

**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, 2023

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
(State or other jurisdiction
of incorporation or organization)

82-3562771
(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 | <input type="checkbox"/> | Accelerated filer | <input type="checkbox"/> |
| Non-accelerated filer | <input checked="" type="checkbox"/> | Small reporting company | <input checked="" type="checkbox"/> |
| | | Emerging growth company | <input type="checkbox"/> |

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

[Table of Contents](#)

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant as of June 30, 2023 (the last business day of the registrant's most recently completed second fiscal quarter) was approximately \$557 million based on the closing price of the registrant's common stock on June 30, 2023 of \$4.97 per share, as reported by The Nasdaq Global Select Market. The number of shares of Registrant's Common Stock outstanding as of March 12, 2024 was 169,091,992.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's Definitive Proxy Statement relating to the 2024 Annual Meeting of Stockholders, which will be filed with the Securities and Exchange Commission on or before April 29, 2024, are incorporated by reference into Part III of this Annual Report.

EXPLANATORY NOTE

Restatement Background

As described in our Current Report on Form 8-K filed with the Securities and Exchange Commission (SEC) on February 16, 2024, the Company received a comment letter (Comment Letter) from the staff of the Division of Corporation Finance of the SEC relating to its Annual Report on Form 10-K for the year ended December 31, 2022, filed with the SEC on February 28, 2023. The Comment Letter included a comment related to the Company's accounting for Allogene Overland Biopharm (CY) Limited (Allogene Overland), a joint venture established by the Company and Overland Pharmaceuticals (CY) Inc. (Overland) pursuant to a Share Purchase Agreement entered into on December 14, 2020 (Share Purchase Agreement), and also related to the associated Exclusive License Agreement between the Company and Allogene Overland entered into on December 14, 2020 (License Agreement) for the purpose of developing, manufacturing and commercializing certain allogeneic CAR T cell therapies for patients in greater China, Taiwan, South Korea and Singapore. Pursuant to the Share Purchase Agreement, the Company acquired shares of Seed Preferred Stock in Allogene Overland (Seed Preferred Shares) 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 which Overland committed to pay \$117.0 million to Allogene Overland, which included an upfront payment and certain quarterly cash payments, to support operations of Allogene Overland. The Company also received \$40 million from Allogene Overland as partial consideration for the License Agreement. The Company's equity investment in Allogene Overland, as represented by the Seed Preferred Shares, was determined to be an equity method investment and originally recorded at zero. Given that the Seed Preferred Shares were recorded at zero and the Company does not have an obligation to contribute capital to Allogene Overland, the Company did not account for its share of losses incurred by Allogene Overland.

Following the receipt of the Comment Letter and a re-evaluation of the accounting for its Seed Preferred Shares, the Company determined that the Seed Preferred Shares should have been initially measured at fair value, and the accounting for the Seed Preferred Shares should be restated. Accordingly, the Company recorded the fair value of the Seed Preferred Shares on the date when they were received in December 2020. Consequently, the initial transaction price to determine revenue related to the License Agreement was also revised to include the fair value of the Seed Preferred Shares. As a result, the Company reflected additional revenues under "Collaboration revenue – related party" in its consolidated statements of operations and comprehensive loss. Further, on the date when the Seed Preferred Shares were received, the Company recorded as "Other expenses" in its consolidated statements of operations and comprehensive loss the basis difference between the fair value of the Seed Preferred Shares and the amount of the Company's underlying equity in net assets of Allogene Overland and reduced the carrying value of the Seed Preferred Shares. Further, the Company recorded its share of net losses of Allogene Overland in each reporting period and reduced the carrying value of the Seed Preferred Shares. This restatement is non-cash in nature and did not have an impact on cash, cash equivalents and marketable investments.

The error resulted in an understatement of collaboration revenue and other expenses in the consolidated statements of operations and comprehensive loss for the years ended December 31, 2022, 2021 and 2020, and an understatement of deferred revenue and equity method investment in the consolidated balance sheets as of December 31, 2022 and 2021. These periods were restated in Amendment No. 1 to the Annual Report on Form 10-K/A for the year ended December 31, 2022 filed with the SEC on March 14, 2024 (as amended, the 2022 Annual Report).

In this Annual Report on Form 10-K for the year ended December 31, 2023 (this Annual Report), the Company is restating its previously issued (i) unaudited condensed consolidated balance sheets as of March 31, 2023 and 2022, June 30, 2023 and 2022 and September 30, 2023 and 2022, (ii) unaudited condensed consolidated statements of operations and comprehensive loss for the three months ended March 31, 2023 and 2022, three and six months ended June 30, 2023 and 2022, and three and nine months ended September 30, 2023 and 2022, (iii) unaudited condensed consolidated statements of cash flows for the three months ended March 31, 2023 and 2022, six months ended June 30, 2023 and 2022, and nine months ended September 30, 2023 and 2022, in each of the Quarterly Reports on Form 10-Q for the quarterly periods ended March 31, 2023, June 30, 2023 and September 30, 2023 (the Prior Quarterly Financial Statements).

Restatement Overview

In connection with the restatement of the Prior Quarterly Financial Statements, the Company, in this Annual Report:

[Table of Contents](#)

1. Restated the Prior Quarterly Financial Statements, in *Note 1. Description of Business and Summary of Significant Accounting Policies*, and *Note 15. Selected Quarterly Financial Data (Unaudited)*, as set forth in Part II, Item 8, Financial Statements and Supplementary Data of this Annual Report; and

2. Amended the results of operation discussion for each of the quarterly periods ended March 31, 2023 and 2022, June 30, 2023 and 2022 and September 30, 2023 and 2022 in Part II, Item 7, Management’s Discussion and Analysis of Financial Condition and Results of Operations of this Annual Report.

