These results serve as the foundation for the ongoing ALPHA3 trial, which is evaluating cema-cel as a consolidation therapy in LBCL patients who are in remission following 1L treatment but remain positive for MRD as detected by an ultrasensitive ctDNA based blood test, Foresight Diagnostics' investigational CLARITY™ , powered by PhasED-Seq™. These patients have extremely low disease burden, a key subgroup who demonstrated excellent disease outcomes in the ALPHA/ALPHA2 trials.

Clinical Development Plan - Non-Hodgkin Lymphoma (NHL)

We are the sponsor of the ALPHA trial of ALLO-501 and ALPHA2 trial of cema-cel, each for patients with R/R NHL or CLL. The ALPHA trial is a Phase 1 clinical trial of ALLO-501 in patients with R/R LBCL and R/R FL. We completed accrual in the ALPHA trial in 2021 and are following patients as part of long-term follow-up. The ALPHA2 trial was initiated as a Phase 1/2 clinical trial for cema-cel in the second quarter of 2020. The Phase 1 portion of the ALPHA2 trial was designed to assess the safety and tolerability at increasing dose levels of cema-cel in patients with R/R LBCL. In the fourth quarter of 2022, we proceeded to the Phase 2 portion of the ALPHA2 trial in adult patients with R/R LBCL. We have also sponsored the EXPAND trial of ALLO-647, which was intended to demonstrate the overall contribution of ALLO-647 to the benefit to risk ratio of the lymphodepletion regimen for cema-cel.

In January 2024 we announced that we would deprioritize the ALPHA2 R/R LBCL and EXPAND trials to focus on our ALPHA3 trial, which seeks to embed cema-cel as part of a 1L consolidation strategy. We have deprioritized the ALPHA2 R/R LBCL trial primarily because the ALPHA3 trial, if successful, could significantly impact the need for cell therapy in later lines of treatment, including the third line (3L) patients being studied in our ALPHA2 trial. The ALPHA3 trial is an open-label, Phase 2, multicenter clinical trial evaluating the safety and efficacy of cema-cel in adult patients with LBCL who have completed R-CHOP and have attained a remission, but who test positive for MRD. The ALPHA3 trial will randomize approximately 240 patients who achieve a complete or partial response to 1L therapy, but who test positive for MRD at their end-of-therapy PET/CT assessment. The patients will be randomized to either treatment with cema-cel or the current standard of care, which is observation. The design, with a primary endpoint of EFS, will initially include two lymphodepletion arms (one with standard fludarabine and cyclophosphamide plus ALLO-647 and one without ALLO-647). One lymphodepletion arm will be discontinued following a planned interim analysis around mid-2025 designed to select the most appropriate regimen for this patient population.

The ALPHA3 trial leverages an investigational diagnostic test developed by Foresight Diagnostics to identify patients who have MRD at the completion of 1L chemoimmunotherapy. Although 1L R-CHOP is curative for many with

LBCL, as noted above, approximately 30% of patients treated will relapse. Under the current standard of care, there is no way to determine which patients are at greater risk of relapse after initially responding to 1L treatment, and so the standard of care has been simply to "watch and wait" for the disease to relapse. Foresight Diagnostics, however, has developed a liquid biopsy testing platform for the measurement of MRD. Based on Foresight Diagnostics' published data, we believe that the Foresight Diagnostics' assay is highly sensitive and predictive of which patients are likely to relapse. By incorporating the Foresight Diagnostics assay into our ALPHA3 trial design, we believe that we can identify the patient population most at risk for relapse and treat those patients with cema-cel.

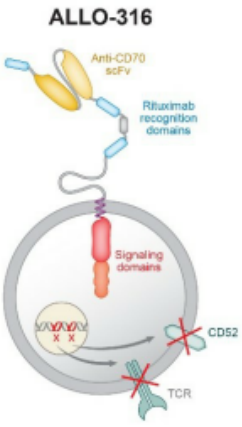
ALPHA3 takes advantage of cema-cel as a one-time, off-the-shelf treatment that can be administered immediately upon discovery of MRD following six cycles of R-CHOP, potentially positioning cema-cel to become the standard "7th cycle" of frontline treatment available to all eligible patients with MRD. ALPHA3 builds on our belief that administration of CAR T therapies to patients with low disease burden improves both safety and efficacy outcomes. Cema-cel's Phase 1 safety profile, with low rates of CRS and immune effector cell-associated neurotoxicity syndrome (ICANS), already permits its use in the outpatient setting in R/R patients and may further improve in patients with no radiological evidence of disease. The ALPHA3 trial was initiated in 2024 and enrollment is currently ongoing with 40 sites activated in the United States.

Assuming favorable outcomes and subject to FDA discussions, we plan to seek FDA approval of cema-cel, and possibly ALLO-647, based on the ALPHA3 trial. Additionally, assuming favorable outcomes, we anticipate that the ALPHA3 data set could be used to support EU regulatory approval. The EMA has granted Marketing Authorizations for products, even when their clinical development programs did not involve any European sites. These approvals are based on thorough evaluations of the products' safety, efficacy, and quality. This practice encompasses a wide range of indications and modalities, including those classified as Advanced Therapy Medicinal Products by the EMA. Later this year, we plan to seek scientific advice from the EMA to assist us with finalizing our regulatory strategy for the EU and the UK. Additionally, in February 2025, we entered into an Amended and Restated Strategic Collaboration Agreement with Foresight Diagnostics which expands our collaboration to enable the development of Foresight Diagnostics' MRD assay as a companion diagnostic in the EU, UK, Canada and Australia in support of Allogene's clinical development of cema-cel.

Anti-CD70 Oncology Development Program

CD70 is an antigen expressed on several types of cancer cells, with strong expression in RCC and limited off-tumor expression. CD70 is selectively expressed in a portion of other solid tumors and blood cancers. While CD70 can be expressed on activated T cells, ALLO-316 was associated with minimal or no fratricide in preclinical studies, meaning that ALLO-316 cells did not mediate the targeted killing of other ALLO-316 cells. Accordingly, we believe progressing allogeneic CAR T cell products directed against CD70 could be promising in solid tumor indications as well as hematological malignancies.

ALLO-316 is manufactured to express a CAR that is designed to target CD70 and gene edited to lack expression of the TCR and CD52 to both minimize the risk of GvHD and to enable use of CD52 monoclonal antibodies to permit a window of persistence of CAR T cells in the patient. In addition, rituximab and CD34 recognition domains have been incorporated in between the scFv and the linker domain, as illustrated below. The rituximab recognition domains allow targeting of cells with rituximab in the event that silencing of CAR T cell activity is desired. The CD34 domain confers recognition by an anti-CD34 antibody, and may be used as a surface marker to monitor ALLO-316 in patients by flow cytometry.



In the first half of 2021, we initiated Phase 1 TRAVERSE clinical trial of ALLO-316 in adult patients with advanced or metastatic ccRCC.

Lead Target Indication: Clear Cell Renal Cell Carcinoma

ccRCC is the most common subtype of renal cancer. Approximately 81,800 new cases of renal cell carcinoma are estimated to be diagnosed in the United States and 14,890 deaths are estimated in 2023, according to the American Cancer Society. The five-year survival rate for patients with advanced kidney cancer is less than 15%.

Systemic therapy (including immunotherapy and molecularly targeted agents), surgery, and radiation therapy all may have a role in the treatment paradigm depending on the extent of disease, sites of involvement, and patient-specific factors. While vascular endothelial growth factor (VEGF)-directed therapies (e.g. sunitinib) represented a first-line standard for over a decade, these therapies have been quickly supplanted by combination therapies incorporating PD-1 immune-checkpoint inhibition as the backbone.

The combination of VEGF and immune check-point inhibitors, such as axitinib and pembrolizumab, respectively, is often used in the first line setting and has shown a median progression-free survival of 15.1 months with an ORR of 59.3% and CR rate of 5.8%. Patients who progress on immune checkpoint-based combination therapies can be treated with agents including cabozantinib, lenvatinib with everolimus, tivozanib, belzutifan or other therapies.

In October 2024, we announced that we received Regenerative Medicine Advanced Therapy (RMAT) designation for ALLO-316 for adult patients with advanced or metastatic RCC. The RMAT designation was based on Phase 1 clinical data from the TRAVERSE trial indicating the potential of ALLO-316 to address the unmet need for patients with difficult-to-treat RCC who have failed multiple standard RCC therapies, including an immune checkpoint inhibitor and a VEGF-targeting therapy.

Results from the Phase 1 ALLO-316 TRAVERSE Trial

On November 7, 2024, we announced interim results from the Phase 1 TRAVERSE trial of ALLO-316 in patients with advanced or metastatic RCC who have progressed on or who are intolerant to standard therapies, including an immune checkpoint inhibitor and a VEGF-targeting therapy. Data from dose escalation cohorts and the ongoing Phase 1b expansion cohort were included. The Phase 1b expansion cohort is evaluating safety and efficacy of ALLO-316 at DL2 (80M CAR T cells) following a standard FC500 (fludarabine (30 mg/m2/day) and cyclophosphamide (500 mg/m2/d) for 3 days) lymphodepletion regimen. The interim results provide proof-of-concept demonstrating the promise of an allogeneic CAR T product candidate to treat CD70-expressing RCC with ALLO-316.

As of the data extract date of October 14, 2024, 39 patients had been enrolled in the ongoing Phase 1 trial, of which 26 were confirmed to have CD70 positive RCC and were evaluable for efficacy outcomes. Following a single infusion of ALLO-316 in heavily pretreated patients, the trial demonstrated best Overall Response Rate (ORR) of 50% and Confirmed Response Rate of 33% in those patients with CD70 Tumor Proportion Score (TPS) of ≥50% who received DL2. Patients with a TPS of ≥50% comprise the majority of patients with advanced or metastatic RCC. Of those with a TPS ≥50, 76% (16/21) experienced a reduction in tumor burden. Two of six (33%) patients with high TPS who received the Phase 1b expansion regimen showed durable responses ongoing at ≥4 months.

Response Rates by CD70 Status and Dose

Patients Evaluable for Disease Outcomes[a] (N=34)					
	CD70 Positive (N=26)				
	All (N=26)	FCA[b] (N=8)	FC[c] (N=18)	DL2 FC500 (Phase 1b) (N=8)	CD70 Negative or Unknown (N=8)
Best overall response,[d] n/N (%) High TPS (≥50) Low TPS (<50)	7/26 (27) 7/21 (33) 0/5 (0)	1/8 (13) 1/6 (17) 0/2 (0)	6/18 (33) 6/15 (40) 0/3 (0)	3/8 (38) 3/6 (50) 0/2 (0)	0/8 (0) NA NA
Confirmed ORR,[e] n/N (%) High TPS (≥50) Low TPS (<50)	5/26 (19) 5/21 (24) 0/5 (0)	1/8 (13) 1/6 (17) 0/2 (0)	4/18 (22) 4/15 (27) 0/3 (0)	2/8 (25) 2/6 (33) 0/2 (0)	0/8 (0) NA NA

[a]Patients evaluable for disease outcome includes those who received ALLO-316 and had at least one tumor assessment.
[b]Standard fludarabine and cyclophosphamide plus ALLO-647
[c]Includes FC300 and FC500
[d]Best overall response across visits did not require confirmation for CR/PR.
[e]Confirmed overall response of CR/PR required confirmation at the subsequent visit.

Regarding safety data, the most common all-grade adverse events were CRS (with only one grade ≥3), fatigue (59%), neutropenia (56%), decreased white blood cell count (54%), anemia (51%) and nausea (51%). ICANS was minimal at 8% and no GvHD occurred.

Most Prevalent Treatment-Emergent Adverse Events (TEAEs) (>40% Any Grade Incidence) and Adverse Events of Special Interest (AESI)

Adverse Event, n(%)	All Patients (N=39)		DL2 FC500 (N=11)	
	All Grades	Grade ≥3	All Grades	Grade ≥3
Any TEAE[a]	39 (100)	29 (81)	11 (100)	8 (73)
CRS	24 (62)	1 (3)	8 (73)	0
Fatigue	23 (59)	1 (3)	2 (18)	0
Neutropenia	22 (56)	20 (51)	7 (64)	7 (64)
White blood cell count decreased	21/(54)	19 (49)	8 (73)	8 (73)
Anemia	20 (51)	13 (33)	7 (64)	5 (46)
Nausea	20 (51)	0	3 (27)	0
Thrombocytopenia	18 (46)	10 (26)	7 (64)	3 (27)
Pyrexia	16 (41)	2 (5)	4 (36)	0
AEs of Special Interest	Any Grade	Grade ≥3	Any Grade	Grade ≥3
Infection[b] Viral infections	24 (62) 13 (33)	12 (31) 2 (5)	5 (46) 2 (18)	2 (18) 0
Neurotoxicity[c] Headache	17 (44) 8 (21)	12 (31) 2 (5)	5 (46) 2 (18)	2 (18) 0
IEC-HS[d]	5 (13)	1 (3)	2 (18)	0
ICANS	3 (8)	0	3 (27)	0
Graft-versus-host disease	0	0	0	0

[a]TEAE included all AEs that started from the first dose date of study drug in each treatment period up to start of another treatment period, death, or the date prior to initiation of another anti-cancer agent, whichever occurred first.
[b]Infection events (62%) were primarily low grade; the most common was viral infections (33%) with cytomegalovirus infection and COVID-19 (any grade, 18% and 15%; Grade ≥3, 0% and 5%, respectively).
[c]Neurotoxicity includes system organ class of nerve system disorders and psychiatric disorders with onset date up to Study Day 30 post ALLO-316 infusion.
[d]IEC-HS includes the preferred terms IEC-HS, HLH, Hemophagocytic lymphohistiocytosis, and atypical HLH. Two patients developed an inflammatory syndrome prior to the existence of IEC-HS as a term in MedDRA, which has been updated as of September 2023.

Two dose-limiting toxicity (DLT) events of autoimmune hepatitis and cardiogenic shock were reported. Each event occurred in two separate participants who received FCA (FC300 plus ALLO-647) lymphodepletion and DL2 of ALLO-316. Three Grade 5 treatment-related adverse events were reported: 1) cardiogenic shock, which was one of the two DLT events; 2) sepsis from multi-drug resistant Klebsiella pneumoniae in a participant who received DL4 of ALLO-316. This participant had a prior episode of muscle abscess and bacteremia from the same multi-drug resistant Klebsiella and was receiving anakinra and dexamethasone for hyperinflammation; 3) failure to thrive in a participant 16 months after treatment with ALLO-316. This subject had tumor response of stable disease (SD) at month 12 and no interval scans to evaluate disease status prior to death.

Clinical Development Plan

The TRAVERSE trial is an open-label, Phase 1, single arm, multicenter clinical trial evaluating the safety and tolerability of ALLO-316 in adult patients with advanced or metastatic ccRCC. Anti-tumor activity, cell kinetics, pharmacodynamics, and correlation of outcome with tumor CD70 expression are evaluated as secondary objectives.

We have developed an investigational in vitro companion diagnostic (IVD) assay designed for use in determining CD70 expression levels for patient selection in TRAVERSE. The trial is now deploying the IVD assay for the purposes of identifying patients most likely to benefit from ALLO-316.

During the advancement of the TRAVERSE trial with ALLO-316, we have observed allogeneic CAR T cell expansion and persistence driven by CD70 CAR that allows elimination of alloreactive host lymphocytes. This biology has brought the potential for clinical efficacy not often seen in patients with R/R RCC but has also resulted in a hyperinflammatory response in some patients as CD70 CAR T cells expand and persist.

Leveraging recent advances in the management of hyperinflammation following autologous CAR T administration, we have developed a diagnostic and treatment algorithm similar to what our management team previously helped develop for CRS and ICANS associated with autologous CAR T. This algorithm may mitigate the treatment-associated hyperinflammatory response without compromising the CAR T function needed to eradicate solid tumors.

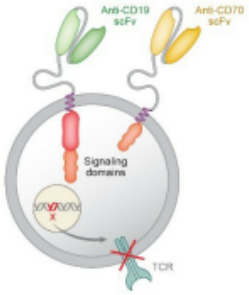
Enrollment in the Phase 1b cohort has been completed and we are now pausing further standard dosing pending durability results for the enrolled patients. Additional data from the Phase 1b expansion cohort is expected to be announced in mid-2025.

Anti-CD19/CD70 Autoimmune Disease Development Program

Autoimmune disease (AID) can affect organs throughout the body. B cells and T cells are two key components of the immune system, each playing distinct roles in the body's defense against pathogens and in maintaining immune tolerance. Effective collaboration between B cells and T cells results in the sustained production of autoantibodies, which are antibodies that mistakenly target and react with a person's own tissues or organs resulting in AID. Autoantibodies are critical to the pathogenesis of many AIDs. As a result, we believe that disruption of the B cell-T cell network could lead to an effective treatment of AIDs. As noted above, CD19 is an antigen expressed on the surface of B cells, including pathogenic autoreactive B cells. Activated T cells, which upregulate CD70, induce sustained production of autoantibodies by B cells from patients affected by AID. Moreover, CD70 expression is elevated on T cells of patients in certain AIDs, suggesting a pathogenic role for CD70+ T cells in AID. Accordingly, we believe progressing allogeneic CAR T cell therapies directed against CD19 and CD70 could be promising in AID indications.

ALLO-329 is manufactured to express two independent CARs designed to target CD19 and CD70. As illustrated below, a single transgene encoding both the CD19 CAR and the CD70 CAR is targeted for insertion into the TRAC locus using site-specific integration, resulting in uniform expression of both CARs and the lack of TCR expression. ALLO-329 is designed to mediate the depletion of CD19+ B cells and pathogenic T cells that upregulate CD70 expression. CD70 is also upregulated on activated B cells and alloreactive lymphocytes. Therefore, ALLO-329 can also target pathogenic CD70+ B cells and prevent allorejection by eliminating CD70+ alloreactive lymphocytes in the patients. The anti-rejection features of ALLO-329 may help reduce or eliminate the need for lymphodepletion prior to treatment with ALLO-329.

ALLO-329



Lead Target Indications: Systemic Lupus Erythematosus (SLE), Lupus Nephritis, Idiopathic Inflammatory Myopathies, and Systemic Sclerosis

In January 2025 we announced that the FDA has cleared our IND for a rheumatology basket study of ALLO-329. Our RESOLUTION trial will evaluate the safety and efficacy of ALLO-329 across multiple autoimmune diseases, including systemic lupus erythematosus (SLE) (including lupus nephritis), idiopathic inflammatory myopathies, and systemic sclerosis. SLE is a chronic, systemic autoimmune disease where the body's immune system mistakenly attacks its own tissues, and is characterized by immune dysregulation, autoantibody production, and inflammation affecting multiple organs. Lupus nephritis (LN) is a serious renal complication of SLE. In LN, the immune system targets the kidneys, leading to inflammation, glomerular damage, and potential renal failure. Idiopathic inflammatory myopathies (IIMs) are a group of rare autoimmune diseases characterized by chronic muscle inflammation and progressive weakness, mainly affecting proximal skeletal muscles. Systemic sclerosis (SSc) is a chronic autoimmune connective tissue disorder characterized by vascular dysfunction, immune dysregulation, and progressive fibrosis affecting the skin and internal organs (lungs, heart, kidneys, and gastrointestinal tract).

Approximately 330,000 cases of SLE (according to Decision Resources Group), 70,000 cases of IIM (according to The Myositis Association), and 100,000 cases of SSc (according to Bergamasco et al, Dove Medical Pres Limited) are estimated to be diagnosed in the United States. These autoimmune diseases generally require targeted immunosuppressive and symptom-specific treatments. SLE is primarily managed with hydroxychloroquine and NSAIDs for mild cases, while severe disease, such as lupus nephritis, necessitates immunosuppressants like mycophenolate mofetil or cyclophosphamide, with biologics such as belimumab and anifrolumab for refractory cases. IIM (including polymyositis and dermatomyositis) is typically treated with high-dose corticosteroids, often combined with methotrexate or azathioprine, while severe or refractory cases may require IVIG or rituximab. SSc management focuses on symptom control, with calcium channel blockers for Raynaud’s phenomenon, mycophenolate mofetil for interstitial lung disease, and vasodilators like sildenafil or bosentan for pulmonary arterial hypertension. Current treatments for SLE, IIM, and SSc have significant limitations, including broad immunosuppression, long-term toxicity, delayed onset of action, disease progression despite therapy, frequent dosing and refractory cases.

Clinical Development Plan

We are developing ALLO-329, an allogeneic CAR T cell product candidate targeting both CD19 and CD70 for the treatment of certain autoimmune diseases. Inclusion of an anti-CD70 CAR in ALLO-329 is designed to reduce or eliminate the need for standard chemotherapy by preventing premature rejection while also targeting CD70+ activated lymphocytes, which may play a direct role in AID pathogenesis. Following the clearance of an IND in January 2025, we plan to initiate a Phase 1 clinical trial (the RESOLUTION trial) of ALLO-329 in adult patients with systemic lupus erythematosus (including lupus nephritis), idiopathic inflammatory myopathies, and systemic sclerosis in mid-2025.

Future Opportunities

Currently, we remain focused on our three key programs described above. As we advance those programs, we may seek to utilize our allogeneic platform to pursue additional targets of interest, particularly through strategic partnerships. These include the additional targets currently in our pipeline as well as other targets that might be validated in the future. For example, we have been developing allogeneic CAR T cell product candidates targeting B-cell maturation antigen (BCMA) for treatment of multiple myeloma (ALLO-715), FLT3 for the treatment of acute myeloid leukemia (ALLO-819), DLL3 for the treatment of small cell lung cancer (ALLO-213), and Claudin 18.2 for the treatment of gastric and pancreatic cancer (ALLO-182).

Our Manufacturing Strategy

We have invested resources to optimize our manufacturing process, including the development of improved analytical methods and instrumentation. We plan to continue to invest in process science, product characterization and manufacturing to continuously improve our manufacturing processes, production and supply chain capabilities over time.

Our product candidates are designed and manufactured via platforms comprised of defined unit operations and technologies. Processes are developed from small to larger scales, incorporating compliant procedures to create cGMP conditions. Although we have a platform-based manufacturing model, each product is unique and for each new product candidate, a developmental phase is necessary to individually customize each engineering step and to create a robust procedure that can later be implemented in a cGMP environment to ensure the production of clinical batches. This work is performed in our process development environment to evaluate and assess variability in each step of the process in order to define the most reliable production conditions.

We are currently utilizing Cell Forge 1 (CF1) our state-of-the-art cell therapy manufacturing facility in Newark, California to manufacture our product candidates. We also utilize separate third-party contractors to manufacture cGMP raw materials that are used for the manufacturing of our product candidates, such as viral vectors that are used to deliver the applicable CAR gene into the T cells. We believe all materials and components utilized in the production of the cell line, viral vector and final T cell product are available from qualified suppliers and suitable for pivotal process development in readiness for registration and commercialization.

Although we are utilizing CF1 for clinical manufacturing, we may continue to rely on CDMOs and other third parties for the manufacturing and processing of our product candidates in the future. We also utilize a CDMO in the United States for the manufacture and supply of ALLO-647 and we plan to continue to rely on the CDMO for future production of ALLO-647. We believe the use of contract manufacturing and testing for our first clinical product candidates has allowed us to rapidly prepare for clinical trials in accordance with our development plans. We plan to maintain a robust supply chain with redundant sources of supply comprised of both internal and external infrastructure. We expect CF1 and third-party manufacturers will be capable of providing and processing sufficient quantities of our product candidates to meet anticipated clinical trial demands.

Strategic Agreements

Allogene Overland Biopharm (CY) Limited (Allogene Overland), later renamed Overland Therapeutics Inc. (Overland Therapeutics), was initially established as a joint venture by us and Overland Pharmaceuticals (CY) Inc. (Overland) pursuant to a Share Purchase Agreement (Share Purchase Agreement), dated December 14, 2020. Concurrently, on December 14, 2020, we entered into a License Agreement (License Agreement) with Allogene Overland for the purpose of developing, manufacturing and commercializing certain allogeneic CAR T cell therapies (JV Licensed Products) for patients in greater China, Taiwan, South Korea and Singapore (the JV Territory).

On May 24, 2024, we, Overland, and Allogene Overland entered into a Share Exchange Agreement (Share Exchange Agreement) pursuant to which Overland's cell therapy business merged into Allogene Overland (the Organizational Restructuring). Under a separate agreement between Overland and HH BioPharma Holdings Ltd. (HBP) executed on May 24, 2024, Overland distributed all Series Seed Preferred Shares of Allogene Overland held by Overland to HBP and HBP has assumed all rights and obligations attached to such shares and all rights and obligations of Overland under the Share Exchange Agreement. In connection with the Organizational Restructuring, on May 24, 2024, we and Allogene Overland PRC, entered into a First Amendment to the License Agreement (the License Amendment) to amend and supplement certain provisions of the License Agreement. Under the License Amendment, we continue to grant Allogene Overland PRC an exclusive license to develop, manufacture, and commercialize the JV Licensed Products in the JV Territory, with us retaining exclusive rights to the JV Licensed Products outside the JV Territory

We have also entered into multiple additional strategic agreements and collaborations, including an Asset Contribution Agreement with Pfizer (the Pfizer Agreement), a License Agreement with Cellectis (the Cellectis Agreement), the Servier Agreement, a Collaboration and License Agreement (the Notch Agreement) with Notch Therapeutics Inc. (Notch), a License and Collaboration Agreement with Antion, and a Strategic Collaboration Agreement with Foresight Diagnostics.

For additional information regarding our significant agreements, see Note 6 to our consolidated financial statements appearing elsewhere in this Annual Report.

Intellectual Property

Our commercial success depends in part on our ability to obtain and maintain proprietary protection for our product candidates, as well as novel discoveries, product development technologies, and know-how. Our commercial success also depends in part on our ability to operate without infringing on the proprietary rights of others and to prevent others from infringing our proprietary rights. Our policy is to develop and maintain protection of our proprietary position by, among other methods, filing or in-licensing U.S. and foreign patents and applications related to our technology, inventions, and improvements that are important to the development and implementation of our business.

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

With respect to both licensed and company-owned intellectual property, we cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we be sure that any of our existing patents or any patents that may be granted to us in the future will be commercially useful in protecting our commercial products and methods of using and manufacturing the same.

We are actively building our intellectual property portfolio around our product candidates and our discovery programs, based on our own intellectual property as well as licensed intellectual property. Following the execution of the Pfizer Agreement, we are the owner of, co-owner of, or the licensee of multiple patents and patent applications in the United States and worldwide. These licensed assets include rights to the Cellectis TALEN® gene-editing technology to engineer T cells that lack functional TCRs and to inactivate the CD52 gene in donor cells. We have exclusive worldwide rights to these patents for certain antigen targets, including BCMA, CD70, FLT3, DLL3 and Claudin 18.2, and have U.S., EU, and UK rights to these patents for CD19. We also have rights to Cellectis intellectual property for technology covering an engineered T cell therapy combining CD52 gene knockout in combination with an anti-CD52 antibody for certain products directed against certain antigen targets. For our lead programs, our patent rights are generally composed of patents and pending patent applications that are solely owned by us, co-owned with Servier, co-owned with Cellectis, co-owned with Pfizer, exclusively licensed from Pfizer, exclusively licensed from Servier, or exclusively licensed from Cellectis.

Our patent portfolio includes protection for our clinical-stage product candidates, ALLO-501, cema-cel, ALLO-316, ALLO-329, ALLO-715, and ALLO-605, as well as our research-stage candidates. With respect to ALLO-501 and cema-cel, we have an exclusive license from Servier to patent rights in the United States covering compositions of matter of and methods of making and using ALLO-501 and cema-cel. With respect to ALLO-715, ALLO-605 and ALLO-316, we have an exclusive license from Pfizer to patent rights covering ALLO-715, ALLO-605, and ALLO-316 in the United States and in foreign jurisdictions. These rights cover compositions of matter of and methods of making and using ALLO-715, ALLO-605 and ALLO-316. We also have patent rights to the TurboCAR™ technology solely owned by us, including technology that covers the TurboCAR™ construct that is part of ALLO-605. More generally, our patent portfolio and filing strategy is designed to provide multiple layers of protection by pursuing claims directed toward, for example: (1) antigen binding domains directed to the targets of our product candidates; (2) CAR constructs used in our product candidates; (3) methods of treatment for therapeutic indications; (4) manufacturing processes, preconditioning methods, and dosing regimens; and (5) immune evasion and other gene and cell engineering technology.

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file, the patent term, generally, 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 patent term adjustment, which compensates a patentee for administrative delays by the United States Patent and Trademark Office in granting a patent, or may be shortened if a patent is terminally disclaimed over an earlier-filed patent. In the United States, the term of a patent that covers an FDA-approved drug may also be eligible for a patent term extension of up to five years under the Hatch-Waxman Act, which is designed to compensate for the patent term lost during the FDA regulatory review process. The length of the patent term extension involves a complex calculation based on the length of time it takes for regulatory review. A patent term extension under the Hatch-Waxman Act cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only one patent applicable to an approved drug may be extended. Moreover, a patent can only be extended once, and thus, if a single patent is applicable to multiple products, it can only be extended based on one product. Similar provisions are available in Europe and certain other foreign jurisdictions to extend the term of a patent that covers an approved drug.

Competition

Oncology is a highly competitive market for drug development. If successfully developed, our products will compete with therapies that have been developed or are in development at biopharmaceutical companies, academic research institutions, governmental agencies and public and private research institutions. We anticipate increasing competition from existing and new cell-based therapies, including products that are both autologous and allogeneic in nature. We also anticipate competition from other therapeutic modalities, including antibodies, bispecific T cell engagers, antibody drug conjugates, and small molecule therapeutics.

Autologous T cell therapies directed at CD19 have been commercialized by Novartis, Kite/Gilead and Bristol-Myers Squibb Company (BMS) and are witnessing increased adoption in the marketplace. In August 2017, Novartis obtained FDA approval to commercialize Kymriah® for the treatment of children and young adults with B-cell ALL that is refractory or has relapsed at least twice. In May 2018, Kymriah® received FDA approval for adults with certain types of LBCL who have not responded to, or who have relapsed after, at least two other types of systemic treatment (3rd-line LBCL), and in May 2022, Kymriah® received FDA approval for the treatment of adult patients with relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy. In October 2017, Kite/Gilead obtained FDA approval to commercialize Yescarta®, for the treatment of adult patients with 3rd-line LBCL. This was followed by approval of Yescarta® for R/R FL in March 2021 and approval of 2nd-line LBCL in April 2022. Kite has also received FDA approval for a second autologous CD19-directed T cell therapy, Tecartus®, for use in patients with R/R mantle cell lymphoma and adult patients with R/R B-cell ALL. In February 2021, BMS obtained FDA approval for its anti-CD19 autologous T cell therapy, Breyanzi® for the treatment of adults with 3rd-line LBCL. The label of Breyanzi® label was extended to 2nd-line LBCL in June 2022, R/R Chronic Lymphocytic Leukemia (CLL) in March 2024, R/R FL in May 2024, and R/R Mantle Cell Lymphoma (MCL) in May 2024.

Autologous cell therapies directed at BCMA have been commercialized by BMS and Jannsen, a Johnson & Johnson company. In March 2021, BMS and partner 2seventy bio, Inc. received FDA approval of Abecma®, an anti-BCMA autologous T cell therapy, for the treatment of adult patients with multiple myeloma who have received at least four prior therapies. Jannsen and partner Legend Bio received approval for Carvykti®, an anti-BCMA autologous T cell therapy, for the same indication in February 2022. Both Abecma® and Carvykti® have succeeded in pivotal trials in earlier lines of R/R myeloma and have gained label extensions into this market in 2024.

Autologous T cell therapies are being developed by a number of additional companies, including but not limited to 2seventy bio, Inc., Adaptimmune Therapeutics PLC, Alaunos Therapeutics, Inc., Arcellx, Inc., Arsenal Biosciences, Inc., AstraZeneca plc, Autolus Therapeutics plc, CARGO Therapeutics, Inc. Eureka Therapeutics, Inc., Galapagos NV, Gilead Sciences, Inc., ImmPACT Bio, USA Inc., Instil Bio, Inc., Iovance Biotherapeutics, Inc., Legend Biotech Corp., Lyell Immunopharma Inc., Mustang Bio, Inc., Triumvira Immunologics, and TScan Therapeutics, Inc.

Autologous CAR T therapy has made significant advances in addressing R/R NHL, and has moved to earlier lines of therapy, as further described above. We do not, however, believe that autologous CAR T therapy will be a viable option in the 1L consolidation setting because of the lengthy lead time for the individualized manufacturing process for autologous CAR T. Once it is determined that a patient is MRD positive following standard 1L treatment, we believe that the speed at which a patient is treated with CAR T therapy will enhance response rates. Published results of front-line chemotherapy outcomes suggest that MRD positive patients are likely to progress, and some patients may do so very quickly (i.e., within a matter of weeks after completing 1L therapy). Furthermore, data suggests that patients who have low burden of disease when they receive CAR T cells tend to have better safety and efficacy outcomes, including lower rates of CRS and more durable remissions. As a result, we believe that it will be important that patients receive CAR T therapy as soon as possible following an MRD positive diagnosis, which will not allow for the lengthy manufacturing process of autologous CAR T.

Allogeneic T cell products have yet to receive FDA approval though the number of companies developing allogeneic product candidates is substantial. These include AstraZeneca, plc, Atara Biotherapeutics, Inc., Beam Therapeutics, Inc., Caribou Biosciences, Inc., CRISPR Therapeutics AG, Editas Medicine, Inc., F. Hoffmann-La Roche AG, Fate Therapeutics, Inc., Gilead Sciences, Inc., Imugene Ltd., Intellia Therapeutics, Inc., Legend Biotech Corp., Precision Biosciences, Inc., and Sana Biotechnology, Inc. Some of the allogeneic T cell candidates under development target the same antigens that are part of our clinical pipeline, such as CD19, BCMA and CD70. Additionally, Cellectis has several fully-owned allogeneic CAR T programs that could compete with programs that fall outside our agreement with Cellectis.

There are also cell therapies under development that are based upon cell types other than the common type of T cells used by us and known as alpha/beta T cells. These include product candidates derived from natural killer cells, natural killer T cells, gamma/delta T cells and macrophage cells. Companies developing such therapies include Adicet Bio, Inc., Artiva Biotherapeutics, Inc., Carisma Therapeutics, Inc., Cytovia Therapeutics, Inc., Celularity, Inc., Century Therapeutics, Inc., Fate Therapeutics, Inc., Gamida Cell Ltd., In8bio, Inc., Lyell Immunopharma, Inc., Nkarta, Inc., Shoreline Bio, Inc., and Takeda Pharmaceutical Company Limited.

Competition may also arise from non-cell based immune oncology platforms. For instance, we may experience competition from companies, such as AbbVie, Inc., Amgen Inc., BMS, Compass Therapeutics, Inc., F. Hoffmann-La Roche

AG, Genmab A/S, GlaxoSmithKline plc, Immunocore Holdings plc, Johnson & Johnson, MacroGenics, Inc., Merck & Co. Inc., Merus N.V., Pfizer, Regeneron Pharmaceuticals, Inc., and Xencor Inc., that are pursuing bispecific T cell engagers that target both the cancer antigen and T cell receptor, thus bringing both cancer cells and T cells in close proximity to maximize the likelihood of an immune response to the cancer cells. Multiple bi-specific T cell engagers targeting BCMA for myeloma and CD20 for lymphoma are advancing rapidly in development and the first products in each category gained FDA approval in 2022. Additionally, companies, such as ADC Therapeutics SA, Amgen Inc., Daiichi Sankyo Company, Limited, Gilead Sciences, Inc., GlaxoSmithKline plc, ImmunoGen, Inc., Pfizer Inc., and Sutro Biopharma, Inc. are pursuing antibody drug conjugates, which utilize the targeting ability of antibodies to deliver cell-killing agents directly to cancer cells.

In addition to the significant competition noted above in oncology markets, as early data in the use of CAR T cell therapy for the treatment of autoimmune disease has been emerging since 2022, there have been many companies initiating autologous and/or allogeneic cell therapy development programs that would be in direct competition to our autoimmune program. For example, we may experience competition in these markets from companies such as Adicet Bio, Inc., Arcellx, Inc., Atara Biotherapeutics, Inc., Autolus Therapeutics plc, BMS, Cabaletta Bio, Inc., Caribou Biosciences, Inc., Cartesian Therapeutics, Inc., CRISPR Therapeutics AG, Fate Therapeutics, Inc., Gracell Biotechnologies, Inc., ImmPACT Bio USA, Inc., Kyverna Therapeutics, Inc., Nkarta, Inc., Novartis, Sana Biotechology, Inc., and TG Therapeutics Inc.

Many of our competitors, either alone or with their collaboration partners, have significantly greater financial resources and expertise in research and development, pre-clinical testing, clinical trials, manufacturing, and marketing than we do. Future collaborations and mergers and acquisitions may result in further resource concentration among a smaller number of competitors.

Our commercial potential could be reduced or eliminated if our competitors develop and commercialize products that are better tolerated, more effective, have fewer or less severe side effects, are more convenient or are less expensive than products 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 or make our development more complicated. The key competitive factors affecting the success of all of our programs are likely to be efficacy, safety, convenience, and cost of manufacturing.

These competitors may also vie for a similar pool of qualified scientific and management talent, sites and patient populations for clinical trials, and investor capital, as well as for technologies complementary to, or necessary for, our programs.

Government Regulation and Product Approval

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

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

U.S. Product Development Process

In the United States, the FDA regulates pharmaceutical and biological products under the Federal Food, Drug and Cosmetic Act (FDCA), the Public Health Service Act (PHSA) and their implementing regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant to

administrative or judicial sanctions. FDA sanctions could include, among other actions, refusal to approve pending applications, withdrawal of an approval, a clinical hold, warning letters, product recalls or withdrawals from the market, product seizures, total or partial suspension of production or distribution injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties. We have been placed on clinical hold previously and any future agency or judicial enforcement action could have a material adverse effect on us. The process required by the FDA before a biological product may be marketed in the United States generally involves the following:

- completion of nonclinical laboratory tests and animal studies according to good laboratory practices (GLPs) and applicable requirements for the humane use of laboratory animals or other applicable regulations;
- submission to the FDA of an IND, which must become effective before human clinical trials may begin;
- approval by an independent Institutional Review Board (IRB) or ethics committee at each clinical site before the trial is commenced;
- performance of adequate and well-controlled human clinical trials according to the FDA's regulations commonly referred to as good clinical practices (GCPs) and any additional requirements for the protection of human research patients and their health information, to establish the safety and efficacy of the proposed biological product for its intended use;
- submission to the FDA of a BLA for marketing approval that includes substantial evidence of safety, purity, and potency from results of nonclinical testing and clinical trials, and which is validated as complete for review by the FDA;
- satisfactory completion of an FDA Advisory Committee review, if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the biological product is produced to assess compliance with cGMP, to assure that the facilities, methods and controls are adequate to preserve the biological product's identity, strength, quality and purity and, if applicable, the FDA's current good tissue practices (GTPs) for the use of human cellular and tissue products;
- potential FDA audit of the nonclinical study and clinical trial sites that generated the data in support of the BLA; and
- FDA review and approval, or licensure, of the BLA.

Before testing any biological product candidate, including our product candidates, in humans, the product candidate enters the preclinical testing stage. Preclinical tests, also referred to as nonclinical studies, include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies to assess the potential safety and activity of the product candidate. The conduct of the preclinical tests must comply with federal regulations and requirements including GLPs. The clinical trial sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. Some preclinical testing may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions regarding the proposed clinical trials and places the trial on a clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. The FDA may also impose clinical holds on a biological product candidate at any time before or during clinical trials due to safety concerns or non-compliance. If the FDA imposes a clinical hold, trials may not recommence without FDA authorization and then only under terms authorized by the FDA. Accordingly, we cannot be sure that submission of an IND will result in the FDA allowing clinical trials to begin, or that, once begun, issues will not arise that suspend or terminate such trials.

Clinical trials involve the administration of the biological product candidate to patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor subject safety, including stopping rules that assure a clinical trial will be stopped if certain adverse events should occur. Each protocol and any amendments to the protocol must be submitted to the FDA as part of the IND. Clinical trials must be conducted and monitored in accordance with the FDA's regulations comprising the GCP requirements, including the requirement that all research patients provide informed consent. Further, each clinical trial must be reviewed and approved by an independent IRB at or servicing each institution at which the clinical trial will be conducted. An IRB is charged with protecting the welfare and rights of trial participants and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the form and content of the informed consent that must be signed by each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. Certain clinical trials involving human gene transfer research also must be overseen by an Institutional Biosafety Committee (IBC), a standing committee to provide peer review of the safety of research plans, procedures, personnel training and environmental risks of work involving recombinant DNA molecules. IBCs are typically assigned certain review responsibilities relating to the use of recombinant DNA molecules, including reviewing potential environmental risks, assessing containment levels, and evaluating the adequacy of facilities, personnel training, and compliance with the National Institutes of Health Guidelines. We may also engage an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board, to provide authorization for whether or not a study may move forward at designated check points based on access to certain data from the study and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. There are also requirements governing the reporting of ongoing clinical studies and clinical study results to public registries.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- *Phase 1.* The biological product is initially introduced into healthy human subjects and tested for safety. In the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients.
- *Phase 2.* The biological product is evaluated in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance, optimal dosage and dosing schedule.
- *Phase 3.* Clinical trials are undertaken to further evaluate dosage, clinical efficacy, potency, and safety in an expanded patient population at geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk to benefit ratio of the product and provide an adequate basis for product labeling.

Long term follow-up for all patients who get marketed product and post-approval clinical trials, sometimes referred to as Phase 4 clinical trials, may be required after initial marketing approval. These clinical trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication, particularly for long-term safety follow-up. 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 results of the clinical trials must be submitted to the FDA. Written IND safety reports must be promptly submitted to the FDA, and the investigators for serious and unexpected adverse events, any findings from other studies, tests in laboratory animals or *in vitro* testing that suggest a significant risk for human patients, or any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must submit an IND safety report within 15 calendar days after the sponsor determines that the information qualifies for reporting. The sponsor also must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction within seven calendar days after the sponsor's initial receipt of the information. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, if at all. The FDA or the sponsor or its data safety monitoring board may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research patients are being exposed to an unacceptable health risk, including risks inferred from other unrelated immunotherapy trials. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the biological product has been associated with unexpected serious harm to patients.

Concurrently with clinical trials, companies usually complete additional studies and must also develop additional information about the physical characteristics of the biological product as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. To help reduce the risk of the introduction of adventitious agents with use of biological products, the PHSA emphasizes the importance of manufacturing control for products whose attributes cannot be precisely defined. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the sponsor must develop methods for testing the identity, strength, quality, potency and purity of the final biological product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the biological product candidate does not undergo unacceptable deterioration over its shelf life.

U.S. Review and Approval Processes

After the completion of clinical trials of a biological product, FDA approval of a BLA must be obtained before commercial marketing of the biological product. The BLA submission must include results of product development, laboratory and animal studies, human trials, information on the manufacture and composition of the product, proposed labeling and other relevant information. The testing and approval processes require substantial time and effort and there can be no assurance that the FDA will accept the BLA for filing and, even if filed, that any approval will be granted on a timely basis, if at all.

Under the Prescription Drug User Fee Act (PDUFA), as amended, each BLA must be accompanied by a significant user fee. The FDA adjusts the PDUFA user fees on an annual basis. PDUFA also imposes an annual program fee for biological products. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on BLAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

Within 60 or 74 days following submission of the application, the FDA reviews a BLA submitted to determine if it is substantially complete before the agency accepts it for filing. The FDA may refuse to file any BLA that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the BLA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review of the BLA. The FDA reviews the BLA to determine, among other things, whether the proposed product is safe, potent, and/or effective for its intended use, and has an acceptable purity profile, and whether the product is being manufactured in accordance with cGMP to assure and

preserve the product's identity, safety, strength, quality, potency and purity. The FDA may refer applications for novel biological products or biological products that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. During the biological product approval process, the FDA also will determine whether a Risk Evaluation and Mitigation Strategy (REMS) is necessary to assure the safe use of the biological product. A REMS is a safety strategy to manage a known or potential serious risk associated with a medicine and to enable patients to have continued access to such medicines by managing their safe use, and could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. If the FDA concludes a REMS is needed, the sponsor of the BLA must submit a proposed REMS. The FDA will not approve a BLA without a REMS, if required.

Before approving a BLA, the FDA will inspect the facilities at which the product is manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. For immunotherapy products, the FDA also will not approve the product if the manufacturer is not in compliance with the GTPs, to the extent applicable. These are FDA regulations and guidance documents that govern the methods used in, and the facilities and controls used for, the manufacture of human cells, tissue, 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 GTP 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. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure that the clinical trials were conducted in compliance with IND trial requirements and GCP requirements. To assure cGMP, GTP and GCP compliance, an applicant must incur significant expenditure of time, money and effort in the areas of training, record keeping, production, and quality control.

Notwithstanding the submission of relevant data and information, the FDA may ultimately decide that the BLA does not satisfy its regulatory criteria for approval and deny approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data. If the agency decides not to approve the BLA in its present form, the FDA will issue a complete response letter that describes all of the specific deficiencies in the BLA identified by the FDA. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical trials. Additionally, the complete response letter may include recommended actions that the applicant might take to place the application in a condition for approval. If a complete response letter is issued, the applicant may either resubmit the BLA, addressing all of the deficiencies identified in the letter, or withdraw the application.

If a product receives regulatory approval, the approval may be limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. The FDA may impose restrictions and conditions on product distribution, prescribing, or dispensing in the form of a risk management plan, or otherwise limit the scope of any approval. In addition, the FDA may require post marketing clinical trials, sometimes referred to as Phase 4 clinical trials, designed to further assess a biological product's safety and effectiveness, and testing and surveillance programs to monitor the safety of approved products that have been commercialized.

In addition, under the Pediatric Research Equity Act (PREA), a BLA or supplement to a BLA must contain data to assess the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of data or full or partial waivers.

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making available in the United States a drug or biologic for this type of disease or condition will be recovered from sales in the United States for that drug or biologic. Orphan drug designation must be requested before submitting a BLA. After the FDA grants orphan drug designation, the generic identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. The orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review or approval process.

If a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications, including a full BLA, to market the same biologic for the same indication for seven years, except in limited

circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity. 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. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the BLA application user fee.

A designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. In addition, exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

Expedited Development and Review Programs

The FDA has a fast track program that is intended to expedite or facilitate the process for reviewing new products that meet certain criteria. Specifically, new products are eligible for fast track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast track designation applies to the combination of the product and the specific indication for which it is being studied. Unique to a fast track product, the FDA may consider for review sections of the BLA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the BLA, the FDA agrees to accept sections of the BLA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the BLA.

Any product submitted to the FDA for approval, including a product with a fast track designation, may also be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. A product is eligible for priority review if it has the potential to provide safe and effective therapy where no satisfactory alternative therapy exists or a significant improvement in the treatment, diagnosis or prevention of a disease compared to marketed products. The FDA will attempt to direct additional resources to the evaluation of an application for a new product designated for priority review in an effort to facilitate the review. Additionally, a product may be eligible for accelerated approval. Products studied for their safety and effectiveness in treating serious or life-threatening diseases or conditions may receive accelerated approval upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require that a sponsor of a drug or biological product receiving accelerated approval perform adequate and well-controlled post-marketing clinical studies. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

Regenerative Medicine Advanced Therapy (RMAT) designation was established by FDA to facilitate an efficient development program for, and expedite review of, any drug that meets the following criteria: (1) it qualifies as a RMAT, which is defined as a cell therapy, therapeutic tissue engineering product, human cell and tissue product, or any combination product using such therapies or products, with limited exceptions; (2) it is intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition; and (3) preliminary clinical evidence indicates that the drug has the potential to address unmet medical needs for such a disease or condition. RMAT designation provides potential benefits that include more frequent meetings with FDA to discuss the development plan for the product candidate and eligibility for rolling review and priority review. Products granted RMAT designation may also be eligible for accelerated approval on the basis of a surrogate or intermediate endpoint 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. Once approved, when appropriate, the FDA can permit fulfillment of post-approval requirements under accelerated approval through the submission of clinical evidence, clinical studies, patient registries, or other sources of real world evidence such as electronic health records; through the collection of larger confirmatory datasets; or through post-approval monitoring of all patients treated with the therapy prior to approval.

Breakthrough therapy designation is also intended to expedite the development and review of products that treat serious or life-threatening conditions. The designation by FDA requires preliminary clinical evidence that a product candidate, alone or in combination with other drugs and biologics, demonstrates substantial improvement over currently available therapy on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Breakthrough therapy designation comes with all of the benefits of fast track designation, which means that the sponsor may file sections of the BLA for review on a rolling basis if certain conditions are satisfied, including an agreement with FDA on the proposed schedule for submission of portions of the application and the payment of applicable user fees before the FDA may initiate a review.

Fast track designation, priority review, RMAT and Breakthrough therapy designation do not change the standards for approval but may expedite the development or approval process.