The financial information that has been previously filed or otherwise reported for the Prior Quarterly Financial Statements is superseded by the information in this Annual Report. *Note 1. Description of Business and Summary of Significant Accounting Policies*, and *Note 15. Selected Quarterly Financial Data (Unaudited)*, as set forth in Part II, Item 8, Financial Statements and Supplementary Data of this Annual Report contain additional information on the restatement and the related financial statement impact.

We have not filed and do not intend to file amendments to our Quarterly Reports on Form 10-Q for any of the quarterly periods in the fiscal year 2023. Accordingly, investors should rely only on the restated financial statements and related disclosures included in the 2022 Annual Report and this Annual Report for the applicable periods or in future filings with the SEC (as applicable), and not on any previously issued or filed reports, earnings releases or similar communications including the aforementioned financial statements.

Internal Control Considerations

As a result of the information described above, management has concluded that the Company's disclosure controls and procedures were not effective at the reasonable assurance level and the Company's internal control over financial reporting was not effective as of the end of each of the periods covered by restatement. In connection with the restatement, the Company has identified a material weakness in the operation of internal control over financial reporting with respect to the technical accounting analysis of significant non-routine transactions. For a discussion of management’s evaluation of our disclosure controls and procedures and the material weakness identified, see Part II, Item 9A, “Controls and Procedures” of this Annual Report.

Table of Contents

| | <u>Page</u> |
|--|-------------|
| <u>PART I</u> | |
| Item 1. Business | 5 |
| Item 1A. Risk Factors | 38 |
| Item 1B. Unresolved Staff Comments | 79 |
| Item 1C. Cybersecurity | 79 |
| Item 2. Properties | 80 |
| Item 3. Legal Proceedings | 81 |
| Item 4. Mine Safety Disclosures | 81 |
| <u>PART II</u> | |
| Item 5. Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities | 82 |
| Item 6. [Reserved] | 83 |
| Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations | 83 |
| Item 7A. Quantitative and Qualitative Disclosures About Market Risk | 99 |
| Item 8. Financial Statements and Supplementary Data | 100 |
| Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure | 141 |
| Item 9A. Controls and Procedures | 141 |
| Item 9B. Other Information | 142 |
| Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections | 142 |
| <u>PART III</u> | |
| Item 10. Directors, Executive Officers and Corporate Governance | 143 |
| Item 11. Executive Compensation | 146 |
| Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters | 146 |
| Item 13. Certain Relationships and Related Transactions, and Director Independence | 146 |
| Item 14. Principal Accounting Fees and Services | 146 |
| <u>PART IV</u> | |
| Item 15. Exhibits, Financial Statement Schedules | 147 |
| Item 16. Form 10-K Summary | 149 |

[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;
- the ultimate outcome of our disputes with Servier, including disagreements relating to development cost contributions and the timeframe during which we have the right to elect a license to CD19 Products outside of the United States subsequent to Servier’s discontinuation of its involvement in the development of all CD19 products pursuant to our Exclusive License and Collaboration Agreement;
- 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;
- our ability to remediate a material weakness in our internal control over financial reporting; 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.

[Table of Contents](#)

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.
- 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.
- We may not be able to submit INDs to commence additional clinical trials on the timelines we expect, and even if we are able to, the FDA may not permit us to proceed.
- 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.
- Our reduction in force undertaken to extend our cash runway and focus more of our capital resources on our prioritized research and development programs might not achieve our intended outcome.

Risks Related to the Development of Our Product Candidates

- Our engineered allogeneic T cell product candidates represent a novel approach to cancer treatment that 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.

[Table of Contents](#)

- We are heavily reliant on our partners for access to TALEN® gene editing technology for the manufacturing and development of our oncology product candidates.
- Servier's discontinuation of its involvement in the development of CD19 Products and Servier's disputes with us and Cellectis may have adverse consequences.

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 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.

Risks Related to Government Regulation

- The FDA 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 similar 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

- We have identified a material weakness in our internal control over financial reporting. This material weakness could continue to adversely affect our ability to report our results of operations and financial condition accurately and in a timely manner.

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.

Earlier this year, we announced our 2024 Platform Vision that we believe will redefine the future of chimeric antigen receptor (CAR) T therapy by leveraging the unique attributes of allogeneic CAR T products. Under our 2024 Platform Vision we are focusing on four 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. *Chronic Lymphocytic Leukemia (CLL)*: New Phase 1 ALPHA2 Cohort is designed to evaluate cema-cel as a CLL treatment in order to address the limitations of autologous therapies in a disease where poor T cell fitness is a known barrier to efficacy.
3. *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.
4. *Renal Cell Carcinoma (RCC)*: Ongoing 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., FACS, 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 four 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 Collectis, S.A. (Collectis), 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

[Table of Contents](#)

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, 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 and CLL. 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 certain AIDs. We also 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.