Post-Approval Requirements

Any products for which we receive FDA approvals are subject to continuing regulation by the FDA, including, among other things, record-keeping requirements, reporting of adverse experiences with the product, providing the FDA with updated safety and efficacy information, product sampling and distribution requirements, and complying with FDA promotion and advertising requirements, which include, among others, standards for direct-to-consumer advertising, restrictions on promoting products for uses or in patient populations that are not described in the product's approved uses (known as "off-label use"), limitations on industry-sponsored scientific and educational activities, and requirements for promotional activities involving the internet. Although a physician may prescribe a legally available product for an off-label use, if the physician deems such product to be appropriate in his/her professional medical judgment, a manufacturer may not market or promote off-label uses. However, it is permissible to share in certain circumstances truthful and not misleading information that is consistent with the product's approved labeling.

In addition, quality control and manufacturing procedures must continue to conform to applicable manufacturing requirements after approval to ensure the long-term stability of the product. cGMP regulations require among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. Manufacturers and other entities involved in the manufacture and distribution of approved products are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. Discovery of problems with a product after approval may result in restrictions on a product, manufacturer, or holder of an approved BLA, including, among other things, recall or withdrawal of the product from the market. In addition, changes to the manufacturing process are strictly regulated, and depending on the significance of the change, may require prior FDA approval before being implemented. Other types of changes to the approved product, such as adding new indications and claims, are also subject to further FDA review and approval.

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

U.S. Marketing Exclusivity

The Biologics Price Competition and Innovation Act (BPCIA) amended the PHSA to authorize the FDA to approve similar versions of innovative biologics, commonly known as biosimilars. A competitor seeking approval of a biosimilar must file an application to establish its molecule as highly similar to an approved innovator biologic, among other requirements. The BPCIA, however, bars the FDA from approving biosimilar applications for 12 years after an innovator biological product receives initial marketing approval. This 12-year period of data exclusivity may be extended by six months, for a total of 12.5 years, if the FDA requests that the innovator company conduct pediatric clinical investigations of the product.

Depending upon the timing, duration and specifics of the FDA approval of the use of our product candidates, some of our U.S. patents, if granted, may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Act. The Hatch-Waxman Act permits a patent restoration term of up to five years, as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of a BLA plus the time between the submission date of a BLA and the approval of that application. Only one patent applicable to an approved product is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The U.S. Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we may intend to apply for restoration of patent term for one of our currently owned or licensed patents to add patent life beyond its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant BLA.

Pediatric exclusivity is another type of regulatory market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric trial in accordance with an FDA-issued "Written Request" for such a trial.

FDA Approval and Regulation of Medical Devices and Companion Diagnostics

If safe and effective use of a therapeutic depends on an in vitro diagnostic, then the FDA generally will require approval or clearance of that diagnostic, known as a companion diagnostic, at the same time that the FDA approves the therapeutic product. In August 2014, the FDA issued final guidance clarifying the requirements that apply to approval of therapeutic products and in vitro companion diagnostics. According to the guidance, if the FDA determines that a companion diagnostic device is essential to the safe and effective use of a novel therapeutic product or indication, the FDA generally will not approve the therapeutic product or new therapeutic product indication if the companion diagnostic device is not approved or cleared for that indication. Approval or clearance of the companion diagnostic device will ensure that the device has been adequately evaluated and has adequate performance characteristics in the intended population. The review of in vitro companion diagnostics in conjunction with the review of our product candidates in development for cancer will, therefore, likely involve coordination of review by the FDA's Center for Drug Evaluation and Research and the FDA's Center for Devices and Radiological Health Office of In Vitro Diagnostics and Radiological Health.

Under the FDCA, in vitro diagnostics, including companion diagnostics, are regulated as medical devices. In the U.S., the FDCA and its implementing regulations, and other federal and state statutes and regulations govern, among other things, medical device design and development, preclinical and clinical testing, premarket clearance or approval, registration and listing, manufacturing, labeling, storage, advertising and promotion, sales and distribution, export and import, and post-market surveillance. Unless an exemption applies, medical devices, including companion diagnostic tests, require marketing clearance or approval from the FDA prior to commercial distribution.

The two primary types of FDA marketing authorization applicable to a medical device are premarket notification ("510(k) clearance") and premarket approval ("PMA"). To obtain 510(k) clearance, a manufacturer must submit to the FDA a premarket notification submission demonstrating that the proposed device is "substantially equivalent" to a legally marketed predicate device. The FDA's 510(k) clearance process usually takes from three to twelve months but may take longer. The FDA may require additional information, including clinical data, to make a determination regarding substantial equivalence. If the FDA agrees that the device is substantially equivalent to a predicate device currently on the market, it will grant 510(k) clearance to commercially market the device. If the FDA determines that the device is "not substantially equivalent" to a previously cleared device, the device is automatically designated as a Class III (i.e., high-risk) device. The device sponsor must then fulfill more rigorous PMA requirements or can request a risk-based classification determination for the device in accordance with the "de novo" process, which is a route to market for novel medical devices that are low to moderate risk and are not substantially equivalent to a predicate device.

After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change or modification in its intended use, will require a new 510(k) clearance or depending on the modification, approval of a PMA application or de novo classification. The FDA requires each manufacturer to determine whether the proposed change requires submission of a 510(k), de novo classification or a PMA in the first instance, but the FDA can review any such decision and disagree with a manufacturer's determination. If the FDA disagrees with a manufacturer's determination, the FDA can require the manufacturer to cease marketing and/or request the recall of the modified device until it receives 510(k) clearance, approval of a PMA application, or issuance of a de novo classification. Also, in these circumstances, the manufacturer may be subject to significant regulatory fines or penalties.

The PMA process, including the gathering of clinical and preclinical data and the submission to and review by the FDA, can take several years or longer. It involves a rigorous premarket review during which the applicant must prepare and provide the FDA with reasonable assurance of the device's safety and effectiveness and information about the device and its components regarding, among other things, device design, manufacturing and labeling. PMA applications are subject to an application fee. In addition, PMAs for certain devices must generally include the results from extensive preclinical and adequate and well-controlled clinical trials to establish the safety and effectiveness of the device for each indication for which FDA approval is sought. In particular, for a diagnostic, a PMA application typically requires data regarding analytical and clinical validation studies. As part of the PMA review, the FDA will typically inspect the manufacturer's facilities for compliance with the QSR which imposes elaborate testing, control, documentation and other quality assurance requirements.

Approval of a PMA is not guaranteed, and the FDA may ultimately respond to a PMA submission with a not approvable determination based on deficiencies in the application and require additional clinical trial or other data that may be expensive and time-consuming to generate and that can substantially delay approval. If the FDA's evaluation of the PMA application is favorable, the FDA typically issues an approvable letter requiring the applicant's agreement to specific conditions, such as changes in labeling, or specific additional information, such as submission of final labeling, in order to

secure final approval of the PMA. If the FDA's evaluation of the PMA or manufacturing facilities is not favorable, the FDA will deny approval of the PMA or issue a not approvable letter. A not approvable letter will outline the deficiencies in the application and, where practical, will identify what is necessary to make the PMA approvable. The FDA may also determine that additional clinical trials are necessary, in which case the PMA may be delayed for several months or years while the trials are conducted and then the data submitted in an amendment to the PMA. If the FDA concludes that the applicable criteria have been met, the FDA will issue a PMA for the approved indications, which can be more limited than those originally sought by the applicant. The PMA can include post-approval conditions that the FDA believes necessary to ensure the safety and effectiveness of the device, including, among other things, restrictions on labeling, promotion, sale and distribution. Once granted, approval may be withdrawn by the FDA if compliance with post approval requirements, conditions of approval or other regulatory standards are not maintained, or problems are identified following initial marketing.

After a device is placed on the market, it remains subject to significant regulatory requirements. Medical devices may be marketed only for the uses and indications for which they are cleared or approved. Device manufacturers must also establish registration and device listings with the FDA. A medical device manufacturer's manufacturing processes and those of its suppliers are required to comply with the applicable portions of the QSR, which cover the methods and documentation of the design, testing, production, processes, controls, quality assurance, labeling, packaging and shipping of medical devices. Domestic facility records and manufacturing processes are subject to periodic unscheduled inspections by the FDA. The FDA also may inspect foreign facilities that export products to the U.S.

Other U.S. Healthcare Laws and Compliance Requirements

In the United States, our activities are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including but not limited to, the Centers for Medicare & Medicaid Services (CMS), other divisions of the U.S. Department of Health and Human Services (HHS) (e.g., the Office of Inspector General, the U.S. Department of Justice (DOJ), and individual U.S. Attorney offices within the DOJ, and state and local governments). For example, our business practices, including any of our research and future sales, marketing and scientific/educational grant programs may be required to comply with the anti-fraud and abuse provisions of the Social Security Act, the false claims laws, the patient data privacy and security provisions of the Health Insurance Portability and Accountability Act (HIPAA), transparency requirements, and similar state, local and foreign laws, each as amended.

The federal Anti-Kickback Statute prohibits, among other things, any person or entity, from knowingly and willfully offering, paying, soliciting or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any item, good, facility or service reimbursable under Medicare, Medicaid or other federal healthcare programs. The term remuneration has been interpreted broadly to include anything of value. The federal Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, formulary managers, and other individuals and entities on the other. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution. The exceptions and safe harbors are drawn narrowly and require strict compliance in order to offer protection. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. Our practices may not in all cases meet all of the criteria for protection under a statutory exception or regulatory safe harbor.

Additionally, the intent standard under the federal Anti-Kickback Statute was amended by the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the Affordable Care Act), to a stricter standard such that a person or entity no longer needs to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation. Rather, if "one purpose" of the remuneration is to induce referrals, the federal Anti-Kickback Statute is violated. In addition, the Affordable Care Act codified case law that a claim that includes items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act (discussed below).

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

The federal civil False Claims Act prohibits, among other things, any person or entity from knowingly presenting, or causing to be presented, a false claim for payment to, or approval by, the federal government or knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes "any request or demand" for money or property presented to the U.S. government. For example, pharmaceutical and other healthcare companies have

been, and continue to be, investigated or prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product and for causing false claims to be submitted because of the companies' marketing of the product for unapproved, and thus non-reimbursable, uses.

HIPAA created additional federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud or to obtain, by means of false or fraudulent pretenses, representations or promises, any money or property owned by, or under the control or custody of, any healthcare benefit program, including private third-party payors and knowingly and willfully falsifying, concealing or covering up by trick, scheme or device, a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services.

Also, many states have similar fraud and abuse statutes or regulations that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

We may be subject to data privacy and security regulations by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (HITECH) and their implementing regulations, imposes requirements on certain types of individuals and entities relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to business associates that are independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity as well as their covered subcontractors. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Additionally, the federal Physician Payments Sunshine Act within the Affordable Care Act, and its implementing regulations, require that certain manufacturers of drugs, devices, biological and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) annually report information to CMS related to certain payments or other transfers of value made or distributed to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as physicians assistants and nurse practitioners) and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, physicians and teaching hospitals and certain ownership and investment interests held by physicians and their immediate family members.

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

If our operations are found to be in violation of any of the federal and state healthcare laws described above or any other governmental regulations that apply to us, we may be subject to significant penalties, including without limitation, civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government programs, such as Medicare and Medicaid, refusal to allow us to enter into government contracts, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings, additional reporting requirements and/or oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we obtain regulatory approval. In the United States and markets in other countries, sales of any products for which we receive regulatory approval for commercial sale will depend, in part, on the extent to which third-party payors provide coverage, and establish adequate reimbursement levels for such products. In the United States, third-party payors include federal and state

healthcare programs, private managed care providers, health insurers and other organizations. The process for determining whether a third-party payor will provide coverage for a product may be separate from the process for setting the price of a product or for establishing the reimbursement rate that such a payor will pay for the product. Third-party payors may limit coverage to specific products on an approved list, or also known as a formulary, which might not include all of the FDA-approved products for a particular indication. Third-party payors are increasingly challenging the price, examining the medical necessity and reviewing the cost-effectiveness of medical products, therapies and services, in addition to questioning their safety and efficacy. We may need to conduct expensive pharmaco-economic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain the FDA approvals. Our product candidates may not be considered medically necessary or cost-effective. A payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage for the product. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

Different pricing and reimbursement schemes exist in other countries. In the EU, governments influence the price of pharmaceutical products through their pricing and reimbursement rules and control of national health care systems that fund a large part of the cost of those products to consumers. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost-effectiveness of a particular product candidate to currently available therapies. Other member states allow companies to fix their own prices for medicines, but monitor and control company profits. The downward pressure on health care costs has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert a commercial pressure on pricing within a country.

The marketability of any product candidates for which we receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. In addition, emphasis on managed care in the United States has increased and we expect will continue to increase the pressure on healthcare pricing. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Healthcare Reform

In the United States and some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post-approval activities, and affect the ability to profitably sell product candidates for which marketing approval is obtained. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

For example, the Affordable Care Act has substantially changed healthcare financing and delivery by both governmental and private insurers.

There have been legal and political challenges and amendments to certain aspects of the Affordable Care Act. For example, on August 16, 2022, the Inflation Reduction Act of 2022 (IRA) was signed into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in Affordable Care Act marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and creating a new manufacturer discount program. It is possible that the Affordable Care Act will be subject to judicial or Congressional challenges in the future. It is unclear how such challenges and any additional healthcare reform measures will impact the Affordable Care Act.

Further legislation or regulation could be passed that could harm our business, financial condition and results of operations. Other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. For example, in August 2011, the Budget Control Act of 2011 was signed into law, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee on Deficit Reduction did not achieve a targeted deficit reduction of at least $1.2 trillion for fiscal years 2012 through 2021, triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect beginning on April 1, 2013 and will stay in effect until 2032 unless additional Congressional action is taken. Additionally, on March 11, 2021, the American Rescue Plan Act of 2021 was signed into law, which eliminated the statutory Medicaid drug rebate cap, previously set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, effective January 1, 2024.

Additionally, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and federal and state legislative activity designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. For example, the IRA, among other things (i) directs HHS to negotiate the price of certain high-expenditure, single-source biologics that have been on the market for at least 11 years covered under Medicare (the "Medicare Price Negotiation Program") and (ii) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions began to take effect progressively in fiscal year 2023. On August 15, 2024, HHS announced the agreed-upon price of the first ten drugs that were subject to price negotiations, although the Medicare drug price negotiation program is currently subject to legal challenges. On January 17, 2025, HHS selected fifteen additional products covered under Part D for price negotiation in 2025. Each year thereafter more Part B and Part D products will become subject to the Medicare Drug Price Negotiation Program. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework.

The current administration is pursuing policies to reduce regulations and expenditures across government including at HHS, the FDA, the Centers for Medicare & Medicaid Services ("CMS") and related agencies. These actions, presently directed by executive orders or memoranda from the Office of Management and Budget, may propose policy changes that create additional uncertainty for our business. These actions may, for example, include directives to reduce agency workforce, rescinding a previous executive order tasking the Center for Medicare and Medicaid Innovation ("CMMI") to consider new payment and healthcare models to limit drug spending and eliminating a previous executive order that directed HHS to establishing an AI task force and developing a strategic plan. Additionally, in its June 2024 decision in Loper Bright Enterprises v. Raimondo ("Loper Bright"), the U.S. Supreme Court overturned the longstanding Chevron doctrine, under which courts were required to give deference to regulatory agencies' reasonable interpretations of ambiguous federal statutes. The Loper Bright decision could result in additional legal challenges to current regulations and guidance issued by federal agencies applicable to our operations, including those issued by the FDA. Congress may introduce and ultimately pass health care related legislation that could impact the drug approval process and make changes to the Medicare Drug Price Negotiation Program created under the IRA.

Individual states in the United States have also become increasingly active in passing legislation and implementing 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.

We anticipate that these and other healthcare reform efforts will continue to result in additional downward pressure on coverage and the price that we receive for any approved product, and could seriously harm our business. Any reduction in reimbursement from Medicare and other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products. Such reforms could have an adverse effect on anticipated revenue from product candidates that we may successfully develop and for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop product candidates.

The Foreign Corrupt Practices Act

The FCPA prohibits any U.S. individual or business from paying, offering, or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Additional Regulation

In addition to the foregoing, state and federal laws regarding environmental protection and hazardous substances, including the Occupational Safety and Health Act, the Resource Conservancy and Recovery Act and the Toxic Substances Control Act, affect our business. These and other laws govern our use, handling and disposal of various biological, chemical and radioactive substances used in, and wastes generated by, our operations. If our operations result in contamination of the environment or expose individuals to hazardous substances, we could be liable for damages and governmental fines. We

believe that we are in material compliance with applicable environmental laws and that continued compliance therewith will not have a material adverse effect on our business. We cannot predict, however, how changes in these laws may affect our future operations.

Europe / Rest of World Government Regulation

In addition to regulations in the United States, we will be subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our products. Whether or not we obtain FDA or ex-US approval of a product, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. Certain countries outside of the United States have a similar process that requires the submission of a clinical trial application much like the IND prior to the commencement of human clinical trials. In the EU, for example, all cell therapy products are considered advanced therapeutic medicinal products (ATMPs) and a clinical trial application must be submitted centrally in accordance with EU clinical trial regulations (CTR) for review by a rapporteur appointed by a member state within the EU region. In addition, an independent ethics committee is needed in each country, much like the IRB, in the US. Once the clinical trial application is approved in accordance with a country's requirements, clinical trial development may proceed. Because biologically sourced raw materials are subject to unique contamination risks, their use may be restricted in some countries.

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

To obtain regulatory approval of an investigational drug or biological product under EU regulatory systems, we must submit an MAA. The application used to file the BLA in the United States is similar to that required in the EU, with the exception of, among other things, country-specific document requirements.

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

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

Privacy Laws and Regulations

In the ordinary course of our business, we and the third parties with whom we work process personal and sensitive data. Accordingly, we are, and may in the future become, subject to numerous data privacy and security obligations, including federal, state, local, and foreign laws, regulations, guidance, and industry standards related to data privacy, security, and protection.

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

The EU GDPR applies extraterritorially, and we are subject to the EU GDPR because of our data processing activities that involve the personal data of individuals located in the European Union, such as in connection with our EU clinical trials. Failure to comply with the requirements of the EU GDPR and the applicable national data protection laws of the EU member states may result in fines of up to €20,000,000 or up to 4% of the total worldwide annual turnover of the preceding financial year, whichever is higher, private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests, and other administrative penalties. The EU GDPR regulations may impose additional responsibility and liability in relation to the personal data that we process and we may be required to put in place additional mechanisms to ensure compliance with the new data protection rules.

Additionally, numerous US states have passed comprehensive privacy laws. For example, the California Consumer Privacy Act (CCPA) creates new individual privacy rights for consumers (as that word is broadly defined in the law) and places increased privacy and security obligations on entities handling personal data of consumers or households. The CCPA requires covered companies to provide new disclosures to California consumers, affords California residents certain rights related to their personal data, including the right to opt-out of certain sales of personal data. The CCPA provides for fines and allows private litigants affected by certain data breaches to recover significant statutory damages. As our business progresses, the CCPA may become applicable and impact (possibly significantly) our business activities and exemplifies the vulnerability of our business to the evolving regulatory environment related to personal data and protected health information. Many other US states have passed similar comprehensive privacy laws, and more are likely to do so in the future.

See the section titled "Risk Factors - Risks Related to Our Business and Industry" and "Risk Factors - Risks Related to Government Regulation" for additional information about the laws and regulations to which we may become subject and about the risks to our business associated with such laws and regulations.

Human Capital

As of March 1, 2025, we had 229 total employees, of which 226 are full-time. Of our full-time employees, 48 hold Ph.D. and/or M.D. degrees, and 186 are engaged in research, development and technical operations. Most of our employees are located in South San Francisco and Newark, 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.

We believe our workforce is key to Allogene's success and we actively focus on the following core elements of human capital: (1) our "One Allogene" culture, (2) belonging, fairness and representation and (3) recruitment, development and retention. We have also strived to create a safe working environment and have increased onsite presence since the end of the pandemic.

One Allogene Culture

We express our culture under the framework of "One Allogene":

One Allogene

We only succeed as a team.
We accomplish more together than as individuals when we unite as one Allogene community.

We are resilient, because we strive to save the lives of people with cancer and improve the lives of people with autoimmune disorders.
We come together with purpose, courage and flexibility despite challenges or uncertainty because every potential patient is someone's partner, parent, child, sibling or friend.

We aim for excellence and give it our all.
We pursue scientific innovation with a focus on quality and integrity in everything we do to forever change how cancer is treated.

We take ownership and get things done.
We are leaders who embrace urgency, initiative and follow through, with the humility to know each one of us is vital to making AlloCAR T™ therapy a reality.

We are good to one another.
We value distinct perspectives, backgrounds and expertise, we earn each other's trust, and assume good intention as we collaborate to help patients.

We are creating a scientific revolution.

We are One Allogene

These core elements of our culture are meant to define how and why we do business. In addition, our core values of collaboration, leadership, innovation and focus help drive our culture and behaviors and are layered into our performance reviews so that we can keep ourselves and our employees accountable.

Belonging, Fairness and Representation

We are committed to cultivating, fostering, and preserving a culture of belonging, fairness and representation where we foster a supportive, empowering and positive environment through respect, collaboration, and open communication. We embrace and encourage differences across all demographics that make our employees unique. We also embrace differences in experience and background, and welcome different opinions and unique perspectives when making decisions. We believe that in cultivating this environment, our staff feel that they are able to contribute to their full potential. As of March 1, 2025, the general demographic makeup of our workforce remains generally consistent with past years.

We are proud of our efforts to attract the best talent from the broadest pool of talent and we continue to focus on broadening our outreach to extend to all groups by posting our open positions on a variety of top job boards to seek a wide range of qualified candidates. We have and will continue to conduct training for interviewers and hiring managers to ensure they are making decisions based solely on facts, not assumptions, or irrelevant information. Our recruiters and hiring managers have active talent recruitment strategies to ensure that we are reaching the best talent available and giving qualified job applicants the opportunity to compete for positions.

Our initiatives embrace and complement our One Allogene culture by ensuring that our Company and its employees are taking responsibility for ensuring a supportive, empowering and positive work environment where employees feel valued, engaged and fully committed to our mission to serve patients. These initiatives are applicable to our practices and policies, such as those on recruitment, compensation and professional development. We are also progressing the ongoing development of an supportive work environment grounded in psychological safety that encourages:

- Respectful communication and cooperation between all employees.
- Valuing and soliciting input, feedback and opinions from relevant staff.
- Teamwork and employee participation, permitting the representation of employee perspectives.
- Employer and employee contributions to the communities we serve to promote a greater understanding and respect for others.

To champion our efforts in this area, we established a governance structure and formed a cross-functional committee (Committee) comprised of employees of various levels, departments and backgrounds to help advance and promote our commitment to maintaining the culture described above, and the responsibility of our employees to treat others with dignity and respect at all times regardless of our differences. All employees are also encouraged to attend and complete annual awareness training to enhance their knowledge to fulfill this responsibility. The Committee continually works to respond to feedback provided by peers, and present suggestions on our practices and policies to encourage and enforce an environment in which all employees feel that they are part of our team and empowered to achieve their best.

We believe in equal pay for equal work. We establish components and ranges of compensation based on market and benchmark data. Within this context, we strive to pay all employees fairly within a reasonable range, taking into consideration factors such as role; market data; internal consistency; job location; relevant experience; and individual, department and company performance. We also regularly review our compensation practices and analyze our compensation decisions for individual employees and our workforce as a whole on at least an annual basis. Since 2020, we have conducted a pay analysis annually which we believe demonstrates that our compensation practices and structure are fair.

Recruitment, Development and Retention

Successful execution of our strategy is dependent on attracting, developing and retaining our employees. We have and believe we will continue to face significant competition for life science talent. We believe, however, that our leadership in the field of allogeneic cell therapy and our culture have allowed us to recruit a talented workforce. In 2024, we recruited over 34 new employees. Our average time to hire was less than 48 days and over 85% of candidates accepted our offers.

We believe our total compensation package also helps recruit and retain our employees. We strive to provide pay, benefits, and services that are competitive to market and create incentives to attract and retain employees. Our compensation package includes market-competitive pay, broad-based stock grants, health care and 401(k) plan benefits, paid time off and family leave, among others. We also provide annual incentive bonus opportunities that are tied to both company performance as well as individual performance to foster a pay-for-performance culture.

Developing our employees is important, and we focus on providing training opportunities and promotional opportunities. Learning and development, training and other resources are an integral part of retaining our employees and creating a culture of learning and leadership within Allogene. Our training offerings provide staff with a variety of opportunities to learn, enhance and practice fundamental leadership skills to enable them to be more effective in their roles and develop their skills for further growth. We also train relevant members of our team on important environmental health and safety topics to help ensure we protect our people and our environment as we operate our business. We encourage our employees to participate

and take advantage of a variety of learning and development resources, including online business skills courses, professional development events, and external training programs based on individual needs. We also actively review employee performance and business needs every six months that lead to promotional opportunities for employees across departments and levels.

Employee Safety

One key aspect of our One Allogene culture is the principle that "We Aim for Excellence and Give it Our All," and that includes prioritizing safety. Ingrained in that concept is the tenet to follow all health and safety policies and procedures and prioritize the safety of our team.

To maintain a safe and healthy workplace, we have a comprehensive Environment, Health and Safety program that focuses on key risk mitigation programs that identify, assess, and correct hazards. We also have a task-based safety training program that is designed for staff to be assigned the appropriate training to understand how to safely perform their duties.

Corporate Information

We were incorporated in Delaware in November 2017. Our principal executive offices are located at 210 East Grand Avenue, South San Francisco, California 94080, and our telephone number is (650) 457-2700. Our corporate website address is www.allogene.com. We make available, free of charge on our website our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and any amendments to those reports, as soon as reasonably practicable after filing such reports with the Securities and Exchange Commission. Alternatively, you may access these reports at the SEC's website at www.sec.gov. Information contained on or accessible through our website is not a part of this report, and the inclusion of our website address in this report is an inactive textual reference only.

Item 1A. Risk Factors

RISK FACTORS

An investment in shares of our common stock involves a high degree of risk. We have identified the following material factors that make an investment in our common stock speculative or risky. You should carefully consider the following risk factors, as well as the other information in this Annual Report. The occurrence of any of the following risks could harm our business, financial condition, results of operations and growth prospects or cause our actual results to differ materially from those contained in forward-looking statements we have made in this Annual Report and those we may make from time to time. The risks described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations.

Risks Related to Our Financial Position and Capital Needs

We have incurred net losses in every period since our inception and anticipate that we will incur substantial net losses in the future.

We are a clinical-stage biopharmaceutical company and investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval and become commercially viable. We are advancing an allogeneic CAR T platform of primarily early-stage product candidates and have no products approved for commercial sale and have not generated any revenue from product sales to date, and we will continue to incur significant research and development and other expenses related to our ongoing operations. To date, we have devoted substantially all of our resources to organizing and staffing our company, business planning, raising capital, securing related intellectual property rights, building our product manufacturing infrastructure, including a dedicated good manufacturing practices (GMP) manufacturing facility, manufacturing our clinical product candidates and conducting discovery, research and development activities for our programs. As a result, we are not profitable and have incurred net losses in each period since our inception. For the year ended December 31, 2024, we reported a net loss of $257.6 million. As of December 31, 2024, we had an accumulated deficit of $1.8 billion.

We expect to incur significant expenditures for the foreseeable future, and we expect these expenditures to increase as we continue our research and development of, and seek regulatory approvals for, product candidates based on our engineered allogeneic T cell platform. Because our allogeneic T cell product candidates are based on new technologies and will require the creation of inventory of mass-produced, off-the-shelf product, they will require extensive research and development and have substantial manufacturing and processing costs. In addition, costs to treat patients with relapsed or refractory cancer and to treat potential side effects that may result from our product candidates can be significant.

We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. For instance, the U.S. Food and Drug Administration (FDA) placed our clinical trials on hold in October 2021, which suspended our clinical programs prior to resolution of the hold in January 2022. Even if we succeed in advancing our clinical trials and commercializing one or more of our product candidates, we will continue to incur substantial research and development and other expenditures to develop and market additional product candidates. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital.

We will need substantial additional financing to develop our products and implement our operating plans. If we fail to obtain additional financing, we may be unable to complete the development and commercialization of our product candidates.

We expect to spend a substantial amount of capital in the development and manufacture of our product candidates. We will need substantial additional financing to develop our products and implement our operating plans. In particular, we will require substantial additional financing to enable commercial production of our products and initiate and complete registrational trials for multiple products in multiple regions. Further, if approved, we will require significant additional capital in order to launch and commercialize our product candidates.

As of December 31, 2024, we had $373.1 million in cash and cash equivalents and investments. Changing circumstances may cause us to consume capital significantly faster than we currently anticipate, and we may need to spend

more money than currently expected because of circumstances beyond our control. We may also need to raise additional capital sooner than we currently anticipate if we choose to expand more rapidly than we presently plan. In any event, we will require additional capital for the further development and commercialization of our product candidates, including funding our internal manufacturing capabilities.

We cannot be certain that additional funding will be available on acceptable terms, or at all. We have no committed source of additional capital and our stock price has faced extreme volatility and has declined. To the extent that we raise additional capital through the sale of equity or convertible debt securities or to the extent that we may issue equity securities in connection with a strategic transaction, the ownership interest of our stockholders will be diluted. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of our product candidates or other research and development initiatives. Our license agreements may also be terminated if we are unable to meet the payment obligations under the agreements. We could be required to seek collaborators for our product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available or relinquish or license on unfavorable terms our rights to our product candidates in markets where we otherwise would seek to pursue development or commercialization ourselves.

Any of the above events could significantly harm our business, prospects, financial condition and results of operations and cause the price of our common stock to decline.

We may fail to meet our publicly announced guidance or other expectations about our business, which would cause our stock price to decline.

We may provide guidance regarding our expected financial and business performance, such as projections regarding our cash runway and projected clinical development and/or regulatory milestones. Correctly identifying key factors affecting business conditions and predicting future events is an inherently uncertain process and our guidance may not ultimately be accurate. Our guidance is based on certain assumptions relating to our expenses which may fluctuate based on how quickly we are able to execute on our operational initiatives, such as the timing of initiation of clinical trials and the rate of enrollment in such trials, and the timing of certain milestone payments, manufacturing expenses, employee expenses, facility expenses, and potential modifications of existing or the establishment of new partnership agreements. If our assumptions are not met or are impacted as a result of various risks and uncertainties, we may have to raise additional capital sooner than we currently expect and the market value of our common stock could decline significantly.

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

Our operations, and those of our CDMOs, contract research organizations (CROs), clinical trial sites and other contractors and consultants, could be subject to business disruptions, including those caused by earthquakes, power shortages, telecommunications failures, cybersecurity attacks, water shortages, floods, hurricanes, tsunamis, typhoons, fires, extreme weather conditions, medical epidemics or pandemics, wars and other geopolitical conflicts (such as Russia's military action against Ukraine and the Israel-Hamas conflict), bank failures, adverse legislative actions and other natural or man-made disasters or business interruptions, for which we are predominantly self-insured. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses.

Our ability to manufacture our product candidates could be disrupted if our operations or those of our suppliers are affected by a man-made or natural disaster or other business interruption. Our corporate headquarters and manufacturing facility are located in California near major earthquake faults and fire and flood zones. The ultimate impact on us, our significant suppliers and our general infrastructure of being located near major earthquake faults and fire and flood zones and being consolidated in certain geographical areas is unknown, but our operations and financial condition could suffer in the event of a major earthquake, fire, flood or other natural disaster.

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 swept into receivership. In addition, on May 1, 2023, the FDIC seized First Republic Bank and sold its assets to JPMorgan Chase & Co. 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. We maintain the majority of our cash and cash equivalents in accounts at 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. In the event of failure of any of the financial institutions where we maintain our cash and cash equivalents, there can be no 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.

Although we assess our banking relationships as we believe necessary or appropriate, our access to cash in amounts adequate to finance or capitalize 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; or 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.

Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited.

U.S. federal net operating losses incurred in tax years beginning after December 31, 2017, may be carried forward indefinitely, but the deductibility of such federal net operating loss carryforwards in a taxable year is limited to 80% of taxable income in such year. Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, if a corporation undergoes an "ownership change" (generally defined as a greater than 50 percentage point change (by value) in the equity ownership of certain stockholders over a rolling three-year period), the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income or taxes may be limited. As a result of our initial public offering (IPO) in October 2018 and private placements and other transactions that have occurred since our incorporation, we may have experienced an "ownership change". We may also experience ownership changes in the future as a result of subsequent shifts in our stock ownership. We anticipate incurring significant additional net losses for the foreseeable future, and our ability to utilize net operating loss carryforwards associated with any such losses to offset future taxable income may be limited to the extent we incur future ownership changes. In addition, at the state level, there may be periods during which the use of net operating loss carryforwards is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. For example, California imposed limits on the usability of California state net operating losses to offset taxable income in tax years beginning after 2023 and before 2027. As a result, we may be unable to use all or a material portion of our net operating loss carryforwards and other tax attributes, which could adversely affect our future cash flows.

Risks Related to Our Business and Industry

Our product candidates are based on novel technologies, which makes it difficult to predict the time and cost of product candidate development and the likelihood of obtaining regulatory approval.

We have concentrated our research, development and manufacturing efforts on our engineered allogeneic T cell therapy and our future success depends on the successful development of this therapeutic approach. We are in the early stages of developing our platform and we have experienced significant development challenges, such as with the prior clinical hold by the FDA, and there can be no assurance that any development problems we have now or experience in the future will not cause

significant delays or unanticipated costs, or that such development problems can be overcome. We may also experience delays in developing a sustainable, reproducible and scalable manufacturing process or transferring that process to commercial facilities or partners, which may prevent us from completing our clinical studies or commercializing our products on a timely or profitable basis, if at all.

In addition, since we are in the early stages of clinical development, we do not know all the doses to be evaluated in pivotal trials or, if approved, commercially. Finding a suitable dose for our cell therapy product candidates as well as ALLO-647 may delay our anticipated clinical development timelines. These unknowns and other emerging findings from our clinical trials may result in protocol amendments, which may result in additional costs and may also delay our anticipated clinical development timelines. In addition, our expectations with regard to our scalability and costs of manufacturing may vary significantly as we develop our product candidates and understand these critical factors.

We are also advancing product candidates against unexplored targets and with new technology. For example, we are advancing ALLO-316 against the CD70 target, and ALLO-329 against CD19 and CD70 targets. ALLO-316 may have limited efficacy, even accounting for the selection of patients with CD70 positive tumors, or have off-target toxicities. As a dual-targeting CAR T product candidate, ALLO-329 may demonstrate limited ability to target and eliminate cells, including both B and T lymphocytes, that express one or both targets. Additionally, there may be unexpected toxicity, such as severe or prolonged immunosuppression or hyperinflammation, arising from targeting both CD19 and CD70 simultaneously. Since CD70 is found on activated T and other immune cells, ALLO-316 and ALLO-329 may also cause fratricide resulting in the loss of ALLO-316 or ALLO-329 cells, either during the manufacturing process or after the cells are administered to patients, or may deplete host T or other immune cells.

CAR T administration and/or the lymphodepletion that is required before administration of CAR T cells, may increase the risk of prolonged blood cell count suppression (cytopenia) or other adverse events including infections or inflammatory conditions such as cytokine release syndrome (CRS), immune effector cell-associated neurotoxicity syndrome (ICANS), and/or immune effector cell-associated hemophagocytic lymphohistiocytosis-like syndrome (IEC-HS), which can be life-threatening and results in death. These events have been observed in our clinical trials and have resulted in pausing enrollment or requiring protocol amendments. For example, in our ongoing ALLO-316 TRAVERSE trial, we implemented risk mitigation measures for IEC-HS, which delayed and increased the cost of conducting the clinical trial.

In our ALPHA3 trial, we are advancing cema-cel for the treatment of patients with LBCL who have completed R-CHOP and have attained a remission, but who still test positive for minimal residual disease (MRD). As part of this trial, under Investigational Device Exemption (IDE), we are using an investigational assay developed by Foresight Diagnostics to determine if a patient is MRD positive. The MRD assay represents a novel approach to detecting the presence of minimal disease and the design of our trial is based on certain assumptions regarding the performance of the MRD assay, including assumptions regarding the anticipated MRD+ rate being consistent with published data. There is a risk that the assay may not function as intended and that the assay may not be sufficiently sensitive to detect the presence of low levels of MRD or sufficiently specific to avoid unacceptable rates of false positives. There is also a risk that the MRD+ rate observed in ALPHA3 may be lower than the previously reported rates as a result of the patient population screened, availability of sufficient patient test material, the performance of the test, and other factors that differ from previously reported rates. In addition, there are logistical risks with collecting and sending patient samples to Foresight Diagnostics for testing, and there is a risk that the MRD assay will not be timely performed on the patient samples. If the MRD assay does not function as intended (e.g., false negatives/positives, or the MRD+ rate is lower than expected), or if the MRD assay is not timely performed on patient samples, it could negatively impact the rate of enrollment, the clinical results of, or the feasibility of the ALPHA3 trial, or negatively impact the market opportunity for cema-cel. In addition, we are reliant on Foresight Diagnostics to perform MRD testing. A delay or failure by Foresight Diagnostics to perform MRD testing may negatively impact our ability to conduct ALPHA3 trial as planned, or prevent us from conducting ALPHA3 trial.

The clinical study requirements of the FDA, European Medicines Agency (EMA) and other comparable foreign regulatory authorities and the criteria these regulators use to determine the safety and efficacy of a product candidate are determined according to the type, complexity, novelty and intended use and market of the potential products. The regulatory approval process for novel product candidates such as ours can be more complex and consequently more expensive and take longer than for other, better known or extensively studied pharmaceutical or other product candidates. For example, the regulatory approval process for cema-cel based on our ALPHA3 trial is more complex because it pairs the approval of cema-cel with a companion diagnostic test. We also face additional challenges in obtaining regulatory approval for ALLO-647, which we use as part of our lymphodepletion regimen, and for which we would seek to obtain approval concurrently with approval of a CAR T cell product candidate. Approvals by the European Commission and FDA for existing autologous CAR T therapies, such as Kymriah® and Yescarta®, may not be indicative of what these regulators may require for approval of our therapies.

Also, the use of healthy donor material in our allogeneic CAR T product candidates may create product variability challenges for us, and we do not yet fully understand the impact of donor variability on clinical outcomes.

More generally, approvals by any regulatory agency may not be indicative of what any other regulatory agency may require for approval or what such regulatory agencies may require for approval in connection with new product candidates. Moreover, our product candidates may not perform successfully in clinical trials or may be associated with adverse events that distinguish them from the autologous CAR T therapies that have previously been approved. For instance, allogeneic product candidates may result in graft-versus-host disease (GvHD) or chromosomal abnormalities not experienced with autologous products. Additionally, any Phase 2 trial results, such as in the ALPHA3 trial, may not be representative of Phase 1 results, which were based on limited patients and a patient population in an advanced stage or LBCL, and such Phase 2 trial results may not be accepted by the FDA as pivotal and sufficient for cema-cel approval, and additional trials may be required to establish that cema-cel is safe and effective. Even if we collect promising initial clinical data of our product candidates, longer-term data may reveal new adverse events or responses that are not durable. Unexpected clinical outcomes would significantly impact our business.

Our business is highly dependent on the success of our lead product candidates. If we are unable to advance clinical development, obtain approval of and successfully commercialize our lead product candidates for the treatment of patients in approved indications, our business would be significantly harmed.

Our business and future success depends on our ability to advance clinical development, obtain regulatory approval of, and then successfully commercialize, our lead product candidates. Because cema-cel, ALLO-316, ALLO-715 and ALLO-605, products designed for use in patients with cancer, and ALLO-329, designed for use in patients with autoimmune disease, are or will be among the first allogeneic products to be evaluated in the clinic, the failure of any such product candidates, or the failure of other allogeneic T cell therapies, including for reasons due to safety, efficacy or durability, may impede our ability to develop our product candidates, and significantly influence physicians' and regulators' opinions in regard to the viability of our entire pipeline of allogeneic T cell therapies. For instance, all of our clinical trials were previously put on clinical hold due to an observation in the phase 1 portion of the ALPHA2 trial. While the clinical hold has been resolved, we could be subject to a clinical hold in the future due to unexpected observations, adverse patient outcomes or other issues.

All of our product candidates, including our lead product candidates, will require additional clinical and non-clinical development, regulatory review and approval in multiple jurisdictions, substantial investment, access to sufficient commercial manufacturing capacity and significant marketing efforts before we can generate any revenue from product sales. In addition, because our other product candidates are based on similar technology as our lead product candidates, if any of the lead product candidates encounters additional safety issues, efficacy problems, manufacturing problems, developmental delays, regulatory issues or other problems, our development plans and business would be significantly harmed.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the U.S. or abroad. The policies of the FDA, the competent authorities of the European Union Member States (EU Member States), the EMA, the European Commission and other comparable regulatory authorities responsible for clinical trials may change and additional government regulations may be enacted. For instance, the regulatory landscape related to clinical trials in the European Union recently evolved. The European Union Clinical Trials Regulation (CTR), which was adopted in April 2014 and repeals the European Union Clinical Trials Directive, became applicable on January 31, 2022. The CTR allows sponsors to make a single submission to both the competent authority and an ethics committee in each EU Member State, leading to a single decision for each EU Member State. The assessment procedure for the authorization of clinical trials has been harmonized as well, including a joint assessment by all EU Member States concerned, and a separate assessment by each EU Member State with respect to specific requirements related to its own territory, including ethics rules. Each EU Member State's decision is communicated to the sponsor via the centralized European Union portal. Once the clinical trial is approved, clinical study development may proceed. The CTR foresees a three-year transition period. The extent to which ongoing and new clinical trials will be governed by the CTR varies. The CTR will apply to clinical trials from an earlier date if the related clinical trial application was made on the basis of the CTR or if the clinical trial has already transitioned to the CTR framework before January 31, 2025. Compliance with the CTR requirements by us and our third-party service providers, such as CROs, may impact our developments plans.

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

Future undesirable or unacceptable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory

approval by the FDA or other comparable foreign regulatory authorities. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. Approved autologous CAR T therapies and those under development have shown frequent rates of CRS, neurotoxicity including immune effector cell-associated neurotoxicity syndrome (ICANS), serious infections, prolonged cytopenia and hypogammaglobulinemia, hemophagocytic lymphohistiocytosis/macrophage activation syndrome (HLH/MAS), immune effector cell-associated HLH-like syndrome (IEC-HS) and adverse events have resulted in the death of patients. We have observed certain of these adverse events for our allogeneic CAR T product candidates. Other adverse events could also emerge in autologous CAR T therapies over time. For instance, patients who received an autologous anti-BCMA CAR T cell therapy have experienced neurocognitive and hypokinetic movement disorder with features of Parkinson's disease that emerged months after treatment and may have been due to BCMA expression within the brain. Our anti-BCMA product candidates have the risk of causing similar adverse events.

In January 2024 the FDA sent letters to all companies with approved autologous CAR T therapies requesting them to add a black box warning on the label of their autologous CAR T therapies. The FDA is requiring label updates to include a black box warning that T-cell malignancies may occur following treatment with BCMA- and CD19-directed genetically modified autologous T-cell immunotherapies. The required warnings are specific to autologous therapies. Such T-cell malignancies have been observed in approximately 1 patient for every 1,000 patients treated with autologous therapies. Because our allogeneic therapies are based on similar technology, until we have treated more patients, there is a risk that we may find similar T-cell malignancies following treatment with our allogeneic CAR T product candidates. If such malignancies are observed, regulatory authorities, such as the FDA, may require a similar black box warning or other safety-related labeling statements on our products' label, if approved, which could prevent us from achieving or maintaining market acceptance and adversely affect our business, financial condition, results of operations and prospects.

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. In addition, we utilize a lymphodepletion regimen, which generally includes combinations of fludarabine, cyclophosphamide and ALLO-647, that may cause serious adverse events. For instance, because some regimens are expected to cause a deep and sometimes prolonged immune suppression, patients will have an increased risk of infection that may be unable to be cleared by the patient and ultimately lead to other serious adverse events or death. Our lymphodepletion regimen has caused such adverse events and may also cause prolonged cytopenia and aplastic anemia. We are also exploring various dosing strategies for lymphodepletion in our clinical trials, such as including varying doses of the chemotherapy agents and/or ALLO-647 or eliminating one or more of the agents, which may alter the risk of serious adverse events or have other undesirable outcomes such as a reduction of the efficacy of treatment.

In our and Servier's clinical trials of allogeneic CAR T product candidates, the most common severe or life-threatening adverse events resulted from CRS, serious infections, febrile neutropenia, prolonged cytopenia including prolonged pancytopenia, haemophagocytic lymphohistiocytosis, hypokalemia, multiple organ dysfunction syndrome, neutropenic sepsis and aplastic anemia. As reported, patients have died from adverse events and future patients may also experience toxicity resulting in death. For additional safety data, please see the section entitled "Business-Product Pipeline and Development Strategy" included in this Annual Report.

As we treat and re-treat more patients with our product candidates in our clinical trials, new less common side effects may also emerge or increased incidence of previously observed side effects may occur. There is a risk that the FDA or other comparable foreign regulatory authorities may not agree that sufficient mitigating procedures are included in our protocols to address such side effects, and FDA or other comparable foreign regulatory authorities may impose a clinical hold as it evaluates risks associated with such side effects and/or as we work with the agency to implement protocol amendments to appropriately manage such side effects. For instance, we observed a chromosomal abnormality that led to a previous clinical hold on our clinical trials. While our investigation concluded that the chromosomal abnormality had no clinical significance and was unrelated to our manufacturing process, our manufacturing processes include gene engineering by using viral vectors and genomic nucleases that may in the future cause insertion, deletion, or chromosomal translocation that may result in allogeneic CAR T cells to proliferate uncontrollably and adverse events.

We may also combine the use of our product candidates with other investigational or approved therapies that may cause separate adverse events or events related to the combination.

If unacceptable toxicities arise in the development of our product candidates, we could suspend or terminate our trials or the FDA or comparable foreign regulatory authorities could order us to cease clinical trials or deny approval of our product candidates for any or all targeted indications. Any data safety monitoring board may also suspend or terminate a clinical trial at any time on various grounds, including a finding that the research patients are being exposed to an unacceptable health risk, including risks inferred from other unrelated immunotherapy trials. Treatment-related side effects could also affect patient recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims. In addition,

these side effects may not be appropriately recognized or managed by the treating medical staff, as toxicities resulting from T cell therapy are not normally encountered in the general patient population and by medical personnel. We have trained and expect to have to train medical personnel using CAR T cell product candidates to understand the side effect profile of our product candidates for both our clinical trials and upon any commercialization of any of our product candidates. Inadequate training in recognizing or managing the potential side effects of our product candidates could result in patient deaths. Any of these occurrences may harm our business, financial condition and prospects significantly.

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

Before obtaining regulatory approvals for the commercial sale of our product candidates, we must demonstrate through lengthy, complex and expensive preclinical testing and clinical trials that our product candidates are both safe and effective for use in each target indication. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials, including in any post-approval studies.

There is typically an extremely high rate of attrition from the failure of product candidates proceeding through clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy profile despite having progressed through preclinical studies and initial clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy, insufficient durability of efficacy or unacceptable safety issues, notwithstanding promising results in earlier trials. Most product candidates that commence clinical trials are never approved as products.

In addition, for any trials that may be completed, we cannot guarantee that the FDA or comparable foreign regulatory authorities will interpret the results as we do, and more trials could be required before we submit our product candidates for approval. For example, FDA may determine that results from our Phase 2 ALPHA3 trial are not sufficient to establish that cema-cel is safe and effective, and FDA may require additional trials. Additionally, although the EMA has previously approved CAR T products based on US clinical trial data which did not include any European sites, the regulatory landscape for CAR T products continues to evolve, and the EMA may require us to conduct clinical trials in the EU in order to obtain approval. To the extent that the results of the trials are not satisfactory to the FDA or comparable foreign regulatory authorities for support of a marketing application, approval of our product candidates may be significantly delayed, or we may be required to expend significant additional resources, which may not be available to us, to conduct additional trials in support of potential approval of our product candidates.

No CAR T therapy has been approved as part of a first-line consolidation strategy for the treatment of LBCL patients, which presents significant regulatory, commercial, and operational risks, and there is no assurance of success in this unproven setting.

To date, no CAR T therapy has been approved for use as part of a first-line consolidation treatment for patients with LBCL, and the regulatory and commercial landscape remains uncertain. Because there is no precedent for regulatory approval of a CAR T therapy in this treatment paradigm, we may face unexpected challenges in generating sufficient clinical data to support an approval, and regulatory authorities may impose additional requirements or take longer than anticipated to evaluate our data.

Additionally, the standard of care for first-line treatment in LBCL is well-established, and physicians and patients may be reluctant to adopt CAR T therapy in this setting due to concerns over safety, efficacy, cost, or logistical challenges associated administration. If our product candidate does not demonstrate compelling clinical benefit over existing treatments or fails to gain market acceptance, we may not achieve the commercial success necessary to sustain our business.

Furthermore, payers and reimbursement authorities may be unwilling to provide coverage for CAR T therapy as a first-line consolidation treatment, particularly if they perceive it as too costly compared to existing alternatives. Even if we obtain regulatory approval, lack of adequate reimbursement could limit patient access and materially impact our ability to generate revenue.

The success of our clinical trial and potential approval in this setting is also dependent on factors outside of our control, such as evolving treatment paradigms, competitive developments, and changes in clinical practice. If we are unable to successfully develop, obtain approval for, and commercialize our CAR T therapy in this novel setting, our business, financial condition, and results of operations could be adversely affected.

The time required for regulatory approval of the CLARITY assay in jurisdictions outside the U.S. may be protracted, which presents regulatory, operational, and commercialization risks.

In certain foreign jurisdictions, such as European Union (EU), we anticipate that the CLARITY assay will be regulated as an in vitro diagnostic medical device. The timeline for this approval of CLARITY in jurisdictions outside the US may be protracted due to the evolving regulatory landscape for medical devices, particularly in the EU, the complexity of demonstrating clinical utility for novel MRD assays, and potential resourcing constraints, such as within EU regulatory bodies.

Further, we do not own or control the CLARITY assay or its regulatory approval process. As a result, we are dependent on others to complete the necessary regulatory filings, respond to inquiries from regulators, and obtain regulatory approvals, such as EU CTA approval, in a timely manner. If they experience delays, fail to meet regulatory requirements, or prioritize other programs over the CLARITY assay, our clinical development efforts outside the US could be significantly delayed. We may have limited visibility into the approval timeline and decision-making process, which could hinder our ability to accurately forecast any trial initiation and enrollment.

Any delay in regulatory approvals of the CLARITY assay, such as a delay in a CTA approval in the EU, could slow patient recruitment and impact the overall timeline of our cema-cel clinical development program. If regulatory challenges prevent the assay from being approved in a reasonable timeframe, we may be forced to identify and validate an alternative MRD assay, which could require additional clinical studies, regulatory interactions, and investment of resources, further delaying our program. Furthermore, an alternative MRD assay with sufficient sensitivity may not exist.

Additionally, if the CLARITY assay is required for commercial use alongside cema-cel, its approval and reimbursement as a medical device could impact the market adoption of cema-cel. Since we do not control the approval or commercialization strategy of the assay, our ability to ensure its availability, pricing, and regulatory compliance will be limited. If Foresight encounters regulatory setbacks or is unable to secure timely approval, our ability to commercialize cema-cel may be adversely affected.

If the approval of the CLARITY assay in any country or region is delayed, denied, or subject to additional regulatory requirements, our cema-cel clinical development timeline, regulatory approval prospects, and potential commercial success in such country or region could be materially impacted, which could adversely affect our business, financial condition, and future growth.

Phase 1 data from our clinical trials is limited and may change as more patient data becomes available or may not be validated in any future or advanced clinical trial.

Data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data becomes available. Phase 1 results are preliminary in nature and should not be viewed as predictive of ultimate success. It is possible that such results will not continue or may not be repeated in any clinical trial of our product candidates. For instance, our Phase 2 ALPHA3 trial design is based in part on Phase 1 data from a limited number of patients treated with various doses of ALLO-501 or cema-cel manufactured using the Alloy process, and the larger Phase 2 ALPHA3 trial, which we anticipate will only include cema-cel manufactured internally at CF1, but may ultimately also include cema-cel manufactured at a contract manufacturer, may not be consistent with the Phase 1 results. Furthermore, because ALPHA3 will include a different patient population versus our Phase 1 ALPHA2 trial, i.e., patients having MRD after front-line treatment versus patients with radiographically measurable disease after a minimum of two prior lines of treatment, it is possible that cema-cel may behave differently in terms of expansion, persistence and the ability to eradicate residual disease. In addition, our experience with our CD19 and BCMA programs indicates that manufacturing can impact clinical outcomes. The manufacturing runs we have completed and tested in the clinic are limited across our product candidates and any manufacturing variability that impacts clinical outcomes would significantly harm our business and prospects. We may also fail to develop any optimized manufacturing processes for any of our programs. Ultimately, if we cannot manufacture our product candidates with consistent and reproducible product characteristics, our ability to develop and commercialize any product candidate would be significantly impacted.

Phase 1 trials of novel products also commonly include a dose exploration phase during which adverse effects of treatment may emerge at higher doses that are new, unexpected, or occur at higher-than-expected frequencies or severity and may limit our ability to develop such products in one or more target indications or patient populations. Similarly, in dose expansion phase, we may discover that adverse effects, either known or novel, may negatively impact the emerging overall benefit-risk profile of our product candidates and may lead to the discontinuation or other significant alteration to the development plan.

Preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, initial, interim and preliminary data should be viewed with caution until the final data are available. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects.

We may not be able to submit INDs or equivalent foreign applications to commence additional clinical trials on the timelines we expect, and even if we are able to, the FDA or other comparable foreign regulatory authorities may not permit us to proceed.

We plan to submit INDs or IND amendments and equivalent foreign applications for additional product candidates or indications in the future. We cannot be sure that submission of an IND or IND amendment or an equivalent foreign application will result in the FDA or other comparable foreign regulatory authorities allowing testing and clinical trials to begin, or that, once begun, issues will not arise that suspend or terminate such clinical trials. The manufacturing of allogeneic CAR T cell therapy remains an emerging and evolving field. Accordingly, we expect Chemistry, Manufacturing and Controls (CMC) related topics, including product specification, will be a focus of IND reviews, which may delay the clearance of INDs or IND amendments. For instance, if we introduce changes to the manufacturing of our product candidates, regulatory authorities may require additional studies or clinical data to support the changes, which could delay our clinical trial timelines. Additionally, even if such regulatory authorities agree with the design and implementation of the clinical trials set forth in an IND, IND amendment or clinical trial application, we cannot guarantee that such regulatory authorities will not change their requirements in the future.

In addition, we have an open IND for ALLO-647, which is being used as part of lymphodepletion in certain of our clinical trials. Any regulatory issues related to ALLO-647 or to the development of ALLO-647, if it is used as part of a lymphodepletion regimen in a clinical study, could delay such study and delay the development of our allogeneic CAR T cell product candidates and significantly affect our business.

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

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

- inability to generate sufficient preclinical, toxicology or other in vivo or in vitro data to support the initiation of clinical studies;
- delays in sufficiently developing, characterizing, controlling or optimizing a manufacturing process suitable for clinical trials, including the validation and deployment of release assays;
- difficulty sourcing healthy donor material of sufficient quality and in sufficient quantity to meet our development needs;
- delays in developing, obtaining regulatory approval for, or implementing suitable assays for screening patients for eligibility for trials with respect to certain product candidates;
- the number of patients who consent to be screened for the ALPHA3 trial may be lower than we expect given the current well-established medical practice of frontline therapy for LBCL and the history of slow patient recruitment in other frontline LBCL trials
- the screen failure rate for clinical trials of our product candidates may be higher than we anticipate, requiring us to screen larger numbers of patients than originally planned. For example, the number of patients who have MRD at the end of front-line treatment in ALPHA3 may be lower than we expect, requiring more patients to be screened;
- delays in reaching a consensus with regulatory agencies on study design;
- delays in reaching agreement on acceptable terms with prospective CROs and clinical study sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical study sites;
- delays in obtaining required IRB approval or approval of other ancillary regulatory committees at each clinical study site;

- imposition of a temporary or permanent clinical hold by regulatory agencies for a number of reasons, including after review of an IND application or amendment, or equivalent application or amendment; as a result of a new safety finding that presents uncertain or unreasonable risk to clinical trial participants; a negative finding from an inspection of our or our collaborator's clinical study operations or our study sites; developments on trials conducted by competitors for related technology that raises FDA or other comparable foreign regulatory authority concerns about risk to patients of the technology broadly; or if the FDA or other comparable foreign regulatory authorities find that the investigational protocol or plan is clearly deficient to meet its stated objectives;
- delays in recruiting suitable patients to participate in our clinical studies;
- difficulty collaborating with patient groups and investigators;
- failure by our CROs, other third parties or us to adhere to clinical study requirements;
- failure to perform in accordance with the FDA's good clinical practices (GCP) requirements or equivalent regulatory guidelines in other countries;
- delays or failures in the transfer of manufacturing processes to any CDMO or our own manufacturing facility or any other development or commercialization partner for the manufacture of product candidates;
- delays in having patients complete participation in a study or return for post-treatment follow-up;
- patients dropping out of a study;
- occurrence of adverse events associated with the product candidate that are viewed to outweigh its potential benefits;
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols;
- changes in the standard of care on which a clinical development plan was based, which may require new or additional trials;
- the cost of clinical studies of our product candidates being greater than we anticipate;
- clinical studies of our product candidates producing negative or inconclusive results, which may result in our deciding, or regulators requiring us, to conduct additional clinical studies or abandon product development programs;
- delays or failure to secure supply agreements with suitable raw material suppliers, or any failures by suppliers to meet our quantity or quality requirements for necessary raw materials;
- shortage, interruption, or failure to secure commercially available and/or investigational drug products that are required to conduct clinical trials with our allogeneic CAR T product candidates; and
- delays in manufacturing, testing, releasing, validating, or importing/exporting sufficient stable quantities of our product candidates for use in clinical studies or the inability to do any of the foregoing.

A pandemic or epidemic may also increase the risk of certain of the events described above and delay our development timelines. Any inability to successfully complete preclinical and clinical development could result in additional costs to us or impair our ability to generate revenue. In addition, if we make manufacturing or formulation changes to our product candidates, we will be required to meet certain regulatory conditions, such as establishing comparability with the product candidates manufactured prior to such changes, and our inability to meet such conditions would result in investment of additional resources, a delay in our manufacturing of such product candidate and an extension of our clinical trial timelines. Clinical study delays could also shorten any periods during which our products have patent protection and may allow our competitors to bring products to market before we do, which could impair our ability to successfully commercialize our product candidates and may harm our business and results of operations.

Our clinical trials may also be delayed because of the availability of drugs required to be used under our protocols. For example, in some of our clinical trials, the study participants receive commercially available drugs for lymphodepletion before our allogeneic CAR T product candidates are administered, and receive other drugs to prevent infections and manage the treatment emergent adverse events. Shortage or lack of availability of these commercially available drugs that are necessary to conduct our clinical trials may cause delays in our clinical trials.

Monitoring and managing toxicities in patients receiving our product candidates is challenging, which could adversely affect our ability to obtain regulatory approval and commercialize.

For our clinical trials of our product candidates, we contract or will contract with academic medical centers and hospitals experienced in the assessment and management of toxicities arising during clinical trials. Nonetheless, these centers and hospitals may have difficulty observing patients and treating toxicities, which may be more challenging due to personnel changes, inexperience, shift changes, house staff coverage or related issues. This could lead to more severe or prolonged

toxicities or even patient deaths, which could result in us or the FDA or other comparable foreign regulatory authorities delaying, suspending, varying, or terminating one or more of our clinical trials, and which could jeopardize regulatory approval. We also expect the centers using our product candidates, if approved, on a commercial basis could have similar difficulty in managing adverse events. Medicines used at centers to help manage adverse side effects of our product candidates may not adequately control the side effects and/or may have a detrimental impact on the efficacy of the treatment. Challenges associated with the use of these medicines may increase with new physicians and centers administering our product candidates.

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

We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. For example, as we progress the ALPHA3, TRAVERSE and RESOLUTION trials, we may face enrollment challenges, including an unwillingness of sites or patients to participate, the exclusion of patients with certain disease characteristics or the ineligibility of patients that have received prior autologous CAR T therapies, which continue to gain adoption. The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients. Because we anticipate a minority of the 1L patients we will test for MRD as part of screening for the ALPHA3 trial will be MRD positive, we will likely experience a very high screen failure rate, which will require screening a large number of patients to complete enrollment in the study. Because of the anticipated high screen failure rate, certain clinical trial sites may decline to participate in ALPHA3 or completion of enrollment may be significantly delayed. Future epidemics or pandemics may result in reduced enrollment and challenges to related clinical trial activities. The enrollment of patients may be more difficult, such as due to the perceptions of the safety of our product candidates, and will depend on many factors, including:

- the patient eligibility criteria defined in the protocol;
- the prevalence of any biomarker required for enrollment, such as MRD or CD70 expression;
- the performance of the diagnostic tests used to determine eligibility for enrollment (e.g., MRD or CD70);
- the size of the patient population required for analysis of the trial's primary endpoints;
- the proximity of patients to study sites;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- our ability to obtain and maintain patient consents;
- the competition from approved products in the same or other lines of therapy and and/or disease indications and from product candidates in other clinical trials; and
- the risk that patients enrolled in clinical trials will drop out of the trials before the infusion of our product candidates or trial completion.

Since we only need to conduct a limited number of manufacturing runs to generate clinical supply, the diversity of our supply is limited during clinical trials. As a result, some patients may have antibodies to certain donor specific antigens at titers that could negatively impact the activity of our product candidates and which would render the patients ineligible for treatment. Furthermore, cellular mechanisms of allogeneic tissue rejection may limit the efficacy of our products. In addition, we have introduced an in vitro companion diagnostic (IVD) assay in the TRAVERSE trial to screen for patients with CD70+ tumors and are utilizing an MRD assay in the ALPHA3 trial to screen for patients who are MRD positive, both of which are restricting the number of patients eligible for the trials.

Development and research use of an experimental diagnostic assay or test, such as that we are using to determine CD70 expression on tumor tissue of potential participants in the TRAVERSE trial or to identify MRD positive patients in the ALPHA3 trial, may influence results of the study in expected or unexpected ways. For example, emerging safety and efficacy outcomes could lead us to impose, tighten or expand "cutoff" values of CD70 expression to determine enrollment eligibility for TRAVERSE. Assay performance or necessary changes we or our partners make to the assay(s) during development may reduce the pace of enrollment or may lead to alterations in the expected benefit risk profile as compared to results collected prior to the change. The diagnostic assay itself may not perform as expected due to identifiable or obscure factors. It is also possible that we may not be aware of such underperformance of the assay which could lead to incorrect conclusions. This could, in turn, impact enrollment and interpretation of the clinical trial results.

Our clinical trials will also compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. For example, our collaboration with Foresight Diagnostics is nonexclusive. As a result, there is a risk that

Foresight Diagnostics might work with our competitors to enable a competing clinical trial involving the same MRD positive patient population that we plan to enroll in ALPHA3, which would reduce the number of patients who are available to participate in ALPHA3, and potentially delay completion of ALPHA3. Since the number of qualified clinical investigators is limited, some of our clinical trial sites are also being used by some of our competitors, which may reduce the number of patients who are available for our clinical trials in that clinical trial site.

As our clinical trials require conditioning patients with chemotherapy, including agents such as cyclophosphamide and fludarabine, and physicians use other drugs prophylactically or to manage adverse events, our ability to enroll may be impacted by the shortage of such agents or drugs. For instance, the FDA has reported a shortage of fludarabine and any failure or delays by us or by our clinical trial sites to obtain sufficient quantities of fludarabine may delay our ability to enroll and treat patients in our clinical trials.

Moreover, because our product candidates represent a departure from more commonly used methods for treating cancer and autoimmune diseases, potential patients and their doctors may be inclined to use conventional therapies, such as chemotherapy, monoclonal antibodies, hematopoietic cell transplantation as well as autologous CAR T cell therapies for treating cancer or hydroxychloroquine, NSAIDs, immunosuppressants, corticosteroids, or other biologics for treating autoimmune diseases, rather than enroll patients in our clinical trial, including if our product candidates have or are perceived to have additional safety or efficacy risks or if using our product candidates may affect insurance coverage of conventional therapies. For instance, the development of autologous CAR T cell therapies continues to rapidly advance, including into earlier lines of treatment of LBCL and treatment of relapsed/refractory (R/R) multiple myeloma, as described under the section entitled "Business-Competition" included in this Annual Report. We also may experience risks associated with a new class of therapies, bispecific antibodies, which have been approved for multiple myeloma and LBCL. The compelling results and related approvals may impact our ability to enroll patients in our clinical trials. Moreover, patients eligible for allogeneic CAR T cell therapies but ineligible for autologous CAR T cell therapies due to aggressive cancer and inability to wait for autologous CAR T cell therapies may be at greater risk for complications and death from therapy or may experience a reduction in efficacy as compared to patients who are well enough and whose disease is sufficiently slow growing as to be eligible for autologous CAR T cell therapy.

Delays in patient enrollment may result in increased costs or may affect the timing or outcome of our clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our product candidates.

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

The FDA often approves new therapies initially only for use in patients with R/R metastatic disease. We may initially seek approval of certain of our product candidates in this setting. Subsequently, for those products that prove to be sufficiently beneficial, if any, we would expect to seek further approval in earlier lines of treatment, and for cema-cel we expect to initially seek approval in the first line consolidation setting. There is no guarantee that our product candidates, even if approved, would be approved for earlier lines of therapy, and, prior to any such approvals, we will have to conduct additional clinical trials, including potentially comparative trials against the then-current standard of care, which in some cases may include comparative trials against approved therapies. We may also target a similar patient population as autologous CAR T product candidates, including approved autologous CAR T products. Our therapies may not be as safe and effective as autologous CAR T therapies and may only be approved for patients who are ineligible for autologous CAR T therapy.

Our projections of both the number of patients who have the cancers or autoimmune diseases we are targeting, as well as the subset of patients with these cancers or autoimmune diseases who have the potential to benefit from treatment with our product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations, or market research and may prove to be incorrect. Further, new studies or therapies may change the estimated incidence or prevalence of these cancers and autoimmune diseases. The number of patients may turn out to be lower than expected. Additionally, the potentially addressable patient population for our product candidates may be limited, such as due to the eligibility criteria of our trials (e.g., MRD+ rates lower than expected), or may not be amenable to treatment with our product candidates, all of which may negatively impact the potential market opportunity for our other product candidates, if approved.

We may fail to successfully manufacture our product candidates, operate our own manufacturing facility, or obtain regulatory approval to utilize or commercialize from our manufacturing facility or at a CDMO, which could adversely affect our clinical trials and the commercial viability of our product candidates.

We may not be able to achieve clinical or commercial manufacturing of our products on our own or at a CDMO, including the inability to satisfy demands for any of our product candidates. We have limited experience in managing the allogeneic T cell engineering process, and our allogeneic processes may be more difficult or more expensive than the approaches taken by our competitors. Until we complete our clinical trials, we cannot be sure that the manufacturing processes employed by us or the technologies that we incorporate for manufacturing will result in consistent T cell production that will be safe and effective.

We operate CF1, a manufacturing facility located in Newark, California, that is designed to support our clinical trials and potential commercial production and worldwide distribution of allogeneic CAR T cell products for blood cancers, solid tumors and autoimmune diseases. Introducing any product manufactured at our manufacturing facility into an ongoing clinical trial would be subject to FDA review, and may result in increased costs and delays in conducting such trial, submitting a biologics license application (BLA) and/or gaining FDA or other comparable foreign regulatory authority approval. Similar conditions may apply if we make process changes to our product candidates, as we plan to do for our BCMA program. In addition, any process or raw material change could introduce unacceptable product variability and impact our ability to manufacture on a consistent and reproducible basis. Ultimately, any failure or delays in manufacturing and qualification of our product candidates at our CDMO or at our own manufacturing facility could delay our clinical trials.

We do not yet have sufficient information to reliably estimate the cost of the commercial manufacturing of our product candidates, and the actual cost to manufacture our product candidates could materially and adversely affect the commercial viability of our product candidates. The commercial dose and treatment regimen may affect our ability to scale and will affect our cost per dose. For instance, because our anti-BCMA product candidates may require a higher dose than cema-cel, it is possible that it may be more difficult to scale production of our anti-BCMA product candidates to meet demand. As a result, we may never be able to develop a commercially viable product. Our manufacturing facility will also require FDA approval, and possibly similar approval from comparable foreign regulatory authorities before it can be used for commercial production, which we may never obtain. Even if approved, we would be subject to ongoing periodic unannounced inspection by the FDA, EMA, the Drug Enforcement Administration and corresponding state agencies to ensure strict compliance with current good manufacturing practices (cGMP), and other government regulations.

The manufacture of biopharmaceutical products is complex and requires significant expertise, including the development of advanced manufacturing techniques and process controls. Manufacturers of cell therapy products often encounter difficulties in production, particularly in validating initial production and ensuring the absence of contamination. Other problems can include difficulties with production costs and yields, quality control, including stability of the product, operator error, shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. The application of new regulatory guidelines or parameters, such as those related to release testing, may also adversely affect our ability to manufacture our product candidates. Furthermore, if contaminants are discovered in our supply of product candidates or in the manufacturing facilities, such supply may have to be discarded and our manufacturing facility may need to be closed for an extended period of time to investigate and remedy the contamination. We cannot assure you that any stability or other issues relating to the manufacture of our product candidates will not occur in the future.

We or any of our vendors may fail to manage the logistics of storing and shipping our raw materials and product candidates. Storage failures and shipment delays and problems caused by us, our vendors or other factors not in our control, such as weather, could result in the inability to manufacture product, the loss of usable product or prevent or delay the delivery of product candidates to patients.

We may also experience manufacturing difficulties due to resource constraints or as a result of labor disruptions, such as due to a future pandemic, epidemic or disputes. If we were to encounter any of these difficulties, our ability to provide our product candidates to patients would be jeopardized.

As a company, we 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.

As a company, we have no experience in marketing products. We intend to develop an in-house marketing organization and sales force, which will require significant capital expenditures, management resources and time. We will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain marketing and sales personnel.

If we are unable or decide not to establish internal sales, marketing and distribution capabilities, we will pursue collaborative arrangements regarding the sales and marketing of our products; however, there can be no assurance that we will

be able to establish or maintain such collaborative arrangements, or if we are able to do so, that they will have effective sales forces or be on favorable terms. Any revenue we receive will depend upon the efforts of such third parties, which may not be successful. We may have little or no control over the marketing and sales efforts of such third parties and our revenue from product sales may be lower than if we had commercialized our product candidates ourselves. We also face competition in our search for third parties to assist us with the sales and marketing efforts of our product candidates.

There can be no assurance that we will be able to develop in-house sales and distribution capabilities or establish or maintain relationships with third-party collaborators to commercialize any product that receives regulatory approval in the United States or in other markets.

A variety of risks associated with conducting research and clinical trials abroad and marketing our product candidates internationally could materially adversely affect our business.

We plan to globally develop our product candidates. Accordingly, we expect that we will be subject to additional risks related to operating in foreign countries, including:

- differing regulatory requirements in foreign countries;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements, including recently imposed tariffs which may impact certain of our key raw materials that we import, and which could impact our cost of goods for our product candidates;
- differing standards and privacy requirements for the conduct of clinical trials;
- geographic variations in genetics, comorbidities, environmental factors, treatment patterns, and healthcare practices may impact the safety profile or efficacy of our product candidates;
- increased difficulties in managing the logistics and transportation of storing and shipping product candidates produced in the United States, shipping the product candidate to the patient abroad, and shipping patient samples to the United States for screening tests;
- import and export requirements and restrictions;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- differing payor reimbursement regimes, governmental payors or patient self-pay systems, and price controls;
- potential liability under the Foreign Corrupt Practices Act of 1977 or comparable foreign regulations;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad;
- challenges with obtaining any local supply of drugs or agents used with our product candidates, which are required by certain local clinical trial sites before conducting any study; and
- business interruptions resulting from future health epidemics or pandemics, or natural or man-made disasters, including earthquakes, tsunamis, fires or other medical epidemics, or geo-political actions, including war and terrorism.

These and other risks associated with our collaborations with Servier and Cellectis, each based in France, our collaboration with Notch, based in Canada, and our joint venture for China, Taiwan, South Korea and Singapore with HBP, may materially adversely affect our ability to attain or maintain profitable operations.

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

The biopharmaceutical industry, and the immuno-oncology industry specifically, is characterized by intense competition and rapid innovation. Our competitors may be able to develop other compounds or drugs that are able to achieve

similar or better results. Our potential competitors include major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies and universities and other research institutions. Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff and experienced marketing and manufacturing organizations and well-established sales forces. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors, either alone or with collaborative partners, may succeed in developing, acquiring or licensing on an exclusive basis drug or biologic products that are more effective, safer, more easily commercialized or less costly than our product candidates or may develop proprietary technologies or secure patent protection that we may need for the development of our technologies and products.

Specifically, engineered T cells face significant competition from multiple companies. Success of other therapies could impact our regulatory strategy and delay or prevent regulatory approval of our product candidates. Even if we obtain regulatory approval of our product candidates, the availability and price of our competitors' products could limit the demand and the price we are able to charge for our product candidates. We may not be able to implement our business plan if the acceptance of our product candidates is inhibited by price competition or the reluctance of physicians to switch from existing methods of treatment to our product candidates, or if physicians switch to other new drug or biologic products or choose to reserve our product candidates for use in limited circumstances. For additional information regarding our competition, see the section entitled "Business-Competition" included in this Annual Report.

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

Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract and retain highly qualified managerial, scientific, medical and other personnel. We are highly dependent on our management, including our Executive Chair, our President and Chief Executive Officer, our Executive Vice President, Research & Development and Chief Medical Officer, our Senior Vice President and Chief Technical Officer, our Chief Financial Officer, and our General Counsel. The loss of the services of any of our executive officers, other key employees, and other scientific and medical advisors, and our inability to find suitable replacements could result in delays in product development and harm our business.

We conduct substantially all of our operations at our facilities in the San Francisco Bay area. This region is headquarters to many other biopharmaceutical companies and many academic and research institutions. Competition for skilled personnel in our market is intense and may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all. Attrition may lead to higher costs for hiring and retention, diversion of management time to address retention matters and disrupt the business.

To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have provided stock options and restricted stock unit (RSU) awards that vest over time or upon the achievement of certain key strategic goals. The value to employees of stock options and RSU awards that vest over time or upon achieving goals have been significantly affected by movements in our stock price that are beyond our control and may at any time be insufficient to counteract more lucrative offers from other companies. We completed an option exchange program in July 2022 to alleviate the significant number of employee options that were underwater at that time. Our stock price has significantly declined since the option exchange program and a significant number of our employee options remain underwater and may not provide the intended incentive for employees to remain at our company. Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us on short notice. Although we have employment agreements with our key employees, these employment agreements provide for at-will employment, which means that any of our employees could leave our employment at any time, with or without notice. We do not maintain "key person" insurance policies on the lives of these individuals or the lives of any of our other employees. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level and senior managers as well as junior, mid-level and senior scientific and medical personnel.

The size of our workforce has fluctuated and we will need to manage the size of our organization as we continue to advance our product candidates.

As our development, manufacturing and commercialization plans and strategies develop, we have grown our employee base and allocated resources to multiple new functions, but in January 2024 we implemented a 22% reduction in force, and we

will need to continue to manage the size of our organization to ensure that we can successfully execute our strategic plans. As our product candidates advance toward commercialization, we expect to hire employees in areas that include sales and marketing. Future growth imposes significant added responsibilities on members of management, including:

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

Our future financial performance and our ability to commercialize our product candidates will depend, in part, on our ability to effectively manage our growth, and our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants. There can be no assurance that the services of independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. We may also be subject to penalties or other liabilities if we mis-classify employees as consultants. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by consultants is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval of our product candidates or otherwise advance our business. There can be no assurance that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, or at all.

If we are not able to effectively expand our organization by hiring and retaining employees and expanding our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to further develop, manufacture and commercialize our product candidates and, accordingly, may not achieve our research, development, manufacturing and commercialization goals. Conversely, if we expand ahead of our business progress, we may take on unnecessary costs.

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

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

If we license products or new technologies or acquire businesses, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture. For instance, our agreements with Cellectis, Servier, Notch, Antion, and Foresight Diagnostics require significant research and development that may not result in the development and commercialization of product candidates. We cannot be certain that, following a strategic transaction or license, we will achieve the results, revenue or specific net income that justifies such transaction.

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

We actively evaluate various strategic transactions on an ongoing basis. We may acquire other businesses, products or technologies as well as pursue joint ventures or investments in complementary businesses. The success of our strategic transactions, including our acquisition of CAR T cell assets from Pfizer, licenses with Cellectis, Servier, Notch, Antion, our strategic collaboration with Foresight Diagnostics, and our joint venture with HBP and any future strategic transactions depends on the risks and uncertainties involved including:

- technical difficulties associated with advancing partnered programs;
- unanticipated liabilities related to acquired companies or joint ventures;
- difficulties integrating acquired personnel, technologies and operations into our existing business;
- retention of key employees;
- managerial challenges associated with the oversight of partnered programs;
- disagreements regarding each party's contractual rights and obligations under our partnership agreements;
- costs and uncertainties related to managing disputes with any strategic partners;
- increases in our expenses and reductions in our cash available for operations and other uses;
- inability of our strategic partners to access suitable capital;
- 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.

If any of these risks or uncertainties occur, we may not realize the anticipated benefit of any acquisition or strategic transaction.

Additionally, foreign acquisitions and joint ventures are subject to additional risks, including those related to integration of operations across different cultures and languages, currency risks, potentially adverse tax consequences of overseas operations and the particular economic, political and regulatory risks associated with specific countries. For instance, our joint venture with HBP has faced challenges relating to the regulatory and competitive environment in China for allogeneic CAR T products, as well as challenges within the capital markets for financing allogeneic CAR T development. Our joint venture may face manufacturing difficulties, such as from changes in raw materials or processes due to local regulations, or delivering our licensed product candidates in China, Taiwan, South Korea or Singapore, which could prevent any development or commercialization of our licensed product candidates in the region. The joint venture will also require significant operational and financial support in the future by us or third parties, and any future financing of the joint venture would increase our expenses or dilute our ownership in the joint venture. We may also face unknown liabilities due to supporting our joint venture, such as due to any misuse of materials supplied to our joint venture.

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.

If our security measures, or those of our CROs, CDMOs, collaborators, contractors, consultants or other third parties with whom we work, are or were compromised or the security, confidentiality, integrity or availability of our information technology, software, services, networks, communications or data is compromised, limited or fails, we could experience a material adverse impact.

In the ordinary course of our business, we and the third parties with whom we work collect, process, receive, store, use, generate, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, process) proprietary, confidential and sensitive information, including personal data (including health information), intellectual property, trade secrets, information we collect about patients in connection with clinical trials, and proprietary business information owned or controlled by ourselves or other parties (collectively, sensitive information).

Cyberattacks, malicious internet-based activity, online and offline fraud and other similar activities threaten the confidentiality, integrity, and availability of our sensitive information and information technology systems, and those of the third parties with whom we work. Such threats are prevalent and are increasing in their frequency, sophistication and intensity, and have become increasingly difficult to detect. These threats come from a variety of sources, including traditional computer "hackers," "hacktivists," organized criminal threat actors, threat actors, personnel (such as through theft or misuse), sophisticated nation-states, and nation-state-supported actors. Some actors now engage and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we, and the third parties with whom we work, may be vulnerable to a heightened risk of these attacks, including retaliatory cyber-attacks, that could materially disrupt our systems and operations, supply chain, and ability to produce and distribute our product candidates. We and the third parties with whom we work are subject to a variety of evolving threats, including but not limited to social-engineering attacks (including through deep fakes, which may be increasingly more difficult to identify as fake, and phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service credential stuffing attacks, credential harvesting, adware, ransomware, supply chain attacks, personnel misconduct or error, attacks

enhanced or facilitated by AI, and other similar threats. Our information technology systems and data, and those of the third parties with whom we work, may also be subject to failure or disruption from software bugs, server malfunction, software or hardware failures, loss of data or other information technology assets, telecommunications failures, natural disasters such as earthquakes, fires, and floods, and other similar issues.

In particular, severe ransomware attacks are becoming increasingly prevalent and severe and can lead to significant interruptions, delays, or outages in our operations, disruptions to our clinical trials, loss of data (including data related to clinical trials), significant expense to restore data or systems, reputational loss and the diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments. In addition, our reliance on third parties could introduce new cybersecurity risks and vulnerabilities, including supply-chain attacks, and other threats to our business operations. Such supply chain attacks have increased in frequency and severity, and we cannot guarantee that third parties' infrastructure in our supply chain have not been compromised or that they do not contain exploitable defects or bugs that could result in a breach to our information technology systems or those of the third parties with whom we work. Additionally, future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program.

We work with certain third parties, such as CROs and CDMOs, to operate critical business systems and process our proprietary, confidential and sensitive information. We also share or receive sensitive information with our CROs, CDMOs, or other third parties. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. If the third parties with whom we work experience a security incident or are perceived to have experienced a security incident, we could experience adverse consequences. While we may be entitled to damages if the third parties with whom we work fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award.

Although we have implemented security measures designed to protect against, mitigate, and remediate security incidents, there can be no assurance that these measures will be effective.

We take steps designed to detect, mitigate, and remediate vulnerabilities in our information systems (such as our hardware and/or software, including that of third parties with whom we work). We have not and may not in the future, however, detect and remediate all such vulnerabilities in our information technology systems, including on a timely basis, because such threats and techniques change frequently, are often sophisticated in nature, and may not be detected until after a security incident has occurred. Unremediated high risk or critical vulnerabilities pose material risks to our business that may be exploited and could result in a security incident. Further, we have experienced and may in the future experience delays in developing and deploying remedial measures designed to address any such identified vulnerabilities. We also face heightened physical and information technology risks due to our sharing office space with other tenants at certain of our sites. Any failure to prevent or mitigate security incidents or improper access to, use of, or disclosure of our clinical data or patients' personal data could result in significant liability under state, federal, and international law and may cause a material adverse impact to our reputation, affect our ability to conduct our clinical trials and potentially disrupt our business. In addition, as many of our employees work from home at least part of the time and utilize network connections outside our premises, including while at home, or in transit, this poses increased risks to our information technology systems and data.

Certain of the previously identified or similar threats have in the past, and any of the identified or similar threats may in the future, cause a security incident or other interruption that could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive information. For example, we have been the target of unsuccessful phishing attempts in the past, and expect such attempts will continue in the future. In addition, from time to time, our vendors inform us of security incidents. For example, in November 2024, one of our vendors notified us that they had detected suspicious activity on their network that compromised several email accounts the vendor used to communicate with us. We took appropriate remedial measures, and based on our investigation, we concluded that the incident did not compromise our systems. To date, we have not determined that such incidents as reported to us were material. However, we may not have all information related to such incidents and future incidents could have an adverse impact on our business. A security incident or other interruption could disrupt our ability (and that of third parties with whom we work) to manufacture or deliver our product candidates.

We may expend significant resources (including financial), or modify our business activities and operations, including our clinical trial activities, in an effort to protect against security incidents or to detect, investigate, mitigate, contain and remediate a security incident. Certain data privacy and security obligations may require us to implement and maintain specific

security measures or use industry-standard or reasonable security measures to protect our information technology systems and sensitive information.

Applicable data protection laws, privacy policies, data protection obligations and public company disclosure obligations may require us, or we may voluntarily choose, to notify relevant stakeholders, including affected individuals, regulators and investors, of certain security incidents, or to implement other requirements, such as providing credit monitoring. Such disclosures and compliance with such requirements are costly, and the disclosures or the failure to comply with such applicable requirements could lead to adverse consequences. A security incident, whether perceived or actual, experienced by us or a third party with whom we work, may cause us to experience adverse consequences. These consequences may include: government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing sensitive information (including personal data); litigation (including class claims) and mass arbitration; indemnification obligations; negative publicity; reputational harm; monetary fund diversions; interruptions in our operations (including availability of data); financial loss; and other similar harms. Whether a cybersecurity incident is reportable to our investors may not be straightforward, may take considerable time to determine, and may be subject to change as the investigation of the incident progresses, including changes that may significantly alter any initial disclosure that we provide. Moreover, experiencing a material cybersecurity incident and any mandatory disclosures could lead to negative publicity, loss of investor or partner confidence in the effectiveness of our cybersecurity measures, diversion of management's attention, governmental investigations, lawsuits, and the expenditure of significant capital and other resources.

Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that the limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations.

We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or adequately mitigate liabilities arising out of our privacy and security practices, or that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims.

In addition to experiencing a security incident, third parties may gather, collect, or infer sensitive information about us from public sources, data brokers, or other means that reveals competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position. Additionally, sensitive information could be leaked, disclosed, or revealed as a result of or in connection with the use of generative artificial intelligence technologies by our employees, personnel, or vendors.

Changes in funding for the FDA, the SEC and other government agencies including comparable foreign regulatory authorities could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA or other comparable foreign regulatory authorities to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept payment of user fees, statutory, regulatory and policy changes, and business disruptions, such as those caused by the COVID-19 pandemic. Average review times at the agency and comparable foreign regulatory authorities have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies or other comparable foreign regulatory authorities may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. In addition, there have recently been terminations of large numbers of federal employees at various federal agencies. If a prolonged government shutdown occurs, it and/or employee terminations or resignations could significantly impact the ability of the FDA or other federal agencies to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns and/or employee terminations or resignations or could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations, or to timely obtain patent protection in the U.S. to protect our technology.

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

These laws may impact, among other things, our clinical research program, as well as our proposed and future sales, marketing and education programs. In particular, the promotion, sales and marketing of healthcare items and services is subject to extensive laws and regulations designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive and other business arrangements. We may also be subject to federal, state and foreign laws governing the privacy and security of identifiable patient information, price reporting, false claims and provider transparency. If our operations are found to be in violation of any of these laws that apply to us, we may be subject to significant civil, criminal and administrative penalties.

We and the third parties with whom we work are subject to stringent and evolving U.S. and foreign laws, regulations, rules, and industry standards, as well as policies, contracts and other obligations related to data privacy and security. Our (or the third parties with whom we work) actual or perceived failure to comply with such obligations could lead to enforcement or litigation (including class claims) and mass arbitration demands, fines or penalties, a disruption of clinical trials or commercialization of products, reputational harm, or other adverse business effects.

In the ordinary course of business, we process sensitive information. Accordingly, we are, and may in the future become, subject to numerous data privacy and security obligations, such as various federal, state, local and foreign data privacy and security laws, regulations, guidance, and industry standards as well as external and internal privacy and security policies, contracts and other obligations that apply to data privacy and security and our processing of personal data and the processing of personal data on our behalf.

In the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act) and other similar laws (e.g., wiretapping laws). For example, the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), as amended by the Health Information Technology for Economic and Clinical Health Act (HITECH), and their respective implementing regulations, imposes requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH, through its implementing regulations, makes certain of HIPAA's privacy and security standards directly applicable to business associates, defined as a person or organization, other than a member of a covered entity's workforce, that creates, receives, maintains or transmits protected health information for or on behalf of a covered entity for a function or activity regulated by HIPAA as well as their covered subcontractors.

In the past few years, numerous U.S. states have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal data. As applicable, such rights may include the right to access, correct, or delete certain personal data, and to opt-out of certain data processing activities, such as targeted advertising, profiling, and automated decision-making. The exercise of these rights may impact our business and ability to provide our products and services. Certain states also impose stricter requirements for processing certain personal data, including sensitive information, such as conducting data privacy impact assessments. These state laws allow for statutory fines for noncompliance. For example, the California Consumer Privacy Act of 2018 (CCPA), applies to personal data of consumers, business representatives, and employees who are California residents, and requires covered companies to provide specific disclosures in privacy notices and honor requests of such individuals to exercise certain privacy rights. The CCPA provides for fines and allows private litigants affected by certain data breaches to recover significant statutory damages. The CCPA and other comprehensive U.S. state privacy laws exempt some data processed in the context of clinical trials, but these developments may further complicate compliance efforts, and increase legal risk and compliance costs for us and the third parties with whom we work. Such laws, if they become applicable to us in the future, may significantly impact our business activities, exemplifying the vulnerability of our business to evolving regulatory environment related to personal data and protected health information. Similar laws are being considered in other states, as well as at the federal and local levels, and we expect more states to pass similar laws in the future.

Outside the United States, an increasing number of laws, regulations and industry standards govern privacy, data protection, information security and cross-border personal data transfers. For example, the European Union's General Data Protection Regulation (EU GDPR), the United Kingdom's GDPR (UK GDPR) (collectively, GDPR), and Australia's Privacy Act, China's Personal Information Protection Law (PIPL), and Canada's Personal Information Protection and Electronic

Documents Act (PIPEDA) (and various related provincial laws) and Anti-Spam Legislation (CASL) impose strict requirements for processing personal data.

For example, under the GDPR, companies may face temporary or definitive bans on data processing and other corrective actions; fines of up to €20,000,000 under the EU GDPR / 17.5 million pounds sterling under the UK GDPR, or up to 4% annual total revenue, in each case, whichever is greater; or private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests.

In the ordinary course of business, we transfer personal data from Europe and other jurisdictions to the United States or other countries. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the European Economic Area (EEA) and the United Kingdom (UK) have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it generally believes are inadequate. Some jurisdictions have adopted, and others may in the future adopt, similarly stringent data localization and cross-border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EEA and UK's standard contractual clauses, the UK's International Data Transfer Agreement / Addendum, and the EU-U.S. Data Privacy Framework and the UK extension thereto (which allows for transfers for relevant U.S.-based organizations who self-certify compliance and participate in the Framework), these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States. If there is no lawful manner for us to transfer personal data from the EEA, UK, or other jurisdictions to the United States, or if the requirements for a legally-compliant transfer are too onerous, we may face significant adverse consequences, including the interruption or degradation of our operations (such as by limiting our ability to conduct clinical trial activities in Europe and elsewhere), the need to relocate part of or all of our business or data processing activities to other jurisdictions (such as Europe) at significant expense, the inability to transfer data and work with partners, vendors and other third parties, increased exposure to regulatory actions, substantial fines, and injunctions against processing personal data necessary to operate our business. Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activist groups. Some European regulators have also ordered certain companies to suspend or permanently cease certain transfers out of Europe for allegedly violating the GDPR's cross-border data transfer limitations. Regulators in the United States such as the Department of Justice are also increasingly scrutinizing certain personal data transfers and have proposed and may enact certain data localization requirements, for example, the executive order from the previous federal administration Preventing Access to Americans' Bulk Sensitive Personal Data and United States Government-Related Data by Countries of Concern.

In addition, privacy advocates and industry groups have proposed, and may in the future propose, standards with which we are legally or contractually bound to comply. We are also bound by contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. We publish privacy notices and other statements regarding data privacy and security. Regulators in the United States are increasingly scrutinizing these statements, and if any of our privacy notices or related materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, misleading, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators or other adverse consequences. Furthermore, our employees and personnel may use generative artificial intelligence technologies to perform their work, and the disclosure and use of personal data in such technologies is subject to various privacy laws and other privacy obligations. Governments have passed and are likely to pass additional laws regulating generative AI. Our use of this technology could result in additional compliance costs, regulatory investigations and actions, and lawsuits.

Obligations related to data privacy and security (including consumers' data privacy expectations) are quickly changing, becoming increasingly stringent, and creating uncertainty. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. As a result, preparing for and complying with these obligations requires significant resources and may necessitate changes to our information technologies, systems and practices, as well as those of any third parties that process personal data on our behalf.

Although we endeavor to comply with our applicable privacy and security obligations, we may at times fail (or be perceived to have failed) to do so. Moreover, despite our efforts, we may not be successful in achieving compliance if our employees, third-party collaborators, service providers, contractors or consultants fail to comply with such obligations, which could negatively impact our business operations and compliance posture. If we or the third parties with whom we work fail, or are perceived to have failed, to address or comply with applicable obligations related to data privacy and security, we could face significant consequences including, but not limited to, government enforcement actions (e.g., investigations, fines, penalties, audits and inspections, and similar); litigation (including class-related claims) and mass arbitration demands; additional

reporting requirements and/or oversight; temporary or permanent bans or restrictions on all or some processing of personal data; orders to destroy or not use personal data; and imprisonment of company officials. In particular, plaintiffs have become increasingly more active in bringing privacy-related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for monumental statutory damages, depending on the volume of data and the number of violations. Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: interruptions or stoppages in our business operations (including clinical trials); inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or substantial changes to our business model or operations.

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

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

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

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

Risks Related to the Development of Our Product Candidates

Our engineered allogeneic T cell product candidates represent a novel approach to cancer treatment and treatment of autoimmune diseases, which creates significant challenges for us.

We are developing a pipeline of allogeneic T cell product candidates that are engineered from healthy donor T cells to express CARs and are intended for use in any eligible patient with certain cancers or autoimmune diseases. Advancing these novel product candidates creates significant challenges for us, including:

- manufacturing our product candidates to our or regulatory specifications and in a timely manner to support our clinical trials, and, if approved, commercialization;
- sourcing clinical and, if approved, commercial supplies for the raw materials used to manufacture our product candidates;

- understanding and addressing variability in the quality of a donor's T cells, which could ultimately affect our ability to produce product in a reliable and consistent manner and treat certain patients;
- educating medical personnel regarding the potential side effect profile of our product candidates, if approved, such as the potential adverse side effects related to CRS, neurotoxicity, GvHD, IEC-HS, prolonged cytopenia, aplastic anemia and neutropenic sepsis;
- using medicines to preempt or manage adverse side effects of our product candidates and such medicines may be difficult to source or costly or may not adequately control the side effects and/or may have other safety risks or a detrimental impact on the efficacy of the treatment;
- conditioning patients with chemotherapy and ALLO-647 or other lymphodepletion agents in advance of administering our product candidates, which may be difficult to source, costly or increase the risk of infections and other adverse side effects;
- obtaining regulatory approval, as the FDA and other comparable foreign regulatory authorities have limited experience with development of allogeneic T cell therapies for cancer or autoimmune diseases; and
- establishing sales and marketing capabilities upon obtaining any regulatory approval to gain market acceptance of a novel therapy.

Gene-editing is a relatively new technology, and if we are unable to use this technology in our intended product candidates, our revenue opportunities will be materially limited.

Cellectis' TALEN technology, which we use in our oncology programs, and Arbor's CRISPR technology, which we use in our AID program, both involve relatively new approaches to gene editing, using sequence-specific DNA-cutting enzymes, or nucleases, to perform precise and stable modifications in the DNA of living-cells and organisms, and we have very little experience with Arbor's CRISPR technology. Cellectis and Arbor have not created nucleases for all gene sequences that we may seek to target, and they may not agree to or have difficulty creating nucleases for other gene sequences that we may seek to target, which could limit the usefulness of this technology. Cellectis and Arbor are our sole sources for this technology, including for certain tools such as nucleases and vectors. If Cellectis or Arbor were to be unwilling or unable to supply these tools, our ability to develop gene-edited product candidates could be materially and adversely impacted, leading to delays in our development programs and potential failure to commercialize certain product candidates.

This technology may also not be shown to be effective in clinical studies that Cellectis, we or other licensees of Cellectis technology or Arbor's CRISPR technology may conduct, or may be associated with safety issues that may negatively affect our development programs. For instance, gene-editing may create unintended changes to the DNA such as a non-target site gene-editing, a large deletion, or a DNA translocation, any of which could lead to oncogenesis. In our ALPHA2 trial, we observed a chromosomal abnormality, and the FDA placed our clinical trials on hold following this observation. While our investigation concluded that gene editing was not responsible for the chromosomal abnormality and the hold was resolved, we may discover future abnormalities caused by gene editing or other factors that would impact our development plans. The gene editing of our product candidates may also not be successful in limiting the risk of GvHD or premature rejection by the patient.

In addition, the gene-editing industry is rapidly developing, and our competitors may introduce new technologies that render our technology obsolete or less attractive. New technology could emerge at any point in the development cycle of our product candidates. As competitors use or develop new technologies, any failures of such technology could adversely impact our program. We also may be placed at a competitive disadvantage, and competitive pressures may force us to implement new technologies at a substantial cost, and which would delay our development programs. In addition, our competitors may have greater financial, technical and personnel resources that allow them to enjoy technological advantages and may in the future allow them to implement new technologies before we can. We cannot be certain that we will be able to implement technologies on a timely basis or at a cost that is acceptable to us. If we are unable to maintain technological advancements consistent with industry standards, our operations and financial condition may be adversely affected.

We are heavily reliant on our partners, Cellectis and Servier, for access to TALEN gene editing technology for the manufacturing and development of our oncology product candidates.

A critical aspect to manufacturing allogeneic T cell product candidates involves gene editing the healthy donor T cells in an effort to avoid GvHD and to limit the patient's immune system from attacking the allogeneic T cells. GvHD results when allogeneic T cells start recognizing the patient's normal tissue as foreign. For our oncology product candidates, we use Cellectis' TALEN gene-editing technology to inactivate a gene coding for TCRα, a key component of the natural antigen receptor of T cells, to cause the engineered T cells to be incapable of recognizing foreign antigens. Accordingly, when injected

into a patient, the intent is for the engineered T cell not to recognize the tissue of the patient as foreign and thus avoid attacking the patient's tissue. In addition, we use TALEN gene editing in our oncology product candidates to inactivate the CD52 gene in donor T cells, which codes for the target of an anti-CD52 monoclonal antibody. Anti-CD52 monoclonal antibodies deplete CD52 expressing T cells in patients while sparing therapeutic allogeneic T cells lacking CD52. By administering an anti-CD52 antibody prior to infusing our oncology product candidates, we believe we have the potential to reduce the likelihood of a patient's immune system from rejecting the engineered allogeneic T cells for a sufficient period of time to enable a window of persistence during which the engineered allogeneic T cells can actively target and destroy the cancer cells. However, the antibody may not have the benefits that we anticipate and could have adverse effects.