| Target | Program | Trial | Study Population | Discovery | IND-enabling | Phase 1 | Phase 2 ¹ | Approved | Designation | Next Milestone |
|---------------------------------|----------------------------------|-----------|-----------------------|-----------|--------------|---------|----------------------|----------|----------------|---------------------------------|
| HEMATOLOGIC MALIGNANCIES | | | | | | | | | | |
| CD19 (Key Program) | cema-cel (ALLO-501A) | ALPHA3 | 1L Consolidation LBCL | ● | ● | ● | ● | | | Start-up activities initiated |
| CD19 | cema-cel | ALPHA2 | 3L LBCL | ● | ● | ● | ● | | FTD RMAT | Deprioritized |
| CD19 | cema-cel + ALLO-647 ² | EXPAND | 3L LBCL | ● | ● | ● | ● | | FTD (ALLO-647) | Deprioritized |
| CD19 (Key Program) | cema-cel | ALPHA2 | r/r CLL | ● | ● | ● | ● | | | Trial initiation Q1 2024 |
| BCMA | ALLO-715 | UNIVERSAL | 5+ Line MM | ● | ● | ● | ● | | RMAT ODD | Reviewing manufacturing process |
| BCMA | ALLO-605 ³ | IGNITE | 5+ Line MM | ● | ● | ● | ● | | FTD ODD | Reviewing manufacturing process |
| CD70 | ALLO-316 | | Various | ● | ● | ● | ● | | | |
| FLT3 | ALLO-819 | | AML | ● | ● | ● | ● | | | |
| SOLID TUMORS | | | | | | | | | | |
| CD70 (Key Program) | ALLO-316 | TRAVERSE | ccRCC | ● | ● | ● | ● | | FTD | Cohort expansion 2024 |
| CD70 | ALLO-316 | | Other Solid | ● | ● | ● | ● | | | |
| DLL3 | ALLO-213 | | SCLC | ● | ● | ● | ● | | | |
| Claudin 18.2 | ALLO-182 | | Gastric & Pancreatic | ● | ● | ● | ● | | | |
| AUTOIMMUNE DISEASE | | | | | | | | | | |
| CD19/CD70 (Key Program) | ALLO-329 | | Various | ● | ● | ● | ● | | | Trial initiation 1H 2025 |

¹Phase 3 may not be required if Phase 2 is registrational

²ALLO-647 (anti-CD52 mAb) is intended to enable expansion and persistence of allogeneic CAR T product candidates

³TurboCAR™

[Table of Contents](#)

Our lead product candidates include:

- *Cemacabtagene ansegedleucel (cema-cel)*. We are currently focused on developing cema-cel in LBCL and CLL.
 - *LBCL*: We plan to initiate a pivotal Phase 2 clinical trial (ALPHA3) in mid-2024 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 230 patients who achieve a complete response or partial response to 1L therapy, but who are MRD positive. The patients will be randomized to either consolidation with cema-cel or the current standard of care, which is observation. The design, with a primary endpoint of event free survival (EFS), will initially include two lymphodepletion arms (one with standard fludarabine and cyclophosphamide plus ALLO-647 and one with standard fludarabine and cyclophosphamide but without ALLO-647). One lymphodepletion arm will be discontinued following a planned interim analysis in mid-2025 designed to select the most appropriate regimen for this patient population. In view of the potential of the earlier line ALPHA3 trial, we have deprioritized the third line (3L) LBCL ALPHA2 and EXPAND trials.
 - *CLL*: We have initiated the Phase 1b cohort of our ALPHA2 trial to evaluate cema-cel following lymphodepletion with fludarabine/cyclophosphamide and ALLO-647 in patients with relapsed/refractory chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL). This cohort will include up to 40 patients, and we expect to release initial data by year-end 2024.
- *ALLO-316*. We are enrolling 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 American Association of Cancer Research (AACR) Annual Meeting in April 2023. See “—Product Pipeline and Development Strategy—Anti-CD70 Development Program—Results from the Phase 1 ALLO-316 TRAVERSE Trial” for information regarding the results. 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. The next update from this trial is planned for a publication in the second quarter of 2024 and will discuss the algorithm. A more comprehensive data update from the ongoing trial with the updated protocol is planned for year-end 2024.
- *ALLO-329*. 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. 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. Initiation of this Phase 1 trial with ALLO-329 is expected in early 2025.
- *ALLO-647*. We are developing an anti-CD52 monoclonal antibody, ALLO-647, which is a proprietary component of our 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. We plan to select the lymphodepletion regimen in mid 2025.
- *Other Product Candidates*: While we have additional programs in our pipeline, our development priorities are focused on cema-cel (1L Consolidation and CLL), 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

[Table of Contents](#)

Internationales Servier SAS (collectively, Servier) to develop and commercialize cema-cel, and we hold the commercial rights to these product candidates in the United States. The Servier Agreement gives us access to Collectis' TALEN® gene-editing technology for cema-cel. We also have an exclusive worldwide oncology license from Collectis 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. Belldgrun 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 Chief Technical Officer, Timothy Moore, has over 30 years of leadership experience in biopharmaceutical manufacturing and operations and was previously Executive Vice President, Technical Operations at Kite, where he was responsible for the process development, manufacturing, quality and supply chain for Yescarta®.

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.** As described in our 2024 Platform Vision, 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. Start-up activities for the ALPHA3 trial are underway and the trial is expected to begin enrolling in mid-2024.
- **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 immune system. Such technologies include our Dagger® technology that utilizes an anti-CD70 CAR to kill alloreactive host T cells. We are also advancing technologies to increase specificity of CAR T activity to avoid potential normal tissue toxicities associated with certain solid tumor targets. 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.
- **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 will be an engineered allogeneic CAR T cell product candidate that targets CD19 and CD70. ALLO-329 will incorporate our Dagger® technology. We are currently focused on developing ALLO-329 for AID. 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 this Phase 1 trial with ALLO-329 is expected in early 2025.

Allogeneic CAR T Cell Therapy

Engineered T Cell Therapies

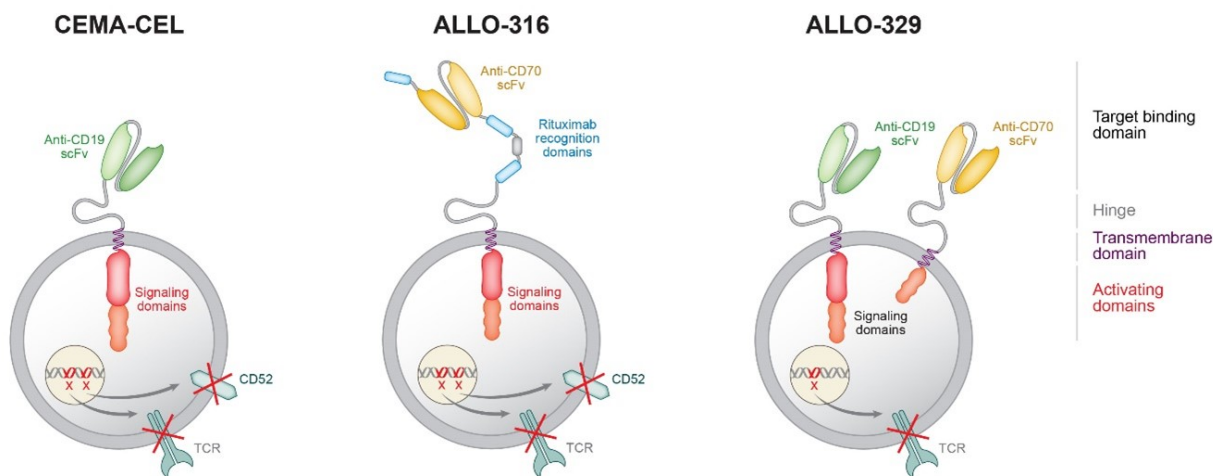
T cells are a type of white blood cell and are involved in both sensing and killing infected or abnormal cells, including cancer cells, as well as coordinating the activation of other cells in an immune response. Engineered T cell therapy is a type of immunotherapy treatment whereby human T cells are 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 as a way 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

[Table of Contents](#)

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 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.

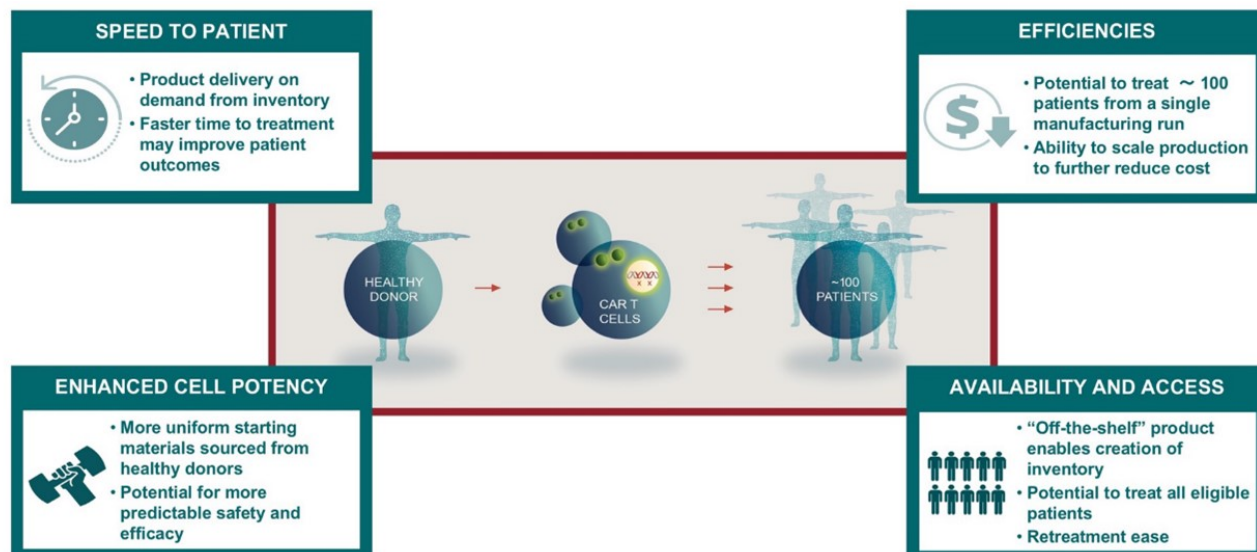
Allogeneic engineered T cells are manufactured in a similar manner as autologous, but our manufacturing has two key differences: (1) our allogeneic T cells are derived from healthy donors, not cancer patients, and (2) our allogeneic T cells are genetically engineered to minimize the risk of GvHD and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