We rely on an agreement with Cellectis for exclusive rights to use TALEN technology for 15 select cancer targets, including BCMA, FLT3, CD70, DLL3, Claudin 18.2 and other targets included in our pipeline. We also rely on Cellectis, through our agreement with Servier, for exclusive rights to UCART19, ALLO-501 and cema-cel. Any other gene-editing technology used to research and develop product candidates directed at targets not covered by our existing agreements with Cellectis and Servier will require significant investment and time for advancement. In addition, the Cellectis gene-editing technology may fail to produce viable product candidates. Moreover, both Servier and Cellectis may terminate our respective agreements in the event of a material breach of the agreements, or upon certain insolvency events. Cellectis has challenged and may in the future challenge certain performance by Servier, such as its development of products licensed under the Cellectis-Servier Agreement in acute lymphoblastic leukemia, and any failure by those parties to resolve such matters may have an adverse impact on us. If our agreements were terminated, we would be required to seek other gene editing technology or abandon our cema-cel and ALLO-316 programs, both of which could materially impact our business and financial position. Further, alternative gene editing technology may not be available to us on reasonable terms, or at all, and advancing other gene editing technology would require significant resources.

We are heavily reliant on our partner, Foresight Diagnostics, for access to their CLARITY™ MRD test for identifying eligible patients for our ALPHA3 trial.

Our ALPHA3 trial design requires the use of Foresight Diagnostics' CLARITY™ MRD test for patient selection. Foresight Diagnostics is a private company founded in 2020. Although Foresight Diagnostics has successfully executed its role in our ALPHA3 trial, it has limited resources and limited experience with its MRD assay and in executing clinical trials or supporting a commercial product. In the future, Foresight Diagnostics may not be able to successfully and timely conduct the ALPHA3 MRD tests, obtain regulatory approval of CLARITY or successfully support commercialization of cema-cel, if approved. If we need to transition to an alternative MRD test in the future, it could result in additional costs, delays, and diversion of resources, any of which would negatively impact our cema-cel development program. Further, we may be unable to identify an alternative approved effective MRD test, which could have a material adverse impact on our business.

Our reliance on specific vendors named in our INDs subject us to risks if these vendors are unable or unwilling to fulfill their obligations or if we need to change vendors, which could delay or prevent the development of our product candidates and commercialization, if approved.

Our investigational new drug (IND) applications name specific third-party vendors to supply certain raw materials, components, technology, and services that are essential to manufacturing our product candidates. We do not have the ability to rapidly secure alternative sources for these materials or services. In addition, because these vendors are specified in our INDs, any change to a new vendor would require additional regulatory submissions and approvals, which could significantly delay or complicate our product development efforts. If any of these vendors becomes unable or unwilling to supply the products or services we require on acceptable terms, in sufficient quantities, or in compliance with applicable regulatory requirements, we may experience:

- Delays in our preclinical studies or clinical trials due to the need to qualify and obtain regulatory approval for an alternate supplier;
- Higher costs associated with the need to qualify and validate a new manufacturing facility and supply chain;
- Difficulty ensuring quality and compliance with cGMP or other regulatory standards at a new vendor site, potentially leading to regulatory enforcement actions against us or significant delays in regulatory approvals or commercialization; and
- Disruption to our development timeline and commercialization efforts, which could materially harm our business, financial condition, and operating results.

Moreover, our reliance on these third parties reduces our control over manufacturing and quality assurance processes. Any performance failure or compliance breach by our named vendors-such as failing to meet regulatory standards or

encountering financial or operational difficulties-could adversely affect the ongoing development and potential commercialization of our product candidates. If we are forced to seek alternative vendors, we may be required to conduct bridging studies or other additional testing to demonstrate comparability of a product candidate when manufactured by a different supplier. Such a process can be time-consuming, expensive, and could delay or limit our ability to obtain regulatory approval or achieve market acceptance of our product candidates. If any of these events occur, our business, financial condition, and results of operations could be materially harmed.

Servier's discontinuation of its involvement in the development of CD19 Products and Servier's disputes with Cellectis, or future disputes with us, may have adverse consequences.

On September 15, 2022, Servier sent a notice of discontinuation (Discontinuation) of its involvement in the development of CD19, including the CD19 Products pursuant to the Original Servier Agreement. Under the Servier Agreement, Servier sublicenses to us certain rights it has licensed from Cellectis relating to Cellectis' TALEN gene editing technology pursuant to the Servier-Cellectis Agreement.

In May 2024 we entered into the Servier Amendment which made various amendments to the Original Servier Agreement, and expanded our licensed territory thereunder to include the European Union and the United Kingdom, and also granted us an option, under certain circumstances, to expand the territory further to include China (including Hong Kong) and Japan. Although we believe that we and Servier are both in full compliance of our respective obligations under the Servier Agreement, there can be no assurance that we will not have future disputes with Servier regarding our respective rights and obligations under our agreements and any future dispute could jeopardize our CD19 Products license, the loss of which would have a significant adverse impact on our business, financial condition, and prospects.

In April 2024 Cellectis filed a Form 20-F with the SEC, stating that Cellectis does not believe that: (1) the Servier-Cellectis Agreement permits Servier to grant a world-wide sub-license to us; and (2) Servier has not complied with its performance obligations under the Servier-Cellectis Agreement, which Cellectis believes may involve material breaches thereof. Cellectis has initiated an arbitration proceeding against Servier through the Centre de Médiation et d'Arbitrage de Paris, wherein Cellectis is seeking a decision terminating the Servier-Cellectis Agreement, and seeking certain compensation. Cellectis has asserted that a favorable determination by the arbitral tribunal, if achieved, would return development and commercialization rights for the licensed products back to Cellectis. Although Servier has advised us that they believe Cellectis' claims are without merit, there is a risk that Cellectis may prevail in the arbitration and terminate the Servier-Cellectis Agreement. Additionally, although we believe the Servier-Cellectis Agreement grants Servier the right to grant sublicenses without further consent from Cellectis, there is a risk that Cellectis may challenge the expansion of our territory under the Servier Agreement to regions outside the US. The Servier Agreement provides us with certain rights to obtain a direct license with Cellectis in the event the Servier-Cellectis Agreement is terminated, however, there can be no assurance that we will be able to obtain such a direct license. Additionally, although the Servier-Cellectis Agreement grants Servier the right to grant sublicenses without further consent from Cellectis, there is a risk that Cellectis could seek to challenge the expansion of our rights under the Servier Agreement to include the European Union and the United Kingdom. The termination of the Servier-Cellectis Agreement, our failure to obtain a direct license with Cellectis after such termination, or a successful challenge to the territorial expansion of our rights under the Servier Agreement would have a significant adverse impact on our business, financial condition, and prospects.

Our oncology development strategy relies on incorporating an anti-CD52 monoclonal antibody as part of the lymphodepletion preconditioning regimen prior to infusing allogeneic CAR T cell product candidates.

Certain of our oncology product candidates utilize an anti-CD52 monoclonal antibody as part of a lymphodepletion regimen to be infused prior to infusing our product candidates. The anti-CD52 antibody may reduce the likelihood of a patient's immune system rejecting the engineered allogeneic T cells for a sufficient period of time to enable a window of persistence during which such engineered allogeneic T cells can actively target and destroy cancer cells. However, the antibody may not have the benefits that we anticipate and could have adverse effects. For instance, our lymphodepletion regimen, including using an anti-CD52 antibody, will cause immune suppression that can be of unpredictable depth and duration and that may be associated with an increased risk of infection, such as to common viral or bacterial or opportunistic pathogens, that may be unable to be cleared and ultimately lead to other serious adverse events or death.

In the prior CALM and PALL trials, a commercially available monoclonal antibody, alemtuzumab, that binds CD52 was used. Alemtuzumab is known to have risk of causing certain adverse events. In 2020, within the context of a procedure based on Article 20 of Regulation 726/2204 (EMA Regulation), the EMA completed a pharmacovigilance review of alemtuzumab in the context of the treatment of multiple sclerosis following reports of immune-mediated conditions and problems affecting the heart and blood vessels, including fatal cases. The EMA recommended that alemtuzumab should not be used in patients with certain heart, circulation or bleeding disorders or in patients who have autoimmune disorders other than

multiple sclerosis. The EMA also recommended that alemtuzumab only be given in a hospital with ready access to intensive care facilities and specialists who can manage serious adverse reactions. The use of our anti-CD52 antibody may result in the same or similar adverse events as alemtuzumab, and we have chosen to administer our product candidates at trial centers experienced at managing patients with advanced malignancies as well as toxicities associated with immunomodulatory therapies, which significantly limits the sites that are eligible to participate in our clinical trials. If the EMA or other regulatory agencies further limit the use of alemtuzumab or anti-CD52 antibodies, our clinical program would be adversely affected.

To secure our own readily available source of anti-CD52 antibody, we are developing our own monoclonal anti-CD52 antibody, ALLO-647, which we use in certain of our clinical trials. ALLO-647 may cause serious adverse events that alemtuzumab may cause, including fatal adverse events, infusion related reactions, immune thrombocytopenia, glomerular nephropathies, thyroid disorders, autoimmune cytopenias, autoimmune hepatitis, hemophagocytic lymphohistiocytosis, acquired hemophilia, infections, stroke, and progressive multifocal leukoencephalopathy. In addition, we are exploring various dosing strategies for lymphodepletion in our clinical trials, such as including varying doses of the chemotherapy agents and/or ALLO-647 or eliminating one or more of the agents, which may alter the risk of serious adverse events or have other undesirable outcomes such as a reduction of the efficacy of treatment. Additionally, our experimental lymphodepletion regimens may show different safety profiles when paired with different allogeneic CAR T product candidates such that regimens deemed safe with one CAR T product candidate may be determined to be associated with unacceptable toxicity when combined with another CAR T candidate or with the same candidate in a different patient population. If observed, these differences may require additional clinical exploration and may cause delays in the execution or termination of development campaigns. See the section entitled "Business-Product Pipeline and Development Strategy" included in this Annual Report for information on safety events.

If we are unable to successfully develop and manufacture ALLO-647 in the timeframe we anticipate, or at all, such as if regulatory authorities do not agree with our selected dose or approve of the use of ALLO-647 in combination with our allogeneic T cell product candidates, our clinical trial timelines and ability to commercialize certain of our oncology product candidates would be significantly delayed.

Risks Related to Our Reliance on 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 meet expected deadlines, we may not be able to obtain regulatory approval of or commercialize our product candidates.

We depend and will continue to depend upon independent investigators and collaborators, such as universities, medical institutions, CROs and strategic partners to conduct our preclinical and clinical trials under agreements with us.

We negotiate budgets and contracts with CROs and study sites, which may result in delays to our development timelines and increased costs. We will rely heavily on these third parties 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 applicable protocol, legal, regulatory and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. We and these third parties are required to comply with GCPs, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of these third parties fail to comply with applicable GCP regulations, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, such regulatory authorities will determine that any of our clinical trials comply with the GCP regulations. In addition, our clinical trials must be conducted with biologic product produced under cGMPs and will require a large number of test patients. Our failure or any failure by these third parties to comply with these regulations or to recruit a sufficient number of patients may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

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 such third parties, we cannot control whether or not they devote sufficient time and resources to our ongoing preclinical, clinical and nonclinical programs. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical studies or other drug development activities, which could affect their performance on our behalf. If these third parties do not successfully carry out

their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to complete development of, obtain regulatory approval of or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.

If any of our relationships with trial sites, or any CRO that we may use in the future, terminates, we may not be able to enter into arrangements with alternative trial sites or CROs or do so on commercially reasonable terms. Switching or adding third parties to conduct our clinical trials involves substantial cost and requires extensive management time and focus. In addition, there is a natural transition period when a new third party commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines.

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

While we utilize CF1 for clinical manufacturing of our CAR T product candidates, we will continue to use CDMOs to manufacture ALLO-647 and several core reagents, and for distribution logistics. There can be no assurance that we will not experience supply or manufacturing issues related to our product candidates or core reagents in the future.

We do not have long-term agreements in place with CDMOs for the manufacture of our cell therapies or of ALLO-647. If we are unable to contract with CDMOs on acceptable terms or at all, our clinical development program would be delayed and our business would be significantly harmed. For example, in December 2024 Novo Holdings completed its acquisition of Catalent, Inc., and shortly thereafter Novo Nordisk acquired three Catalent fill-finish sites and related assets from Novo Holdings. ALLO-647 is manufactured at one of these sites, and we have been advised by Novo Nordisk that we will need to transfer such manufacturing to a different site. Although we believe that we currently have sufficient ALLO-647 inventory for our near-term requirements, the transfer to a new manufacturing site will be time consuming, costly, and subject to uncertainty. In addition, the transfer will require regulatory approval. We may be unable to complete the manufacturing site transfer in a timely manner, if at all, which could significantly delay our clinical development timelines. If we are unable to establish an alternative manufacturing site or unable to do so in a timely manner, if at all, it could significantly delay our clinical development timelines.

We have built CF1 and have transitioned the manufacturing of certain product candidates to our manufacturing facility, and we are reliant on CF1 as our sole manufacturing site for certain of our product candidates. Manufacturing product candidates in our own facility requires that we meet certain regulatory conditions, which may delay or extend our clinical trial timelines. If, for any reason, we are unable to continue manufacturing our product candidates at CF1, there is a risk that we may need to re-engage our CDMO to manufacture material, which would be costly and there is a risk that the CDMO may be unavailable or may fail in manufacturing, such as due to the CDMO having to retrain its personnel, or train new personnel, to manufacture our material. Any disruptions to CF1's operations, whether due to regulatory non-compliance, supply chain constraints, equipment failures, natural disasters, or other unforeseen circumstances, could have a material adverse effect on our ability to manufacture our products and meet clinical or commercial demand. If CF1 becomes unavailable for any reason, our ability to continue product development and commercialization could be significantly impaired, leading to delays, increased costs, and potential loss of revenue.

We have not yet caused our product candidates to be manufactured or processed on a commercial scale and may not be able to achieve manufacturing and processing and may be unable to create an inventory of mass-produced, off-the-shelf product to satisfy demands for any of our product candidates. Our clinical supply is also limited to small quantities and any latent defects discovered in our supply could significantly delay our development timelines.

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

- We may be unable to identify manufacturers on acceptable terms or at all because the number of potential manufacturers is limited and the FDA or other comparable foreign regulatory authorities may have questions regarding any replacement contractor. This may require new testing and regulatory interactions. In addition, a new manufacturer would have to be educated in, or develop substantially equivalent processes for, production of our products after receipt of FDA or other comparable foreign regulatory authorities questions, if any.

- Our third-party manufacturers might be unable to timely formulate and manufacture our product or core reagents or produce the quantity and quality required to meet our clinical and commercial needs, if any.
- Contract manufacturers may not be able to execute our manufacturing procedures appropriately.
- Contract manufacturers may be subject to adverse legislative actions.
- Manufacturers are subject to ongoing periodic unannounced inspection by the FDA, the Drug Enforcement Administration and corresponding state agencies or other comparable foreign regulatory authorities to ensure strict compliance with cGMP and other government regulations and corresponding foreign standards. We do not have control over third-party manufacturers' compliance with these regulations and standards.
- We may not own, or may have to share, the intellectual property rights to any improvements made by our third-party manufacturers in the manufacturing process for our products.
- Our future contract manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store and distribute our products or core reagents.
- Our third-party manufacturers could breach or terminate their agreement with us.

Our contract manufacturers would also be subject to the same risks we face in developing our own manufacturing capabilities, as described above. Our current and potential future CDMOs may also be required to shut down in response to health epidemics or pandemics, or they may prioritize manufacturing for therapies or vaccines for other diseases. In addition, our CDMOs have certain responsibilities for storage of raw materials and in the past have lost or failed to adequately store our raw materials. We also rely on third parties to store our released product candidates, and any failure to adequately store our product candidates could result in significant delay to our development timelines. Any additional or future damage or loss of raw materials or product candidates could materially impact our ability to manufacture and supply our product candidates. Each of these risks could delay our clinical trials, the approval, if any, of our product candidates by the FDA or other comparable foreign regulatory authorities or the commercialization of our product candidates or result in higher costs or deprive us of potential product revenue.

In addition, we rely on third parties to perform release tests on our product candidates prior to delivery to patients. If these tests are not appropriately done and test data are not reliable, patients could be put at risk of serious harm.

We rely on T cells from healthy donors to manufacture our product candidates, and if we do not obtain an adequate supply of T cells from qualified donors, development of those product candidates, or commercialization, if approved, may be adversely impacted.

Unlike autologous CAR T companies, we are reliant on receiving healthy donor material to manufacture our product candidates. Healthy donor T cells vary in type and quality, and this variation makes producing standardized product candidates more difficult and makes the development and commercialization pathway of those product candidates more uncertain. We 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 the manufacturing runs we have completed and tested in the clinic are limited across our product candidates. As we gain experience, we may find that our screening process fails to identify suitable donor material and we may discover unacceptable variability with the material after production. We may also have to update our specifications for new risks that may emerge, such as to screen for new viruses or chromosomal abnormalities.

We have strict specifications for donor material, which include specifications required by regulatory authorities. If we are unable to identify and obtain donor material that satisfy specifications, agree with regulatory authorities on appropriate specifications, or address variability in donor T cells, there may be inconsistencies in the product candidates we produce 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.

In addition, vendors face challenges in obtaining donor material. While we have donor material on hand, if our vendors are unable to secure donor material, we may no longer have sufficient donor material to manufacture our product candidates.

Cell-based therapies rely on the availability of specialty raw materials, which may not be available to us on acceptable terms or at all.

Our product candidates require many specialty raw materials, including viral vectors that deliver the CAR sequence and electroporation technology, some of which are manufactured by small companies with limited resources and experience to

support a commercial product, and the suppliers may not be able to deliver raw materials to our specifications. We do not have contracts with many of the suppliers, and we may not be able to contract with them on acceptable terms, or at all. As a result of logistical challenges and recent inflation, we may experience higher costs or delays in receiving, or fail to secure entirely, key raw materials to support clinical or commercial manufacturing. Certain raw materials also require third-party testing, and some of the testing service companies may not have capacity or be able to conduct the testing that we request.

In addition, many of our suppliers normally support blood-based hospital businesses and generally do not have the capacity to support commercial products manufactured under cGMP by biopharmaceutical firms. The suppliers may be ill-equipped to support our needs, including generating data required for a BLA and in non-routine circumstances like an FDA or other comparable foreign regulatory authorities inspection or medical crisis, such as widespread contamination.

We also face competition for supplies from other cell therapy companies. Such competition may make it difficult for us to secure raw materials or the testing of such materials on commercially reasonable terms or in a timely manner.

Some raw materials are currently available from a single supplier, or a small number of suppliers. We cannot be sure that these suppliers will remain in business or that they will not be purchased by one of our competitors or another company that is not interested in continuing to produce these materials for our intended purpose. In addition, the lead time needed to establish a relationship with a new supplier can be lengthy, and we may experience delays in meeting demand in the event we must switch to a new supplier. For example, for certain raw materials we previously had to find an alternative supplier, which required qualifying the new supplier, which required meeting regulatory requirements for such qualification. If we need to transition to an alternative supplier in the future, it could result in additional costs, delays, diversion of resources or reduced manufacturing yields, any of which would negatively impact our operating results. Further, we may be unable to enter into agreements with a new supplier on commercially reasonable terms, which could have a material adverse impact on our business.

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

Our research and development activities involve the controlled use of potentially hazardous substances, including chemical and biological materials. We and our suppliers are subject to federal, state and local laws and regulations in the United States governing the use, manufacture, storage, handling and disposal of medical and hazardous materials, and there is a risk of contamination or injury resulting from medical or hazardous materials. For instance, we have had and may continue to have environmental notice of violations at our manufacturing facility. As a result of any such contamination or injury, we may incur liability or local, city, state or federal authorities may curtail the use of these materials and interrupt our business operations. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. We do not have any insurance for liabilities arising from medical or hazardous materials. In addition, we have previously shipped certain materials to Allogene Overland PRC in China and may do so in the future to its successor entity. Any violation by our joint venture in the use, manufacture, storage, handling and disposal under foreign law may subject us to additional liability.

Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development and production efforts, which could harm our business, prospects, financial condition or results of operations.

Risks Related to Government Regulation

The FDA and other comparable foreign regulatory approval processes are lengthy and time-consuming, and we may experience significant delays in the clinical development and regulatory approval of our product candidates.

The research, testing, manufacturing, labeling, approval, selling, import, export, marketing, and distribution of drug products, including biologics, are subject to extensive regulation by the FDA and other regulatory authorities in the United States and comparable foreign regulatory authorities. We are not permitted to market any biological drug product in the United States or elsewhere until we receive approval of a BLA from the FDA or equivalent approvals from other comparable foreign regulatory authorities. We have not previously submitted a BLA to the FDA, or similar approval filings to comparable foreign regulatory authorities. A BLA or equivalent foreign application must include extensive preclinical and clinical data and supporting information to establish the product candidate’s safety and effectiveness for each desired indication. The BLA or equivalent foreign application must also include significant information regarding CMC matters for the product, and any delay

or failure in generating such data to meet the evolving CMC regulatory requirements would delay any BLA filing or equivalent foreign application.

We expect the novel nature of our product candidates to create further challenges in obtaining regulatory approval. For example, the FDA or other comparable foreign regulatory authorities have limited experience with commercial development of allogeneic T cell therapies for cancer. We may also request clinical trial initiation or regulatory approval of future CAR-based product candidates by target, regardless of cancer type or origin, which the FDA or other comparable foreign regulatory authorities may have difficulty accepting. The FDA or other comparable foreign regulatory authorities may also require a panel of experts, referred to as an Advisory Committee, to deliberate on the adequacy of the safety and efficacy data to support licensure. The opinion of the Advisory Committee, although not binding, may have a significant impact on our ability to obtain licensure of the product candidates based on the completed clinical trials, as the FDA or comparable foreign regulatory authorities often adheres to the 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.

We have previously experienced a delay in our clinical trials due to a clinical hold, and may experience future delays in completing planned clinical trials for a variety of reasons, including delays related to:

- obtaining regulatory authorization to begin a trial, if applicable, including regulatory approval of any companion diagnostic, if applicable;
- the availability of financial resources to commence and complete the planned trials;
- reaching agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- developing and implementing processes and procedures with collaborators relating to the collection and transfer of patient samples and the timely performance of a companion diagnostic on such samples;
- obtaining approval at each clinical trial site by an independent IRB or a positive opinion from an Ethics Committee;
- obtaining regulatory and other approvals to modify the conduct of a clinical trial;
- recruiting suitable patients to participate in a trial;
- delays by a collaboration partner in running a companion diagnostic on patient samples;
- having patients complete a trial, including having patients enrolled in clinical trials dropping out of the trial prior to treatment, or return for post-treatment follow-up;
- clinical trial sites deviating from trial protocol or dropping out of a trial;
- addressing any patient safety concerns that arise during the course of a trial;
- adding new clinical trial sites; or
- manufacturing sufficient quantities of qualified materials under cGMPs, releasing product in accordance with specifications, and delivering product candidates for use in clinical trials.

We could also encounter future delays if physicians encounter unresolved ethical issues associated with enrolling patients in clinical trials of our product candidates in lieu of prescribing existing treatments that have established safety and efficacy profiles, or with respect to the ALPHA3 trial, in lieu of observation alone. Further, a clinical trial may be suspended or terminated by us, the Institutional Review Boards (IRBs) or Ethics Committees for the institutions in which such trials are being conducted or by the FDA or other comparable foreign regulatory authorities due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other comparable foreign regulatory authorities resulting in the imposition of a clinical hold, safety issues or adverse side effects, failure to demonstrate a benefit from using a product candidate, changes in governmental regulations or administrative actions, lack of adequate funding to continue the clinical trial, or based on a recommendation by any Data Safety Monitoring Committee. The FDA or other comparable foreign regulatory authorities' review of our data of our clinical trials may, depending on the data, also result in the delay, suspension or termination of one or more of our clinical trials, which would also delay or prevent the initiation of our other planned clinical trials. If we experience termination of, or delays in the completion of, any clinical trial of our product candidates, the commercial prospects for our product candidates will be harmed, and our ability to generate product revenue will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product development and approval process and jeopardize our ability to commence product sales and generate revenue.

Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may ultimately lead to the denial of regulatory approval of our product candidates.

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 or maintaining any regulatory approval.

Because we are developing novel CAR T cell immunotherapy product candidates that are unique biological entities, the regulatory requirements that we will be subject to are not entirely clear. Even with respect to more established products that fit into the categories of gene therapies or cell therapies, the regulatory landscape is still developing and guidance from regulatory authorities may continue to change in the future.

Moreover, there is substantial, and sometimes uncoordinated, overlap in those responsible for regulation of existing gene therapy products and cell therapy products. For example, in the United States, the FDA has established the Office of Tissues and Advanced Therapies (OTAT), formerly known as the Office of Cellular, Tissue and Gene Therapies (OCTGT), within its Center for Biologics Evaluation and Research (CBER) to consolidate the review of gene therapy and related products, and the Cellular, Tissue and Gene Therapies Advisory Committee to advise CBER on its review. Gene therapy clinical trials are also subject to review and oversight by an institutional biosafety committee (IBC), a local institutional committee that reviews and oversees basic and clinical research conducted at the institution participating in the clinical trial. Although the FDA decides whether individual gene therapy protocols may proceed, review process and determinations of other reviewing bodies can impede or delay the initiation of a clinical study, even if the FDA has reviewed the study and approved its initiation. Conversely, the FDA can place an IND application on clinical hold even if such other entities have provided a favorable review. Furthermore, each clinical trial must be reviewed and approved by an independent IRB at or servicing each institution at which a clinical trial will be conducted. In addition, adverse developments in clinical trials of gene therapy products conducted by others may cause the FDA or other regulatory bodies to change the requirements for approval of any of our product candidates.

Complex regulatory environments exist in other jurisdictions in which we might consider seeking regulatory approvals for our product candidates, further complicating the regulatory landscape. For example, in the European Union a special committee called the Committee for Advanced Therapies (CAT) was established within the EMA in accordance with Regulation (EC) No 1394/2007 on advanced-therapy medicinal products (ATMPs) to assess the quality, safety and efficacy of ATMPs, and to follow scientific developments in the field. ATMPs include gene therapy products as well as somatic cell therapy products and tissue engineered products. In this regard, on May 28, 2014, the EMA issued a recommendation that UCART19 be considered a gene therapy product under Regulation (EC) No 1394/2007 on ATMPs. We cannot conclude that our product candidates will receive a similar recommendation.

These various regulatory review committees and advisory groups and new or revised guidelines that they promulgate from time to time may lengthen the regulatory review process, require us to perform additional studies, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of our product candidates or lead to significant post-approval limitations or restrictions. Because the regulatory landscape for our CAR T cell immunotherapy product candidates is new, we may face even more cumbersome and complex regulations than those emerging for gene therapy products and cell therapy products. Furthermore, even if our product candidates obtain required regulatory approvals, such approvals may later be withdrawn as a result of changes in regulations or the interpretation of regulations by applicable regulatory agencies.

Delay or failure to obtain, or unexpected costs in obtaining, the regulatory approval necessary to bring a potential product to market could decrease our ability to generate sufficient product revenue to maintain our business.

The FDA or comparable foreign regulatory authorities may disagree with our regulatory plan and we may fail to obtain regulatory approval of our CAR T cell product candidates.

The general approach for FDA or comparable foreign regulatory authorities approval of a new biologic or drug is for the sponsor to provide dispositive data from two well-controlled, Phase 3 clinical studies of the relevant biologic or drug in the relevant patient population. Phase 3 clinical studies typically involve hundreds of patients, have significant costs and take years to complete. We expect ongoing FDA, EMA, or comparable foreign regulatory authorities feedback on our trials, some of which may lead to changes in the trials, which could cause future delays to our trials. In addition, even if we believe the results are sufficiently compelling, such as for the ALPHA3 trial, the FDA, EMA, or comparable foreign regulatory authorities could ultimately require longer-term follow-up results, additional data from our clinical trials or additional trials that could delay or prevent our first BLA submission. The FDA, EMA, or comparable foreign regulatory authorities may require that we conduct a comparative trial against an approved therapy including potentially an approved autologous T cell therapy, which would

significantly delay our development timelines and require substantially more resources. In addition, the FDA, EMA, or comparable foreign regulatory authorities may only allow us to evaluate patients that have failed or who are ineligible for autologous therapy, which are extremely difficult patients to treat and patients with advanced and aggressive cancer, and our product candidates may fail to improve outcomes for such patients.

If the FDA or European Commission grant accelerated approval for our product candidates, as a condition for accelerated approval, the FDA or the European Commission may require us to perform post-marketing studies to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical endpoint, and the drug or biologic may be subject to withdrawal procedures by the FDA that are more accelerated than those available for regular approvals. The FDA or European Commission may ultimately refuse to grant accelerated approval for our product candidates and require a Phase 3 clinical trial prior to approval, particularly since our product candidates represent a novel treatment. In addition, the standard of care may change with the approval of new products in the same indications that we are studying. This may result in the FDA, the European Commission, or other regulatory agencies requesting additional studies to show that our product candidate is superior to the new products.

Our clinical trial results may also not support approval. In addition, our product candidates could be delayed in receiving approval or fail to receive regulatory approval for many reasons, including the following:

- the inability to resolve any future clinical hold;
- the FDA, EMA, or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA, EMA, or comparable foreign regulatory authorities that our product candidates are safe and effective for any of their proposed indications;
- the results of clinical trials may not meet the level of statistical significance required by the FDA, EMA, or comparable foreign regulatory authorities for approval, including due to the heterogeneity of patient populations;
- we may be unable to demonstrate that our product candidates' clinical and other benefits outweigh their safety risks;
- the FDA, EMA, or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to the satisfaction of the FDA, EMA, or comparable foreign regulatory authorities to support the submission of a BLA or other comparable submission in foreign jurisdictions or to obtain regulatory approval in the United States or elsewhere;
- the FDA, EMA, or comparable foreign regulatory authorities will review extensive CMC data, our manufacturing process and inspect the relevant commercial manufacturing facility and may not approve our manufacturing process or facility;
- the approval policies or regulations of the FDA, EU, or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval; and
- we may be unable to agree on any required pediatric investigation plan with regulatory authorities prior to any BLA filing.

We may be unable to obtain regulatory approval for ALLO-647 in a timely manner or at all, which could delay any approval or commercialization of our allogeneic T cell product candidates.

As we are concurrently developing ALLO-647 to be used as part of the lymphodepletion regimen for certain of our allogeneic CAR T cell product candidates, mapping a co-development path for dual approval of ALLO-647 and any of our CAR T cell product candidates and coordinating concurrent review with different divisions of competent regulatory authorities create additional regulatory uncertainty for us and may delay the development of our product candidates. As an example, coordinating concurrent review with the divisions of the FDA creates such regulatory uncertainty and may delay the development of our product candidates. We expect the Center for Drug Evaluation and Research division of the FDA to exercise authority over the regulatory approval of ALLO-647 while the CBER division will oversee the regulatory approval of our allogeneic CAR T cell product candidates.

In addition, the FDA is requiring us to demonstrate the overall contribution of ALLO-647 to the benefit to risk ratio of the lymphodepletion regimen for cema-cel. We plan to assess ALLO-647 through part one of the ALPHA3 trial. Some clinical trial sites may elect not to participate, and we cannot be certain when or whether we will be able to successfully enroll the ALPHA3 trial in a timely manner or that the outcome of this study will support FDA approval of both cema-cel and

ALLO-647. Any delays to ALLO-647 approval could delay any approval or commercialization of our allogeneic CAR T cell product candidates. We anticipate that the EMA, or comparable foreign regulatory authorities will impose equivalent obligations as part of the marketing authorization process in their territory.

If we, or our collaborators, are required by the FDA, or comparable foreign regulatory authorities, to obtain approval (or clearance, or certification) of a companion diagnostic device in connection with approval of one of our product candidates, and we, or our collaborators, do not obtain, or face delays in obtaining, approval (or clearance, or certification) of a companion diagnostic device, we will not be able to commercialize the product candidate, and our ability to generate revenue will be materially impaired.

According to FDA guidance, if the FDA determines that a companion diagnostic device is essential to the safe and effective use of a novel therapeutic product or 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. If a satisfactory companion diagnostic is not commercially available, we may be required to create or obtain one that would be subject to regulatory approval requirements. For example, we are collaborating with Foresight Diagnostics as part of our clinical trial enrollment process for ALPHA3 to identify patients with MRD that we believe may be most likely to benefit from treatment with cema-cel. The process of validating such diagnostic can be time consuming and costly.

Companion diagnostics are developed in conjunction with clinical programs for the associated product and are subject to regulation as medical devices by the FDA and comparable foreign regulatory authorities, and, to date, the FDA has generally required premarket approval of companion diagnostics for cancer therapies. Generally, when a companion diagnostic is essential to the safe and effective use of a therapeutic product, the FDA requires that the companion diagnostic be approved concurrent with approval of the therapeutic product and before a product can be commercialized. In the EEA, companion diagnostics are deemed to be in vitro diagnostic medical devices (IVDs) and are governed by Regulation 2017/746 (IVDR). IVDs, including companion diagnostics, must conform with the general safety and performance requirements (GSPR) of the IVDR by December 2028.

If the FDA, or a comparable foreign regulatory authority, requires approval (or certification or clearance) of a companion diagnostic for any of our product candidates, whether before or after the product candidate obtains marketing approval, we and/or third-party collaborators may encounter difficulties in developing and obtaining approval (or clearance, or certification) for these companion diagnostics. Any delay or failure by us or third-party collaborators to develop or obtain regulatory approval (or clearance, or certification) of a companion diagnostic could delay or prevent approval or continued marketing of our related product candidates. We, or our collaborators, may also experience delays in developing a sustainable, reproducible, and scalable manufacturing process for the companion diagnostic or in transferring that process to commercial partners or negotiating insurance reimbursement plans, all of which may prevent us from completing our clinical trials or commercializing our product candidates, if approved, on a timely or profitable basis, if at all.

Our ALPHA3 trial design requires the use of Foresight Diagnostics' PhasED-Seq™ Circulating Tumor DNA Platform as a companion diagnostic for cema-cel. Although the Foresight CLARITY™ Investigational Use Only (IUO) MRD test, powered by PhasED-Seq, has received IDE approval from the FDA allowing PhasEd-Seq to be used as part of the ALPHA3 trial, there can be no assurance that Foresight Diagnostic will be able to obtain the necessary regulatory approvals to support ALPHA3 clinical trial sites outside the US, or that we would be able to manage logistical challenges associated with timely international shipment of patient samples to Foresight's US facility for testing, all of which could delay the expansion of our ALPHA3 trial to trial sites outside the US.

Furthermore, in order to commercialize cema-cel based on the outcome of our ALPHA3 trial, the Foresight Diagnostics' MRD assay must be approved by regulatory agencies, and in some jurisdictions approved as a companion diagnostic test. A delay or failure by Foresight Diagnostics to obtain regulatory approval may delay the commercialization of cema-cel, if approved based on the outcome of our ALPHA3 trial.

Regenerative Medicine Advanced Therapy designation and fast track designation may not lead to a faster development or regulatory review or approval process and it does not increase the likelihood that our product candidates will receive marketing approval.

We have received Regenerative Medicine Advanced Therapy (RMAT) designation for cema-cel, ALLO-316, and ALLO-715 and fast track designation for ALLO-605, ALLO-316, and ALLO-647. There is no assurance that we will be able to obtain RMAT designation or fast track designation for any of our additional product candidates. RMAT designation and fast track designation do not change the FDA's standards for product approval, and there is no assurance that such designation will

result in expedited review or approval or that the approved indication will not be narrower than the indication covered by the designation. Additionally, RMAT designation and fast track designation can be revoked if the criteria for eligibility cease to be met as clinical data emerges.

We plan to seek orphan drug designation for some or all of our product candidates across various indications, but we may be unable to obtain such designations or to maintain the benefits associated with orphan drug designation, including market exclusivity, which may cause our revenue, if any, to be reduced.

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

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

The FDA granted orphan drug designation to ALLO-605 and ALLO-715 for the treatment of multiple myeloma. We plan to seek orphan drug designation for additional product candidates in specific orphan indications in which there is a medically plausible basis for the use of these products, but may never receive such designations. Some of our product candidates target indications that are not orphan indications. In addition, even with orphan drug designation, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan designated indication and may be lost if the FDA later determines that the request for designation was materially defective or if we are unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition, or if a subsequent applicant demonstrates clinical superiority over our products, if approved.

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

The gene-editing technologies that we use are novel. Public perception may be influenced by claims that gene editing is unsafe, and products incorporating gene editing may not gain the acceptance of the public or the medical community. Given the previous clinical hold involved a chromosomal abnormality, our manufacturing or gene editing may be further scrutinized or may be viewed as unsafe, even though our investigation found that the abnormality was not related to our manufacturing or gene editing. In particular, our success will depend upon physicians specializing in our targeted diseases prescribing our product candidates 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 gene editing may result in fewer physicians prescribing our treatments or may reduce the willingness of patients to utilize our treatments or participate in clinical trials for our product candidates.

In addition, given the novel nature of gene-editing and cell therapy technologies, governments may place import, export or other restrictions in order to retain control or limit the use of the technologies. For instance, any limits on exporting certain of our technology to China may adversely affect Overland Therapeutics, a joint venture between us and HBP. Increased negative public opinion or more restrictive government regulations either in the United States or internationally, would have a

negative effect on our business or financial condition and may delay or impair the development and commercialization of our product candidates or demand for such product candidates.

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

The Biologics Price Competition and Innovation Act of 2009 (BPCIA) was enacted as part of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the Affordable Care Act) to establish an abbreviated pathway for the approval of biosimilar and interchangeable biological products. The regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as "interchangeable" based on its similarity to an approved biologic. Under the BPCIA, an application for a biosimilar product cannot be approved by the FDA until 12 years after the reference product was approved under a BLA. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty and could have a material adverse effect on the future commercial prospects for our biological products.

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

The European Union provides opportunities for data and market exclusivity for innovative medicinal products in relation to which marketing authorization is granted. Upon grant of marketing authorization, innovative medicinal products are generally entitled to benefit from eight years of data exclusivity and 10 years of market exclusivity. Data exclusivity, if granted, prevents regulatory authorities in the European Union from referencing the innovator's data to assess an application for marketing authorization for a generic or a biosimilar for eight years from the date of authorization of the innovative product, after which an application may be made for authorization of a generic or biosimilar, and the innovator's data may be referenced. The market exclusivity period prevents a successful generic or biosimilar applicant from commercializing its product in the European Union until 10 years have elapsed from the initial marketing authorization of the reference product in the EU. The overall ten-year period may, occasionally, be extended for a further year to a maximum of 11 years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. However, there is no guarantee that a product will be considered by the EU's regulatory authorities to be a new chemical/biological entity, and products may not qualify for data exclusivity.

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

The use of engineered T cells as a potential cancer treatment is a recent development and may not become broadly accepted by physicians, patients, hospitals, cancer treatment centers and others in the medical community. We expect physicians in the large bone marrow transplant centers to be particularly important to the market acceptance of our products and we may not be able to educate them on the benefits of using our product candidates for many reasons. For example, certain of the product candidates that we will be developing 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 a safe and effective treatment;
- the potential and perceived advantages of our product candidates over alternative treatments;
- the prevalence and severity of any side effects;
- product labeling or product insert requirements of the FDA or other comparable foreign regulatory authorities;

- limitations or warnings contained in the labeling approved by the FDA or other comparable foreign regulatory authorities;
- the timing of market introduction of our product candidates as well as competitive products;
- the cost of treatment in relation to alternative treatments;
- the availability of coverage and adequate reimbursement by third-party payors and government authorities;
- the willingness of patients to pay out-of-pocket in the absence of coverage and adequate reimbursement by third-party payors and government authorities;
- relative convenience and ease of administration, including as compared to alternative treatments and competitive therapies; and
- the effectiveness of our sales and marketing efforts.

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 products or technologies are introduced that are more favorably received than our products, are more cost effective or render our products obsolete.

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

Successful sales of our product candidates, if approved, depend on the availability of coverage and adequate reimbursement from third-party payors including governmental healthcare programs, such as Medicare and Medicaid, managed care organizations and commercial payors, among others. Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we obtain regulatory approval. In addition, because our product candidates represent new approaches to the treatment of cancer, we cannot accurately estimate the potential revenue from our product candidates.

Patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Obtaining coverage and adequate reimbursement from third-party payors is critical to new product acceptance.

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

The advancement of healthcare reform may negatively 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 foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products. Such reforms could have an adverse effect on anticipated revenue from product candidates that we may successfully develop and for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop product candidates. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors, which may adversely affect our future profitability.

Our business could be negatively impacted by environmental, social and corporate governance (ESG) matters or our reporting of such matters.

There is an increasing focus from certain investors, employees, partners, and other stakeholders concerning ESG matters, and in many cases with conflicting views. While we have had internal efforts directed at ESG matters and preparations for increased future disclosures, we may be perceived by certain stakeholders as not acting responsibly in connection with these matters, which could negatively impact us. Moreover, the SEC recently adopted rules designed to enhance and standardize climate-related disclosures, which have been stayed pending judicial review. If these rules or other climate-related disclosures

rules become effective, they may significantly increase our compliance and reporting costs and may also result in disclosures that certain investors or other stakeholders deem to negatively impact our reputation or that harm our stock price. Additionally, the increasing divergent expectations and standards among policymakers, regulators and investors, could make it more difficult to comply with the various federal, state and foreign ESG-related regulations in the jurisdictions in which we may have operations.

Risks Related to Our Intellectual Property

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

We are dependent on patents, know-how and proprietary technology, both our own and licensed from others. We depend substantially on our license agreements with Pfizer, Servier and Cellectis. These licenses may be terminated upon certain conditions. Any termination of these licenses could result in the loss of significant rights and could harm our ability to commercialize our product candidates. For example, we are dependent on our license with Cellectis for gene-editing technology that is necessary to produce certain of our engineered T cells. In addition, we are reliant on Servier in-licensing from Cellectis some of the intellectual property rights they are licensing to us, including certain intellectual property rights relating to ALLO-501 and cema-cel. To the extent these licensors fail to meet their obligations under their license agreements, which we are not in control of, we may lose the benefits of our license agreements with these licensors. For instance, Cellectis has challenged and may in the future challenge certain performance by Servier, such as its development of products licensed under the Cellectis-Servier Agreement in ALL, and any failure by those parties to resolve such matters may have an adverse impact on us. In the future, we may also enter into additional license agreements that are material to the development of our product candidates.

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

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

For example, previously we and Servier had different interpretations regarding the respective parties' respective rights and obligations under the Original Servier Agreement. In May 2024, we entered into the Servier Amendment which clarified each parties rights and obligations. There can be no assurance that further contract interpretation issues will not arise or that we would be able to amicably resolve such issues. If other issues arise over intellectual property that we have licensed, or license in the future, it could prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, and we may be unable to successfully develop and commercialize the affected product candidates.

We are generally also subject to all of the same risks with respect to protection of intellectual property that we license, as we are for intellectual property that we own, which are described below. If we or our licensors fail to adequately protect this intellectual property, our ability to commercialize products could suffer.

If our efforts to protect the proprietary nature of the intellectual property related to our technologies are not adequate, we may not be able to compete effectively in our market.

We rely upon a combination of patents, trade secret protection and license agreements to protect the intellectual property related to our technologies. Any disclosure to or misappropriation by third parties of our confidential proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in our market.

Under the Servier Agreement, we have an exclusive license to develop and commercialize certain anti-CD19 allogeneic T cell product candidates, including cema-cel, and we hold the commercial rights to these product candidates in the

United States, the European Union and the United Kingdom. We also have an exclusive worldwide license from Cellectis to its TALEN gene-editing technology for the development of allogeneic T cell product candidates directed against 15 different cancer antigens. The Servier Agreement gives us access to TALEN gene-editing technology for all product candidates under the agreement. Certain intellectual property which is covered by these agreements may have been developed with funding from the U.S. government. If so, our rights in this intellectual property may be subject to certain research and other rights of the government.

Additional patent applications have been filed, and we anticipate additional patent applications will be filed, both in the United States and in other countries, as appropriate. However, we cannot predict:

- if and when patents will issue;
- the degree and range of protection any issued patents will afford us against competitors including whether third parties will find ways to invalidate or otherwise circumvent our patents;
- whether or not others will obtain patents claiming aspects similar to those covered by our patents and patent applications; or
- whether we will need to initiate litigation or administrative proceedings which may be costly whether we win or lose.

Composition of matter patents for biological and pharmaceutical products such as CAR-based product candidates often provide a strong form of intellectual property protection for those types of products, as such patents provide protection without regard to any method of use. We cannot be certain that the claims in our pending patent applications covering compositions of matter of our product candidates will be considered patentable by the United States Patent and Trademark Office (USPTO) or by patent offices in foreign countries, or that the claims in any of our issued patents will be considered valid and enforceable by courts in the United States or foreign countries. Method of use patents protect the use of a product for the specified method. This type of patent does not prevent a competitor from making and marketing a product that is identical to our product for an indication that is outside the scope of the patented method. Moreover, even if competitors do not actively promote their product for our targeted indications, physicians may prescribe these products "off-label." Although off-label prescriptions may infringe method of use patents, the practice is common and such infringement is difficult to prevent or prosecute.

The strength of patents in the biotechnology and pharmaceutical fields involves complex legal and scientific questions and can be uncertain. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our product candidates or uses thereof in the United States or in other foreign countries. Even if the patents do successfully issue, third parties may challenge the patentability, validity, enforceability or scope thereof, for example through inter partes review (IPR), post-grant review or ex parte reexamination before the USPTO, or oppositions and other comparable proceedings in foreign jurisdictions, which may result in such patents being cancelled, narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing their products to avoid being covered by our claims. If the breadth or strength of protection provided by the patents and patent applications we hold with respect to our product candidates is threatened, it could dissuade companies from collaborating with us to develop, and threaten our ability to commercialize, our product candidates. Further, if we encounter delays in our clinical trials, the period of time during which we could market our product candidates under patent protection would be reduced. United States patent applications containing at any time a claim not entitled to a priority date before March 16, 2013 are subject to the "first to file" system implemented by the America Invents Act (2011).

This first to file system will require us to be cognizant of the time from invention to filing of a patent application. Since patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain that we were the first to file any patent application related to our product candidates. Furthermore, for United States applications in which all claims are entitled to a priority date before March 16, 2013, an interference proceeding can be provoked by a third-party or instituted by the USPTO, to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. For United States applications containing a claim not entitled to priority before March 16, 2013, there is a greater level of uncertainty in the patent law in view of the passage of the America Invents Act, which brought into effect significant changes to the United States patent laws, including new procedures for challenging patent applications and issued patents.

Confidentiality agreements with employees and third parties, including any strategic partners, may not prevent unauthorized disclosure or use of trade secrets and other proprietary information.

In addition to the protection afforded by patents, we seek to rely on trade secret protection and confidentiality agreements to protect proprietary 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 proprietary know-how, information or technology that is not covered by patents. Trade secrets, however, may be difficult to protect. Although we require all of our employees to assign their inventions to us, and require all of our employees and key consultants who have access to our proprietary know-how, information, or technology to enter into confidentiality agreements, we cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed or inappropriately used, or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Furthermore, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. For example, we have and may continue to transfer technology to Overland Therapeutics or its affiliates in certain developing countries, and we cannot be certain that we or Overland Therapeutics or any of its affiliates will be able to protect or enforce any proprietary rights in these countries. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent unauthorized material disclosure of our intellectual property to third parties, we will not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, operating results and financial condition.

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

Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. There is a substantial amount of litigation involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may give rise to claims of infringement of the patent rights of others.

Third parties may assert that we or our collaboration partners infringe their patents or are otherwise employing their proprietary technology without authorization and may sue us and/or our collaboration partners. For example, in July 2024 Roche Molecular Systems, Inc. and Roche Sequencing Solutions, Inc. (collectively, Roche) filed lawsuits in Federal District Courts in California and Delaware against Foresight Diagnostics Inc. (Foresight Diagnostics), who is our collaboration partner, as well as Stanford University and three of Foresight's founders, alleging misappropriation of trade secrets, unfair competition and breach of contract relating to Foresight Diagnostics' PhasED-Seq Circulating Tumor DNA Platform which is being used as part of our ALPHA3 clinical trial to identify MRD+ patients. As part of the lawsuit, Roche seeks to obtain ownership of certain Stanford patents covering the PhasED-Seq technology that are licensed to Foresight Diagnostics. Foresight Diagnostics has stated that it believes that Roche's allegations are meritless and that it intends to vigorously defend against the case, and in October 2024 Foresight Diagnostics and Stanford filed motions seeking to have the lawsuits dismissed. If Roche obtains an injunction or otherwise prevails in its lawsuits, we may be required to seek alternative means for gaining access to the PhasED-Seq MRD assay or find an alternative MRD assay to use in the ALPHA3 trial, either of which may not be available to us on commercially reasonable terms or at all, and/or could significantly delay or prevent the completion of the trial or our plans to commercialize cema-cel as part of a 1L consolidation strategy, if approved, which could materially adversely affect our business, operating results and financial condition.

In addition, we are aware of several U.S. patents held by third parties that may be considered by those third parties to be relevant to cell-based therapies. Generally, conducting clinical trials and other development activities in the United States is not considered an act of infringement. If and when any of our product candidates is approved by the FDA, third parties may then seek to enforce their patents by filing a patent infringement lawsuit against us or our collaboration partners. Patents issued 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. We may not be able to prove in litigation that any patent enforced against us or one of our collaboration partners is invalid.

Additionally, there may be third-party patents of which we are currently unaware with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our product candidates may be alleged to infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of our product candidates, constructs or molecules used in or formed during the manufacturing process, or any final product itself, the holders of any such patents may be able to block our ability to commercialize the product candidate unless we obtained a license under the applicable patents, or until such patents expire or they are finally determined to be held not infringed, unpatentable, invalid or unenforceable. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of

use, including combination therapy or patient selection methods, the holders of any such patent may be able to block our ability to develop and commercialize the product candidate unless we obtained a license or until such patent expires or is finally determined to be held not infringed, unpatentable, invalid or unenforceable. In either case, such a license may not be available on commercially reasonable terms or at all. 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 impaired or delayed, which could in turn significantly harm our business.

Parties who may make claims against us or our collaboration partners may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business and may impact our reputation. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign any of our alleged infringing products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize our product candidates, which could harm our business significantly.

We may not be successful in obtaining or maintaining necessary rights to product components and processes for our development pipeline through acquisitions and in-licenses.

Presently we have rights to the intellectual property, through licenses from third parties and under patent applications that we own or will own, that we believe will facilitate the development of our product candidates. Because our programs may involve additional product technology that may require the use of proprietary rights held by third parties, the growth of our business will likely depend in part on our ability to acquire, in-license or use these proprietary rights.

We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify. We may fail to acquire such rights or 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 event, we may be required to expend significant time and resources to develop or license replacement technology. We may need to cease use of the compositions or methods covered by such third-party intellectual property rights.

The licensing and acquisition of third-party intellectual property rights is a competitive area, and companies, which 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 commercialize our 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.

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

Competitors may infringe our patents or the patents of our licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, 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. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure.

Interference proceedings provoked by third parties or brought by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our licensors. An unfavorable outcome could result in a loss of our current patent rights and could require us to cease using the related technology or to attempt to license

rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Litigation or interference proceedings may result in a decision adverse to our interests and, even if we are successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent, alone or with our licensors, misappropriation of our trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as in the United States.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

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

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

The lives of our patents may not be sufficient to effectively protect our products and business.

Patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after its first effective filing date. Although various extensions may be available, the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired for a product, we may be open to competition from biosimilar or generic medications. In addition, although upon issuance in the United States a patent's life can be increased based on certain delays caused by the USPTO, this increase can be reduced or eliminated based on certain delays caused by the patent applicant during patent prosecution. If we do not have sufficient patent life to protect our products, our business and results of operations will be adversely affected.

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

We or our licensors may in the future be subject to claims that former employees, collaborators, or other third parties have an interest in our patents or other intellectual property as an inventor or co-inventor. For example, we may have inventorship disputes arise from conflicting obligations of consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship. If we or our licensors fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we or our licensors are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Issued patents covering our product candidates could be found unpatentable, invalid or unenforceable if challenged in court or the USPTO.

If we or one of our licensing partners initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that the patent covering our product candidate, as applicable, is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include IPR, ex parte re-examination and post grant review in the United States, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover and protect our product candidates.

The outcome following legal assertions of unpatentability, invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we, our patent counsel and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of unpatentability, invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates. Such a loss of patent protection could have a material adverse impact on our business.

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

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve both technological and legal complexity, and is therefore costly, time-consuming and inherently uncertain. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. For example, in the 2013 case, *Assoc. for Molecular Pathology v. Myriad Genetics, Inc.*, the U.S. Supreme Court held that certain claims to DNA molecules are not patentable. While we do not believe that any of the patents owned or licensed by us will be found invalid based on this decision, we cannot predict how future decisions by the courts, the U.S. Congress or the USPTO may impact the value of our patents.

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

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

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries where Overland Therapeutics or its affiliates may do business, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biopharmaceutical products, which could make it difficult for us or Overland Therapeutics or any of its affiliates to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.

We have received confidential and proprietary information from third parties. In addition, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of these third parties or our employees' former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial cost and be a distraction to our management and employees.

Risks Related to Ownership of Our Common Stock

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

The trading price of our common stock following our IPO in October 2018 has been and is likely to continue to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. In addition to the factors discussed in this "Risk Factors" section, these factors include:

- the commencement, enrollment or results of our clinical trials of our product candidates or any future clinical trials we may conduct, or changes in the development status of our product candidates;
- our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial;
- adverse results or delays in clinical trials;
- any delay in our regulatory filings for our product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings, including without limitation the FDA's issuance of a "refusal to file" letter or a request for additional information;
- our failure to commercialize our product candidates;
- adverse regulatory decisions;
- changes in laws or regulations applicable to our products, including but not limited to clinical trial requirements for approvals;
- adverse developments concerning the manufacture or supply of our product candidates;
- our inability to obtain adequate product supply for any approved product or inability to do so at acceptable prices;
- our inability to establish collaborations if needed;
- additions or departures of key scientific or management personnel;
- unanticipated serious safety concerns related to immuno-oncology or related to the use of our product candidates or pre-conditioning regimen;
- introduction of new products or services offered by us or our competitors;
- changes in the status of one or more of our license or collaboration agreements, including any material disputes, amendments or terminations;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- our ability to effectively manage our growth;
- the size and growth of our initial cancer or autoimmune diseases target markets;
- our ability to successfully treat additional types of cancers or at different stages, or to treat autoimmune diseases;
- actual or anticipated variations in quarterly operating results;
- our cash position;
- our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public;
- publication of research reports about us or our industry, or immunotherapy in particular, or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- changes in the market valuations of similar companies;
- overall performance of the equity markets;
- sales of our common stock by us or our stockholders in the future;
- trading volume of our common stock;
- changes in accounting practices;
- ineffectiveness of our disclosure controls or internal controls;
- disagreements with our auditor or termination of an auditor engagement;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- changes in the structure of healthcare payment systems;
- significant lawsuits, including patent or stockholder litigation;
- significant business disruptions caused by health epidemics or pandemics, or natural or man-made disasters;

- general political and economic conditions; and
- other events or factors, many of which are beyond our control.

In addition, the stock market in general, and the Nasdaq Global Select Market and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company's securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management's attention and resources, which would harm our business, operating results or financial condition.

Our failure to establish and maintain effective internal control over financial reporting could result in material misstatements in our financial statements, our failure to meet our reporting obligations and cause investors to lose confidence in our reported financial information, which in turn could cause the trading price of our common stock to decline.

Maintaining effective disclosure controls and procedures and internal control over financial reporting are necessary for us to produce reliable financial statements. We are required, pursuant to Section 404 (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 control over financial reporting. Complying with Section 404 requires a rigorous compliance program as well as adequate time and resources. We may not be able to complete our internal control evaluation, testing and any required remediation in a timely fashion. Additionally, if we or our auditors identify one or more material weaknesses in our internal control over financial reporting, we will not be able to assert that our internal controls are effective. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of the company's annual or interim financial statements will not be prevented or detected on a timely basis.

In 2021, we implemented a new enterprise resource planning (ERP) system, which required the investment of significant financial and human resources. We plan to continue to implement new ERP modules, which we also expect will require significant resources. Any failure to maintain or implement new or improved internal controls related to our ERP system or otherwise could result in material weaknesses, result in material misstatements in our consolidated financial statements and cause us to fail to meet our reporting obligations. This could cause us to lose public confidence and could cause the trading price of our common stock to decline.

For so long as we remain a non-accelerated filer, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal control over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act. An independent assessment of the effectiveness of our internal control over financial reporting could detect problems that our management's assessment might not. Undetected material weaknesses in our internal control over financial reporting could lead to financial statement restatements and require us to incur the expense of remediation.

In the past, we have identified a material weakness in our internal control over financial reporting, and if we are unable to implement and maintain effective internal control over financial reporting in the future, investors may lose confidence in the accuracy and completeness of our financial reports, and the market price of our common stock may be materially adversely affected.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with GAAP. Our management is likewise required, on a quarterly basis, to evaluate the effectiveness of our internal controls and to disclose any changes and material weaknesses identified through such evaluation in those internal controls. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis.

In the past, we have identified material weaknesses in our internal control over financial reporting. All material weaknesses previously identified were fully remediated in the fourth quarter of 2024.

If, in the future, we have a material weakness in our internal controls over financial reporting, we may not detect errors on a timely basis and our consolidated 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 harm our operating results, 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. Any failure to report our financial results on an accurate and timely basis could result in sanctions, lawsuits, delisting of our shares from the Nasdaq Global Select Market or other adverse consequences that would materially harm our business. In addition, we could become subject to investigations by the stock exchange on which our securities are listed, the SEC, and other regulatory authorities, and become subject to litigation from investors and stockholders, which could harm our reputation and our financial condition, or divert financial and management resources from our core business.

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

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

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

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. Some of these provisions include:

- a board of directors divided into three classes serving staggered three-year terms, such that not all members of the board will be elected at one time;
- a prohibition on stockholder action through written consent, which requires that all stockholder actions be taken at a meeting of our stockholders;
- a requirement that special meetings of stockholders be called only by the chair of the board of directors, the chief executive officer, or by a majority of the total number of authorized directors;
- advance notice requirements for stockholder proposals and nominations for election to our board of directors;
- a requirement that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of not less than two-thirds of all outstanding shares of our voting stock then entitled to vote in the election of directors;
- a requirement of approval of not less than two-thirds of all outstanding shares of our voting stock to amend any bylaws by stockholder action or to amend specific provisions of our certificate of incorporation; and
- the authority of the board of directors to issue preferred stock on terms determined by the board of directors without stockholder approval and which preferred stock may include rights superior to the rights of the holders of common stock.

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

General Risk Factors

Unstable market, economic and geo-political conditions may have serious adverse consequences on our business, financial condition and stock price.

The global credit and financial markets have experienced extreme volatility and disruptions in the past. These disruptions have resulted and may continue to result in severely diminished liquidity and credit availability, high inflation, declines in consumer confidence, disruptions in access to bank deposits or lending commitments due to bank failures and

uncertainty about economic stability, declines in economic growth, and uncertainty about economic stability. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment, higher inflation, or continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly and more dilutive. Our portfolio of corporate and government bonds would also be adversely impacted. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our operations, growth strategy, financial performance and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive an economic downturn or rising inflation, which could directly affect our ability to attain our operating goals on schedule and on budget.

Other international and geo-political events could also have a serious adverse impact on our business. For instance, in February 2022, Russia initiated military action against Ukraine, and in October 2023, Hamas attacked Israel. In both cases, ongoing conflicts have ensued. In response to the Russian invasion, the United States and certain other countries imposed significant sanctions and trade actions against Russia and could impose further sanctions, trade restrictions, and other retaliatory actions. While we cannot predict the broader consequences, these conflicts and retaliatory and counter-retaliatory actions could materially adversely affect global trade, currency exchange rates, inflation, regional economies, and the global economy, which in turn may increase our costs, disrupt our supply chain, impair our ability to raise or access additional capital when needed on acceptable terms, if at all, or otherwise adversely affect our business, financial condition, and results of operations.

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

Sales of a substantial number of shares of our common stock in the public market or the perception that these sales might occur, including by any of our directors, officers or larger stockholders, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that sales may have on the prevailing market price of our common stock.

If securities or industry analysts issue an adverse or misleading opinion regarding our stock, our stock price and trading volume could decline.

The trading market for our common stock could be influenced by the research and reports that industry or securities analysts publish about us or our business. If any of the analysts who cover us issue an adverse or misleading opinion regarding us, our business model, our intellectual property or our stock performance, or if the clinical trials and operating results fail to meet the expectations of analysts, our stock price would likely decline. If one or more analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity.

Risk management and strategy

We take a risk-based approach in implementing and maintaining various information security processes designed to identify, assess and manage material risks from threats to our critical computer networks, third party hosted services, communications systems, hardware and software, and our critical data, including intellectual property, confidential information that is proprietary, strategic or competitive in nature, and information related to our clinical trials, products in development, and proprietary technologies (“Information Systems and Data”).

Our information security function, supported by members of our IT and Legal departments and our third-party IT service providers, helps identify, assess and manage the Company’s cybersecurity threats and risks. This team helps to identify and assess risks from cybersecurity threats by monitoring and evaluating our threat environment using various methods including, for example: automated tools, subscribing to reports and services that identify cybersecurity threats and analyzing such reports of threats and actors, conducting scans of our threat environment, evaluating threats reported to us, coordinating with law enforcement as appropriate about certain threats, having third parties conduct threat assessments, conducting vulnerability assessments, and working with third parties to conduct certain tests of our environment.

Depending on the environment and systems, we implement and maintain various technical, physical, and organizational measures, processes, standards and policies designed to manage and mitigate material risks from cybersecurity threats to our Information Systems and Data, including, for example: incident detection and response procedures; an incident response policy; a vulnerability management policy; a disaster recovery plan; conducting risk assessments; encrypting certain of our data; maintaining network security controls, segmenting certain data; maintaining access and physical security controls; asset management, tracking, and disposal protocols; systems monitoring; a assessing vendor risk; employee training; penetration testing conducted by third parties; and maintaining cybersecurity insurance.

The cybersecurity risk management and mitigation measures we implement for certain of our Information Assets including for example (1) cybersecurity risk is addressed as a component of the Company's enterprise risk management assessment processes; (2) the information security function works with senior management to prioritize our risk management processes and mitigate cybersecurity threats that are more likely to lead to a material impact to our business; (3) our senior management evaluates material risks from cybersecurity threats against our overall business objectives and reports to the audit committee of the board of directors on at least a quarterly basis, which evaluates our overall enterprise risk, (4) policies and procedures to manage how Information Systems and Data are collected, maintained and stored, (5) communicating with and training personnel on cybersecurity risks and trends.

We use third-party service providers to assist us from time to time to identify, assess, and manage material risks from cybersecurity threats, including for example: professional services firms, cybersecurity consultants, cybersecurity software providers, managed cybersecurity service providers, and penetration testing firms. We conduct penetration tests and audits of our Information Systems and Data environment with an external cybersecurity firm at least annually.

We use third-party service providers to perform a variety of functions throughout our business, such as application providers, contract research organizations (CROs), contract development and manufacturing organizations (CDMOs) and supply chain resources. We assess vendors using a risk-based approach to manage cybersecurity risks associated with our use of certain of these providers. Through these practices, we may conduct risk assessments of vendors, provide and review security questionnaires, review vendors' written information security programs and security assessments, and impose contractual obligations related to information security on our vendors. Depending on the nature of the services provided, the sensitivity of the Information Systems and Data at issue, and the identity of the provider, our vendor management process may involve different levels of assessment designed to help identify cybersecurity risks associated with a provider and impose contractual obligations related to cybersecurity on the provider.

For a description of the risks from cybersecurity threats that may materially affect the Company and how they may do so, see our risk factors under Part I. Item 1A. Risk Factors in this Annual Report on Form 10-K, including "*If our security measures, or those of our CROs, CDMOs, collaborators, contractors, consultants or other third parties upon whom we rely, are or were compromised or the security, confidentiality, integrity or availability of our information technology, software, services, networks, communications or data is compromised, limited or fails, we could experience a material adverse impact.*"

Governance

Our board of directors addresses the Company's cybersecurity risk management as part of its general oversight function. The board of directors' audit committee is responsible for overseeing Company's cybersecurity risk management processes, including oversight of mitigation of risks from cybersecurity threats. Members of the Audit Committee receive scheduled quarterly updates from senior management.

Our cybersecurity risk assessment and management processes are implemented and maintained by certain Company management, including our Director of IT Security and Vice President of IT. Our Director of IT Security has over 13 years of experience leading IT security and has certifications including CISSP and CCSP. Our Vice President IT has over 20 years of experience in IT, data engineering, and data analytics.

Our Vice President of IT Security is responsible for hiring appropriate personnel, helping to integrate cybersecurity risk considerations into the Company's overall IT risk management strategy, communicating key priorities to relevant personnel, overseeing cybersecurity operations, and managing the cybersecurity technologies, processes, and projects. Our Vice President of IT is responsible for approving budgets, helping prepare for cybersecurity incidents, approving cybersecurity processes, and conducting regular reviews of security assessments and other security-related reports.

Our cybersecurity incident response and vulnerability management policies are designed to escalate certain cybersecurity incidents to members of management depending on the circumstances, including the Vice President of IT and General Counsel. The Vice President of IT and General Counsel work with the Company's cross functional incident response team to help the Company mitigate and remediate cybersecurity incidents of which they are notified. In addition, the Company's incident response and vulnerability management policies and procedures include reporting to the audit committee of the board of directors for certain cybersecurity incidents.

The audit committee receives periodic reports from Data Management, Analytics and Integration and General Counsel concerning the Company's significant cybersecurity threats and risk and the processes the Company has implemented to address them. The audit committee also receives various reports, summaries or presentations related to cybersecurity threats, risk and mitigation.

Item 2. Properties.

Our corporate headquarters are located in South San Francisco, California, which consists of approximately 68,072 square feet for office and laboratory space. Our lease for our headquarter space commenced on March 1, 2019. On December 10, 2021, we amended our lease for an additional 47,566 square feet of office and laboratory space as part of the same building as our headquarters. The lease relating to the expansion premises commenced on April 1, 2022. The lease for both the existing and expansion premises will expire on March 31, 2032.

We entered into an additional lease in October 2018 for approximately 14,943 square feet of office and laboratory space in South San Francisco near our headquarters. On December 10, 2021, we amended our lease to extend the term of the lease to be co-terminus with our lease for our headquarters.

In February 2019, we entered into a lease for approximately 118,000 square feet to develop a state-of-the-art cell therapy manufacturing facility in Newark, California. The lease commenced in November 2020 and has an initial term of 15 years and eight months.

We believe that our existing facilities and other available properties will be sufficient for our needs for the foreseeable future.

Item 3. Legal Proceedings.

From time to time, we may become involved in litigation or other legal proceedings. We are not currently a party to any litigation or legal proceedings that, in the opinion of our management, are likely to have a material adverse effect on our business. Regardless of outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

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

Our common stock is listed on The Nasdaq Global Select Market under the symbol "ALLO".

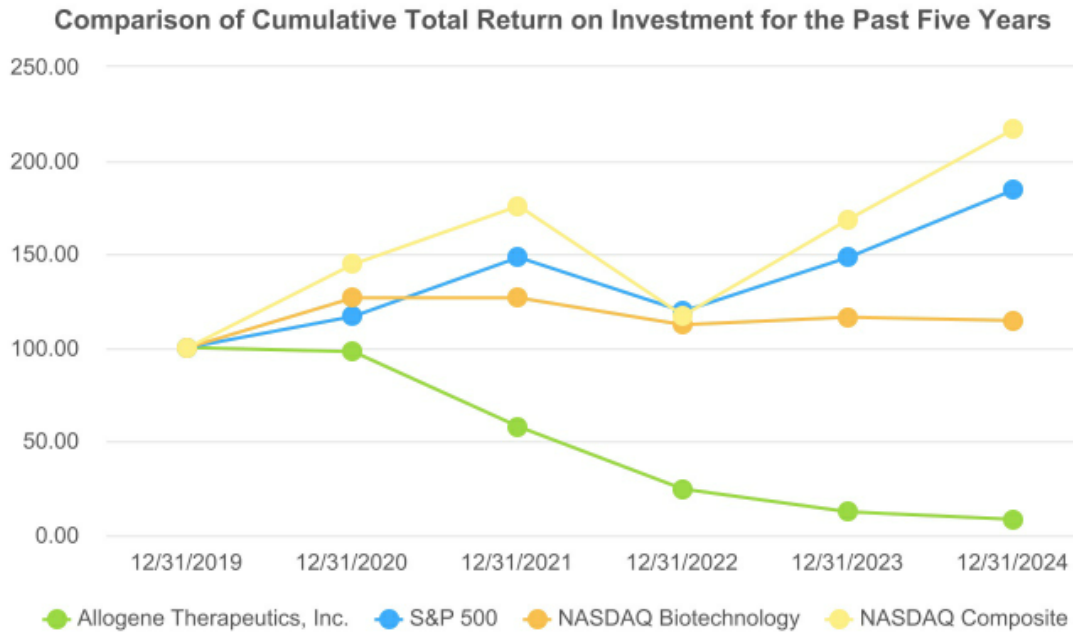
Holders of Common Stock

As of March 7, 2025, there were approximately 62 holders of record of our common stock.

Stock Performance Graph

This performance graph shall not be deemed "filed" for purposes of Section 18 of the Exchange Act, or incorporated by reference into any of our filings under the Securities Act or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

The following graph shows the value of an investment of $100 from December 31, 2019 through December 31, 2024, in our common stock, the Standard & Poor's 500 Index (S&P 500), the Nasdaq Biotechnology Index, and Nasdaq Composite Index. The historical stock price performance of our common stock shown in the performance graph is not necessarily indicative of future stock price performance.



	Cumulative Total Return date ended					
	12/31/2019	12/31/2020	12/31/2021	12/31/2022	12/31/2023	12/31/2024
Allogene Therapeutics, Inc.	$ 100.00	$ 97.79	$ 57.81	$ 24.37	$ 12.44	$ 8.25
S&P 500	$ 100.00	$ 116.82	$ 148.24	$ 119.42	$ 148.35	$ 184.12
Nasdaq Biotechnology	$ 100.00	$ 126.49	$ 126.78	$ 111.98	$ 116.16	$ 114.57
Nasdaq Composite	$ 100.00	$ 144.51	$ 175.42	$ 117.35	$ 168.31	$ 216.52

Dividend Policy

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings to support our operations and finance the growth and development of our business. We do not intend to pay cash dividends on our common stock for the foreseeable future. Any future determination related to our dividend policy will be made at the discretion of our board of directors and will depend upon, among other factors, our results of operations, financial condition, capital requirements, contractual restrictions, business prospects and other factors our board of directors may deem relevant.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

Unregistered Sales of Equity Securities and Use of Proceeds

None.

Item 6. [Reserved]

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

The following discussion contains management's discussion and analysis of our financial condition and results of operations and should be read together with the historical consolidated financial statements and the notes thereto included in "Financial Statements and Supplementary Data". This discussion contains forward-looking statements that reflect our plans, estimates and beliefs and involve numerous risks and uncertainties, including but not limited to those described in the "Risk Factors" section of this Annual Report. Actual results may differ materially from those contained in any forward-looking statements. You should carefully read "Special Note Regarding Forward-Looking Statements" and "Risk Factors."

Overview

We are a clinical stage immuno-oncology company pioneering the development of genetically engineered allogeneic T cell product candidates for the treatment of cancer and autoimmune diseases. We are developing a pipeline of "off-the-shelf" T cell product candidates that are designed to target and kill cancer cells in patients or eliminate pathogenic autoreactive cells in patients with autoimmune disorders. Our engineered T cells are allogeneic, meaning they are derived from healthy donors for intended use in any patient, rather than from an individual patient for that patient's use, as in the case of autologous T cells. We believe this key difference will enable us to deliver readily available treatments faster, more reliably, at greater scale, and to more patients.

We have a deep pipeline of allogeneic chimeric antigen receptor (CAR) T cell product candidates targeting multiple promising antigens in a host of hematological malignancies, solid tumors and autoimmune diseases. Last year we announced our 2024 Platform Vision under which we are now focusing on three core programs.

We are currently focused on developing cemacabtagene ansegedleucel (cema-cel, previously ALLO-501A) in large B-cell lymphoma (LBCL). In June 2024, we initiated a pivotal Phase 2 clinical trial (ALPHA3) for cema-cel as part of a first line (1L) treatment plan for newly diagnosed and treated LBCL patients who are likely to relapse and need further therapy, and we now have 40 sites activated. The design of the ALPHA3 1L consolidation trial builds upon the results demonstrated in the Phase 1 ALPHA2 trial and leverages an investigational diagnostic test developed by Foresight Diagnostics, Inc. that we believe will identify patients who have achieved remission by standard disease assessment but who have minimal residual disease (MRD) at the completion of 1L chemoimmunotherapy. The ALPHA3 trial is designed to study the impact of treating MRD positive patients with cema-cel. The study will randomize approximately 240 patients who achieve a complete response or partial response to 1L therapy, but who are MRD positive. Patients will be randomized to receive either consolidation with cema-cel or the current standard of care, which is observation. The study design, which has event free survival (EFS) as its primary endpoint, initially includes two lymphodepletion arms:

- FCA: standard fludarabine and cyclophosphamide plus ALLO-647
- FC: standard fludarabine and cyclophosphamide without ALLO-647

One of these lymphodepletion arms will be discontinued following a planned interim analysis designed to identify the most appropriate regimen for this patient population. An initial safety and futility interim analysis will occur once 12 patients in each arm have been enrolled and followed for MRD conversion. If both treatment arms perform better than the control arm according to the futility criteria, but neither treatment arm shows a trend toward superiority relative to the other in this interim analysis, additional patients may be enrolled and analyzed before we select the final lymphodepletion regimen. The selection of the lymphodepletion regimen is anticipated around mid-2025, depending on the interim analyses results and overall trial progress. Efficacy analyses are expected to occur in 2026, and will include the Independent Data Safety Monitoring Board (IDSMB) interim EFS analysis in the first half of 2026 and the data readout of the primary EFS analysis is expected around year-end 2026. A biologics license application (BLA) submission is targeted for 2027. In view of the potential of the earlier line ALPHA3 trial, we have deprioritized the third line (3L) LBCL ALPHA2 and EXPAND trials.

We have completed enrollment in an expansion cohort in a Phase 1b clinical trial (TRAVERSE) of ALLO-316, an allogeneic CAR T cell product candidate targeting CD70, in adult patients with advanced or metastatic clear cell renal cell carcinoma (RCC). On October 29, 2024, we announced that we had received Regenerative Medicine Advanced Therapy (RMAT) designation for ALLO-316 for adult patients with advanced or metastatic RCC. We have implemented a protocol amendment that incorporates a diagnostic and treatment algorithm into the study design. The algorithm is designed to mitigate the treatment-associated hyperinflammatory response without compromising the CAR T function needed to eradicate solid tumors.

In November 2024, we provided a data update from patients with CD70 positive RCC, and highlighted that the newly implemented diagnostic and management algorithm appears effective in abating IEC-HS while preserving CAR T efficacy. Additional data from dose escalation cohorts, as well as a Phase 1b expansion cohort, was presented at the 2024 International Kidney Cancer Symposium (IKCS, November 8, 2024) and the Society for Immunotherapy of Cancer's (SITC) Annual Meeting (November 9, 2024).

As of the October 14, 2024, data cutoff, 39 patients had been enrolled in the ongoing Phase 1 trial, of which 26 were confirmed to have CD70 positive RCC and were evaluable for efficacy outcomes. The median time from enrollment to the start of therapy was five days. Data from dose escalation cohorts and ongoing Phase 1b expansion cohort are included in the presentations. The Phase 1b expansion cohort is evaluating safety and efficacy of ALLO-316 at DL2 (80M CAR T cells) following a standard FC500 (fludarabine (30 mg/m2/day) and cyclophosphamide (500 mg/m2/d) for three days) lymphodepletion regimen. The Phase 1b expansion cohort has now completed enrollment with 20 patients enrolled. We are now pausing further standard dosing pending durability results for the enrolled patients. Additional data from the Phase 1b expansion cohort is expected to be announced in mid-2025.

We are developing ALLO-329, a next-generation allogeneic CAR T cell product candidate targeting both CD19 and CD70 for the treatment of certain autoimmune diseases (AID). Inclusion of an anti-CD70 CAR in ALLO-329 incorporates the Dagger® technology, which is designed to reduce or eliminate the need for standard chemotherapy by preventing premature rejection while targeting CD19+ B-cells and CD70+ activated T-cells, both of which play a role in AID. In January 2025, we announced that the FDA has cleared our investigational new drug (IND) application for a Phase 1 rheumatology basket study of ALLO-329 (RESOLUTION trial). Our RESOLUTION trial will evaluate the safety and efficacy of ALLO-329 across multiple autoimmune diseases, including systemic lupus erythematosus (SLE) (including lupus nephritis), idiopathic inflammatory myopathies, and systemic sclerosis. We expect to initiate the Phase 1 trial with ALLO-329 in mid-2025 and anticipate having proof-of-concept around year-end 2025.

We are developing an anti-CD52 monoclonal antibody, ALLO-647, which is a proprietary component of our oncology lymphodepletion regimen. ALLO-647 may be able to reduce the likelihood of a patient's immune system rejecting the engineered allogeneic T cells for a sufficient period of time to enable a window of persistence during which our engineered allogeneic T cells can actively target and destroy cancer cells. During Part A of our pivotal ALPHA3 trial, we will be assessing ALLO-647's contribution to the overall benefit to risk ratio of the lymphodepletion regimen for cema-cel. Patients will be randomized to receive cema-cel and a lymphodepletion regimen with fludarabine and cyclophosphamide either with or without ALLO-647. As described above, one of these lymphodepletion arms will be discontinued following a planned interim analysis designed to identify the most appropriate regimen for this patient population. The selection of the final regimen with which we will complete enrollment in the study (Part B) is anticipated around mid-2025, depending on the interim analyses results and overall trial progress.

While we have additional programs in our pipeline, our clinical development priorities are focused on cema-cel (1L Consolidation), ALLO-316 and ALLO-329. The development of our other product candidates is currently focused on pre-clinical studies, including studies of BCMA and DLL3 CARs with and without our CD70 Dagger® protein, and various manufacturing improvements that may be applicable to such product candidates, we continue to explore opportunities to partner with collaborators on product candidates across our pipeline.

In May 2024, we entered into an Amendment and Settlement Agreement (the Servier Amendment) under which we expanded the geographic territory for our CD19 license to include the European Union and the United Kingdom. The Servier Amendment also grants us an option to further expand the licensed territory to include China and Japan upon the objective showing of sufficient resources to develop licensed products in those countries, which could be met through the Company entering into a strategic partnership covering those countries. Later this year, we plan to seek scientific advice from European and UK regulatory authorities to assist us with finalizing our regulatory strategy for the EU and the UK. Additionally, in February 2025, we entered into an Amended and Restated Strategic Collaboration Agreement with Foresight Diagnostics which expands our collaboration to enable the development of Foresight Diagnostics' MRD assay as a companion diagnostic in the EU, UK, Canada and Australia in support of Allogene's clinical development of cema-cel.

Since inception, we have had significant operating losses. Our net loss was $257.6 million for the year ended December 31, 2024. As of December 31, 2024, we had an accumulated deficit of $1.8 billion. As of December 31, 2024, we had $373.1 million in cash and cash equivalents and investments and we expect our cash runway to fund operations into the second half of 2026. We expect to continue to incur net losses for the foreseeable future, and we expect our research and development expenses and general and administrative expenses will continue to increase.

Our License and Collaboration Agreements

Below is a summary of the key terms for certain of our licenses and collaboration agreements. For a more detailed description of these agreements, see Note 6 to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

Asset Contribution Agreement with Pfizer

In April 2018, we entered into an Asset Contribution Agreement (the Pfizer Agreement) with Pfizer pursuant to which we acquired certain assets and assumed certain liabilities from Pfizer, including agreements with Cellectis S.A. (Cellectis) and Servier as described below, and other intellectual property for the development and administration of CAR T cells for the treatment of cancer.

Research Collaboration and License Agreement with Cellectis

In June 2014, Pfizer entered into a Research Collaboration and License Agreement with Cellectis. In April 2018, Pfizer assigned the agreement to us pursuant to the Pfizer Agreement. In March 2019, we terminated the agreement with Cellectis and entered into a new license agreement with Cellectis (the Cellectis Agreement). Under the Cellectis Agreement, Cellectis granted us an exclusive, worldwide, royalty-bearing license, on a target-by-target basis, with sublicensing rights under certain conditions, under certain of Cellectis's intellectual property, including its TALEN and electroporation technology, to make, use, sell, import, and otherwise exploit and commercialize CAR T products directed at certain targets, including BCMA, CD70, Claudin 18.2, DLL3 and FLT3 (the Allogene Targets), for human oncologic therapeutic, diagnostic, prophylactic and prognostic purposes.

Exclusive License Agreement with Servier

In October 2015, Pfizer entered into an Exclusive License Agreement with Servier (the Original Servier Agreement) to develop, manufacture and commercialize certain allogeneic anti-CD19 CAR products, including UCART19, in the United States with the option to obtain the rights over certain additional allogeneic anti-CD19 CAR product candidates and for allogeneic CAR T cell product candidates directed against one additional target. In April 2018, Pfizer assigned the agreement to us pursuant to the Pfizer Agreement. In October 2019, we agreed to waive our rights to the one additional target.

In May 2024, we entered into an Amendment and Settlement Agreement (the Servier Amendment) with Servier under which we: (1) expanded our territory under the Original Servier Agreement to include the European Union and the United Kingdom, and provides for an option to further expand our territory to include China and Japan, (2) waived certain of our rights to elect to convert certain of our license rights to a worldwide license, (3) revised our future milestone payments to coincide with Servier's milestone payments to Cellectis under the Servier-Cellectis Agreement, (4) agreed to pre-pay a future €20 million milestone payment into an escrow account, and (5) increased the United States tiered royalty rates to a range from the low tens to the mid teen percentages, and agreed to an ex-U.S. royalty rate of 10%. For more information, see "Risk Factors-*Servier's discontinuation of its involvement in the development of CD19 Products and Servier's disputes with Cellectis, or future disputes with us, may have adverse consequences."*

Collaboration and License Agreement with Notch

On November 1, 2019, we entered into a Collaboration and License Agreement (the Notch Agreement) with Notch Therapeutics Inc. (Notch), pursuant to which Notch granted us an exclusive, worldwide, royalty-bearing, sublicensable license under certain of Notch's intellectual property to develop, make, use, sell, import, and otherwise commercialize therapeutic

gene-edited T cell and/or natural killer cell products from induced pluripotent stem cells directed at certain CAR targets for initial application in NHL, B-cell precursor acute lymphoblastic leukemia (ALL) and multiple myeloma. In addition, Notch has granted us an option to add certain specified targets to our exclusive license in exchange for an agreed upon per-target option fee.

On January 25, 2024, we entered into an Amended and Restated Collaboration and License Agreement (the Amended Notch Agreement) with Notch. The Amended Notch Agreement amends and restates the Notch Agreement. Under the Amended Notch Agreement, we have relinquished our exclusive rights to all original CAR targets (the Released Targets) except for one CAR target, and have agreed to limit our option right to only one additional CAR target. If the option is exercised, we will have a minimum funding commitment for the overall development program. If Notch subsequently out-licenses any of the Released Targets (whether through an out-license, partnership, sale, or other transaction), we will be entitled to receive a percentage of upfront and/or milestone payments associated therewith up to a set cap of $30.0 million, and will be entitled to a low, single-digit royalty on net sales of products containing a Released Target.

In January 2025, Notch announced that securing additional investment and/or additional partners to take their research forward remains challenging, and therefore they significantly reduced their workforce to preserve cash and provide the time to explore alternate paths forward.

Strategic Alliance with The University of Texas MD Anderson Cancer Center

On October 6, 2020, we entered into a strategic five-year collaboration agreement with The University of Texas MD Anderson Cancer Center (MD Anderson) for the preclinical and clinical investigation of allogeneic CAR T cell product candidates.

License Agreement with Allogene Overland Biopharm (PRC) Co., Limited

On December 14, 2020, we entered into a License Agreement with Allogene Overland Biopharm (CY) Limited (Allogene Overland) (the License Agreement), a joint venture established by us and Overland Pharmaceuticals (CY) Inc. (Overland), pursuant to a Share Purchase Agreement (Share Purchase Agreement), dated December 14, 2020, for the purpose of developing, manufacturing and commercializing certain allogeneic CAR T cell therapies directed at four targets, BCMA, CD70, FLT3 and DLL3 (Overland Licensed Products) for patients in greater China, Taiwan, South Korea and Singapore (the JV Territory). Allogene Overland subsequently assigned the License Agreement to a wholly owned subsidiary, Allogene Overland BioPharm (HK) Limited (Allogene Overland HK). On April 1, 2022, Allogene Overland HK assigned the License Agreement to Allogene Overland Biopharm (PRC) Co., Limited (Allogene Overland PRC).

On May 24, 2024, we, Overland and Allogene Overland entered into a Share Exchange Agreement (Share Exchange Agreement) pursuant to which Overland's cell therapy business merged into Allogene Overland (the Organizational Restructuring). Under a separate agreement between Overland and HH BioPharma Holdings Ltd. (HBP) executed on May 24, 2024, Overland distributed all Series Seed Preferred Shares of Allogene Overland held by Overland to HBP and HBP has assumed all rights and obligations attached to such shares and all rights and obligations of Overland under the Share Exchange Agreement.

In connection with the Organizational Restructuring, on May 24, 2024, we and Allogene Overland PRC entered into a First Amendment to Exclusive License Agreement (the License Amendment) to amend and supplement certain provisions of the License Agreement. Under the License Amendment, we continue to grant Allogene Overland PRC an exclusive license to develop, manufacture, and commercialize the Overland Licensed Products in the Territory, with us retaining exclusive rights to the Overland Licensed Products outside the JV Territory, and the royalty obligations to us were amended to a flat mid single-digit royalty on net sales in the JV Territory that are no longer subject to reductions as previously provided. The License Amendment also provides us with additional rights to terminate the License Agreement in its entirety or with respect to the relevant Overland Licensed Product(s) if Allogene Overland PRC fails to initiate manufacturing technology transfer with respect to an Overland Licensed Product as agreed in the License Amendment, or if HBP commits a funding default or a material breach of its representations, warranties, or covenants under the Share Exchange Agreement. The License Amendment also provides that the License Agreement will terminate automatically if our ownership in Allogene Overland falls below 7.5% (other than due to our sale of the shares of Allogene Overland), unless at that time we and Allogene Overland PRC have mutually agreed on the manufacturing technology transfer plan for the Overland Licensed Product(s) and Allogene Overland PRC elects to continue the license for such Overland Licensed Product(s) with increased milestones and royalties. Under the License Amendment terms such increased milestones and royalties consist of up to $115 million in milestone payments for each Overland Licensed Product and tiered mid single-digit to low double-digit royalties on net sales in the JV Territory.

As part of the Organizational Restructuring, Allogene Overland was renamed to Overland Therapeutics Inc. (Overland Therapeutics).

Collaboration and License Agreement with Antion

On January 5, 2022, we entered into an exclusive collaboration and global license agreement (Antion Collaboration and License Agreement) with Antion Biosciences SA (Antion) for Antion's miRNA technology (miCAR), to advance multiplex gene silencing as an additional tool to develop next generation allogeneic CAR T products. On July 11, 2023, we entered into an amendment to the Antion Collaboration and License Agreement, which included a $2.0 million investment in Antion's preferred shares and the acquisition of warrants to purchase an additional $3.0 million of Antion's preferred shares.

Strategic Collaboration Agreement with Foresight Diagnostics

On January 3, 2024, we entered into a Strategic Collaboration Agreement (the Foresight Agreement) with Foresight Diagnostics, Inc. (Foresight Diagnostics). Pursuant to the Foresight Agreement, the parties have agreed to collaborate on a non-exclusive basis in the development of Foresight Diagnostics' MRD assay as an in vitro diagnostic to identify the MRD+ patient population to be enrolled in our ALPHA3 trial of cemacabtagene ansegedleucel, or cema-cel (previously known as ALLO-501A) for treatment of large B cell lymphoma (LBCL). Under the Foresight Agreement, we have agreed to use commercially reasonable efforts to obtain regulatory approval of cema-cel, and Foresight Diagnostics has agreed to use commercially reasonable efforts to obtain regulatory approval of an MRD assay for use as an in vitro diagnostic with cema-cel.

On February 19, 2025, we entered into an Amended and Restated Strategic Collaboration Agreement with Foresight Diagnostics which expands our collaboration to include the development of Foresight Diagnostics' MRD assay as a companion diagnostic for use with cema-cel as part of a possible EU and/or UK clinical development program, and as part of an expansion of ALPHA3 to Canadian and Australian clinical trial sites in support of our US clinical development program. In total, we have agreed to fund approximately $37.3 million in MRD assay development costs, milestone payments for U.S., and certain international regulatory submissions and assay utilization costs to process clinical samples.

Components of Results of Operations

Revenues

As of December 31, 2024, our revenue has been exclusively generated from the License Agreement with Overland Therapeutics. See Note 6 to our consolidated financial statements appearing elsewhere in this Annual Report for more information related to our recognition of revenue and the License Agreement.

In the future, we may generate revenue from a combination of product sales, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements or a combination of these approaches. We expect that any revenue we generate will fluctuate from quarter to quarter as a result of the timing and amount of license fees, milestones and other payments, and the amount and timing of payments that we receive upon the sale of our products, to the extent any are successfully commercialized. If we fail to complete the development of our product candidates in a timely manner or obtain regulatory approval of them, our ability to generate future revenue, and our results of operations and financial position, will be materially adversely affected.

Operating Expenses

Research and Development

To date, our research and development expenses have related primarily to discovery efforts, preclinical and clinical development, and manufacturing of our product candidates. Research and development expenses for the year ended December 31, 2024 included costs associated with our clinical and preclinical stage pipeline candidates and research into newer technologies. The most significant research and development expenses relate to costs incurred for the development of our most advanced product candidates and include:

- expenses incurred under agreements with our collaboration partners and third-party contract organizations, investigative clinical trial sites that conduct research and development activities on our behalf, and consultants;
- costs related to production of clinical materials, including fees paid for raw materials and to contract manufacturers;
- laboratory and vendor expenses related to the execution of preclinical and clinical trials;
- employee-related expenses, which include salaries, benefits and stock-based compensation;
- facilities and other expenses, which include expenses for rent and maintenance of facilities, depreciation and amortization expense and supplies; and

- other significant research and development costs including overhead costs.

We expense all research and development costs in the periods in which they are incurred. We accrue for costs incurred as the services are being provided by monitoring the status of the project and the invoices received from our external service providers. We adjust our accrual as actual costs become known. Where contingent milestone payments are due to third parties under research and development arrangements or license agreements, the milestone payment obligations are expensed when the milestone results are achieved.

Research and 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 our research and development expenses to increase in the future as our clinical programs progress and as we seek to initiate clinical trials of additional product candidates. The cost of advancing our manufacturing process as well as the cost of manufacturing product candidates for clinical trials are included in our research and development expense. We also expect to incur increased research and development expenses as we selectively identify and develop additional product candidates. However, it is difficult to determine with certainty the duration and completion costs of our current or future preclinical programs and clinical trials 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 that include, but are not limited to, the following:

- per patient trial costs;
- biomarker analysis costs;
- the cost and timing of manufacturing for the trials;
- the number of patients that participate in the trials;
- the number of sites included in the trials;
- the number of patients we are required to screen with eligibility tests (e.g. MRD assays) in order to reach our enrollment targets;
- the countries in which the trials are conducted;
- the length of time required to enroll eligible patients;
- the total number of cells that patients receive;
- the drop-out or discontinuation rates of patients;
- potential additional safety monitoring or other studies requested by regulatory agencies, including to resolve any future clinical hold;
- the duration of patient follow-up; and
- the efficacy and safety profile of the product candidates.

In addition, the probability of success for each product candidate will depend on numerous factors, including safety, efficacy, competition, manufacturing capability and commercial viability. We will determine which programs to pursue and how much to fund each program in response to the scientific and clinical success of each product candidate, as well as an assessment of each product candidate's commercial potential.

Because our product candidates are still in clinical and preclinical development and the outcome of these efforts is uncertain, we cannot estimate the actual amounts necessary to successfully complete the development and commercialization of product candidates or whether, or when, we may achieve profitability.

General and Administrative

General and administrative expenses consist primarily of salaries and other staff-related costs, including stock-based compensation for options and restricted stock units granted. Other significant costs include costs relating to facilities and overhead costs, legal fees relating to corporate and patent matters, insurance, investor relations costs, fees for accounting and consulting services, information technology, costs and support for our board of directors and board committees, and other general and administrative costs. General and administrative costs are expensed as incurred, and we accrue for services provided by third parties related to the above expenses by monitoring the status of services provided and receiving estimates from our service providers, and adjusting our accruals as actual costs become known.

Other Income (Expense), Net:

Interest and Other Income, Net

Interest and other income, net primarily consists of interest earned on our cash and cash equivalents and investments, as well as investment gains and losses recognized during the period.

Interest Expense

Interest expense related to the California Institute of Regenerative Medicine (CIRM) award is accrued upon cash receipt.

Other Expenses, net

Other expenses, net consist of non-operating income and expenses, including primarily our share of net losses for the period from, and impairment of, our equity method investments and impairment of our equity investments.

Results of Operations

Comparison of the Years Ended December 31, 2024 and 2023

The following sets forth our results of operations for the years ended December 31, 2024 and 2023 (dollars in thousands):

	Year Ended December 31,		Change	
	2024	2023	$	%
Collaboration revenue - related party	$ 22	$ 95	$ (73)	(77)%
Operating expenses:				
Research and development	192,299	242,914	(50,615)	(21)%
General and administrative	65,205	71,673	(6,468)	(9)%
Impairment of long-lived asset	15,717	13,245	2,472	19%
Total operating expenses	273,221	327,832	(54,611)	(17)%
Loss from operations	(273,199)	(327,737)	54,538	(17)%
Other income (expense), net:				
Interest and other income, net	20,153	18,307	1,846	10%
Interest expense	(181)	-	(181)	(100)%
Other expenses, net	(3,920)	(17,835)	13,915	(78)%
Total other income (expense), net	16,052	472	15,580	3,301%
Loss before income taxes	(257,147)	(327,265)	70,118	(21)%
Income tax expense	(443)	-	(443)	(100)%
Net loss	$ (257,590)	$ (327,265)	$ 69,675	(21)%

Collaboration revenue - related party

Revenue recognized in the years ended December 31, 2024 and 2023 was mainly due to participation in the joint steering committee performance obligation related to the License Agreement entered into with Overland Therapeutics on December 14, 2020.

Research and Development Expenses

The following table shows the primary components of our research and development expenses for the periods presented:

	Year Ended December 31,		
	2024	2023	Change
Personnel	$ 79,993	$ 112,457	$ (32,464)
Development costs	62,264	74,644	(12,380)
Facilities and depreciation	40,941	44,684	(3,743)
Other	9,101	11,129	(2,028)
Total research and development expenses	192,299	242,914	(50,615)

Our research and development expenses included $91.1 million of internal expense and $101.2 million of external expenses for the year ended December 31, 2024. Of the $101.2 million of the external expenses for the year ended December 31, 2024, $36.4 million was related to our cema-cel program. Our research and development expenses included $119.0 million of internal expenses and $123.9 million of external expenses for the year ended December 31, 2023. Of the $123.9 million of the external expenses for the year ended December 31, 2023, $43.2 million was related to our cema-cel program.

Research and development expenses were $192.3 million and $242.9 million for the years ended December 31, 2024 and 2023, respectively. The net decrease of $50.6 million was primarily due to a decrease in personnel related costs of $32.5 million, of which $11.5 million was decreased stock-based compensation expense, external costs related to the advancement of our product candidates of $12.4 million due to the timing of process development activities and manufacturing runs and facilities, depreciation, and other expense of $5.8 million.

General and Administrative Expenses

General and administrative expenses were $65.2 million and $71.7 million for the years ended December 31, 2024 and 2023, respectively. The net decrease of $6.5 million was primarily due to a decrease in personnel related costs of $5.3 million, of which $2.7 million was decreased stock-based compensation expense, and a decrease in legal and professional services of $1.2 million.

Impairment of long-lived asset

During the year ended December 31, 2024, we recorded impairments as the carrying values of sublet property asset groups were not recoverable due to the market conditions. During the year ended December 31, 2024, we recognized total impairment charge of $15.7 million.

During the year ended December 31, 2023, we recorded impairments as the carrying values of sublet property asset groups were not recoverable due to the change in how this property was being used. During the year ended December 31, 2023 we recognized total impairment charge of $13.2 million.

Interest and Other Income, Net

Interest and other income, net was $20.2 million and $18.3 million for the years ended December 31, 2024 and 2023, respectively. The $1.9 million increase was primarily due to higher yields and a corresponding increase in the interest earned on our cash, cash equivalents and investments.

Interest expense

Interest expense was related to the CIRM award proceeds received for the year ended December 31, 2024. No such interest expense was recorded for the year ended December 31, 2023.

Other expenses, net

Other expenses, net were $3.9 million and $17.8 million for the years ended December 31, 2024 and 2023, respectively. The $13.9 million decrease was primarily due to lower share of net losses in our equity method investments of $9.0 million and lower impairment losses of $5.0 million related to our equity method investment and equity investment.

Liquidity and Capital Resources

To date, we have incurred significant net losses and negative cash flows from operations. As of December 31, 2024, we had $373.1 million in cash, cash equivalents and investments. We believe that the aggregate of our current cash, cash

equivalents and investments available for operations will be sufficient to fund our operations for at least the next 12 months from the date this Annual Report on Form 10-K is filed with the SEC.

Our operations have been financed primarily by net proceeds from the sale and issuance of our convertible preferred stock, the issuance of convertible promissory notes, net proceeds from our IPO, our at-the-market (ATM) offerings, our June 2020 underwritten public offering, an upfront cash payment of $40.0 million received in December 2020 pursuant to our License Agreement with Overland Therapeutics, and our May 2024 registered offering. In November 2019, we entered into a sales agreement with Cowen and Company, LLC (Cowen), as amended on November 2, 2022 and November 2, 2023, under which we may from time to time issue and sell shares of our common stock through Cowen in ATM offerings. During the years ended December 31, 2024 and 2023, we sold an aggregate of 2,539,134 and 20,894,565 shares of common stock, respectively, in ATM offerings resulting in net proceeds of $6.8 million and $91.1 million, respectively. The specified dollar limit on the amount of common stock that may be sold under the sales agreement was removed pursuant to the November 2, 2023 amendment to the sales agreement. In May 2024, we completed an underwritten offering pursuant to which we issued and sold 37,931,035 shares of our common stock. We received net proceeds of $105.2 million, after deducting underwriting discounts and commissions and offering expenses payable by us.