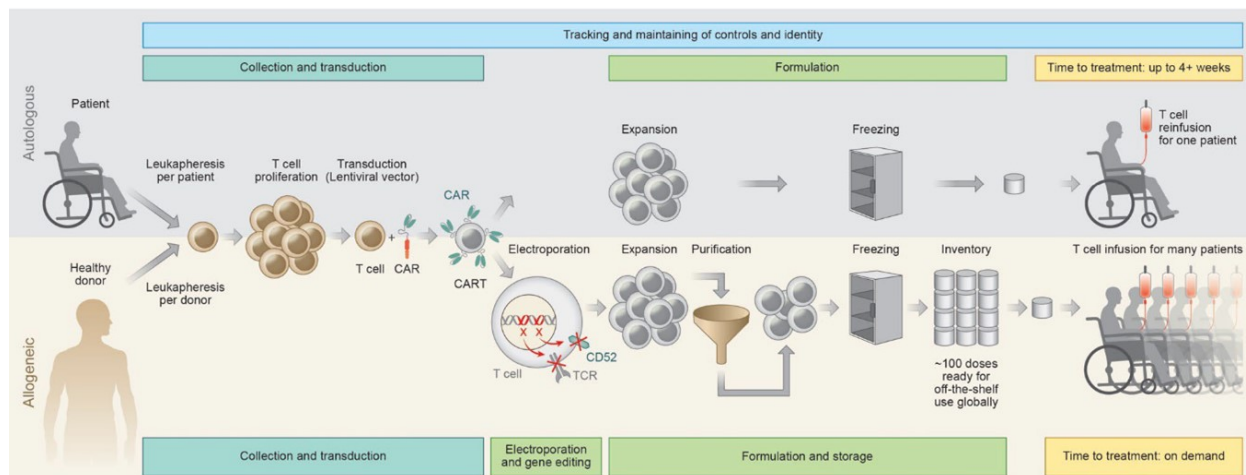
Table of Contents

- **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 are building 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, as illustrated in the figure below which depicts our manufacturing process for our oncology CAR-T product candidates.

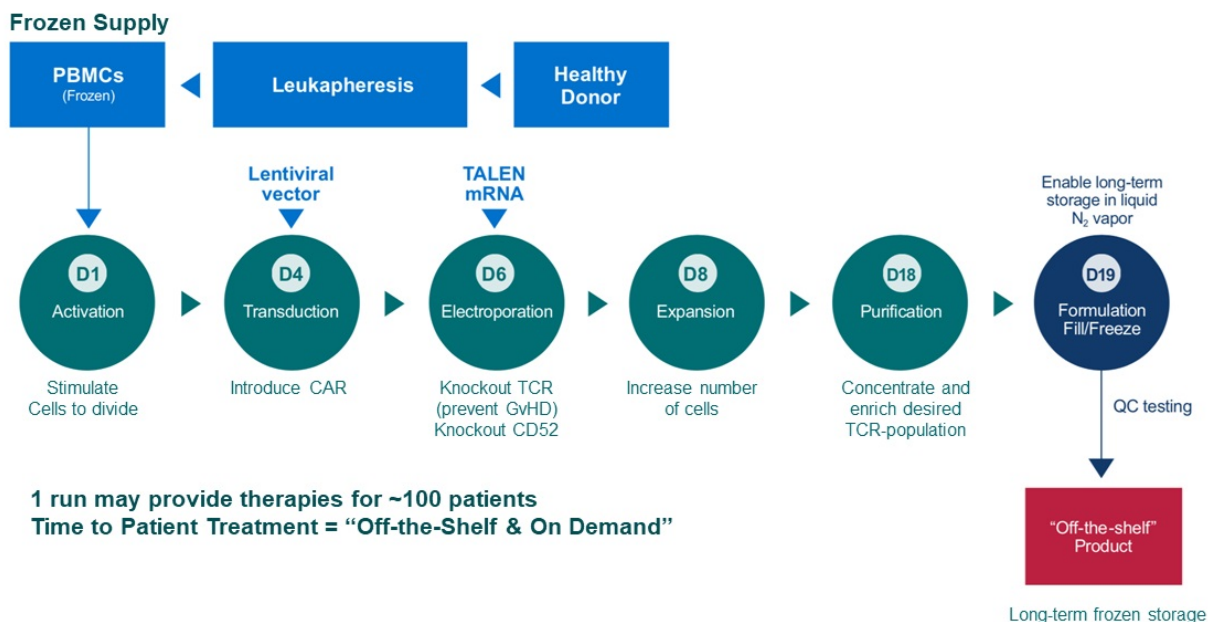


The three primary steps to creating our engineered allogeneic CAR T cells are: (1) collection and transduction, (2) gene editing, and (3) purification, formulation, and storage. We start with collecting white blood cells from a healthy donor, which are subsequently stimulated to proliferate and transduced 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 that is present on cancer cells. Next, we use gene editing tools to edit the T cell genome to inactivate TCR α and CD52. Inactivation of TCR α and CD52 is intended to reduce the risk of GvHD and allow the allogeneic

[Table of Contents](#)

T cells to expand and persist in patients, respectively. 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.

The figure below illustrates the steps in a manufacturing run for our engineered oncology allogeneic CAR T product candidates.