Capital Resources

Our primary use of cash is for operating expenses, which consist primarily of clinical manufacturing and research and development expenditures related to our lead product candidates, other research efforts, and to a lesser extent, general and administrative expenditures. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our outstanding accounts payable and accrued expenses and other current liabilities.

Our product candidates are still in the early stages of clinical and preclinical development and the outcome of these efforts is uncertain. Accordingly, we cannot estimate the actual amounts necessary to successfully complete the development and commercialization of our product candidates or whether, or when, we may achieve profitability. Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity or debt financings and collaboration and license arrangements. If, and when, we do raise additional capital through public or private equity offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we are unable to raise capital when needed, we will need to delay, reduce or terminate planned activities to reduce costs. Doing so will likely harm our ability to execute our business plans.

Cash Flows

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

	Year Ended December 31,	
	2024	2023
	(in thousands)	
Net cash (used in) provided by:		
Operating activities	$ (200,300)	$ (237,733)
Investing activities	75,688	163,289
Financing activities	116,675	95,695
Net increase (decrease) in cash, cash equivalents and restricted cash	$ (7,937)	$ 21,251

Operating Activities

During the year ended December 31, 2024, cash used in operating activities of $200.3 million was attributable to a net loss of $257.6 million, substantially offset by non-cash charges of $82.1 million and a net change of $24.8 million in our net operating assets and liabilities. The non-cash charges consisted primarily of stock-based compensation of $51.7 million, impairment of long-lived assets of $15.7 million, depreciation and amortization of $13.6 million, non-cash rent expense of $5.3 million, impairment of equity investment and equity method investment of $2.0 million, and share of losses from equity method investments of $1.7 million, partially offset by net amortization and accretion on investment securities of $8.3 million. The net change in operating assets and liabilities was primarily due to deposit placed in escrow related to the Servier Amendment of $20.8 million, decrease in operating lease liabilities of $6.3 million, decrease in accounts payable of $0.5 million, increase in

prepaid expenses and other current assets of $0.5 million and decrease in accrued and other current liabilities of $1.3 million, partially offset by decrease in other long-term assets of $4.3 million, and increase in other long-term liabilities of $0.3 million.

During the year ended December 31, 2023, cash used in operating activities of $237.7 million was attributable to a net loss of $327.3 million, substantially offset by non-cash charges of $110.8 million and a net change of $21.3 million in our net operating assets and liabilities. The non-cash charges consisted primarily of stock-based compensation of $66.0 million, depreciation and amortization of $14.2 million, impairment of long-lived assets of $13.2 million, share of losses from equity method investments of $10.7 million, impairment of equity investment and equity method investment of $7.0 million, net amortization and accretion on investment securities of $6.8 million, and non-cash rent expense of $6.6 million. The net change in operating assets and liabilities was primarily due to decrease in accounts payable of $7.5 million, decrease in accrued and other current liabilities of $6.8 million, decrease in operating lease liabilities of $6.0 million, increase in other long-term assets of $1.5 million and decrease in other long-term liabilities of $0.6 million, partially offset by decrease in prepaid expense and other current assets of $1.1 million.

Investing Activities

During the year ended December 31, 2024, net cash provided by investing activities of $75.7 million was related to cash inflows from maturities of investments of $432.5 million and cash provided by investment sales of $5.4 million, partially offset by the purchase of investments of $361.5 million and purchases of property and equipment of $0.7 million.

During the year ended December 31, 2023, net cash provided by investing activities of $163.3 million was related to cash inflows from maturities of investments of $597.8 million and cash provided by investment sales of $5.6 million, partially offset by the purchase of investments of $438.6 million and purchases of property and equipment of $1.5 million.

Financing Activities

During the year ended December 31, 2024, net cash provided by financing activities of $116.7 million was related to net proceeds from the issuance of common stock through our May 2024 registered offering of $105.3 million, net proceeds from the issuance of common stock through ATM transactions of $6.8 million, proceeds from the CIRM award of $2.3 million, proceeds from the sale of common stock through our employee stock purchase plan of $1.5 million, and proceeds from the issuance of common stock upon exercise of stock options of $0.8 million.

During the year ended December 31, 2023, net cash provided by financing activities of $95.7 million was related to net proceeds from the issuance of common stock through ATM transactions of $91.1 million, proceeds from the sales of common stock through our employee stock purchase plan of $2.5 million, and proceeds from the issuance of common stock upon the exercise of stock options of $2.1 million.

Contractual Obligations and Commitments

Material Cash Commitments and Requirements

Our commitments primarily consist of obligations under our agreements with Pfizer, Cellectis, Servier, Notch and Foresight. Under these agreements we are required to make milestone payments upon successful completion of certain regulatory and sales milestones on a target-by-target and country-by-country basis. The payment obligations under the license agreements are contingent upon future events such as our achievement of specified development, regulatory and commercial milestones and we will be required to make development milestone payments and royalty payments in connection with the sale of products developed under these agreements. As of December 31, 2024, we were unable to estimate the timing or likelihood of achieving the milestones or making future product sales. For additional information regarding our agreements, see Note 6 to our consolidated financial statements included elsewhere in this Annual Report.

Our operating lease obligations primarily consist of lease payments on our research, lab and office facilities in South San Francisco, California, as well as lease payments on our cell manufacturing facility in Newark, California. For additional information regarding our lease obligations, see Note 7 to our consolidated financial statements included elsewhere in this Annual Report.

On October 6, 2020, we announced we entered into a strategic five-year collaboration agreement with MD Anderson for the preclinical and clinical investigation of allogeneic CAR T cell product candidates. We and MD Anderson are collaborating on the design and conduct of preclinical and clinical studies with oversight from a joint steering committee. Under the terms of the agreement, we have committed up to $15.0 million of funding for the duration of the agreement. Payment of

this funding is contingent on mutual agreement to study orders in order for any study to be included under the alliance. We made an upfront payment of $3.0 million to MD Anderson in the year ended December 31, 2020 and made an additional upfront payment of $3.0 million to MD Anderson in October 2023. We are committed to make further payments to MD Anderson each year upon the anniversary of the agreement effective date through the duration of the agreement term, however, if MD Anderson has sufficient funds to continue the agreed-upon research projects, we may defer the additional payment to a later date. The agreement may be terminated by either party for material breach by the other party. Individual studies may be terminated for, among other things, material breach, health and safety concerns or where the institutional review board, the review board at the clinical site with oversight of the clinical study, requests termination of any study. Where any legal or regulatory authorization is finally withdrawn or terminated, the relevant study will also terminate automatically.

In July 2020, we entered into a Solar Power Purchase and Energy Services Agreement for the installation and operation of a solar photovoltaic generating system and battery energy storage system at our manufacturing facility in Newark, California. The agreement has a term of 20 years and commenced in September 2022. We are obligated to pay for electricity generated from the system at an agreed rate for the duration of the agreement term. Termination of the agreement by us will result in a termination payment due of approximately $4.3 million. In connection with the agreement, we maintain a letter of credit for the benefit of the service provider in the amount of $4.3 million.

We also have a Change in Control and Severance Plan that requires the funding of specific payments, if certain events occur, such as a change of control and the termination of employment without cause.

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 United States generally accepted accounting principles. The preparation of these consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the consolidated financial statements, as well as the reported expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We believe that the assumptions and estimates associated with accrued research and development expenditures, stock-based compensation and impairment of long-lived assets have the most significant impact on our consolidated financial statements. Therefore, we consider these to be our critical accounting policies and estimates.

Accrued Research and Development Costs

We accrue liabilities for estimated costs of research and development activities conducted by our collaboration partners and third-party service providers, which include the conduct of preclinical and clinical studies, and contract manufacturing activities. We recorded the estimated costs of research and development activities based upon the estimated amount of services provided but not yet invoiced, and includes these costs in the accrued and other current liabilities on the consolidated balance sheets and within research and development expense on the consolidated statements of operations and comprehensive loss.

We accrue for these costs based on factors such as estimates of the work completed in accordance with agreements established with our collaboration partners and third-party service providers. We make estimates in determining the accrued liabilities balance in each reporting period. As actual costs become known, we adjust its accrued liabilities.

Stock-Based Compensation

We recognize compensation costs related to stock-based awards granted to employees and directors, including stock options, based on the estimated fair value of the awards on the date of grant. We estimate the grant date fair value, and the resulting stock-based compensation, using the Black-Scholes option-pricing model, the lattice option pricing model or Monte Carlo simulation, whichever provides us the more precise grant fair value based on accounting guidance. The grant date fair value of the stock-based awards is generally recognized on a straight-line basis over the requisite service period, which is generally the vesting period of the respective awards.

For the years ended December 31, 2024, and 2023, stock-based compensation was $51.7 million, and $66.0 million, respectively. As of December 31, 2024 and 2023, we had $69.2 million and $108.7 million, respectively, of total unrecognized stock-based compensation.

Impairment of Long-lived Assets

Our long-lived assets, including right-of-use assets, are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability is measured by comparison of the carrying amount of an asset group to the future net undiscounted cash flows that the assets are expected to generate. The long-lived assets recoverability test is performed at the asset group level, i.e., the lowest level for which identifiable cash flows are largely independent of the cash flows of other assets and liabilities. If this test indicates that the carrying amount of the asset group is not recoverable, an impairment loss is measured as the amount by which the carrying amount of an asset group exceeds its fair value. Any impairment loss is allocated to the long-lived assets of the group on a pro rata basis using the relative carrying amounts of those assets, except that the carrying amount of an individual asset shall not be reduced below its fair value.

Recent Accounting Pronouncements

Please refer to Note 2 to our consolidated financial statements for a discussion of new accounting standards and updates that may impact us.

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

Interest Rate Risk

Our cash, cash equivalents and investments of $373.1 million as of December 31, 2024, consist of bank deposits, money market funds and available-for-sale securities. Such interest-earning instruments carry a degree of interest rate risk; however, historical fluctuations in interest income have not been significant for us. A 10% change in the interest rates in effect on December 31, 2024 would not have had a material effect on the fair market value of our cash equivalents and available-for-sale securities.

Foreign Currency Exchange Rate Risk

Our collaboration agreement with Servier requires collaboration payments for shared clinical development costs to be paid in euros, and thus we face foreign exchange risk as a result of entering into transactions denominated in currencies other than U.S. dollars. Due to the uncertain timing of expected payments in foreign currencies, we do not utilize any forward exchange contracts. All foreign transactions settle on the applicable spot exchange basis at the time such payments are made. An adverse movement in foreign exchange rates could have an effect on payments due and made to our collaboration partner as well as other foreign suppliers and for license agreements. A 10% change in the applicable foreign exchange rates during the periods presented would not have had a material effect on our consolidated financial statements. As of December 31, 2024, 2024, we had $20.8 million of deposit placed in escrow. As of December 31, 2024, we had no receivables and $0.1 million of current liabilities denominated in foreign currency.

Item 8. Financial Statements and Supplementary Data.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

For the years ended December 31, 2024 and 2023

Report of Independent Registered Public Accounting Firm

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

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Allogene Therapeutics, Inc. (the Company) as of December 31, 2024 and 2023, 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, 2024, and the related notes (collectively referred to as the "consolidated financial st atements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2024 and 2023, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2024, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

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

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

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

Critical Audit Matter

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

Impairment of Long-Lived Assets

Description of the Matter	As discussed in Note 5 to the consolidated financial statements, the Company's long-lived assets are assessed for recoverability whenever events or changes in circumstances indicate that the carrying amount of the asset may not be recoverable. When indicators of impairment exist, the Company compares the estimated future undiscounted net cash flows to the carrying amount of the asset group. If the carrying amount of the asset group exceeds the future undiscounted cash flows, an impairment is measured based on the difference between the carrying amount of the asset group and its fair value. Indicators of impairment were identified for the year ended December 31, 2024. As a result the Company recorded an impairment charge of $15.7 million for its right-of-use asset and related leasehold improvements. Auditing the Company's impairment model was challenging due to the subjective assumption of market rental rates used as an input in determining the fair value of the right-of-use asset and related leasehold improvements.
How We Addressed the Matter in Our Audit	To test the Company's accounting for the impairment over the right-of-use asset and related leasehold improvements, our audit procedures included, among others, utilizing our valuation specialists to assist in evaluating the reasonableness of the Company's valuation methodology and the market rental rate assumption, performing an evaluation of market rental rates by benchmarking to other properties of similar type and within the geographic area, and testing the completeness and accuracy of the significant inputs within the model.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2018.

San Mateo, California
March 13, 2025

ALLOGENE THERAPEUTICS, INC.
Consolidated Balance Sheets
(In thousands, except share and per share amounts)

	December 31, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 75,218	$ 83,155
Short-term investments	217,258	365,542
Prepaid expenses and other current assets	10,910	10,418
Total current assets	303,386	459,115
Long-term investments	80,673	-
Operating lease right-of-use asset	45,205	63,703
Property and equipment, net	86,056	99,478
Deposit placed in escrow	20,773	-
Restricted cash	10,292	10,292
Other long-term assets	2,325	6,604
Equity method investments	-	3,645
Total assets	$ 548,710	$ 642,837
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 5,394	$ 5,897
Accrued and other current liabilities	30,129	31,182
Total current liabilities	35,523	37,079
Lease liability, noncurrent	83,247	88,346
Other long-term liabilities	7,761	5,179
Total liabilities	126,531	130,604
Commitments and Contingencies (Notes 6 and 7)		
Stockholders' equity:		
Preferred stock, $0.001 par value: 10,000,000 authorized as of December 31, 2024 and December 31, 2023; no shares were issued and outstanding as of December 31, 2024 and December 31, 2023	-	-
Common stock, $0.001 par value: 400,000,000 shares authorized as of December 31, 2024 and December 31, 2023; and 212,210,597 and 168,642,238 shares issued and outstanding as of December 31, 2024 and December 31, 2023, respectively	212	169
Additional paid-in capital	2,241,879	2,075,252
Accumulated deficit	(1,819,823)	(1,562,233)
Accumulated other comprehensive loss	(89)	(955)
Total stockholders' equity	422,179	512,233
Total liabilities and stockholders' equity	$ 548,710	$ 642,837

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

ALLOGENE THERAPEUTICS, INC.
Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except share and per share amounts)

	Year Ended December 31,	
	2024	**2023**
Collaboration revenue - related party	$ 22	$ 95
Operating expenses:		
Research and development	192,299	242,914
General and administrative	65,205	71,673
Impairment of long-lived asset	15,717	13,245
Total operating expenses	273,221	327,832
Loss from operations	(273,199)	(327,737)
Other income (expense), net:		
Interest and other income, net	20,153	18,307
Interest expense	(181)	-
Other expenses, net	(3,920)	(17,835)
Total other income (expense), net	16,052	472
Loss before income taxes	(257,147)	(327,265)
Income tax expense	(443)	-
Net loss	(257,590)	(327,265)
Other comprehensive loss:		
Net unrealized gain on available-for-sale investments	866	8,971
Net comprehensive loss	$ (256,724)	$ (318,294)
Net loss per share, basic and diluted	$ (1.32)	$ (2.09)
Weighted-average number of shares used in computing net loss per share, basic and diluted	194,811,756	156,931,778

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

ALLOGENE THERAPEUTICS, INC.
Consolidated Statements of Stockholders' Equity
(In thousands, except share and per share data)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
	Shares	Amount				
Balance - December 31, 2022 (As Restated)	144,438,304	$ 144	$ 1,911,632	$ (1,234,968)	$ (9,926)	$ 666,882
Issuance of common stock from ATM offering, net of commissions and offering costs of $1.7 million	20,894,565	21	91,091	-	-	91,112
Issuance of common stock upon exercise of stock options and vesting of RSUs	2,718,410	3	2,084	-	-	2,087
Vesting of early exercised common stock	-	-	1,999	-	-	1,999
Stock-based compensation	-	-	65,951	-	-	65,951
Employee stock purchase plan	590,959	1	2,495	-	-	2,496
Net loss (As Restated)	-	-	-	(327,265)	-	(327,265)
Net unrealized gain on available-for-sale investments	-	-	-	-	8,971	8,971
Balance - December 31, 2023	168,642,238	169	2,075,252	(1,562,233)	(955)	512,233
Issuance of common stock from ATM offering, net of commissions and offering costs of $0.1 million	2,539,134	2	6,762	-	-	6,764
Issuance of common stock from registered offering, net of commissions and offering costs of $4.7 million	37,931,035	38	105,245	-	-	105,283
Issuance of common stock upon exercise of stock options and vesting of RSUs	2,569,680	2	811	-	-	813
Vesting of early exercised common stock	-	-	532	-	-	532
Stock-based compensation	-	-	51,743	-	-	51,743
Employee stock purchase plan	528,510	1	1,534	-	-	1,535
Net loss	-	-	-	(257,590)	-	(257,590)
Net unrealized gain on available-for-sale investments	-	-	-	-	866	866
Balance - December 31, 2024	212,210,597	$ 212	$ 2,241,879	$ (1,819,823)	$ (89)	$ 422,179

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

ALLOGENE THERAPEUTICS, INC.
Consolidated Statements of Cash Flows
(in thousands)

	Year Ended December 31,	
	2024	**2023**
Cash flows from operating activities:		
Net loss	$ (257,590)	$ (327,265)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	51,743	65,951
Depreciation and amortization	13,639	14,199
Net amortization/accretion on investment securities	(8,348)	(6,809)
Impairment of long-lived asset	15,717	13,245
Impairment of equity investment and equity method investment	1,957	7,000
Non-cash rent expense	5,264	6,644
Income tax expense	443	-
Non-cash collaboration revenue - related party	(14)	(63)
Share of loss from equity method investments	1,688	10,672
Changes in operating assets and liabilities:		
Deposit placed in escrow	(20,773)	-
Prepaid expenses and other current assets	(492)	1,086
Other long-term assets	4,279	(1,455)
Accounts payable	(503)	(7,502)
Accrued and other current liabilities	(1,262)	(6,823)
Operating lease liabilities	(6,307)	(6,002)
Other long-term liabilities	259	(611)
Net cash used in operating activities	(200,300)	(237,733)
Cash flows from investing activities:		
Purchases of property and equipment	(694)	(1,516)
Proceeds from sales of investments	5,398	5,623
Proceeds from maturities of investments	432,459	597,811
Purchase of investments	(361,475)	(438,629)
Net cash provided by investing activities	75,688	163,289
Cash flows from financing activities:		
Proceeds from issuance of common stock from ATM offering, net of commissions and issuance costs	6,764	91,112
Proceeds from issuance of common stock from public offering, net of commissions and issuance costs	105,283	-
Proceeds from issuance of common stock and upon exercise of stock options	813	2,087
Proceeds from issuance of common stock under the employee stock purchase plan	1,535	2,496
Proceeds from CIRM award	2,280	-
Net cash provided by financing activities	116,675	95,695
Net increase (decrease) in cash, cash equivalents and restricted cash	(7,937)	21,251
Cash, cash equivalents and restricted cash - beginning of period	93,447	72,196
Cash, cash equivalents and restricted cash - end of period	$ 85,510	$ 93,447
Non-cash operating, investing and financing activities:		
Right-of-use asset obtained in exchange for lease liability	$ 2,409	$ -
Property and equipment purchases in accounts payable and accrued and other current liabilities	$ 64	$ -
Non-cash deferred revenue and other long-term liabilities	$ 3,079	$ 3,094
Supplemental disclosure:		
Cash paid for amounts included in the measurement of lease liabilities	$ (12,505)	$ (12,049)

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

ALLOGENE THERAPEUTICS, INC.
Notes to Consolidated Financial Statements

Note 1.
Description of Business and Summary of Significant Accounting Policies

Allogene Therapeutics, Inc. (the Company or Allogene) was incorporated on November 30, 2017 in the State of Delaware and is headquartered in South San Francisco, California. Allogene is a clinical stage immuno-oncology company pioneering the development of genetically engineered allogeneic T cell product candidates for the treatment of cancer and autoimmune diseases. The Company is developing a pipeline of "off-the-shelf" T cell product candidates that are designed to target and kill cancer cells in patients or eliminate pathogenic autoreactive cells in patients with autoimmune disorders. The Company's engineered T cells are allogeneic, meaning they are derived from healthy donors for intended use in any patient, rather than from an individual patient for that patient's use, as in the case of autologous T cells. The Company believes this key difference will enable it to deliver readily available treatments faster, more reliably, at greater scale, and to more patients.

Public Offerings

In November 2019, the Company entered into a sales agreement with Cowen and Company, LLC (Cowen), as amended on November 2, 2022 and November 2, 2023, under which the Company may from time to time issue and sell shares of its common stock through Cowen in at-the-market (ATM) offerings. The aggregate compensation payable to Cowen as the Company's sales agent equals up to 3.0% of the gross sales price of the shares sold through Cowen pursuant to the sales agreement. During the year ended December 31, 2023, the Company sold an aggregate of 20,894,565 shares of common stock in ATM offerings resulting in net proceeds of $91.1 million. The specified dollar limit on the amount of common stock that may be sold under the sales agreement was removed pursuant to the November 2, 2023 amendment to the sales agreement. During the year ended December 31, 2024, the Company sold an aggregate of 2,539,134 shares of common stock in ATM offerings resulting in net proceeds of $6.8 million.

Registered Offering

On May 13, 2024, the Company entered into (i) an underwriting agreement (Underwriting Agreement) with Goldman Sachs & Co. LLC (Underwriter) and (ii) a Securities Purchase Agreement (Securities Purchase Agreement) with certain members of the Company's Board of Directors and executive officers or their respective affiliates (Purchasers), pursuant to which the Company sold and issued to the Underwriter and the Purchasers an aggregate of 37,931,035 shares of common stock of the Company at a purchase price of $2.90 per share, in a registered offering transaction (Registered Offering) for aggregate gross proceeds of $110.0 million, before deducting the underwriting discount and commissions and estimated offering expenses payable by the Company. The Registered Offering closed on May 16, 2024. The aggregate fee payable by the Company to the Underwriter was $4.7 million, plus the reimbursement of certain expenses. The Purchasers purchased an aggregate of 1,034,484 shares of common stock of the Company in the Registered Offering.

Need for Additional Capital

The Company has sustained operating losses and expects to continue to generate operating losses for the foreseeable future. The Company's ultimate success depends on the outcome of its research and development activities as well as the ability to commercialize the Company's product candidates. The Company had cash, cash equivalents and investments of $373.1 million as of December 31, 2024. Since inception through December 31, 2024, the Company has incurred cumulative net losses of $1,819.8 million. Management expects to incur additional losses in the future to fund its operations and conduct product research and development and recognizes the need to raise additional capital to fully implement its business plan.

The Company intends to raise additional capital through the issuance of equity securities, debt financings or other sources in order to further implement its business plan. However, if such financing is not available at adequate levels, the Company will need to reevaluate its operating plan and may be required to delay the development of its product candidates. The Company expects that its cash and cash equivalents and investments will be sufficient to fund its operations for at least the next 12 months from the date the Company's Annual Report on Form 10-K is filed with the Securities and Exchange Commission (SEC).

Basis of Presentation

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (GAAP).

In June 2020, the Company formed a wholly-owned, Netherlands-based subsidiary, Allogene Therapeutics, B.V., to help prepare for and assist with the Company's activities in Europe. The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary, Allogene Therapeutics, B.V. All material intercompany balances and transactions have been eliminated during consolidation. The subsidiary was dissolved on January 3, 2024.

Reclassification of Prior Period Balances

The deferred revenue was reclassified to be included in the accrued and other current liabilities in the balance sheet as of December 31, 2023 to conform to the consolidated balance sheet presentation at December 31, 2024. The presentation of non-cash rent expense and operating lease liabilities in the consolidated statement of cash flow for the year ended December 31, 2023 were reclassified to conform with the consolidated statement of cash flow presentation for the year ended December 31, 2024. These reclassifications have no effect on the reported net income for the years ended December 31, 2024 and 2023.

Use of Estimates

The preparation of consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities as of the date of the consolidated financial statements and the reported amounts of expenses during the reporting period. Significant estimates and assumptions made in the accompanying consolidated financial statements include but are not limited to the fair value of common stock, the fair value of stock options, the fair value of investments, income tax uncertainties, the CIRM award liability and certain accruals. The Company evaluates its estimates and assumptions on an ongoing basis using historical experience and other factors and adjusts those estimates and assumptions when facts and circumstances change. Actual results could differ from those estimates.

Concentration of Credit and other Risks and Uncertainties

Financial instruments, which potentially subject the Company to significant concentrations of credit risk, consist primarily of cash and cash equivalents and investments. The primary objectives for the Company’s investment portfolio are the preservation of capital and the maintenance of liquidity. The Company does not enter into any investment transaction for trading or speculative purposes.

The Company’s investment policy limits investments to certain types of instruments such as certificates of deposit, commercial paper, money market instruments, asset-backed securities, obligations issued by the U.S. government and U.S. government agencies as well as corporate debt securities, and places restrictions on maturities and concentration by type and issuer. The Company maintains cash balances in excess of amounts insured by the FDIC and concentrated within a limited number of financial institutions. The accounts are monitored by management and management believes that the financial institutions are financially sound, and, accordingly, minimal credit risk exists with respect to these financial institutions. As of December 31, 2024 and 2023, the Company has not experienced any significant credit losses in such accounts or investments.

The Company is subject to a number of risks common for early-stage biopharmaceutical companies including, but not limited to, the ability to achieve any clinical or commercial success of its product candidates, ability to obtain regulatory approval of its product candidates, the need for substantial additional financing to achieve its goals, uncertainty of broad adoption of its approved products, if any, by physicians and patients, significant competition, dependency on the Company's contract manufacturing organization, and ability to manufacture.

Segments

Operating segments are defined as components of an entity for which separate financial information is available and that is regularly reviewed by the Chief Operating Decision Maker (CODM) in deciding how to allocate resources to an individual segment and in assessing performance. The Company’s CODM is its Chief Executive Officer. The Company has determined it operates in a single operating segment and has one reportable segment. The Company’s method for measuring profitability on a reportable segment basis is net profit or loss. The Company's CODM does not evaluate operating segments using asset or liability information. Additional significant segment expenses are provided on a quarterly basis to the CODM to support the CODM’s decision making process. Refer to Note 15 for additional information.

Cash, Cash Equivalents and Restricted Cash

The Company considers all highly liquid investments purchased with original maturities of three months or less from the purchase date to be cash equivalents. Cash equivalents consist primarily of amounts invested in bank money market accounts and money market mutual funds.

The Company has issued letters of credit under separate lease and other agreements which have been collateralized by restricted cash. This cash is classified as long-term restricted cash on the accompanying consolidated balance sheets based on the terms of the underlying agreements.

Investments

Investments are available-for-sale and are carried at estimated fair value. The Company's valuations of marketable securities are generally derived from independent pricing services based upon quoted prices in active markets for similar securities, with prices adjusted for yield and number of days to maturity, or based on industry models using data inputs, such as interest rates and prices that can be directly observed or corroborated in active markets. Management determines the appropriate classification of its investments in debt securities at the time of purchase and at the end of each reporting period. Investments with original maturities of less than three months at the date of purchase are classified as cash and cash equivalents. Investments with original maturities beyond three months at the date of purchase and which mature at, or less than twelve months from the consolidated balance sheet date are classified as current.

Unrealized gains and losses are excluded from earnings and are reported as a component of other comprehensive income. The Company periodically evaluates whether declines in fair values of its available-for-sale securities below their book value are other-than-temporary. This evaluation consists of several qualitative and quantitative factors regarding the severity and duration of the unrealized loss as well as the Company's ability and intent to hold the available-for-sale security until a forecasted recovery occurs. Additionally, the Company assesses whether it has plans to sell the security or it is more likely than not it will be required to sell any available-for-sale securities before recovery of its amortized cost basis. Realized gains and losses and declines in fair value considered to be other than temporary, if any, on available-for-sale securities are included in interest and other income, net. The cost of investments sold is based on the specific-identification method. Interest income on investments is included in interest and other income, net.

Fair Value Measurement

Assets and liabilities recorded at fair value on a recurring basis in the consolidated balance sheets are categorized based upon the level of judgment associated with the inputs used to measure their fair values. Fair value is defined as the exchange price that would be received for an asset or an exit price that would be paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. The authoritative guidance on fair value measurements establishes a three-tier fair value hierarchy for disclosure of fair value measurements as follows:

Level 1-Observable inputs such as unadjusted, quoted prices in active markets for identical assets or liabilities at the measurement date.

Level 2-Inputs (other than quoted prices included in Level 1) are either directly or indirectly observable for the asset or liability. These include quoted prices for similar assets or liabilities in active markets and quoted prices for identical or similar assets or liabilities in markets that are not active.

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

Property and Equipment, Net

Property and equipment are stated at cost less accumulated depreciation and amortization. Depreciation is computed on a straight-line basis over the estimated useful lives of the related assets, generally three to
seven years. Maintenance and repairs are charged to operations as incurred. Upon sale or retirement of assets, the cost and related accumulated depreciation are removed from the consolidated balance sheets and the resulting gain or loss is reflected in other expense.

The Company has determined the estimated life of assets to be as follows:

Laboratory equipment	5 years
Computer equipment and purchased software	3 - 5 years
Fixtures and furniture	7 years
Leasehold improvements	Shorter of lease term or useful life

The Company capitalizes implementation costs associated with internal use cloud computing arrangements in alignment with ASC 350-40 internal-use software. Costs incurred in preliminary project stage and post implementation stage are expensed as incurred. Costs incurred during the application development stage of implementation are capitalized in other long-term assets on the consolidated balance sheets. Capitalized implementation costs from cloud computing arrangements are amortized over the term of the cloud-based service arrangement.

California Institute for Regenerative Medicine (CIRM) Award

Accounting for the CIRM award does not fall under ASC 606, Revenue from Contracts and Customers, as CIRM does not meet the definition of a customer. No income associated with the CIRM award will be recognized until it is confirmed with CIRM that the award does not require repayment. Until then such award will be recognized, along with any interest, as a long-term liability upon cash receipt. Any estimated interest accrued for the CIRM award received is recognized as interest expense in the consolidated statements of operations. The Company will not recognize a receivable of future awards until it is approved by CIRM. See Note 5 below for more details.

Leases

For its long-term operating leases, the Company recognizes a right-of-use asset and a lease liability on its consolidated balance sheets. The lease liability is determined as the present value of future lease payments using an estimated rate of interest that the Company would pay to borrow equivalent funds on a collateralized basis at the lease commencement date. The right-of-use asset is based on the liability adjusted for any prepaid or deferred rent. The lease term at the commencement date is determined by considering whether renewal options and termination options are reasonably assured of exercise.

Rent expense for the operating lease is recognized on a straight-line basis over the lease term and is included in operating expenses on the consolidated statements of operations and comprehensive loss. Variable lease payments include lease operating expenses.

The Company elected to exclude from its consolidated balance sheets recognition of leases having a term of 12 months or less (short-term leases) and elected to not separate lease components and non-lease components for its long-term real-estate leases.

Equity Method Investments

The Company uses the equity method of accounting for equity investments in companies if the investment provides the ability to exercise significant influence, but not control, over operating and financial policies of the investee. The Company's proportionate share of the net income or loss of these companies is included in other expenses, net in the consolidated statement of operations. Judgment regarding the level of influence over each equity method investment includes considering key factors such as our ownership interest, representation on the board of directors, participation in policy-making decisions and material purchase and sale transactions.

The Company evaluates equity method investments for impairment whenever events or changes in circumstances indicate that the carrying amount of the investment might not be recoverable. Factors considered when reviewing an equity method investment for impairment include the length of time (duration) and the extent (severity) to which the fair value of the equity method investment has been less than cost, the investee’s financial condition and near-term prospects and the intent and ability to hold the investment for a period of time sufficient to allow for anticipated recovery. An impairment that is other-than-temporary is recognized in the period identified.

Variable Interest Entities

For entities in which the Company has variable interests, the Company focuses on identifying if one of the entities is the primary beneficiary through having the power to direct the activities that most significantly impact the variable interest

entity's economic performance and having the obligation to absorb losses or the right to receive benefits from the variable interest entity. If the Company is the primary beneficiary of a variable interest entity, the assets, liabilities, and results of operations of the variable interest entity will be included in the Company's consolidated financial statements. The Company did not consolidate any variable interest entities in any of the periods presented because the Company determined that it was not the primary beneficiary.

Accrued Research and Development Costs

The Company records accrued liabilities for estimated costs of research and development activities conducted by collaboration partners and third-party service providers, which include the conduct of preclinical studies and clinical trials, and contract manufacturing activities. The Company records the estimated costs of research and development activities based upon the estimated amount of services provided but not yet invoiced and includes these costs in accrued and other current liabilities on the consolidated balance sheets and within research and development expenses on the consolidated statements of operations and comprehensive loss.

The Company accrues for these costs based on factors such as estimates of the work completed and in accordance with agreements established with its collaboration partners and third-party service providers. The Company makes significant judgments and estimates in determining the accrued liabilities balance at the end of each reporting period. As actual costs become known, the Company adjusts its accrued liabilities.

Income Taxes

Income taxes are accounted for under the asset and liability method. Under this method, deferred tax assets and liabilities are determined based on the difference between the financial statement and tax bases of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to affect taxable income. Management makes an assessment of the likelihood that the resulting deferred tax assets will be realized. A valuation allowance is provided when it is more likely than not that some portion or all of a deferred tax asset will not be realized. Due to the Company's historical operating performance and net losses, the net deferred tax assets have been fully offset by a valuation allowance.

The Company recognizes uncertain income tax positions at the largest amount that is more likely than not to be sustained upon audit by the relevant taxing authority. An uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained. Changes in recognition or measurement are reflected in the period in which judgment occurs. The Company's policy is to recognize interest and penalties related to the underpayment of income taxes as a component of the provision for income taxes.

Stock-Based Compensation

The Company measures its stock-based awards granted to employees, consultants and directors based on the estimated fair values of the awards and recognizes the compensation over the requisite service period. The Company uses the Black-Scholes option-pricing model, the lattice option pricing model or Monte Carlo simulation to estimate the fair value of its stock-based awards. Stock-based compensation is recognized using the straight-line method. As the stock compensation expense is based on awards ultimately expected to vest, it is reduced by forfeitures. The Company accounts for forfeitures as they occur.

Net Loss Per Share

Basic net loss per share is calculated by dividing the net loss by the weighted-average number of shares of common stock outstanding for the period, without consideration for potential dilutive shares of common stock. Since the Company was in a loss position for all periods presented, basic net loss per share is the same as diluted net loss per share since the effects of potentially dilutive securities are antidilutive. Shares of common stock subject to repurchase are excluded from the weighted-average shares.

Comprehensive Loss

Comprehensive loss includes net loss and certain changes in stockholders' equity that are excluded from net loss. For the years ended December 31, 2024 and 2023, this was comprised of unrealized gains and losses, net of tax, on the Company's investments.

Impairment of Long-Lived Assets

Long-lived assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability is measured by comparison of the carrying amount of an asset group to the future net undiscounted cash flows that the assets are expected to generate. The long-lived assets recoverability test is performed at the asset group level, i.e., the lowest level for which identifiable cash flows are largely independent of the cash flows of other assets and liabilities. If this test indicates that the carrying amount of the asset group is not recoverable, an impairment loss is measured as the amount by which the carrying amount of an asset group exceeds its fair value. Any impairment loss is allocated to the long-lived assets of the group on a pro rata basis using the relative carrying amounts of those assets, except that the carrying amount of an individual asset shall not be reduced below its fair value. The Company recorded long-lived assets impairment losses of $15.7 million and $13.2 million for the years ended December 31, 2024 and 2023, respectively (see Note 5).

Revenue Recognition

The Company's revenue has been generated through collaboration research and license agreements. The terms of these agreements may contain multiple deliverables which may include (i) grant of licenses, (ii) transfer of know-how, (iii) research and development activities, (iii) clinical manufacturing, and (iv) product supply. The payment terms of these agreements may include nonrefundable upfront fees, payments for research and development activities, payments based upon the achievement of certain milestones, royalty payments based on product sales derived from the collaboration, and payments for supplying product.

The Company analyzes its collaboration arrangements to assess whether they are within the scope of ASC 808, Collaborative Arrangements (ASC 808) to determine whether such arrangements involve joint operating activities performed by parties that are both active participants in the activities and exposed to significant risks and rewards dependent on the commercial success of such activities. This assessment is performed throughout the life of the arrangement based on changes in the responsibilities of all parties in the arrangement. For collaboration arrangements within the scope of ASC 808 that contain multiple elements, the Company first determines which elements of the collaboration are deemed to be within the scope of ASC 808 and those that are more reflective of a vendor-customer relationship and, therefore, within the scope of Topic 606, Revenue from Contracts with Customers (ASC 606). For elements of collaboration arrangements that are accounted for pursuant to ASC 808, an appropriate recognition method is determined and applied consistently, generally by analogy to Topic 606.

For elements of those arrangements that the Company determines should be accounted for under ASC 606, the Company assesses which activities in the collaboration agreements are performance obligations that should be accounted for separately and determines the transaction price of the arrangement, which includes the assessment of the probability of achievement of future milestones and other potential consideration. A performance obligation represents a promise in a contract to transfer a distinct good or service to a customer, which represents a unit of accounting in accordance with ASC 606. A performance obligation is considered distinct from other obligations in a contract when it provides a benefit to the customer either on its own or together with other resources that are readily available to the customer and is separately identified in the contract. The Company considers a performance obligation satisfied once the Company has transferred control of a good or service to the customer, meaning the customer has the ability to use and obtain the benefit of the good or service. A portion of the consideration should be allocated to each distinct performance obligation. The total consideration which the Company expects to collect in exchange for the Company's products is an estimate and may be fixed or variable. The Company constrains the estimated variable consideration when it assesses it is probable that a significant reversal in the amount of cumulative revenue recognized may occur in future periods. The transaction price is re-evaluated, including the estimated variable consideration included in the transaction price and all constrained amounts, in each reporting period and as uncertain events are resolved or other changes in circumstances occur. The allocation of the transaction price is performed based on standalone selling prices, which are based on estimated amounts that the Company would charge for a performance obligation if it were sold separately. Revenue is recognized when, or as, performance obligations in the contracts are satisfied, in the amount reflecting the expected consideration to be received from the goods or services transferred to the customers. Funds received in advance are recorded as deferred revenue and are recognized as the related performance obligation is satisfied.

Research and Development Expenses

Research and development costs are expensed as incurred and consist of salaries and benefits, including associated stock-based compensation, and laboratory supplies and facility costs, as well as fees paid to other entities that conduct certain research and development activities on the Company's behalf. Research and development expenses also include costs incurred for internal and sponsored collaborative research and development activities. Costs associated with co-development activities performed under the various license and collaboration agreements are included in research and development expenses.

Nonrefundable advance payments for goods or services to be received in the future for use in research and development activities are capitalized and then expensed as the related goods are delivered or the services are performed.

Note 2.
Recent Accounting Guidance

Recently Adopted Accounting Pronouncements

In November 2023, the Financial Accounting Standards Board (FASB) issued Accounting Standard Update (ASU) 2023-07, Segment Reporting (Topic 280): *Improvements to Reportable Segment Disclosures* (ASU 2023-07), which requires all public entities, including public entities with a single reportable segment, to provide in interim and annual periods one or more measures of segment profit or loss used by the chief operating decision maker to allocate resources and assess performance. Additionally, the standard requires disclosures of significant segment expenses and other segment items as well as incremental qualitative disclosures. The Company adopted this standard effective January 1, 2024 and applied the disclosure requirements retrospectively to all prior periods presented in the consolidated financial statements. Adoption of the new guidance had no significant impact on the Company's consolidated financial statements.

Recent Accounting Pronouncements Not Yet Adopted

In December 2023, the FASB issued ASU 2023-09, Income taxes (Topic 740), *Improvement to income tax disclosures*, which enhances the disclosures required for income taxes in the Company’s annual financial statements. This standard is effective for fiscal years beginning after December 15, 2024, with early adoption permitted. The Company does not plan to adopt this standard early. The adoption of this standard is not expected to have a material impact on the Company’s financial statements.

In November 2024, the FASB issued ASU 2024-03, *Income Statement-Reporting Comprehensive Income-Expense Disaggregation Disclosures (Subtopic 220-40)*, which requires new disclosures to disaggregate prescribed natural expenses underlying any income statement caption. ASU 2024-03 is effective for annual periods in fiscal years beginning after December 15, 2026, and interim periods thereafter. Early adoption is permitted. ASU 2024-03 applies on a prospective basis for periods beginning after the effective date. However, retrospective application to any or all prior periods presented is permitted. The Company is currently assessing the impact ASU 2024-03 will have on the consolidated financial statements and disclosures.

Note 3.
Fair Value Measurements

The Company follows authoritative accounting guidance, which among other things, defines fair value, establishes a consistent framework for measuring fair value and expands disclosure for each major asset and liability category measured at fair value on either a recurring or nonrecurring basis. Fair value is an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability.

The Company measures and reports its cash equivalents, restricted cash, and investments at fair value.

Money market funds are measured at fair value on a recurring basis using quoted prices and are classified as Level 1. Investments are measured at fair value based on inputs other than quoted prices that are derived from observable market data and are classified as Level 2 inputs, except for investments in U.S. treasury securities which are classified as Level 1.

There were
no Level 3 assets or liabilities as of December 31, 2024 or 2023.

Financial assets subject to fair value measurements on a recurring basis and the level of inputs used in such measurements by major security type as of December 31, 2024 are presented in the following table:

	December 31, 2024			
	Level 1	Level 2	Level 3	Fair Value
	(in thousands)			
Financial Assets:				
Money market funds [1]	$ 65,780	$ -	$ -	$ 65,780
Commercial Paper	-	66,255	-	66,255
Corporate bonds	-	82,725	-	82,725
U.S. treasury securities	85,728	-	-	85,728
U.S. agency securities	-	58,514	-	58,514
Asset-backed securities	-	9,700	-	9,700
Total financial assets	$ 151,508	$ 217,194	$ -	$ 368,702

[1] Included within cash and cash equivalents on the Company's consolidated balance sheets

Financial assets subject to fair value measurements on a recurring basis and the level of inputs used in such measurements by major security type as of December 31, 2023 are presented in the following table:

	December 31, 2023			
	Level 1	Level 2	Level 3	Fair Value
	(in thousands)			
Financial Assets:				
Money market funds [1]	$ 78,536	$ -	$ -	$ 78,536
Corporate bonds	-	97,166	-	97,166
U.S. treasury securities	229,516	-	-	229,516
U.S. agency securities	-	38,860	-	38,860
Total financial assets	$ 308,052	$ 136,026	$ -	$ 444,078

[1] Included within cash and cash equivalents on the Company's consolidated balance sheets

The carrying amounts of accounts payable and accrued liabilities approximate their fair values due to their short-term maturities. The Company's Level 2 securities are valued using third-party pricing sources. The pricing services utilize industry standard valuation models, including both income and market-based approaches, for which all significant inputs are observable, either directly or indirectly.

There were no transfers of assets between the fair value measurement levels during the years ended December 31, 2024 or 2023.

Note 4.
Investments

The fair value and amortized cost of cash equivalents and available-for-sale securities by major security type as of December 31, 2024 are presented in the following tables:

	December 31, 2024			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
	(in thousands)			
Money market funds	$ 65,780	$ -	$ -	$ 65,780
Commercial paper	66,269	19	(34)	66,254
Corporate bonds	82,716	53	(45)	82,724
U.S. treasury securities	85,765	54	(91)	85,728
U.S. agency securities	58,566	20	(70)	58,516
Asset-backed securities	9,695	5	-	9,700
Total cash equivalents and investments	$ 368,791	$ 151	$ (240)	$ 368,702
Classified as:				
Cash equivalents				$ 70,771
Short-term investments				217,258
Long-term investments				80,673
Total cash equivalents, and investments				$ 368,702

The fair value and amortized cost of cash equivalents and available-for-sale securities by major security type as of December 31, 2023 are presented in the following tables:

	December 31, 2023			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
	(in thousands)			
Money market funds	$ 78,536	$ -	$ -	$ 78,536
Corporate bonds	97,265	113	(212)	97,166
U.S. treasury securities	229,563	132	(179)	229,516
U.S. agency securities	39,225	-	(365)	38,860
Total cash equivalents and investments	$ 444,589	$ 245	$ (756)	$ 444,078
Classified as:				
Cash equivalents				$ 78,536
Short-term investments				365,542
Long-term investments				-
Total cash equivalents, and investments				$ 444,078

The fair values of available-for-sale debt investments by contractual maturity as of December 31, 2024 and 2023 were as follows:

	December 31,	
	2024	2023
	(in thousands)	
Due in 1 year or less	$ 222,250	$ 365,542
Due in 1 - 2 years	70,972	-
Due in 3 years	9,700	-
Instruments not due at a single maturity date	65,780	78,536
Total cash equivalents and investments	$ 368,702	$ 444,078

There were no significant realized losses on available-for-sale securities for the year ended December 31, 2024. Realized losses on available-for-sale securities for the year ended December 31, 2023 were $1.0 million. As of December 31, 2024 and 2023, unrealized losses on available-for-sale securities are not attributed to credit risk. The Company believes that it is more likely than not that investments in an unrealized loss position will be held until maturity and all interest and principal will be received. The Company does not intend to sell these investments and it is more likely than not that the Company will not be required to sell the investment before recovery of its amortized cost basis. The Company believes that an allowance for credit losses is unnecessary because the unrealized losses on certain of the Company's available-for-sale securities are due to market factors. As of December 31, 2024 and 2023, securities with a fair value of zero and $48.4 million, respectively, were in a continuous net unrealized loss position for more than 12 months. To date, the Company has not recorded any impairment charges on available-for-sale securities.

The Company has made an accounting policy election not to recognize an allowance for credit losses for accrued interest receivable on available-for-sale securities. As of December 31, 2024 and 2023, the Company recognized $1.9 million and $1.7 million, respectively, of accrued interest receivable from available-for-sale securities within prepaid expenses and other current assets on the consolidated balance sheets.

Note 5.
Balance Sheet Components

Property and Equipment, Net

	December 31,	
	2024	2023
	(in thousands)	
Leasehold improvements	$ 108,127	$ 108,621
Laboratory equipment	31,595	33,157
Computer equipment and purchased software	4,658	4,663
Furniture and fixtures	4,214	4,121
Total	148,594	150,562
Less: accumulated depreciation	(62,538)	(51,084)
Total property and equipment, net	$ 86,056	$ 99,478

Depreciation expense for the years ended December 31, 2024, and 2023 was $ 13.6 million, and $14.2 million, respectively. Disposals of property and equipment were $0.3 million and less than $0.1 million for the years ended December 31, 2024 and 2023, respectively.

The Company reviews for indicators of impairment on a quarterly basis which includes the change in how its property is being used. During the year ended December 31, 2024, the Company made a decision to sublease one of its leased buildings in South San Francisco. The Company vacated and ceased occupancy of this building and currently the Company is actively marketing the leased building for sublease. The Company determined that the change in how this building is being used was an indicator of impairment. The Company identified this to-be-sublet property as a separate asset group. The Company concluded that the carrying value of this to-be-sublet property asset group was not recoverable and the estimated fair value of this asset group was below its carrying value. The decrease in the fair value of this asset group was mainly due to the lower estimated sublease income based on current commercial rental market conditions compared to the lease payments in accordance with the initial operating lease agreement. The Company performed discounted cash flow analysis to estimate the fair value of its right-of-use asset and leasehold improvements. The key inputs to this valuation were expected sublease rental income of $1.9 million through March 2032 and the risk-adjusted annual discount rate of 9.5%. Based on this analysis, the Company concluded the fair value of the right-of-use asset and leasehold improvements of $1.2 million was lower than its net book value of $7.5 million. The Company recognized an aggregate long-lived asset impairment charge of $6.2 million on the right-of-use asset and leasehold improvements for the year ended December 31, 2024.

Previously, in December 2023, the Company made a decision to sublease one of its other leased buildings in South San Francisco. The Company had vacated and ceased occupancy of this building in December 2023 and in January 2025, the Company executed two subleases for the majority of the leased building. During the year ended December 31, 2023, the Company recognized long-lived asset impairment charge of $13.2 million on the right-of-use asset by applying a discounted cash flow method to estimate fair value of its right-of-use asset. The key inputs to this valuation were expected sublease rental income of $22.7 million through March 31, 2032 and annual discount rate of 9.0%. During the year ended December 31, 2024, the Company revised its valuation based on terms with a subtenant for a portion of the building and new market data. The expected sublease rental income based on the revised valuation was $4.7 million through March 31, 2032 and the annual

discount rate did not change. The Company concluded the fair value of the right-of-use asset of $3.1 million was lower than its book value of $12.6 million and recognized an additional long-lived asset impairment charge of $9.5 million on the right-of-use asset for the year ended December 31, 2024.