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

| Target | Program | Trial | Study Population | Discovery | IND-enabling | Phase 1 | Phase 2 ¹ | Approved | Designation | Next Milestone |
|---------------------------------|-------------------------------------|-----------|--------------------------|-----------|--------------|---------|----------------------|----------|----------------|------------------------------------|
| HEMATOLOGIC MALIGNANCIES | | | | | | | | | | |
| CD19 (Key Program) | cema-cel (ALLO-501A) | ALPHA3 | 1L Consolidation LBCL | ● | ● | ● | ● | ● | | Start-up activities initiated |
| CD19 | cema-cel | ALPHA2 | 3L LBCL | ● | ● | ● | ● | ● | FTD RMAT | Deprioritized |
| CD19 | cema-cel + ALLO-647 ² | EXPAND | 3L LBCL | ● | ● | ● | ● | ● | FTD (ALLO-647) | Deprioritized |
| CD19 (Key Program) | cema-cel | ALPHA2 | r/r CLL | ● | ● | ● | ● | ● | | Trial initiation Q1 2024 |
| BCMA | ALLO-715 | UNIVERSAL | 5+ Line MM | ● | ● | ● | ● | ● | RMAT ODD | Reviewing manufacturing process |
| BCMA | ALLO-605 ³ | IGNITE | 5+ Line MM | ● | ● | ● | ● | ● | FTD ODD | Reviewing manufacturing process |
| CD70 | ALLO-316 | | Various | ● | ● | ● | ● | ● | | |
| FLT3 | ALLO-819 | | AML | ● | ● | ● | ● | ● | | |
| SOLID TUMORS | | | | | | | | | | |
| CD70 (Key Program) | ALLO-316 | TRAVERSE | ccRCC | ● | ● | ● | ● | ● | FTD | Cohort expansion 2024 |
| CD70 | ALLO-316 | | Other Solid | ● | ● | ● | ● | ● | | |
| DLL3 | ALLO-213 | | SCLC | ● | ● | ● | ● | ● | | |
| Claudin 18.2 | ALLO-182 | | Gastric & Pancreatic | ● | ● | ● | ● | ● | | |
| AUTOIMMUNE DISEASE | | | | | | | | | | |
| CD19/ CD70 (Key Program) | ALLO-329 | | Various | ● | ● | ● | ● | ● | | Trial initiation 1H 2025 |

¹Phase 3 may not be required if Phase 2 is registrational;

²ALLO-647 is intended to enable expansion and persistence of allogeneic CAR T product candidates;

³TurboCAR™

Anti-CD19 Oncology Development Program

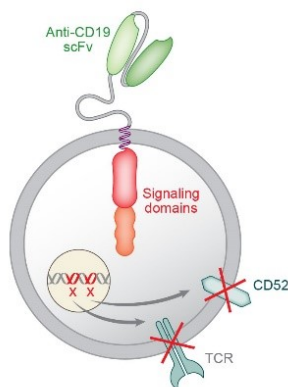
CD19 is an antigen expressed on the surface of B cells, including on B cells that are malignant. B cells are considered non-essential tissue, as they are not absolutely required for patient survival. We believe CD19 is a validated target for the treatment of B cell leukemias and lymphomas. Multiple autologous 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. While we continue to work to redefine our relationship with Servier, in the interim, we have assumed all responsibility for the CD19 development program.

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 TCRαβ 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 in the event that 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.

CEMA-CEL



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 June 3, 2023, 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 at the American Society of Clinical Oncology (ASCO) Annual Meeting. We conducted an extensive Phase 1 program designed to evaluate and optimize all aspects of our lead product candidate, including the dose and schedule of cema-cel and ALLO-647.

The long-term data included an updated analysis of data from 12 CAR T-naïve patients with R/R LBCL who received a single dose of ALLO-501/cema-cel manufactured using the Alloy™ process following a lymphodepletion regimen (FCA90) comprised of fludarabine (30 mg/m²/day x 3 days) and cyclophosphamide (300 mg/m²/day x 3 days) plus ALLO-647 (30 mg/day x 3 days). The median time from enrollment to the start of therapy was three days and all 12 patients were followed through a minimum of six months (data cutoff April 20, 2023).

The updated data from the Phase 1 trials of ALLO-501 and cema-cel are foundational for our ALPHA3 trial and continue to support the ability of a single administration of allogenic CAR T cells to induce durable complete remissions at a rate similar to approved autologous CD19 CAR T therapies. Among the 12 patients treated with the single dose FCA90

[Table of Contents](#)

regimen, the overall response rate (ORR) was 67% and 58% achieved CRs with 42% maintaining CR through month six. Of the five patients who were in CR at six months, four (80%) remained in CR. The fifth patient had disease progression at 24 months. The median duration of response was 23.1 months with three patients remaining in remission for over 24 months and the longest remaining in remission for over 31 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) |

The ALPHA and ALPHA2 Phase 1 trials demonstrated a manageable safety profile and treatment was generally well tolerated with no GvHD and no observed dose limiting toxicities (DLTs). Among patients treated with single dose FCA90, there was no Grade 3+ CRS or neurotoxicity. One patient (8%) experienced a Grade 3+ infection and two (17%) experienced prolonged Grade 3+ cytopenia. As previously reported, one Grade 5 event occurred. No new Grade 5 events have occurred.

| | All R/R CAR T naïve LBCL (N=33) | | Patients Treated with Phase 2 Regimen (N=12) | |
|--------------------------|---------------------------------|-------------|--|-------------|
| | All Gr N (%) | Gr 3+ N (%) | All Gr N (%) | Gr 3+ N (%) |
| CRS | 8 (24) | 0 | 4 (33) | 0 |
| ICANS | 0 | 0 | 0 | 0 |
| Neurotoxicity | 13 (39) | 2 (6) | 4 (33) | 0 |
| GvHD | 0 | 0 | 0 | 0 |
| IRR | 16 (49) | 3 (9) | 8 (67) | 0 |
| Infection | 19 (58) | 5 (15) | 8 (67) | 1 (8) |
| Prolonged Gr3+ Cytopenia | - | 4 (12) | - | 2 (17) |

Second Target Indication: Chronic Lymphocytic Leukemia (CLL)

CLL is also a hematologic cancer originating from malignant lymphocytes. Within the United States, annually approximately 20,700 new cases of CLL are estimated to be diagnosed with approximately 4,400 deaths estimated to occur according to 2024 figures from the American Cancer Society. Targeted therapy can be used to treat CLL, including treatment with Bruton tyrosine kinase inhibitors (BTKi) or B-cell lymphoma 2 inhibitors (BCL2i). Although such frontline therapies can be effective in achieving a remission, CLL remains incurable, and the disease will likely relapse and require further line(s) of therapy. While recent autologous CD19 CAR T data has been a positive step for patients with R/R CLL, outcomes in CLL following CAR T treatment have yet to meet expectations set in R/R LBCL. This is likely due in part to T cell dysfunction and the potential for high circulating tumor burden in CLL, making the isolation of functional T cells for autologous CAR T manufacturing difficult. We believe that our AlloCAR T™ products, such as cema-cel which is derived from healthy donor cells, could potentially create a clinically meaningful advance for these late-stage CLL patients, with a one-time dose and simpler administration and logistics.

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 are also sponsoring 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 will seek 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 will be an open-label, Phase 2, multicenter clinical trial evaluating the safety and efficacy of cema-cel in adult patients with

[Table of Contents](#)

LBCL who have completed R-CHOP and have attained a remission, but who test positive for MRD. The ALPHA3 trial will randomize approximately 230 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 in mid-2025 designed to select the most appropriate regimen for this patient population.

The ALPHA3 trial will leverage 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. Start-up activities for ALPHA3 are underway and we plan to initiate the trial in mid-2024.

Assuming favorable outcomes and subject to FDA discussions, we plan to seek FDA approval of cema-cel and ALLO-647 on the basis of the ALPHA3 trial.

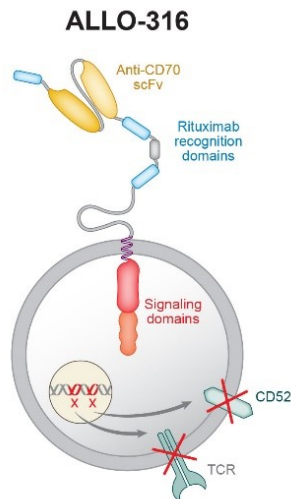
Clinical Development Plan - Chronic Lymphocytic Leukemia (CLL)

We have initiated a new CLL cohort as part of our ALPHA2 trial. This new cohort is a Phase 1b cohort that is a single-arm, open-label, multicenter study evaluating the safety and efficacy of cema-cel following lymphodepletion with fludarabine/cyclophosphamide and ALLO-647 in patients with R/R CLL/SLL. This trial will include patients with high-risk CLL treated with ≥ 1 prior line of BTKi-based therapy or those treated with ≥ 2 prior lines of therapy, including a BTKi and BCL2i. The primary endpoint of the phase 1b portion of this study is safety. Secondary endpoints include overall response rate, duration of response, time to response, and progression-free survival per investigator assessment. Up to approximately 40 patients may be enrolled in sites across the United States. This study leverages currently active ALPHA2 trial sites in the U.S. which should allow it to advance quickly. We opened enrollment in the first quarter and anticipate initial data by year end 2024.

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.

Results from the Phase 1 ALLO-316 TRAVERSE Trial

On April 17, 2023, 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. 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 March 23, 2023, in the ten patients with tumors known to express CD70, the disease control rate (DCR) was 100% including three patients who achieved a partial response (PR) (two confirmed and one unconfirmed, with the longest response lasting until month eight). Cell expansion in patients with CD70 positive disease was robust and there was a trend toward greater tumor shrinkage in patients with high CD70 expression.

| | All Patients (n=18) | CD70+ Patients (n=10) |
|------------------------------------|------------------------|--------------------------|
| Overall Response Rate (ORR), n (%) | 3 (17) | 3 (30) |
| Disease Control Rate (DCR), n (%) | 16 (89) | 10 (100) |
| Partial Response (PR), n (%) | 3 (16) | 3 (30) |

[Table of Contents](#)

There were 19 patients evaluable for safety, and the data demonstrated an adverse event profile generally consistent with autologous CAR T therapies. One dose limiting toxicity of Grade 3 auto-immune hepatitis occurred in the second dose level. Grade 3+ prolonged cytopenia was observed in three patients (18%). CRS was all low grade with the exception of one case of Grade 3 CRS. Neurotoxicity, which is now defined more broadly, was generally low grade and reversible with most events being fatigue or headache. There were no cases of ICANS. Infections occurred in eight patients of which four were Grade 3+ including one Grade 5 respiratory failure due to Covid-19 infection deemed unrelated to study treatment. Grade 3+ prolonged cytopenia was observed in three patients (16%). There were no cases of GvHD.

| | All Patients (n=19) | |
|---------------------------|------------------------|----------------|
| | All Grades n (%) | Gr 3+ n (%) |
| CRS | 11 (58) | 1 (5) |
| Infusion-Related Reaction | 1 (5) | 0 |
| Neurotoxicity | 13 (68) | 2 (11) |
| ICANS | 0 | 0 |
| GvHD | 0 | 0 |
| Infection | 8 (42) | 4 (21) |
| Prolonged Gr3+ Cytopenia | 0 | 3 (16) |

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. TRAVERSE will continue to explore varying cell dose and lymphodepletion regimens in CD70 positive RCC patients.