Accrued Liabilities

Accrued liabilities consist of the following:

	December 31,	
	2024	2023
	(in thousands)	
Accrued compensation and related benefits	$ 12,146	$ 12,665
Accrued research and development expenses	9,402	9,315
Accrued lease liability	7,509	6,775
Unvested shares liability	-	532
Other	1,072	1,809
Total accrued and other current liabilities	$ 30,129	$ 31,096

Accrued and Other Current Liabilities

On January 4, 2024, the Company's Board of Directors approved a reduction in the Company's workforce of approximately 22% of the Company's employees in connection with the Company's pipeline prioritization and clinical development strategy. The reduction in workforce was completed by June 30, 2024. During the year ended December 31, 2024, the Company paid approximately $3.0 million for severance and other employee benefits. As of December 31, 2024, less than $0.1 million of the severance and other employee benefits accrual was included in accrued and other current liabilities on the consolidated balance sheets.

CIRM Award

On April 26, 2024, the Company was awarded up to $15.0 million from CIRM to support the clinical development of ALLO-316, an AlloCAR TTM investigational product targeting CD70 in development for the treatment of advanced or metastatic renal cell carcinoma (RCC).

Pursuant to terms of the award, the disbursements are tied to the achievement of specified operational milestones. In addition, the terms of the award include a co-funding requirement pursuant to which the Company is required to spend up to approximately $25.9 million of its own capital to fund the CIRM funded research project. The award was made in accordance with the CIRM Grants Administration Policy for Clinical Stage Projects which may require the award to be repaid by the Company. Under the terms of the CIRM award, the Company is obligated to pay royalties based on a low single digit royalty percentage on net sales of CIRM-funded product candidate. The maximum royalty that the Company may be required to pay to CIRM is equal to nine times the total amount awarded and paid to the Company.

After completing the CIRM funded research project and at any time after the award period end date (but no later than the ten-year anniversary of the date of the award), the Company has the right, upon its election, to convert the award into a loan. The terms of conversion into a loan will be determined based on various factors and could result in 80% to 100% plus interest at 10% per annum plus the Secured Overnight Financing Rate of the total award dependent upon the phase of clinical development of the product candidate at the time of the Company's election to be repaid to CIRM.

No income associated with the CIRM award will be recognized until it is confirmed with CIRM that the award does not require repayment. Upon cash receipt, the CIRM award and accrued interest will be recognized as other long-term liabilities on the consolidated balance sheets. The Company will not recognize a receivable of future awards until it is approved by CIRM.

The Company received $2.3 million from CIRM through December 31, 2024 and accounted for the proceeds as a liability within other long-term liabilities on the consolidated balance sheets. During the year ended December 31, 2024, the Company recorded interest expense of $0.2 million. As of December 31, 2024, $0.2 million of accrued interest was included in other long-term liabilities.

In February 2025, the Company met an additional operational milestone and received an additional award of $3.4 million from CIRM.

Note 6.
License and Collaboration Agreements

Asset Contribution Agreement with Pfizer

In April 2018, the Company entered into an Asset Contribution Agreement (the Pfizer Agreement) with Pfizer pursuant to which the Company acquired certain assets, including certain contracts and intellectual property for the development and administration of chimeric antigen receptor (CAR) T cells for the treatment of cancer. The Company is required to make milestone payments upon successful completion of regulatory and sales milestones on a target-by-target basis for the targets including CD19 and B-cell maturation antigen (BCMA), covered by the Pfizer Agreement. The aggregate potential milestone payments upon successful completion of various regulatory milestones in the United States and the European Union are $30.0 million or $60.0 million, depending on the target, with aggregate potential regulatory and development milestones of up to $840.0 million. The aggregate potential milestone payments upon reaching certain annual net sales thresholds in North America, Europe, Asia, Australia and Oceania (the Territory) for a certain number of targets covered by the Pfizer Agreement are $325.0 million per target. The sales milestones in the foregoing sentence are payable on a country-by-country basis until the last to expire of any Pfizer Royalty Term, as described below, for any product in such country in the Territory. In October 2019, the Territory was expanded to all countries in the world. No milestone or royalty payments were made in the years ended December 31, 2024 and 2023.

Pfizer is also eligible to receive, on a product-by-product and country-by-country basis, royalties in single-digit percentages on annual net sales for products covered by the Pfizer Agreement. The Company’s royalty obligation with respect to a given product in a given country begins upon the first sale of such product in such country and ends on the later of (i) expiration of the last claim of any applicable patent or (ii) 12 years from the first sale of such product in such country.

Research Collaboration and License Agreement with Cellectis

As part of the Pfizer Agreement, Pfizer assigned to the Company a Research Collaboration and License Agreement (the Original Cellectis Agreement) with Cellectis S.A. (Cellectis). On March 8, 2019, the Company entered into a License Agreement (the Cellectis Agreement) with Cellectis. In connection with the execution of the Cellectis Agreement, on March 8, 2019, the Company and Cellectis also entered into a letter agreement (the Letter Agreement), pursuant to which the Company and Cellectis agreed to terminate the Original Cellectis Agreement. The Original Cellectis Agreement included a research collaboration to conduct discovery and pre-clinical development activities to generate CAR T cells directed at targets selected by each party, which was completed in June 2018.

Pursuant to the Cellectis Agreement, Cellectis granted to the Company an exclusive, worldwide, royalty-bearing license, on a target-by-target basis, with sublicensing rights under certain conditions, under certain of Cellectis’s intellectual property, including its TALEN and electroporation technology, to make, use, sell, import, and otherwise exploit and commercialize CAR T products directed at certain targets, including BCMA, CD70, Claudin 18.2, DLL3 and FLT3 (the Allogene Targets), for human oncologic therapeutic, diagnostic, prophylactic and prognostic purposes. In addition, certain Cellectis intellectual property rights granted by Cellectis to the Company and to Servier pursuant to the Exclusive License and Collaboration Agreement by and between Servier and Pfizer, dated October 30, 2016, which Pfizer assigned to the Company in April 2018, will survive the termination of the Original Cellectis Agreement.

Pursuant to the Cellectis Agreement, the Company granted Cellectis a non-exclusive, worldwide, royalty-free, perpetual and irrevocable license, with sublicensing rights under certain conditions, under certain of the Company's intellectual property, to make, use, sell, import and otherwise commercialize CAR T products directed at certain targets (the Cellectis Targets).

The Cellectis Agreement provides for development and sales milestone payments by the Company of up to $185.0 million per product that is directed against an Allogene Target, with aggregate potential development and sales milestone payments totaling up to $2.8 billion. Cellectis is also eligible to receive tiered royalties on annual worldwide net sales of any products that are commercialized by the Company that contain or incorporate, are made using or are claimed or covered by, Cellectis intellectual property licensed to the Company under the Cellectis Agreement (the Allogene Products), at rates in the high single-digit percentages. Such royalties may be reduced, on a licensed product-by-licensed product and country-by-country basis, for generic entry and for payments due under licenses of third-party patents. Pursuant to the Cellectis Agreement, and subject to certain exceptions, the Company is required to indemnify Cellectis against all third-party claims related to the development, manufacturing, commercialization or use of any Allogene Product or arising out of the Company’s material breach of the representations, warranties or covenants set forth in the Cellectis Agreement, and Cellectis is required, subject to certain exceptions, to indemnify the Company against all third party claims related to the development, manufacturing, commercialization or use of CAR T products directed at Cellectis Targets or arising out of Cellectis’ material breach of the representations, warranties or covenants set forth in the Cellectis Agreement.

The royalties are payable, on a licensed product-by-licensed product and country-by-country basis, until the later of (i) the expiration of the last to expire of the licensed patents covering such product; (ii) the loss of regulatory exclusivity afforded such product in such country, and (iii) the tenth anniversary of the date of the first commercial sale of such product in such country; however, in no event shall such royalties be payable, with respect to a particular licensed product, past the twentieth anniversary of the first commercial sale for such product.

Depending on the Cellectis Target, the Company has a right of first refusal or right of first negotiation to purchase or license from Cellectis rights to develop and commercialize products against such Cellectis Targets.

Under the Cellectis Agreement, the Company has certain diligence obligations to progress the development of CAR T product candidates and to commercialize one CAR T product per Allogene Target in one major market country where the Company has received regulatory approval. If the Company materially breaches any of its diligence obligations and fails to cure within 90 days, then with respect to certain targets, such target will cease to be an Allogene Target and instead will become a Cellectis Target.

Unless earlier terminated in accordance with its terms, the Cellectis Agreement will expire on a product-by-product and country-by-country basis, upon expiration of all royalty payment obligations with respect to such licensed product in such country. The Company has the right to terminate the Cellectis Agreement at will upon 60 days' prior written notice, either in its entirety or on a target-by-target basis. Either party may terminate the Cellectis Agreement, in its entirety or on a target-by-target basis, upon 90 days' prior written notice in the event of the other party's uncured material breach. The Cellectis Agreement may also be terminated by the Company upon written notice at any time in the event that Cellectis becomes bankrupt or insolvent or upon written notice within 60 days of a consummation of a change of control of Cellectis.

All costs the Company incurred in connection with this agreement were recognized as research and development expenses in the consolidated statement of operations. For the years ended December 31, 2024 and 2023, no clinical development milestones were achieved.

Exclusive License Agreement with Servier

As part of the Pfizer Agreement, Pfizer assigned to the Company an Exclusive License Agreement (the Original Servier Agreement), with Les Laboratoires Servier SAS and Institut de Recherches Internationales Servier SAS (collectively, Servier) to develop, manufacture and commercialize certain allogeneic anti-CD19 CAR T cell product candidates, including UCART19, in the United States with the option to obtain the rights over additional anti-CD19 product candidates and for allogeneic CAR T cell product candidates directed against one additional target. In October 2019, the Company agreed to waive its rights to the one additional target.

Under the Original Servier Agreement, the Company has an exclusive license to develop, manufacture and commercialize licensed products directed against CD19, including UCART19, ALLO-501 and cemacabtagene ansegedleucel (cema-cel, previously ALLO-501A) (collectively, CD19 Products) in the field of anti-tumor adoptive immunotherapy in the United States, with an exclusive option to obtain the same rights for additional product candidates in the United States and, if Servier does not elect to pursue development or commercialization of those product candidates in certain markets outside of the United States pursuant to its license, outside of the United States as well. The Company is not required to make any additional payments to Servier to exercise an option. If the Company opts-in to another product candidate, Servier has the right to obtain rights to such product candidate outside the United States and to share development costs for such product candidate.

On May 10, 2024, the Company and Servier entered into an Amendment and Settlement Agreement (the Servier Amendment) which restructured the parties' relationship under the Original Servier Agreement (as amended, the Servier Agreement). The Company's licensed territory was expanded to include the European Union and the United Kingdom. The Company was also granted an option to further extend its licensed territory to include China and Japan upon the objective showing of sufficient resources to develop licensed products in those countries, which could be met through the Company entering into a strategic partnership covering those countries. Additionally, the Company agreed to waive certain of its rights under the Original Servier Agreement to elect a conversion of its license to the CD19 Products to a worldwide license. Under the Servier Agreement, the Company is required to use commercially reasonable efforts to develop, manufacture and commercialize a CD19 Product.

Under the Servier Agreement, Servier sublicenses to the Company certain rights which Servier licenses from Cellectis pursuant to a License, Development and Commercialization Agreement by and between Cellectis and Servier, dated February 7, 2014, as amended by Amendment No. 1 to the License, Development and Commercialization Agreement, dated March 4, 2020

(as amended, the Servier-Cellectis Agreement). As amended by the Servier Amendment, all of the Company's future milestone payments (regulatory and sales) under the Original Servier Agreement were modified to be the same as, and to coincide with, Servier's milestone payments to Cellectis that are required under the Servier-Cellectis Agreement. The Servier Agreement provides for aggregate potential milestone payments by the Company to Servier of up to €75.0 million upon successful completion of various regulatory milestones and first commercial sale milestones in the United States, European Union and the United Kingdom for the initial indication of each licensed product, of which €60.0 million remains for the initial indication for cema-cel, with additional payments of €55.0 million, due for each subsequent indication, of which €50.0 million remains for the first subsequent indication for cema-cel, and aggregate potential payments by the Company to Servier of up to €80.0 million upon achievement of certain net sales milestones for each licensed product. Should Servier's rights and obligations under the Servier-Cellectis Agreement be assigned to the Company, these milestone payments would terminate, and the Company would assume Servier's milestone payment obligations to Cellectis. In the absence of any such assignment, Servier will remain responsible for making milestone payments that may be due to Cellectis under the Servier-Cellectis Agreement.

The Company transferred €20.0 million into an escrow account in connection with a potential future milestone payment, which is included in the remaining €60.0 million in milestone payments referenced above for the initial indication for cema-cel. Such milestone payment will be triggered, if at all, upon the occurrence of one of these events: (1) the Company doses the first subject in its first phase 3 clinical study for a CD19 CAR T product that is a licensed product under the Servier Agreement, (2) the Company submits a phase 2 clinical study for a licensed product to the U.S. Food and Drug Administration or the European Medicines Agency, and such phase 2 clinical study is accepted for regulatory approval as a pivotal study, or (3) a final and definitive decision of a tribunal or court finding that under the Servier-Cellectis Agreement the milestone has occurred and the €20.0 million payment is due to Cellectis. As of December 31, 2024, the Company recorded €20.0 million as deposit placed in escrow in the consolidated balance sheets.

The Company is obligated to pay to Servier royalties on annual net sales of any licensed products that are commercialized by the Company that are directed at CD19. Such royalties include tiered royalties on annual net sales in the United States and a flat royalty on annual net sales in territories outside the United States. The United States royalty rates are in a range from the low tens to the mid teen percentages, and the ex-U.S. royalty rate is 10%. Such royalties may be reduced for interchangeable drug entry, expiration of patent rights and amounts paid pursuant to licenses of third-party patents. This royalty obligation begins upon the first commercial sale of such product in a given country and ends after the later of a defined number of years or the expiration of the last to expire licensed patent covering the product in such country. The net effect of the Servier Amendment is that the Company's royalty rate in the United States for the first half of the first tier of net sales was increased by a low single digit percentage as compared to the Original Servier Agreement. Should Servier's rights and obligations under the Servier-Cellectis Agreement be assigned to the Company, each tier of royalty rates in the United States to Servier would be reduced by 10%, the ex-U.S. royalties to Servier would terminate, and the Company would assume Servier's royalty obligations to Cellectis. In the absence of any such assignment, Servier will remain responsible for making royalty payments that may be due to Cellectis under the Servier-Cellectis Agreement.

The parties agreed that co-development performed by the Company and Servier under the Servier Agreement, including all development performed by Servier and for product candidates that the Company was co-developing with Servier (for which specified development costs were split under the Original Servier Agreement with the Company responsible for 60% and Servier responsible for 40%), including the CD19 Products, ceased as of December 15, 2022, and that all development costs incurred by either party after that date shall be borne solely by such party.

The parties agreed to waive any and all outstanding claims that were asserted relating to alleged violations of the Original Servier Agreement, including all claims that such party was entitled to various payments or refunds from the other party under the Original Servier Agreement, and any and all claims that either party now has or may have in the future related to such outstanding claims, and mutual releases with respect to such claims were granted.

The Company will recognize expense related to the revised milestones and royalties when payments become probable. There was no gain or loss related to the expanded license territories and ceased Servier co-development. For the year ended December 31, 2024 and 2023, the Company recorded $5.4 million and zero in research and development expenses upon achievement of a regulatory milestone, respectively.

Research Collaboration and License Agreement with Notch Therapeutics

On November 1, 2019, the Company entered into a Collaboration and License Agreement (the Notch Agreement) with Notch Therapeutics Inc. (Notch), pursuant to which Notch granted to Allogene an exclusive, worldwide, royalty-bearing, sublicensable license under certain of Notch's intellectual property to develop, make, use, sell, import, and otherwise commercialize therapeutic gene-edited T cell and/or natural killer (NK) cell products from induced pluripotent stem cells

directed at certain CAR targets for initial application in non-Hodgkin lymphoma, acute lymphoblastic leukemia and multiple myeloma. In addition, Notch has granted Allogene an option to add certain specified targets to its exclusive license in exchange for an agreed per-target option fee.

The Notch Agreement includes a research collaboration to conduct research and pre-clinical development activities to generate engineered cells directed to Allogene's exclusive targets, which will be conducted in accordance with an agreed research plan and budget under the oversight of a joint development committee. Allogene will reimburse Notch's costs incurred in accordance with such plan and budget. Currently, there is no outstanding research plan or budget under the Notch Agreement. The term of the research collaboration will expire upon the earlier of (i) the fifth anniversary of the date of the Notch Agreement, (ii) at Allogene's election, following the joint development committee's determination that for each exclusive target, Notch has met certain success criteria, or (iii) the joint development committee's determination that the research collaboration cannot be reasonably pursued against any exclusive target due to technical infeasibility or safety issues.

In connection with the execution of the Notch Agreement, Allogene made an upfront payment to Notch of $10.0 million in return for a license to access Notch's technology in order to conduct research pursuant to the Notch Agreement. In addition, Allogene made a $5.0 million investment in Notch's series seed convertible preferred stock, resulting in Allogene having a 25% ownership interest in Notch's outstanding capital stock on a fully diluted basis immediately following the investment. In connection with this investment, an Allogene representative served on the Notch Board of Directors. In February 2021, the Company made an additional $15.9 million investment in Notch's Series A preferred stock. In October 2021, the Company made an additional $1.8 million investment in Notch's common stock. Immediately following this transaction, the Company's share in Notch was 23% on a voting interest basis. On May 17, 2024, Notch closed a Series B preferred stock financing with a combination of new and existing investors (Notch Series B Financing). The Company did not participate in the Notch Series B Financing but received Series B preferred stock as part of its anti-dilution rights. Immediately following this transaction, the Company's share in Notch was 13%. In connection with the Notch Series B Financing, the Company waived its right to appoint one member of the Notch board of directors, but retained board observation rights. The Company no longer has any significant influence over Notch and as a result of the decrease in ownership and influence, accounted for its investment in Notch as an equity investment measured at cost less any impairment effective May 17, 2024.

Under the Notch Agreement, Notch will be eligible to receive up to $7.3 million upon achieving certain agreed research milestones, up to $4.0 million per exclusive target upon achieving certain pre-clinical development milestones, and up to $283.0 million per exclusive target and cell type (i.e., T cell or NK cell) upon achieving certain clinical, regulatory and commercial milestones. Notch is also entitled to receive tiered royalties in the mid to high single digit range on Allogene's sales of licensed products, subject to certain reductions, for a term, on a country-by-country and product-by-product basis, commencing on first commercial sale of such product in such country and continuing until the latest of (i) the date upon which there is no valid claim of the licensed patents in such country of sale that covers such product, (ii) the expiration of applicable data or other regulatory exclusivity in such country of sale or (iii) a defined period from the first commercial sale of such product in such country.

The terms of the Notch Agreement will continue on a product-by-product and country-by-country basis until Allogene's payment obligations with respect to such product in such country have expired. Following such expiration, Allogene's license with respect to such product and country shall be perpetual, irrevocable, fully paid up and royalty-free. Allogene may terminate the Collaboration Agreement in whole or on a product-by-product basis upon ninety days' prior written notice to Notch. Either party may also terminate the Collaboration Agreement with written notice upon material breach by the other party, if such breach has not been cured within a defined period of receiving such notice, or in the event of the other party's insolvency.

On January 25, 2024, the Company entered into an Amended and Restated Collaboration and License Agreement (the Amended Notch Agreement) with Notch. The Amended Notch Agreement amends and restates the Notch Agreement. Under the Amended Notch Agreement, the Company has relinquished its exclusive rights to all original CAR targets (the Released Targets) except for one CAR target, and has agreed to limit its option right to only one additional CAR target. If the option is exercised, the Company will have a minimum funding commitment for the overall development program. If Notch subsequently out-licenses any of the Released Targets (whether through an out-license, partnership, sale, or other transaction), the Company will be entitled to receive a percentage of upfront and/or milestone payments associated therewith up to a set cap of $30.0 million, and will be entitled to a low, single-digit royalty on net sales of products containing a Released Target. In addition, with respect to the Company's previous equity investment in Notch, the Amended Notch Agreement grants the Company certain anti-dilution protections up to certain limits for certain pre-IPO equity financings. As of December 31, 2024, no Released Targets were out-licensed by Notch. On May 17, 2024, in connection with the Notch Series B Financing the Company waived certain of its anti-dilution rights in exchange for a low single digit percentage reduction in the royalty rate for

the royalties the Company is obliged to pay to Notch under our Notch intellectual property license should the Company commercialize a licensed product.

In January 2025, Notch announced that securing additional investment and/or additional partners to take their research forward remains challenging, and therefore they significantly reduced their workforce to preserve cash and provide the time to explore alternate paths forward.

For the years ended December 31, 2024 and 2023, the Company recorded zero and $1.8 million, respectively, in collaboration costs as research and development expenses. No milestones were achieved for the years ended December 31, 2024 and 2023. For the year ended December 31, 2024, the Company recorded $2.0 million in other expenses, net as impairment loss on its equity investment in Notch. For the year ended December 31, 2023, the Company recorded $3.0 million in other expenses, net as impairment loss on its equity method investment in Notch.

Strategic Alliance with The University of Texas MD Anderson Cancer Center

On October 6, 2020, the Company entered into a strategic five-year collaboration agreement with The University of Texas MD Anderson Cancer Center (MD Anderson) for the preclinical and clinical investigation of allogeneic CAR T cell product candidates. The Company and MD Anderson are collaborating on the design and conduct of preclinical and clinical studies with oversight from a joint steering committee.

Under the terms of the agreement, the Company has committed up to $15.0 million of funding for the duration of the agreement. Payment of this funding is contingent on mutual agreement to study orders in order for any study to be included under the alliance. The Company made an upfront payment of $3.0 million to MD Anderson in the year ended December 31, 2020 and made an additional upfront payment of $3.0 million to MD Anderson in the year ended December 31, 2023. The Company is committed to make further payments to MD Anderson each year upon the anniversary of the agreement effective date through the duration of the agreement term, however, if MD Anderson has sufficient funds to continue the agreed-upon research projects, the Company may defer the additional payment to a later date. These costs are expensed to research and development as MD Anderson renders the services under the strategic alliance.

The agreement may be terminated by either party for material breach by the other party. Individual studies may be terminated for, among other things, material breach, health and safety concerns or where the institutional review board, the review board at the clinical site with oversight of the clinical study, requests termination of any study. Where any legal or regulatory authorization is finally withdrawn or terminated, the relevant study will also terminate automatically.

For the years ended December 31, 2024 and 2023, the Company recorded $1.6 million and $0.9 million, respectively, in collaboration costs under this agreement as research and development expenses.

Investment in and License Agreement with Overland Therapeutics, Inc.

Allogene Overland, later renamed Overland Therapeutics Inc. (Overland Therapeutics), was initially established as a joint venture by the Company and Overland Pharmaceuticals (CY) Inc. (Overland) pursuant to a Share Purchase Agreement (Share Purchase Agreement), dated December 14, 2020. Concurrently, on December 14, 2020, the Company entered into a License Agreement (License Agreement) with Allogene Overland for the purpose of developing, manufacturing and commercializing certain allogeneic CAR T cell therapies for patients in greater China, Taiwan, South Korea and Singapore (the JV Territory).

Pursuant to the Share Purchase Agreement, the Company acquired Seed Preferred Shares in Allogene Overland representing 49% of Allogene Overland's outstanding stock as partial consideration for the License Agreement, and Overland acquired Seed Preferred Shares representing 51% of Allogene Overland's outstanding stock for $117.0 million in upfront and certain quarterly cash payments, to support operations of Allogene Overland. The Company received $40.0 million from Allogene Overland as partial consideration for the License Agreement. Until the Organizational Restructuring (as defined below), the Company and Overland were the sole equity holders in Allogene Overland.

Pursuant to the License Agreement, the Company granted Allogene Overland an exclusive license to develop, manufacture and commercialize certain allogeneic CAR T cell candidates directed at four targets, BCMA, CD70, FLT3, and DLL3 (Overland Licensed Products), in the JV Territory. As consideration, the Company would also be entitled to additional regulatory milestone payments of up to $40.0 million and, subject to certain conditions, tiered low-to-mid single-digit sales royalties. Subsequent to entering into the License Agreement, Allogene Overland assigned the License Agreement to a wholly-

owned subsidiary, Allogene Overland BioPharm (HK) Limited (Allogene Overland HK). On April 1, 2022, Allogene Overland HK assigned the License Agreement to Allogene Overland Biopharm (PRC) Co., Limited (Allogene Overland PRC).

On May 24, 2024, the Company, Overland, and Allogene Overland entered into a Share Exchange Agreement (Share Exchange Agreement) pursuant to which Overland's cell therapy business merged into Allogene Overland (the Organizational Restructuring).

Under the Share Exchange Agreement, Allogene Overland acquired from Overland a 100% equity interest in Overland Pharmaceuticals (US) Inc. (Overland US). Overland US includes certain research and development, clinical, and general and administrative staff, as well as select cell therapy assets, including its lead program, OL-101, an autologous GPRC5D-BCMA bispecific dual targeting CAR T for refractory multiple myeloma. Upon completion of the closing of the share exchange, Overland US became a wholly owned subsidiary of Allogene Overland, Overland's ownership increased to 82% and the Company's ownership decreased to 18%. Under a separate agreement between Overland and HH BioPharma Holdings Ltd. (HBP) executed on May 24, 2024, Overland distributed all Series Seed Preferred Shares of Allogene Overland held by Overland to HBP and HBP has assumed all rights and obligations attached to such shares and all rights and obligations of Overland under the Share Exchange Agreement.

In connection with the Organizational Restructuring, on May 24, 2024, the Company and Allogene Overland PRC, entered into a First Amendment to the License Agreement (the License Amendment) to amend and supplement certain provisions of the License Agreement. Under the License Amendment, the Company continues to grant Allogene Overland PRC an exclusive license to develop, manufacture, and commercialize the Licensed Products in the JV Territory, with the Company retaining exclusive rights to the Licensed Products outside the JV Territory, and the royalty obligations to the Company were amended to a flat mid single-digit royalty on net sales in the JV Territory that are no longer subject to reductions. The License Amendment also provides the Company with additional rights to terminate the License Agreement in its entirety or with respect to the relevant Overland Licensed Products if Allogene Overland PRC fails to initiate manufacturing technology transfer with respect to an Overland Licensed Product as agreed in the License Amendment, or if HBP commits a funding default or a material breach of its representations, warranties, or covenants under the Share Exchange Agreement. The License Amendment also provides that the License Agreement will terminate automatically if the Company's ownership in Allogene Overland falls below 7.5% (other than due to the Company's sale of the shares of Allogene Overland), unless at that time Allogene Overland PRC and the Company have mutually agreed on the manufacturing technology transfer plan for the Overland Licensed Products and Allogene Overland PRC elects to continue the license for such Overland Licensed Products with increased milestones and royalties. Under the License Amendment terms such increased milestones and royalties consist of up to $115.0 million in milestone payments for each Overland Licensed Product and tiered mid single-digit to low double-digit royalties on net sales in the JV Territory.

As part of the Organizational Restructuring, Allogene Overland was renamed Overland Therapeutics Inc. (Overland Therapeutics).

Based on the License Agreement, promises that the Company concluded were distinct performance obligations included: (1) the license of intellectual property and delivery of know-how, (2) the manufacturing license, related know-how and support, (3) know-how developed in future periods, and (4) participation in the joint steering committee.

In order to determine the transaction price, the Company evaluated all the consideration to be received over the duration of the contract. Fixed consideration exists in the form of the upfront payment and Seed Preferred Shares in Overland Therapeutics. Regulatory milestones and royalties were considered variable consideration. The Company constrains the estimated variable consideration when it assesses it is probable that a significant reversal in the amount of cumulative revenue recognized may occur in future periods. Milestone fees were constrained and not included in the transaction price due to the uncertainties of research and development. The Company re-evaluates the transaction price, including the estimated variable consideration included in the transaction price and all constrained amounts, in each reporting period and as uncertain events are resolved or other changes in circumstances occur.

The Company estimated the fair value of the shares of Seed Preferred Stock at $79.0 million, using probability adjusted future cash infusions based on the upfront and certain quarterly cash payments of $117.0 million committed by Overland. The probability for the future quarterly cash payments of 65% was developed based on consideration of the Company's expectations for future cash infusions from Overland and was applied on a cumulative basis for each quarterly payment. The present value of the future quarterly cash payments was estimated using 11.9% annual discount rate. The fair value measurement is based on significant inputs not observable in the market and, therefore, represents a Level 3 measurement.

The Company determined that the initial transaction price consists of the upfront payment of $40.0 million and noncash consideration of $79.0 million received in the form of the shares of Seed Preferred Stock. The allocation of the transaction price is performed based on standalone selling prices, which are based on estimated amounts that the Company would charge for a performance obligation if it were sold separately. The initial transaction price of $119.0 million was allocated as follows: (i) $114.0 million to the license of intellectual property and know-how, which was recognized upon grant of license and delivery of know-how in the consolidated financial statements for the year ended December 31, 2021 when the know-how was delivered; (ii) $2.3 million to the manufacturing license, related know-how and support, which will be recognized as services are delivered; (iii) $2.1 million to the know-how developed in future periods, which will be recognized as services are delivered, and (iv) $0.6 million to participation in the joint steering committee, which will be recognized over time as the services are delivered. Funds received in advance are recorded as deferred revenue and will be recognized as the performance obligations are satisfied.

Based on the License Amendment, the Company determined that the remaining transaction price was $4.6 million and it was allocated as follows: (i) $1.9 million to the manufacturing license, related know-how and support, which will be recognized as services are delivered and (ii) $2.7 million to the know-how developed in future periods, which will be recognized as services are delivered. As of December 31, 2024, $4.6 million of deferred revenue was recorded in other long-term liabilities.

The Company determined that Overland Therapeutics is a variable interest entity as of December 31, 2024 and 2023. The Company does not have the power to direct the activities which most significantly affect Overland Therapeutics' economic performance. Accordingly, the Company did not consolidate Overland Therapeutics because the Company determined that it was not the primary beneficiary. After the Organizational Restructuring, the Company has 20% voting rights of Overland Therapeutics' board of directors. The Company concluded that it has significant influence over Overland Therapeutics and continued to account for its investment in Overland Therapeutics as an equity method investment. In connection with the Organizational Restructuring, the Company recorded an increase in its equity method investment in Overland Therapeutics and corresponding gain of $1.1 million. The Company's total equity investment in Overland Therapeutics was zero as of December 31, 2024 and 2023 (see Note 8). For the years ended December 31, 2024 and 2023, the Company recognized less than $0.1 million of collaboration revenue.

Collaboration and License Agreement with Antion

On January 5, 2022, the Company entered into an exclusive collaboration and global license agreement (Antion Collaboration and License Agreement) with Antion Biosciences SA (Antion) for Antion's miRNA technology (miCAR), to advance multiplex gene silencing as an additional tool to develop next generation allogeneic CAR T products. Pursuant to the agreement, Antion will exclusively collaborate with the Company on oncology products for a defined period. The Company will also have exclusive worldwide rights to commercialize products incorporating Antion technology developed during the collaboration.

The Antion Collaboration and License Agreement includes an exclusive research collaboration to conduct research and development of the use of Antion's proprietary technologies to produce certain products for a defined period, which will be conducted in accordance with an agreed research plan and budget under the oversight of a joint steering committee. The Company will reimburse Antion's costs incurred in accordance with such plan and budget.

In connection with the execution of the Antion Collaboration and License Agreement, the Company made an upfront payment to Antion of $3.5 million in return for a license to access Antion's technology in order to conduct research pursuant to the agreement. The upfront payment was fully recognized as research and development expense as the license had no foreseeable alternative future use. In addition, the Company made a $3.0 million investment in Antion's preferred stock. The Company accounts for its investment in Antion's preferred stock as an equity investment measured at cost less any impairment. In connection with this investment, a Company representative was appointed to Antion's Board of Directors.

In July 2023, the Company and Antion entered into an amendment to the Antion Collaboration and License Agreement. Under the terms of this amendment, Antion's exclusivity obligation relating to the collaboration was terminated; however, Antion agreed to certain restrictions on its ability to pursue products directed against specific targets. Also, in lieu of the Company's prior obligation to make a $3.0 million investment in Antion following the completion of certain milestones, the Company agreed to make a $2.0 million investment in Antion's preferred stock and acquired warrants to purchase an additional $3.0 million of Antion's preferred stock.

Under the Antion Collaboration and License Agreement, Antion will be eligible to receive up to $35.3 million for four products upon achievement of certain development and regulatory milestones. For each additional product, Antion will be

eligible to receive $2.0 million upon achievement of a regulatory milestone. Antion is also entitled to receive a low single-digit royalty on the Company's sales of licensed products, subject to certain reductions.

For the years ended December 31, 2024 and 2023, the Company recorded zero and $1.8 million, respectively, in research and development expenses related to the upfront payment and collaboration costs. For the years ended December 31, 2024 and 2023, the Company recorded zero and $0.4 million, respectively, in research and development expenses related to the achievement of a milestone under the Antion Collaboration and License Agreement. For the years ended December 31, 2024 and 2023, the Company recorded zero and $4.0 million, respectively, in other expenses, net as impairment loss on its equity investment in Antion.

Strategic Collaboration Agreement with Foresight Diagnostics

On January 3, 2024, the Company entered into a Strategic Collaboration Agreement with Foresight Diagnostics, Inc. (Foresight Diagnostics) (the Foresight Agreement). Pursuant to the Foresight Agreement, the parties have agreed to collaborate on a non-exclusive basis in the development of Foresight Diagnostics' minimal residual disease (MRD) assay based on their PhasED-Seq Circulating Tumor DNA Platform as an in vitro diagnostic to identify the MRD+ patient population to be enrolled in the Company's ALPHA3 trial of cema-cel, for treatment of large B cell lymphoma. Under the Foresight Agreement, the Company has agreed to use its commercially reasonable efforts to obtain regulatory approval of cema-cel, and Foresight Diagnostics has agreed to use its commercially reasonable efforts to obtain regulatory approval of its MRD assay for use as an in vitro diagnostic with cema-cel. Under the Foresight Agreement, the Company has agreed to fund approximately $26.2 million in MRD assay development costs, milestone payments for regulatory submissions and assay utilization to process clinical samples.

On February 19, 2025, the Company entered into an Amended and Restated Strategic Collaboration Agreement with Foresight Diagnostics which expands our collaboration to include the development of Foresight Diagnostics' MRD assay as a companion diagnostic for use with cema-cel as part of a possible EU and/or UK clinical development program, and as part of an expansion of ALPHA3 to Canadian and Australian clinical trial sites in support of our US clinical development program. In total, we have agreed to fund approximately $37.3 million in MRD assay development costs, milestone payments for U.S., and certain international regulatory submissions and assay utilization costs to process clinical samples, all in addition to the financial commitments under the Foresight Agreement.

For the year ended December 31, 2024, the Company recorded $3.5 million of research and development expenses related to clinical trials start readiness milestones.

Note 7.
Commitments and Contingencies

Leases

In August 2018, the Company entered into an operating lease agreement (HQ Lease) for office and laboratory space which consists of approximately 68,000 square feet located in South San Francisco, California. The lease term was 127 months beginning August 2018 through February 2029 with an option to extend the term for seven years which was not reasonably assured of exercise. The Company has made certain tenant improvements, including the addition of laboratory space, and has received $5.0 million of tenant improvement allowances through December 31, 2020. The rent payments began on March 1, 2019 after an abatement period. In December 2021, the Company amended its lease agreement to lease an additional 47,566 square feet of office and laboratory space in South San Francisco, California, as part of the same building as the Company's current headquarters. The lease term commenced in April 2022 and is for a period of 120 months. The rent payments for the expansion premises began in August 2022 after an abatement period. The lease term for the existing premises was also extended and the lease for both the existing and expansion premises will expire on March 31, 2032 with an option to extend the term for eight years which is not reasonably assured of exercise.

In October 2018, the Company entered into an operating lease agreement for office and laboratory space which consists of 14,943 square feet located in South San Francisco, California. The lease term was 124 months beginning November 2018 through February 2029, with an option to extend the term for another seven years which was not reasonably assured of exercise. The Company has made certain tenant improvements, including the upgrading of current office and laboratory space with a lease incentive allowance of $0.8 million. Rent payments began in November 2018. In December 2021, the Company amended its lease agreement to extend the term of the lease to be co-terminus with the HQ Lease. The lease term will expire on March 31, 2032 with an option to extend the term for eight years which is not reasonably assured of exercise.

In February 2019, the Company entered into a lease agreement for approximately 118,000 square feet of space to develop a cell therapy manufacturing facility in Newark, California. The lease term is 188 months and began in November 2020. Upon certain conditions, the Company has two ten-year options to extend the lease, both of which are not reasonably assured of exercise. The Company has received $3.0 million of tenant improvement allowances for costs related to the design and construction of certain Company improvements.

In February 2023, the Company entered into a sublease with Bellco Capital Advisors Inc. (Bellco) for 2,218 square feet of office space in Los Angeles, California. The sublease term is 115 months, subject to certain early termination rights. The sublease commenced on January 1, 2024.

The Company maintains letters of credit for the benefit of landlords which is disclosed as restricted cash in the consolidated balance sheets. Restricted cash related to letters of credit due to landlords was $6.0 million as of December 31, 2024 and 2023.

The balance sheet classification of our lease liabilities were as follows (in thousands):

	December 31, 2024	December 31, 2023
Operating lease liabilities		
Current portion included in accrued and other current liabilities	$ 7,509	$ 6,775
Long-term portion of lease liabilities	83,247	88,346
Total operating lease liabilities	$ 90,756	$ 95,121

The components of lease costs for operating leases, which were recognized in operating expenses, were as follows (in thousands):

	Year Ended December 31,	
	2024	2023
Operating lease cost	$ 11,468	$ 12,711
Variable lease cost	3,105	3,102
Total lease costs	$ 14,573	$ 15,813

Cash paid for amounts included in the measurement of lease liabilities for the year ended December 31, 2024 was $12.5 million and was included in net cash used in operating activities in the Company's consolidated statements of cash flows.

The undiscounted future non-cancellable lease payments under the Company's operating leases as of December 31, 2024 is as follows:

Year ending December 31:	(in thousands)
2025	$ 12,921
2026	13,164
2027	13,613
2028	14,078
2029 and thereafter	65,390
Total undiscounted lease payments	119,166
Less: Present value adjustment	(28,410)
Total	$ 90,756

Operating lease liabilities are based on the net present value of the remaining lease payments over the remaining lease term. In determining the present value of lease payments, the Company uses its estimated incremental borrowing rate. The weighted average discount rate used to determine the operating lease liability was 6.26%. As of December 31, 2024, the weighted average remaining lease term for our operating leases is 8.11 years.

The Company did not incur any significant rent expense for short-term leases for the years ended December 31, 2024 and 2023, respectively.

Certain lease agreements require the Company to return designated areas of leased space to its original condition upon termination of the lease agreement. At the inception of such leases, the Company records an asset retirement obligation and a

corresponding capital asset in an amount equal to the estimated fair value of the obligation. To determine the fair value of the obligation, the Company estimates the cost for a third-party to perform the restoration work. In subsequent periods, for each asset retirement obligation, the Company records interest expense to accrete the asset retirement obligation liability to full value and depreciate each capitalized asset retirement obligation asset, both over the term of the associated lease agreement. Asset retirement obligations were $0.7 million and $0.6 million as of December 31, 2024 and 2023, respectively.

Other Commitments

Solar Power Purchase and Energy Services Agreement

In July 2020, the Company entered into a Solar Power Purchase and Energy Services Agreement for the installation and operation of a solar photovoltaic generating system and battery energy storage system at the Company's cell therapy manufacturing facility in Newark, California. The agreement has a term of 20 years and commenced in September 2022. The Company is obligated to pay for electricity generated from the system at an agreed rate for the duration of the agreement term. Termination of the agreement by the Company will result in a termination payment due of approximately $4.3 million. In connection with the agreement, the Company maintains a letter of credit for the benefit of the service provider in the amount of $4.3 million which is recorded as restricted cash in the consolidated balance sheets as of December 31, 2024 and 2023.

License Agreements for Intellectual Property

The Company has entered into certain license agreements for intellectual property which is used as part of its development and manufacturing processes. Each of these respective agreements are generally cancellable by the Company. These agreements require payment of annual license fees and may include conditional milestone payments for achievement of specific research, clinical and commercial events, and royalty payments. The timing and likelihood of any significant conditional milestone payments or royalty payments becoming due was not probable as of December 31, 2024.

Contingencies

In the normal course of business, the Company enters into contracts and agreements that contain a variety of representations and warranties and provide for general indemnifications. The Company’s exposure under these agreements is unknown, because it involves claims that may be made against the Company in the future, but have not yet been made. The Company accrues a liability for such matters when it is probable that future expenditures will be made and such expenditures can be reasonably estimated.

Indemnification

In accordance with the Company’s amended and restated certificate of incorporation and amended and restated bylaws, the Company has indemnification obligations to its officers and directors for certain events or occurrences, subject to certain limits, while they are serving in such capacity. There have been no claims to date, and the Company has a directors and officers liability insurance policy that may enable it to recover a portion of any amounts paid for future claims.

Note 8.
Equity Investments and Equity Method Investments

Notch Therapeutics

In conjunction with the execution of the Notch Agreement (see Note 6), the Company also entered into a Share Purchase Agreement with the Company acquiring shares of Notch’s Series Seed convertible preferred stock for a total investment cost of $5.1 million which includes transaction costs of $0.1 million, resulting in a 25% ownership interest in Notch. In February 2021, the Company made a $15.9 million investment in Notch's Series A preferred stock. Immediately following this transaction, the Company's share in Notch was 20.7% on a voting interest basis. In October 2021, the Company made an additional $1.8 million investment in Notch's common stock. Immediately following this transaction, the Company's share in Notch was 23.0% on a voting interest basis. On May 17, 2024, Notch closed the Notch Series B Financing which caused the Company’s share in Notch to decrease to 13% immediately following this transaction.

Accordingly, effective May 17, 2024, the Company started to account for its investment in Notch as an equity investment measured at cost less impairment. The Company’s total equity investment in Notch as of December 31, 2024 was zero . The Company’s total equity investment in Notch as of December 31, 2023 was $3.6 million and the Company accounted for the investment using the equity method of accounting. For the year to date period through May 17, 2024, the Company

recognized its share of Notch's net loss of $1.7 million under the other expenses, net caption within the consolidated statements of operations. For the year ended December 31, 2023, the Company recognized its share of Notch's net loss of $6.2 million under the other expenses, net caption within the consolidated statements of operations. As of December 31, 2024, the Company's equity investment in Notch was categorized as Level 3 within the fair value hierarchy. During the years ended December 31, 2024 and 2023, the Company recognized $2.0 million and $3.0 million, respectively, of impairment loss under the other expenses, net caption within the consolidated statements of operations.

Overland Therapeutics, Inc.

In conjunction with the execution of the License Agreement with Allogene Overland (see Note 6), the Company also entered into the Share Purchase Agreement and a Shareholders' Agreement with the joint venture company acquiring shares of Allogene Overland's Seed Preferred Shares representing a 49% ownership interest in exchange for entering into a License Agreement. Upon completion of the Organizational Restructuring, Overland's ownership in Allogene Overland increased to 82% and the Company's ownership decreased to 18%. As part of the Organizational Restructuring, Overland distributed all Series Seed Preferred Shares of Allogene Overland held by Overland to HBP and Allogene Overland was renamed to Overland Therapeutics.

The Company's total equity investment in Overland Therapeutics as of December 31, 2024 and 2023 was zero and the Company accounted for the investment using the equity method of accounting. For the year ended December 31, 2024, the Company recognized its gain from the Organizational Restructuring of $1.1 million which was offset by its share of Overland Therapeutics' net loss of $1.1 million under the other expenses, net caption within the consolidated statement of operations. During the year ended December 31, 2023, the Company recognized its share of Overland Therapeutics' net loss of $4.5 million under the other expenses, net caption within the consolidated statement of operations.

Note 9.
Stockholders' Equity

Preferred Stock

Pursuant to the Amended and Restated Certificate of Incorporation filed on October 15, 2018, as amended, the Company is authorized to issue a total of
10,000,000 shares of preferred stock, of which no shares were issued and outstanding at December 31, 2024 and 2023.

Common Stock

Pursuant to the Certificate of Amendment of Amended and Restated Certificate of Incorporation filed on June 17, 2022, the Company is authorized to issue a total of 400,000,000 shares of common stock, of which 212,210,597 and 168,642,238 shares were issued and outstanding at December 31, 2024 and 2023, respectively.

Common stockholders are entitled to dividends if and when declared by the Company's Board of Directors subject to the prior rights of the preferred stockholders. As of December 31, 2024 and 2023, no dividends on common stock had been declared by the Company's Board of Directors.

Note 10.
Stock-Based Compensation

2018 Equity Incentive Plan

In June 2018, the Company adopted its 2018 Equity Incentive Plan (Prior 2018 Plan). The Prior 2018 Plan provided for the Company to sell or issue common stock or restricted common stock, or to grant incentive stock options or nonqualified stock options for the purchase of common stock, to employees, members of the Company's Board of Directors and consultants of the Company under terms and provisions established by the Company's Board of Directors. In September 2018, the Board of Directors adopted a new amended and restated 2018 Equity Incentive Plan as a successor to and continuation of the Prior 2018 Plan, which became effective in October 2018 (the 2018 Plan), which authorized additional shares for issuance and provided for an automatic annual increase to the number of shares issuable under the 2018 Plan by an amount equal to 5% of the total number of shares of common stock outstanding on December 31st of the preceding calendar year. The term of any stock option granted under the 2018 Plan cannot exceed 10 years. The Company generally grants stock-based awards with service conditions only. Options granted typically vest over a four-year period but may be granted with different vesting terms. Restricted Stock Units granted typically vest annually over a four-year period but may be granted with different vesting terms. Options shall not have an exercise price less than 100% of the fair market value of the Company's common stock on the grant date. If the individual possesses more than 10% of the combined voting power of all classes of stock of the Company, the exercise price

shall not be less than 110% of the fair market value of a common share of stock on the date of grant. This requirement is applicable to incentive stock options only.

As of December 31, 2024 and 2023, there were 8,838,676 and 6,468,650 shares reserved by the Company under the 2018 Plan for the future issuance of equity awards.

Stock Option Exchange Program

On June 21, 2022, the Company commenced an offer to exchange certain eligible options held by eligible employees of the Company for new options (the Exchange Offer). The Exchange Offer expired on July 19, 2022. Pursuant to the Exchange Offer, 199 eligible holders elected to exchange, and the Company accepted for cancellation, eligible options to purchase an aggregate of 3,666,600 shares of the Company's common stock, representing approximately 93.5% of the total shares of common stock underlying the eligible options. On July 19, 2022, immediately following the expiration of the Exchange Offer, the Company granted new options to purchase 3,666,600 shares of common stock, pursuant to the terms of the Exchange Offer and the 2018 Plan. The exercise price of the new options granted pursuant to the Exchange Offer was $13.31 per share, which was the closing price of the common stock on the Nasdaq Global Select Market on the grant date of the new options. The new options are subject to a new three-year vesting schedule, vesting in equal annual installments over the vesting term. Each new option has a maximum term of seven years.

The exchange of stock options was treated as a modification for accounting purposes. The incremental expense of $5.2 million for the modified options was calculated using a lattice option pricing model. The incremental expense and the unamortized expense remaining on the exchanged options as of the modification date are being recognized over the new three-year service period.

Stock Option Activity

The following summarizes option activity under the 2018 Plan:

	Outstanding Options			
	Number of Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contract Term	Aggregate Intrinsic Value
			(in years)	(in thousands)
Balance, December 31, 2023	21,812,946	$ 9.93	7.53	$ 662
Options granted	6,211,389	3.08	8.69	
Options exercised	(357,993)	2.27		$ 597
Options forfeited	(3,481,458)	10.93		
Balance, December 31, 2024	24,184,884	$ 8.14	7.53	$ 1
Exercisable, December 31, 2024	17,673,060	$ 9.63	7.11	$ -
Vested and expected to vest, December 31, 2024	24,184,884	$ 8.14	7.53	$ -

The aggregate intrinsic values of options exercised, outstanding, exercisable, vested and expected to vest were calculated as the difference between the exercise price of the options and the closing price of the Company's common stock on the Nasdaq Global Select Market on December 31, 2024. The aggregate intrinsic value of options exercised during the years ended December 31, 2024 and 2023 was $0.6 million and $2.3 million, respectively. During the years ended December 31, 2024 and 2023, the estimated weighted-average grant-date fair value of employee options granted was $2.05 per share and $3.33 per share, respectively. As of December 31, 2024 and 2023, there was $35.5 million and $58.1 million, respectively, of unrecognized stock-based compensation related to unvested stock options, which is expected to be recognized over a weighted-average period of 1.85 years and 2.42 years, respectively.

The fair value of employee, consultant and director stock option awards was estimated at the date of grant using a Black-Scholes option-pricing model with the following assumptions:

	Year Ended December 31,	
	2024	2023
Fair value of common stock	$1.40 - $3.32	$2.72 - $7.23
Expected term in years	5.02 - 6.25	5.27 - 6.08
Expected volatility	72.85% - 74.09%	73.18% - 74.10%
Expected risk-free interest rate	3.42% - 4.32%	3.45% - 4.61%
Expected dividend	0%	0%

The Black-Scholes option-pricing model and the lattice option pricing model require the use of subjective assumptions which determine the fair value of stock-based awards. These assumptions include:

Fair value of common stock- For all grants subsequent to the Company's IPO in October 2018, the fair value of common stock was determined by taking the closing price per share of common stock per Nasdaq.

Expected term- The expected term represents the period that stock-based awards are expected to be outstanding. The expected term for option grants is determined using the simplified method. The simplified method deems the term to be the average of the time-to-vesting and the contractual life of the stock-based awards.

Expected volatility- Prior to November 2024, the Company used an average historical stock price volatility of comparable public companies within the biotechnology and pharmaceutical industry that were deemed to be representative of future stock price trends as the Company does not have sufficient trading history for its common stock. For grants subsequent to October 2024, the Company uses an average historical stock price volatility of its common stock as it accumulated sufficient historical stock price data.

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

Expected dividend-The Company has never paid dividends on its common stock and has no plans to pay dividends on its common stock. Therefore, the Company used an expected dividend yield of
zero.

Expected exercise barrier - The modified options are assumed to be exercised upon vesting and when the ratio of stock market price to exercise price reaches
2.57, or expiration, whichever is earlier.

Restricted Stock Unit Activity

The following summarizes restricted stock unit activity under the 2018 Plan:

	Outstanding Restricted Stock Units			
	Restricted Stock Units	Weighted-Average Grant Date Fair Value per Share	Weighted Average Remaining Vesting Life	Aggregate Intrinsic Value
			(in years)	(in thousands)
Unvested December 31, 2023	12,180,471	$ 6.68	2.00	$ 39,099
Granted	5,625,325	3.94	1.24	
Vested	(2,168,832)	9.48		
Forfeited	(2,293,171)	7.82		
Unvested December 31, 2024	13,343,793	$ 4.87	1.58	$ 28,422
Vested and expected to vest, December 31, 2024	13,343,793	$ 4.87	1.58	$ 28,422

For the year ended December 31, 2024, the Company granted 35,000 performance-based restricted stock units to certain executive officers and other employees pursuant to the 2018 Plan. These awards are subject to the holders' continuous

service to the Company through each applicable vesting event. Through December 31, 2024, the Company believes that the achievement of the requisite performance conditions for these awards are not probable. As a result, no compensation expense has been recognized related to the performance-based restricted stock units in the year ended December 31, 2024. The Company recognized $2.4 million and $2.2 million in stock-based compensation expense related to the restricted units with a market condition for the years ended December 31, 2024 and 2023, respectively.

For the years ended December 31, 2024 and 2023, total fair value of vested restricted stock units, performance based restricted stock units and restricted stock units with a market condition as of their grant dates was $20.6 million, and $33.3 million, respectively. As of December 31, 2024 and 2023, there was $33.7 million and $50.7 million, respectively, of unrecognized stock-based compensation which is expected to be recognized over a weighted average period of 2.10 years and 2.36 years, respectively.

Employee Stock Purchase Plan

In October 2018, the stockholders approved the 2018 Employee Stock Purchase Plan (ESPP), which initially reserved 1,160,000 shares of the Company's common stock for employee purchases under terms and provisions established by the Board of Directors. Effective January 1, 2024 and 2023, the number of shares authorized under the ESPP for employee purchases increased by 1,686,422 and 1,444,383 shares, respectively. The ESPP is intended to qualify as an "employee stock purchase plan" under Section 423 of the Internal Revenue Code. Under the current offering adopted pursuant to the ESPP, each offering period is approximately 24 months, which is generally divided into four purchase periods of approximately six months.

Employees are eligible to participate if they are employed by the Company. Under the ESPP, employees may purchase common stock through payroll deductions at a price equal to 85% of the lower of the fair market value of common stock on the first trading day of each offering period or on the purchase date. The ESPP provides for consecutive, overlapping 24-month offering periods. The offering periods are scheduled to start on the first trading day on or after March 16 or September 16 of each year, except for the first offering period which commenced on October 11, 2018, the first trading day after the effective date of the Company's registration statement. Contributions under the ESPP are limited to a maximum of 15% of an employee's eligible compensation.

The fair values of the rights granted under the ESPP were calculated using the following assumptions:

	Year ended December 31,	
	2024	**2023**
Expected term (in years)	0.50 - 2.00	0.50 - 2.00
Volatility	76.16% - 88.69%	67.32% - 85.05%
Risk-free interest rate	3.49% - 5.25%	4.05% - 5.35%
Dividend yield	0%	0%

Stock-based compensation expense

The following table presents stock-based compensation expense by award type that was recorded as research development and general and administrative expense in its consolidated statements of operations and comprehensive loss:

	Year Ended December 31,	
	2024	**2023**
Stock options	$ 27,817	$ 34,350
Restricted stock units, performance based restricted stock units and restricted stock units with a market condition	21,997	28,497
Employee stock purchase plan	1,929	3,104
Total stock-based compensation expense	$ 51,743	$ 65,951

Note 11.
Related Party Transactions

Collaboration Revenue and Equity Method Investment

In December 2020, the Company entered into the License Agreement with Overland Therapeutics, a corporate joint venture entity and related party (see Note 6). The License Agreement was subsequently assigned to a wholly owned subsidiary of Allogene Overland, Allogene Overland HK. On April 1, 2022, Allogene Overland HK assigned the License Agreement to Allogene Overland Biopharm (PRC) Co., Limited. On May 24, 2024, the License Agreement was amended.

Consulting Agreements

In June 2018, the Company entered into a services agreement with Two River Consulting LLC (Two River) a firm affiliated with the Company's President and Chief Executive Officer, the Company's Executive Chair of the board of directors, and a director of the Company to provide various managerial, clinical development, administrative, accounting and financial services to the Company. In December 2023, the service agreement between the Company and Two River was terminated. The cost incurred for services provided under this agreement was $0.3 million for the year ended December 31, 2023.

In August 2018, the Company entered into a consulting agreement with Bellco Capital LLC (Bellco). Pursuant to the consulting agreement, Bellco provides certain services for the Company, which are performed by Dr. Belldegrun, the Company's executive chair, and include without limitation, providing advice and analysis with respect to the Company's business, business strategy and potential opportunities in the field of allogeneic CAR T cell therapy and any other aspect of the CAR T cell therapy business as the Company may agree. In consideration for these services, the Company paid Bellco $38,583 per month in arrears commencing January 2021 and $40,217 per month in arrears commencing January 2022. The Company may also, at its discretion, pay Bellco an annual performance award in an amount up to 60% of the aggregate compensation payable to Bellco in a calendar year. The Company also reimburses Bellco for out of pocket expenses incurred in performing the services. The costs incurred for services provided, bonus and out-of-pocket expenses incurred under this consulting agreement were $0.7 million and $0.9 million for the years ended December 31, 2024 and 2023, respectively.

As of both December 31, 2024 and 2023, amount due to Bellco of $0.2 million was recorded in accrued and other current liabilities in the accompanying consolidated balance sheets.

Sublease Agreements

In December 2018, the Company entered into a sublease with Bellco Capital LLC for 1,293 square feet of office space in Los Angeles, California for a three year term. On April 1, 2020, Bellco assumed all rights, title, interests and obligations under the sublease from Bellco Capital LLC. In November 2021, the sublease was extended to June 30, 2025. The sublease was amended, effective in July 2022, to move to a nearby location, with office space of 737 square feet. The Company's executive chairman, Arie Belldegrun, M.D., is a trustee of the Belldegrun Family Trust, which controls Bellco. In 2023, the Company exercised its early termination right under the sublease agreement and the sublease was terminated effective December 31, 2023.

In February 2023, the Company entered into a new subleased agreement with Bellco for 2,218 square feet of office space in Los Angeles, California, from Bellco. The sublease term is 115 months, subject to certain early termination rights. The sublease commenced on January 1, 2024. The total right of use asset and associated liability recorded related to this related party lease was $2.2 million and $2.5 million, respectively, as of December 31, 2024. The Company paid approximately $0.2 million towards its share of the security deposit. For the year ended December 31, 2024, the Company recorded $0.3 million of rent expense related to this lease.

Note 12.
401(k) Plan

In April 2018, the Company began to sponsor a 401(k) retirement savings plan for the benefit of its employees. All employees are eligible to participate, provided they meet the requirements of the plan. The Company made contributions to the plan for eligible participants, and recorded contribution expenses of $
1.9 million and $2.5 million for the years ended December 31, 2024 and 2023, respectively.

Note 13.
Income Taxes

The Company has incurred net operating losses for all the periods presented. The Company has not reflected any benefit of such net operating loss carryforwards in the accompanying consolidated financial statements.

The Company has established a full valuation allowance against its deferred tax assets due to the uncertainty surrounding the realization of such assets.

The Company's income tax expense consists of the following:

	Year Ended December 31,	
	2024	2023
	(in thousands)	
Current:		
Federal	-	-
State	-	-
	-	-
Deferred:		
Federal	443	-
State	-	-
	443	-
Provision (benefit) for income taxes	$ 443	$ -

Reconciliation of the benefit for income taxes calculated at the statutory rate to our benefit for income taxes is as follows:

	Year Ended December 31,	
	2024	2023
	(in thousands)	
Tax benefit at federal statutory rate	$ (54,001)	$ (68,725)
State taxes, net of federal benefit	1,954	(21,610)
Stock-based compensation	9,413	11,442
Research tax credits	(2,793)	(3,873)
Change in valuation allowance	45,661	82,526
Other	209	240
Benefit for incomes taxes	$ 443	$ -

Deferred income taxes reflect the net tax effects of (a) temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes, and (b) operating losses and tax credit carryforwards.

Significant components of our deferred tax assets and liabilities are as follows:

	Year Ended December 31,	
	2024	2023
	(in thousands)	
Deferred tax assets:		
Net operating loss carryforwards	$ 243,798	$ 211,124
Tax credit carryforwards	37,108	32,826
Intangibles	10,757	14,524
Accrued expenses	2,710	3,039
Lease liabilities	22,085	26,358
Stock based compensation	21,871	25,350
Investments	26,009	28,735
Capitalized R&D	89,090	73,492
Other	2,396	2,189
Total deferred tax assets	455,824	417,637
Deferred tax liabilities:		
Right of use leased assets	(11,000)	(17,652)
Other	(36)	(301)
Total deferred tax liabilities	(11,036)	(17,953)
Net deferred tax assets	444,788	399,684
Valuation allowance	(444,788)	(399,684)
Net deferred tax assets	$ -	$ -

Realization of deferred tax assets is dependent upon future earnings, if any, the timing and amount of which are uncertain. Due to the lack of earnings history, the net deferred tax assets have been fully offset by a valuation allowance. The valuation allowance increased by approximately $
45.2 million and $80.1 million during the years ended December 31, 2024 and 2023, respectively.

The following table sets forth the Company's federal and state NOL carryforwards and federal research and development tax credits as of December 31, 2024:

	Amount	Expiration
	(in thousands)	
Net operating losses, federal	$ 833,401	Indefinite
Net operating losses, federal	$ 2	2037
Net operating losses, state	$ 986,041	2037-2044
Tax credits, federal	$ 31,038	2038-2044
Tax credits, state	$ 23,999	Indefinite
California Competes Tax credits, state	$ 9,000	2026 -2028

Current federal and California tax laws include substantial restrictions on the utilization of NOLs and tax credit carryforwards in the event of an ownership change of a corporation. Accordingly, the Company's ability to utilize NOLs and tax credit carryforwards may be limited as a result of such ownership changes. Such a limitation could result in the expiration of carryforwards before they are utilized.

Effective June 27, 2024 California's Senate Bill 167 (SB 167) introduced pivotal tax changes, including the suspension of NOLs for businesses earning over $1 million and a cap on business tax credits at $5 million. In addition, on June 29, 2024 Senate Bill 175 (SB 175) introduced an allowance for refunds on a range of tax credits-including, for the first time, the R&D credit. SB 167, which contains several tax measures, includes provisions that retroactively suspend California net operating losses (NOL) and limit the use of business tax credits for tax years beginning on and after January 1, 2024, and before January 1, 2027. SB 175 states that for taxable years beginning on or after January 1, 2024, and before January 1, 2027, taxpayers can

receive a refundable credit equal to 20% of the qualified credits that could have been taken if the $5 million limitation under SB 167 had not been imposed. The Company evaluated the impact of SB 167 and determined that the legislation did not materially impact the Company's income tax provision for the year ended December 31, 2024.

We apply the provisions of ASC Topic 740 to account for uncertain income tax positions. A reconciliation of the beginning and ending amount of unrecognized tax benefits is as follows:

	December 31,	
	2024	2023
	(in thousands)	
Balance at beginning of the year:	$ 18,895	$ 14,570
Additions based on tax positions related to current year	3,120	4,325
Additions to tax position of prior year	-	-
Reductions to tax position of prior years	-	-
Lapse of the applicable statute of limitations	-	-
Balance at end of the year	$ 22,015	$ 18,895

It is the Company's policy to include penalties and interest expense related to income taxes as a component of interest and other income, net, as necessary. As of December 31, 2024 and 2023, there were no accrued interest and penalties related to uncertain tax positions. The reversal of the uncertain tax benefits would not affect the effective tax rate to the extent that the Company continues to maintain a full valuation allowance against its deferred tax assets. Unrecognized tax benefits may change during the next 12 months for items that arise in the ordinary course of business. We are subject to examination by U.S. federal or state tax authorities for all years since inception.

Note 14.
Net Loss and 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 data):

	Year Ended December 31,	
	2024	2023
Numerator:		
Net loss	$ (257,590)	$ (327,265)
Denominator:		
Weighted average common shares outstanding	194,811,756	156,931,778
Net loss per share, basic and diluted	$ (1.32)	$ (2.09)

Since the Company was in a loss position for all periods presented, basic net loss per share is the same as diluted net loss per share as the inclusion of all potential dilutive securities 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:

	Year Ended December 31,	
	2024	2023
Stock options to purchase common stock	24,184,884	21,812,946
Restricted stock units subject to vesting	13,343,793	12,180,471
Expected shares purchased under Employee Stock Purchase Plan	1,913,748	2,168,264
Early exercised stock options subject to future vesting	-	29,180
Total	39,442,425	36,190,861

Note 15.
Segment Reporting

The Company has one reportable segment related to developing and commercializing genetically engineered allogeneic T cell product candidates for the treatment of cancer and autoimmune diseases. The segment derives its current revenues from research and development collaborations.

The CEO, as the CODM, manages and allocates resources for the Company's operations at a consolidated company basis by assessing how to best deploy available resources across functions and research and development projects. The CEO uses consolidated, single-segment financial information for purposes of evaluating performance, planning and forecasting future period financial results, and allocating resources.

The table below is the summary of the segment profit or loss information, including the significant segment expenses (in thousands):

	Years Ended December 31,	
	2024	2023
Collaboration revenue - related party	$ 22	$ 95
Significant operating expenses:		
Cema-cel	36,369	43,225
All other development costs	23,937	24,463
Payroll	70,862	87,854
Facilities & IT-related spend	31,727	33,674
Supporting external spend	27,337	43,248
Other operating expenses	82,989	95,368
Total operating expenses	273,221	327,832
Other income (Expense), net	16,052	472
Loss before income taxes	(257,147)	(327,265)
Benefit (expense) from income taxes	(443)	-
Net loss	(257,590)	(327,265)

Cema-Cel includes external development and clinical trial costs related to ALPHA3, ALPHA2, CLL, and ALLO-501 programs. All other development costs include external development and clinical trial costs related to ALLO-329, ALLO-316, ALLO-647, BCMA, and other programs. Supporting external spend includes professional services, research and development lab supplies and other supporting activities related to the research and development and other business operations. Other operating expenses is primarily related to non-cash expenses such as stock-based compensation, impairment, and depreciation and amortization. The measure of segment assets is reported on the consolidated balance sheets as total assets. Primarily, all revenue generated and all long-lived assets are maintained in the United States.

Note 16.
Subsequent Events

On December 13, 2024, the Company entered into a sublease agreement for approximately 21,793 square feet of office space in one of its leased buildings in South San Francisco. The sublease commenced on January 1, 2025, and the sublease term is 24 months, which will expire on December 31, 2026. The Company will receive approximately $0.7 million in base rent payments over the sublease term.

On January 1, 2025, the Company entered into an additional sublease agreement for approximately 24,218 square feet of office and laboratory space in one of its leased buildings in South San Francisco. The sublease commenced on February 1, 2025, and the sublease term is 24 months, which will expire on January 31, 2027. The Company will receive approximately $1.6 million in base rent payments over the sublease term.

On February 19, 2025, the Company entered into an Amended and Restated Strategic Collaboration Agreement with Foresight Diagnostics which expands our collaboration to include the development of Foresight Diagnostics' MRD assay as a companion diagnostic for use with cema-cel as part of a possible EU and/or UK clinical development program, and as part of an expansion of ALPHA3 to Canadian and Australian clinical trial sites in support of our US clinical development program. As part of this amendment, we have agreed to fund approximately $37.3 million in MRD assay development costs, milestone payments for U.S., and certain international regulatory submissions and assay utilization costs to process clinical samples, all in addition to the financial commitments under the Foresight Agreement.

On February 3, 2025, the Company received an additional award of $3.4 million from CIRM for achieving a specified operational milestone related to the clinical development of ALLO-316.

Subsequent to the year ended December 31, 2024, the Company sold an aggregate of 3,842,282 shares of common stock in ATM offerings resulting in net proceeds of $10.0 million.

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

None.

Item 9A. Controls and Procedures.

Conclusions Regarding the Effectiveness of Disclosure Controls and Procedures

As of December 31, 2024, management, with the participation of our Chief Executive Officer and Chief Financial Officer, performed an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act. Our disclosure controls and procedures are designed to provide reasonable assurance that information required to be disclosed in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including the Chief Executive Officer and the Chief Financial Officer, to allow timely decisions regarding required disclosures.

Any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objective and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of December 31, 2024, the design and operation of our disclosure controls and procedures were effective at a reasonable assurance level.

Management's Annual Report on Internal Control Over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rule 13a-15(f). Our internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external purposes in accordance with generally accepted accounting principles. 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.

Management has assessed the effectiveness of our internal control over financial reporting based on the framework set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control-Integrated Framework (2013 framework). Based on our evaluation, management has concluded that our internal control over financial reporting was effective as of December 31, 2024.

Inherent Limitations of Internal Controls

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 risks that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Prior Material Weakness

A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of a company's annual and interim financial statements will not be detected or prevented on a timely basis.

As described in the Company's Annual Report on Form 10-K for the year ended December 31, 2023 (Annual Report), which was filed with the Securities and Exchange Commission (SEC) on March 14, 2024, Note 1 of the Consolidated Financial Statements under the paragraph Restatement of Financial Statements, the Company re-evaluated its prior accounting for shares received in the License Agreement and Share Purchase Agreement entered into on December 14, 2020, with Allogene Overland. Upon reassessment, the Company has determined that the 49% of Allogene Overland's Seed Preferred Shares received as a partial consideration for the License Agreement should be initially measured at fair value. The Company identified a material weakness in the operation of internal controls over financial reporting with respect to the technical accounting analysis of significant non-routine transactions.

Remediation Measures

We identified and implemented steps designed to remediate the foregoing material weakness. We finalized the design and operation of our controls related to the technical accounting analysis of significant non-routine transactions which includes hiring personnel in our accounting with an appropriate level of knowledge and experience to effectively perform technical accounting analysis of significant non-routine transactions, in addition to, engaging third-party subject matter experts with significant relevant experience. As of December 31, 2024, we validated the effectiveness of controls with respect to the technical accounting analysis of significant non-routine transactions. The applicable controls have been in operation for a sufficient period of time and management has concluded, through testing, that these controls are operating effectively. Accordingly, the material weakness associated with technical accounting analysis of significant non-routine transactions was remediated as of December 31, 2024.

Changes in Internal Control over Financial Reporting

We regularly review our system of internal control over financial reporting and make changes to our processes and systems to improve controls and increase efficiency, while ensuring that we maintain an effective internal control environment. Changes may include such activities as implementing new, more efficient systems, consolidating activities, and migrating processes. There were key changes to our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the year ended December 31, 2024 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. These changes are discussed above in our remediation measures.

Item 9B. Other Information.

None.

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

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this Item and not set forth below will be set forth in the sections headed “Election of Directors” and “Information Regarding the Board of Directors and Corporate Governance” in our definitive proxy statement for our 2025 Annual Meeting of Stockholders to be filed with the SEC on or before April 30, 2025 (our Proxy Statement) and is incorporated in this Annual Report by reference.

Our Board of Directors consists of the following members:

Elizabeth Barrett, 62, has served as member of our Board since July 2021. Ms. Barrett is a director and President and Chief Executive Officer of UroGen Pharma Ltd. (“UroGen”), a biotechnology company dedicated to developing and commercializing innovative solutions that treat urothelial and specialty cancers. At UroGen, Ms. Barrett spearheaded the 2020 approval of Jelmyto® for the treatment of low-grade upper tract urothelial carcinoma. Before joining UroGen, Ms. Barrett served as the Chief Executive Officer of Novartis Oncology, where she managed the development and launch of the autologous CAR T therapy Kymriah®, and as a member of the Executive Committee of Novartis Oncology from February 2018 to December 2018. Prior to that, Ms. Barrett served at Pfizer Inc. ("Pfizer") in various capacities, most recently as the Global President of Oncology, and before that as Pfizer’s Regional President of US Oncology Business Unit since March 2009. Prior to Pfizer, she was Vice President and General Manager of the Oncology.

Arie Belldegrun, M.D., 75, is a co-founder of Allogene and has served as Executive Chair of our Board since November 2017. From March 2014 until October 2017, Dr. Belldegrun served as the President and Chief Executive Officer of Kite Pharma, Inc. ("Kite") and as a director from June 2009 until October 2017. Dr. Belldegrun has served as Chair of UroGen since December 2012, Chair of Kronos Bio, Inc., since June 2017, and director of Ginkgo Bioworks, Inc., since September 2021. Dr. Belldegrun has also served on the boards of several private companies: Breakthrough Properties LLC and Breakthrough Services LLC since April 2019, ByHeart, Inc., since October 2019, and IconOVir Bio, Inc., since June 2020. Dr. Belldegrun has also served as Chairman of Bellco Capital LLC since 2004, as Chair and Partner of Two River Group since June 2009, and as Senior Managing Director of Vida Ventures, LLC since November 2017. He is certified by the American Board of Urology and is a Fellow of the American Association of Genitourinary Surgeons. Dr. Belldegrun is Research Professor, holds the Roy and Carol Doumani Chair in Urologic Oncology, and is Director of the Institute of Urologic Oncology at the David Geffen School of Medicine at the University of California, Los Angeles (“UCLA”). Prior to joining UCLA in October of 1988, he was a research fellow at NCI/NIH in surgical oncology and immunotherapy from July 1985 to August 1988 under Dr. Steven Rosenberg. Dr. Belldegrun received his M.D. from the Hebrew University Hadassah Medical School in Jerusalem before completing his post graduate studies in Immunology at the Weizmann Institute of Science and his residency in Urologic Surgery at Harvard Medical School.

David Chang, M.D., Ph.D., 65, is a co-founder of Allogene and has served as our President and Chief Executive Officer and as a member of our Board since June 2018. Dr. Chang has served on the boards of two private companies: Chair of the Board of Directors of IconOVir Bio, Inc., since June 2020, and director of 1200 Pharma LLC since June 2021. Dr. Chang served on the Board of Directors of Notch Therapeutics, Inc. (“Notch”), a private research-stage biotechnology company, from November 2019 to March 2022. Prior to joining us, Dr. Chang served as the Chief Medical Officer and Executive Vice President, Research and Development of Kite from June 2014 until March 2018. Dr. Chang previously held senior positions at Amgen Inc. ("Amgen"), a biopharmaceutical company, including Vice President, Global Development from July 2006 to May 2014, Senior Director, Oncology-Therapeutics from July 2005 to June 2006 and Director, Medical Sciences from December 2002 to June 2005. Prior to that, he was an Associate Professor at the UCLA School of Medicine. He has also served as a Venture Partner of Vida Ventures, LLC since November 2017, and Two River, LLC since October 2017. In addition, he serves as a member of the American Association for Cancer Research Oncology Development Fund Investment Advisory Committee, CalTech Cheng Medical Engineering Advisory Council and of the MIT Corporation Biology Visiting Committee. Dr. Chang obtained a B.S. in Biology from the Massachusetts Institute of Technology and an M.D. and Ph.D. from Stanford University.

John DeYoung, 62, has served as a member of our Board since April 2018. Mr. DeYoung is Vice President of Worldwide Business Development for Pfizer’s Oncology Business Unit. He is a member of Pfizer’s Oncology Leadership Team and its Worldwide Business Development Leadership Team. Mr. DeYoung joined Pfizer in 1991 and has held leadership positions in Finance, Marketing, Commercial Development and Business Development. Mr. DeYoung received his bachelor’s degree in business from Michigan State University in 1985 and his MBA from the University of Chicago in 1990.

Franz Humer, Ph.D., 78, has served as a member of our Board since April 2018. Dr. Humer currently serves on the board of directors of LetterOne Holdings S.A. and as Chair of the board of directors of Kallyope, Inc. In addition, Dr. Humer

serves on the board of directors of the International Centre for Missing and Exploited Children and is Chair of the Humer Foundation. Dr. Humer previously served as Chair of the board of directors of Neogene Therapeutics, Inc., a private research-stage biotechnology company, from October 2020 until January 2023 and as a member of the board of directors of Kite from September 2015 until October 2017. He also served as an independent director of Citigroup Inc. from 2012 until 2018, Chugai Pharmaceuticals Ltd. (Japan) from 2002 until 2014, and Arix Bioscience plc from April 2016 to December 2019. He served as Chair of Diageo plc from 2005 to 2017. He served as a member of the board of directors of WISeKey SA, a publicly traded global cybersecurity company, from May 2016 to December 2017. In addition, Dr. Humer served as Head of Pharmaceuticals and then as Chief Operating Officer of F. Hoffmann-La Roche Ltd. from 1996 to 1998, prior to serving as Chief Executive Officer of Roche Group from 1998 to 2001 and later as Chair and Chief Executive Officer from 2001 to 2008. His tenure as Chair of Roche Holding Ltd. extended from 2008 to 2014. Before joining Roche Group, he served on the board of Glaxo Holdings plc and was responsible for research, business development, manufacturing, commercial strategy, and all non-US operations for 13 years. In 1973, Dr. Humer joined Schering Plough Corporation where he held various General Management positions in Latin America and Europe. Dr. Humer attended the University of Innsbruck, where he obtained a Ph.D. in Law, and INSEAD in Fontainebleau, where he obtained an MBA.

Joshua Kazam, 48, has served as a member of our Board since November 2017. Mr. Kazam served as our President from November 2017 until June 2018. He was a founder of Kite and served as a member of Kite's board of directors from Kite's inception in June 2009 until October 2017. In June 2009, Mr. Kazam co-founded Two River, LLC, a life-science consulting and investment firm. Mr. Kazam has served on the board of Kronos Bio, Inc. since June 2017 and Capricor Therapeutics, Inc. from May 2005 until May 2019. He has also served on the boards of the following private companies: Vision Path, Inc. (d/b/a Hubble Contacts) since May 2016, ByHeart, Inc. since November 2016, Breakthrough Properties LLC and Breakthrough Services LLC since April 2019, and IconOVir Bio, Inc. since August 2018. Mr. Kazam has also served on the boards of several blank check companies formed for the purpose of effecting a business combination with one or more businesses: Screaming Eagle Acquisition Corp. since January 2022, Tishman Speyer Innovation Corp. II since February 2021, TS Innovation Acquisitions Corp. from November 2020 until June 2021, Soaring Eagle Acquisition Corp. from February 2021 to September 2021, Flying Eagle Acquisition Corp. from February 2020 until December 2020, Diamond Eagle Acquisition Corp. from January 2019 until April 2020, and Platinum Eagle Acquisition Corp. from January 2018 to March 2019. Mr. Kazam has served as the President of Desert Flower Foundation since June 2016. Mr. Kazam received his bachelor's degree in Entrepreneurial Management from the Wharton School of the University of Pennsylvania and is a Member of the Wharton School's Undergraduate Executive Board.

Stephen Mayo, Ph.D., 63, has served as a member of our Board since July 2022. Since 2021, he has served as a member of the board of directors and as a member of the research and development and audit committees of Sarepta Therapeutics, Inc. Since 2021, Dr. Mayo has served as a member of the board of directors and on the audit and research committees of Merck & Co. In addition, he serves on the scientific advisory boards of Vida Ventures and Evozyne. He co-founded Molecular Simulations Inc. (now Biovia) and Xencor, a public antibody engineering company. Dr. Mayo is currently the Bren Professor of Biology and Chemistry and Merkin Institute Professor at California Institute of Technology (Caltech). He joined the Caltech faculty in 1992, was a Caltech-based Howard Hughes Medical Institute Investigator from 1994 to 2007, served as Vice Provost for Research from 2007 to 2010 and Chair of the Division of Biology and Biological Engineering from 2010 to 2020. Dr. Mayo was elected to the National Academy of Sciences in 2004 for his pioneering contributions in the field of protein design. He served as an elected board member for the American Association for the Advancement of Science from 2010 to 2014 and as a presidential appointee on the National Science Foundation's National Science Board from 2013 to 2018. Dr. Mayo holds a B.S. in Chemistry from Pennsylvania State University and a Ph.D. in Chemistry from Caltech. He completed postdoctoral work at both UC Berkeley and Stanford University School of Medicine in chemistry and biochemistry, respectively.

Deborah Messemer, 67, has served as a member of our Board since September 2018. Ms. Messemer has served as director of TPG Inc. since January 2022 and PayPal Holdings, Inc. since January 2019. Ms. Messemer is a certified public accountant and joined KPMG LLP ("KPMG"), the U.S. member firm of KPMG International, in 1982 and was admitted into the partnership in 1995. Most recently, she served as the Managing Partner of KPMG's Bay Area and Northwest region until her retirement in September 2018. Ms. Messemer spent the majority of her career in KPMG's audit practice as an audit engagement partner serving public and private clients in a variety of industry sectors. In addition to her operational and audit signing responsibilities, she has significant experience in SEC filings, due diligence, initial public offerings, mergers and acquisitions, and internal controls over financial reporting. Ms. Messemer received a bachelor's degree in accounting from the University of Texas at Arlington.

Vicki Sato, Ph.D., 76, has served as a member of our Board since July 2021. She was a professor of management practice at Harvard Business School from September 2006 to July 2017 and was a professor in the Department of Molecular and Cell Biology at Harvard University from July 2005 until October 2015. Previously, she served as President of Vertex

Pharmaceuticals, Inc. ("Vertex"), a publicly-traded biotechnology company, which she joined in 1992. Prior to becoming President of Vertex, she was the Chief Scientific Officer and Senior Vice President of Research and Development. Prior to joining Vertex, Dr. Sato served as Vice President of Research at Biogen Inc. Dr. Sato is a member of the board of directors of the following publicly-traded companies: Denali Therapeutics, Inc. and Vir Biotechnology, Inc. She previously served on the board of directors of Akouos, Inc., Bristol Myers Squibb Company and BorgWarner, Inc., both publicly-traded companies. Dr. Sato received her A.B. in Biology from Radcliffe College and her A.M. and Ph.D. in Biology from Harvard University. She conducted her postdoctoral work at both the University of California, Berkeley and Stanford Medical Center.

Todd Sisitsky, 53, has served as a member of our Board since April 2018. Mr. Sisitsky is a board member and President of TPG, Inc. and Co-Managing Partner of TPG Capital, TPG's scale private equity business in the U.S. and Europe, and co-leads the firm's investment activities in the healthcare services, pharmaceuticals and medical device sectors. He also serves on the executive committee of TPG Holdings. He has played leadership roles in connection with TPG's investment in us, Adare Pharmaceuticals, Aptalis, Biomet, Exactech, Fenwal, Healthscope, IASIS Healthcare, Immucor, IQVIA Holdings, Inc. (and predecessor companies IMS Health and Quintiles), Par Pharmaceutical, and Surgical Care Affiliates. Mr. Sisitsky currently serves as director of the following additional public companies: Convey Health Solutions, Inc., and IQVIA Holdings, Inc. Prior to joining TPG in 2003, Mr. Sisitsky worked at Forstmann Little & Company and Oak Hill Capital Partners. He received an MBA from the Stanford Graduate School of Business, where he was an Arjay Miller Scholar, and earned his undergraduate degree from Dartmouth College, where he graduated summa cum laude. Mr. Sisitsky currently serves as the chair of the Dartmouth Medical School board of advisors, and as a board member of Grassroot Soccer.

Owen Witte, M.D., 75, has served as a member of our Board since April 2018. Dr. Witte previously served as a member of the board of directors of Kite from March 2017 until October 2017. Dr. Witte joined the UCLA faculty in 1980, where he is presently a University Professor of microbiology, immunology and molecular genetics, the UCLA David Saxon Presidential Chair in Developmental Immunology and previously served as the director of the Eli and Edythe Broad Center of Regenerative Medicine and Stem Cell Research. Dr. Witte was appointed a University Professor by the University of California Board of Regents, an honor reserved for scholars of the highest international distinction. Dr. Witte is a member of the National Academy of Sciences, the American Academy of Arts and Sciences, and the National Academy of Medicine. Dr. Witte currently serves on several editorial and advisory boards. He previously served on the board of directors for the American Association for Cancer Research. He was appointed by President Obama to the President's Cancer Panel. Dr. Witte holds a bachelor's degree from Cornell University and an M.D. from Stanford University. He completed postdoctoral research at the Massachusetts Institute of Technology.

In addition to Dr. Chang, our executive officers include the following:

Zachary Roberts, M.D., Ph.D., 47, has served as our Chief Medical Officer since April 2023 and as our Executive Vice President, Research and Development, since January 2023. Previously, Dr. Roberts served as Chief Medical Officer for Instil Bio, Inc. (Instil) from March 2020 to November 2022. Prior to joining Instil, he served in various roles for Kite, during his five-year tenure, with his last position as Vice President, Clinical Development from February 2018 to May 2019. Prior to joining Kite, Dr. Roberts served in various roles in Amgen, with his last position as Clinical Research Medical Director for Amgen Oncology from January 2015 to July 2015. Dr. Roberts completed his training in internal medicine and hematology/oncology at the Massachusetts General Hospital and Dana Farber Cancer Institute. He earned his B.S. in microbiology and immunology from the University of Maryland, College Park and both his Ph.D. in immunology and his M.D. from the University of Maryland, Baltimore.

Geoffrey Parker, 60, has served as our Executive Vice President, Chief Financial Officer since October 2023. Prior to joining us, Mr. Parker served as Chief Operating Officer, Chief Financial Officer and Executive Vice President of Tricida, Inc. Prior to joining Tricida, Mr. Parker served as Chief Financial Officer of Anacor Pharmaceuticals, and served as a Partner and Managing Director at Goldman Sachs, where he led the West Coast Healthcare Investment Banking group. In addition, Mr. Parker currently serves as a member of the board of directors of Perrigo Company plc. He earned an A.B. with a double major in Economics and Engineering Sciences from Dartmouth College and an MBA from the Stanford Graduate School of Business.

Earl Douglas, 62, has served as our Senior Vice President, General Counsel and Compliance Officer since August 2023 and as our corporate secretary since January 2024. Before joining Allogene, Mr. Douglas served as Executive Vice President, General Counsel of Applied Molecular Transport. Prior to that role, he served in the same capacity for Kiverdi, Inc. He has also served as Vice President, General Counsel at BioMimetic Therapeutics, Spinal Dynamics, and OPX Biotechnologies. He previously served as Counsel with Wilson Sonsini Goodrich & Rosati, and earlier in his career practiced as an Associate with Weil, Gotshal & Manges. He earned his B.S. in chemical engineering from the Massachusetts Institute of Technology (MIT) and his J.D. from Columbia University School of Law.

Benjamin Beneski, 48, has served as our Senior Vice President and Chief Technical Officer since March 2025. Mr. Beneski joined Allogene in 2019 as our Executive Director and Plant Manager, where he played a pivotal role in the design, construction, and successful startup of Cell Forge 1, our state-of-the-art cell therapy manufacturing facility. Since then, Mr. Beneski has advanced through a series of increasingly senior roles, including Vice President of Manufacturing and Vice President of Product Development and Manufacturing where he led the development of next-generation platforms, effectively managed internal and external manufacturing networks, and drove key initiatives to support IND submissions and ensure commercial readiness. Prior to joining Allogene, Mr. Beneski held senior manufacturing roles at various biotechnology companies, including Vir Biotechnology and Amgen. He earned B.S. in chemical engineering from Stevens Institute of Technology and an MBA from Northeastern University.

We have adopted a code of ethics for directors, officers (including our principal executive officer, principal financial officer and principal accounting officer) and employees, known as the Code of Business Conduct and Ethics. The Code of Business Conduct and Ethics is available on our website at http://www.allogene.com under the Governance section of our Investors page. In addition, we intend to promptly disclose on our website, to the extent required by the rules and regulations of the SEC, (i) the nature of any amendment to the Code of Business Conduct and Ethics that applies to our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions, and (ii) the nature of any waiver, including an implicit waiver, from a provision of the Code of Business Conduct and Ethics that is granted to one of these specified individuals, the name of such person who is granted the waiver and the date of the waiver. Stockholders may request a free copy of the Code of Business Conduct and Ethics from our Compliance Officer, c/o Allogene Therapeutics, Inc., 210 E. Grand Avenue, South San Francisco, CA 94080.

Item 11. Executive Compensation.

The information required by this Item will be set forth in the section headed “Executive Compensation” in our Proxy Statement and is incorporated in this Annual Report by reference.

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

The information required by this Item will be set forth in the section headed “Security Ownership of Certain Beneficial Owners and Management” in our Proxy Statement and is incorporated in this Annual Report by reference.

Information regarding our equity compensation plans will be set forth in the section headed “Executive Compensation” in our Proxy Statement and is incorporated in this Annual Report by reference.

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

The information required by this Item will be set forth in the sections headed “Transactions With Related Persons” and “Information Regarding the Board of Directors and Corporate Governance” in our Proxy Statement and is incorporated in this Annual Report by reference.

Item 14. Principal Accounting Fees and Services.

The information required by this Item will be set forth in the section headed “-Ratification of Selection of Independent Registered Public Accounting Firm” in our Proxy Statement and is incorporated in this Annual Report by reference.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a)(1) Financial Statements.

The response to this portion of Item 15 is set forth under Part II, Item 8 above.

(a)(2) Financial Statement Schedules.

All schedules have been omitted because they are not required or because the required information is given in the Financial Statements or Notes thereto set forth under Item 8 above.

(a)(3) Exhibits.

The exhibits listed in the Exhibit Index below are filed or incorporated by reference as part of this Annual Report.

Exhibit Index

Exhibit Number	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. 001-38693), filed with the SEC on October 15, 2018).
3.2	Certificate of Amendment of 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. 001-38693), filed with the SEC on June 17, 2022).
3.3	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. 001-38693), filed with the SEC on October 15, 2018).
4.1	Reference is made to Exhibits 3.1, 3.2 and 3.3
4.2	Form of Common Stock Certificate of the Registrant (incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-227333), filed with the SEC on October 2, 2018.
4.3	Description of Common Stock (incorporated by reference to Exhibit 4.3 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2022, filed with the SEC on February 28, 2023).
10.1+	Form of Indemnity Agreement by and between the Registrant and its directors and officers (incorporated by reference to Exhibit 10.1 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-227333), filed with the SEC on October 2, 2018).
10.2+	Indemnification Agreement, dated April 6, 2018, by and between the Registrant and John DeYoung (incorporated by reference to Exhibit 10.2 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-227333), filed with the SEC on October 2, 2018).
10.3+	Allogene Therapeutics, Inc. Amended and Restated 2018 Equity Incentive Plan (Prior Plan) and Forms of Stock Option Grant Notice, Option Agreement, Notice of Exercise and Early Exercise Stock Purchase Agreement thereunder, as amended (incorporated by reference to Exhibit 10.2 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-227333), filed with the SEC on September 14, 2018).
10.4+	Allogene Therapeutics, Inc. Amended and Restated 2018 Equity Incentive Plan and Forms of Stock Option Grant Notice, Option Agreement, Notice of Exercise, Restricted Stock Unit Grant Notice and Restricted Stock Unit Award Agreement thereunder (incorporated by reference to Exhibit 99.2 to the Registrant's Registration Statement on Form S-8 (File No. 333-227965), filed with the SEC on October 24, 2018).
10.5+	Allogene Therapeutics, Inc. 2018 Employee Stock Purchase Plan (incorporated by reference to Exhibit 99.3 to the Registrant's Registration Statement on Form S-8 (File No. 333-227965), filed with the SEC on October 24, 2018).
10.6+	Allogene Therapeutics, Inc. 2018 Change in Control Plan and Severance Benefit Plan (incorporated by reference to Exhibit 10.6 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-227333), filed with the SEC on October 2, 2018).
10.7+	Non-Employee Director Compensation Policy (incorporated by reference to Exhibit 10.7 to the Registrant's Annual Report on Form 10-K (File No. 001-38693), filed with the SEC on March 14, 2024).
10.8+	Employment Agreement, dated June 25, 2018, by and between the Registrant and David Chang, M.D., Ph.D. (incorporated by reference to Exhibit 10.12 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-227333), filed with the SEC on September 14, 2018).

10.9+	Employment Letter of Agreement, dated December 28, 2022, by and between the Registrant and Zachary Roberts, M.D., Ph.D. (incorporated by reference to Exhibit 10.13 to the Registrant's Annual Report on Form 10-K (File No. 001-38693), filed with the SEC on February 28, 2023).
10.10+	Employment Letter of Agreement, dated August 11, 2023, by and between the Registrant and Earl Douglas (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-38693), filed with the SEC on November 2, 2023).
10.11+	Employment Letter of Agreement, dated October 12, 2023, by and between the Registrant and Geoffrey Parker (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-38693), filed with the SEC on November 2, 2023).
10.12*	License Agreement, dated March 8, 2019, between the Registrant and Cellectis S.A. (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-38693), filed with the SEC on May 7, 2019).
10.13*‡	Exclusive License and Collaboration Agreement, dated October 30, 2015, by and between the Registrant (assignee of Pfizer Inc.) and Les Laboratoires Servier and Institut de Recherches Internationales Servier.
10.14*	Amendment and Settlement Agreement, dated May 10, 2024, by and between Les Laboratoires Servier, Institut de Recherches Internationales Servier and Allogene Therapeutics, Inc. (incorporated by reference to Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-38693), filed with the SEC on August 7, 2024).
10.15*	Asset Contribution Agreement, dated April 2, 2018, by and between the Registrant and Pfizer Inc. (incorporated by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-38693), filed with the SEC on November 2, 2023).
10.16*	Amended and Restated Collaboration and License Agreement, dated January 17, 2024, by and between the Registrant and Notch Therapeutics Inc. (incorporated by reference to Exhibit 10.18 to the Registrant's Annual Report on Form 10-K (File No. 001-38693), filed with the SEC on March 14, 2024).
10.17	Lease, dated August 1, 2018, by and between the Registrant and Britannia Pointe Grand Limited Partnership (incorporated by reference to Exhibit 10.11 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-227333), originally filed with the SEC on September 14, 2018).
10.18	First Amendment, dated December 10, 2021, to the Lease, dated August 1, 2018, by and between the Registrant and Britannia Pointe Grand Limited Partnership (incorporated by reference to Exhibit 10.18 to the Registrant's Annual Report on Form 10-K (File No. 001-38693), filed with the SEC on February 23, 2022).
10.19	Lease Agreement, dated October 25, 2018, by and between the Registrant and HCP, Inc. (incorporated by reference to Exhibit 10.17 to the Registrant's Annual Report on Form 10-K (File No. 001-38693), filed with the SEC on March 8, 2019).
10.20	First Amendment, dated December 10, 2021, to the Lease Agreement, dated October 25, 2018, by and between the Registrant and Healthpeak Properties, Inc. (formerly known as HCP, Inc.) (incorporated by reference to Exhibit 10.20 to the Registrant's Annual Report on Form 10-K (File No. 001-38693), filed with the SEC on February 23, 2022).
10.21	Lease Agreement, dated February 19, 2019, by and between the Registrant and Silicon Valley Gateway Technology Center, LLC (incorporated by reference to Exhibit 10.18 to the Registrant's Annual Report on Form 10-K (File No. 001-38693), filed with the SEC on March 8, 2019).
10.22	First Amendment, dated September 4, 2019, to the Lease Agreement, dated February 19, 2019, by and between the Registrant and Silicon Valley Gateway Technology Center, LLC (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-38693), filed with the SEC on November 5, 2019).
10.23	Second Amendment, dated July 15, 2020, to the Lease Agreement, dated February 19, 2019, by and between the Registrant and Silicon Valley Gateway Technology Center, LLC (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-38693) for the quarter ended June 30, 2020, filed with the SEC on August 5, 2020).
10.24*‡	Exclusive License Agreement, dated December 14, 2020, by and between the Registrant and Allogene Overland Biopharm (CY) Limited (incorporated by reference to Exhibit 10.23 to the Registrant's Annual Report on Form 10-K (File No. 001-38693) for the year ended December 31, 2020, filed with the SEC on February 25, 2021).
10.25*‡	First Amendment to the License Agreement, dated May 24, 2024, by and between Allogene Therapeutics Inc. and Allogene Overland BioPharm (PRC) Co., Limited (incorporated by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-38693), filed with the SEC on August 7, 2024).

10.26*‡	Share Purchase Agreement, dated December 14, 2020, by and among the Registrant, Overland Pharmaceuticals (CY) Inc. and Allogene Overland Biopharm (CY) Limited (incorporated by reference to Exhibit 10.24 to the Registrant's Annual Report on Form 10-K (File No. 001-38693) for the year ended December 31, 2020, filed with the SEC on February 25, 2021).
10.27*	First Amendment to the Share Purchase Agreement, dated May 11, 2022, by and among the Registrant, Overland Pharmaceuticals (CY) Inc. and Allogene Overland Biopharm (CY) Limited (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-38693) for the quarter ended June 30, 2022, filed with the SEC on August 9, 2022).
10.28*‡	Amended and Restated Shareholders' Agreement, dated May 24, 2024, by and among Allogene Overland Biopharm (CY) Limited, Allogene Therapeutics Inc. and HH BioPharma Holdings Ltd. (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-38693), filed with the SEC on August 7, 2024).
10.29*‡	Share Exchange Agreement, dated May 24, 2024, by and among Allogene Overland Biopharm (CY) Limited, Overland Pharmaceuticals (CY) Inc. and Allogene Therapeutics Inc. (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-38693), filed with the SEC on August 7, 2024).
19.1	Allogene Therapeutics, Inc. Insider Trading Policy
23.1	Consent of Independent Registered Public Accounting Firm.
24.1	Power of Attorney. Reference is made to the signature page hereto.
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
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	Allogene Therapeutics, Inc. Incentive Compensation Recoupment Policy (incorporated by reference to Exhibit 97.1 to the Registrant's Annual Report on Form 10-K (File No. 001-38693), filed with the SEC on March 14, 2024).
101.INS	Inline XBRL Instance 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	The cover page of the Company's Annual Report on Form 10-K has been formatted in Inline XBRL.

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+ Indicates management contract or compensatory plan.

* Certain portions of this exhibit (indicated by "[***]") have been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K because it is both not material and is the type of information that the Registrant treats as private or confidential.

‡ Schedules have been omitted pursuant to Item 601(a)(5) of Regulation S-K.

Item 16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized, in South San Francisco, California, on March 13, 2025.

Allogene Therapeutics, Inc.

By: /s/ David Chang, M.D., Ph.D.
David Chang, M.D., Ph.D.
President, Chief Executive Officer and Member of the Board of Directors
(*Principal Executive Officer*)

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints David Chang, M.D., Ph.D. and Geoffrey Parker, and each of them, as his or her true and lawful attorneys-in-fact and agents, each with the full power of substitution, for him or her and in his or her name, place or stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or their or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

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

Signature	Title	Date
/s/ David Chang, M.D., Ph.D. David Chang, M.D., Ph.D.	President, Chief Executive Officer and Member of the Board of Directors (*Principal Executive Officer*)	March 13, 2025
/s/ Geoffrey Parker Geoffrey Parker	Chief Financial Officer (*Principal Financial Officer*)	March 13, 2025
/s/ Annie Yoshiyama Annie Yoshiyama	Senior Vice President and Corporate Controller *(Principal Accounting Officer)*	March 13, 2025
/s/ Arie Belldegrun, M.D. Arie Belldegrun, M.D.	Executive Chair of the Board of Directors	March 13, 2025
/s/ Elizabeth Barrett Elizabeth Barrett	Member of the Board of Directors	March 13, 2025
/s/ John DeYoung John DeYoung	Member of the Board of Directors	March 13, 2025
/s/ Franz Humer, Ph.D. Franz Humer, Ph.D.	Member of the Board of Directors	March 13, 2025
/s/ Joshua Kazam Joshua Kazam	Member of the Board of Directors	March 13, 2025
/s/ Stephen Mayo, Ph.D. Stephen Mayo, Ph.D.	Member of the Board of Directors	March 13, 2025
/s/ Deborah Messemer Deborah Messemer	Member of the Board of Directors	March 13, 2025
/s/ Vicki Sato, Ph.D. Vicki Sato, Ph.D.	Member of the Board of Directors	March 13, 2025
/s/ Todd Sisitsky Todd Sisitsky	Member of the Board of Directors	March 13, 2025
/s/ Owen Witte, M.D. Owen Witte, M.D.	Member of the Board of Directors	March 13, 2025


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