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. We have recently implemented a protocol amendment to further maximize the benefit-risk of ALLO-316 in patients with CD70+ RCC.

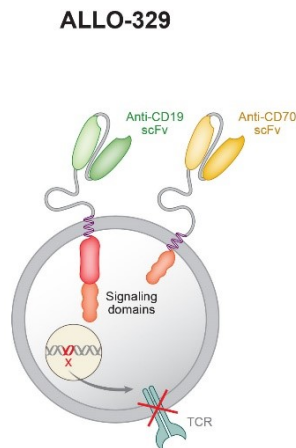
The next update from this trial is planned for a medical forum in second quarter 2024 and will discuss the safety algorithm that is believed to be an important advance for the TRAVERSE trial. A more robust data update from the ongoing trial with the updated protocol is planned for later in 2024.

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.

[Table of Contents](#)

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.



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. Initiation of this Phase 1 trial with ALLO-329 is expected in early 2025.

Future Opportunities

Currently, we remain focused on our four 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.

Historically, we have used a CDMO to manufacture our cell-based product candidates in the United States, and we managed all other aspects of the supply, including planning, CDMO oversight, disposition and distribution logistics. The CDMO is subject to cGMP requirements, using qualified equipment and materials. We also have utilized 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.

[Table of Contents](#)

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 that we call Cell Forge 1 (CF1). We completed the intended build-out of the majority of the facility at the end of 2020.

We are currently utilizing CF1 for clinical manufacturing of our product candidates. We continue to rely upon certain third-party contractors to manufacture cGMP raw materials. Introducing product manufactured at CF1 into an ongoing clinical trial will require that we meet certain regulatory conditions, such as establishing comparability with the product candidates manufactured at our CDMO, and our inability to meet such conditions would result in investment of additional resources and delay of our clinical trial timeline.

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

On December 14, 2020, we entered into a License Agreement with Allogene Overland Biopharm (CY) Limited (Allogene Overland), a joint venture established by us and Overland Pharmaceuticals (CY) Inc., pursuant to a Share Purchase Agreement, dated December 14, 2020, for the purpose of developing, manufacturing and commercializing allogeneic CAR T cell therapies for patients in greater China, Taiwan, South Korea and Singapore.

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 7 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

[Table of Contents](#)

certain antigen targets, including BCMA, CD70, FLT3, DLL3 and Claudin 18.2, and have U.S. rights to these patents for CD19. We also have rights to a Cellectis U.S. patent 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, 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-715, ALLO-605 and ALLO-316, 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). 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.

Autologous cell therapies directed at BCMA have been commercialized by BMS and Janssen, 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. Janssen 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 are expected to gain label extensions into this market.

[Table of Contents](#)

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., Autolus Therapeutics plc, CARGO Therapeutics, Inc. Eureka Therapeutics, Inc., Galapagos NV, Gilead Sciences, Inc., Gracell Biotechnologies, Inc., ImmPACT Bio, USA Inc., Instil Bio, Inc., Iovance Biotherapeutics, Inc., Legend Biotech Corp., Mustang Bio, Inc., Novartis International AG, 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., Fate Therapeutics, Inc., Gilead Sciences, Inc., Imugene Ltd., Intellia Therapeutics, Inc., Legend Biotech Corp., Poseida Therapeutics, Inc., 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, Collectis has several fully-owned allogeneic CAR T programs that could compete with programs that fall outside our agreement with Collectis.

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, Harpoon Therapeutics, Inc., Immunocore Holdings plc, Johnson & Johnson, MacroGenics, 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., Atara Biotherapeutics, Inc., Autolus Therapeutics plc, BMS, Cabaletta Bio, Inc., Cartesian Therapeutics, Inc., CRISPR Therapeutics AG, Fate Therapeutics, Inc., Gracell Biotechnologies, Inc., ImmPACT Bio USA, Inc., Kyverna Therapeutics, Inc., Nkarta, Inc., Novartis, and Sana Biotechnology, 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.

[Table of Contents](#)

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

[Table of Contents](#)

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.

[Table of Contents](#)

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.

The FDA granted orphan drug designation to ALLO-715 and ALLO-605 for the treatment of multiple myeloma.

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

[Table of Contents](#)

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.

We have received RMAT designation for ALLO-715 and cema-cel in r/r multiple myeloma and r/r LBCL, respectively, and fast track designation for cema-cel, ALLO-605, ALLO-316 and ALLO-647.

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

[Table of Contents](#)

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 PHS Act 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

[Table of Contents](#)

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

[Table of Contents](#)

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

[Table of Contents](#)

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,

[Table of Contents](#)

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. The ACA, among other things, increased the minimum level of Medicaid rebates payable by manufacturers of brand name drugs; required collection of rebates for drugs paid by Medicaid managed care organizations; required manufacturers to participate in a coverage gap discount program, under which they must agree to offer point-of-sale discounts (increased to 70 percent, effective as of January 1, 2019) off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D; imposed a non-deductible annual fee on pharmaceutical manufacturers or importers who sell certain "branded prescription drugs" to specified federal government programs, implemented a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted, or injected expanded the types of entities eligible for the 340B drug discount program; expanded eligibility criteria for Medicaid programs; created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and established a Center for Medicare Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

There have been legal and political challenges to certain aspects of the Affordable Care Act. For example, President Trump signed several executive orders and other directives designed to delay, circumvent, or loosen certain requirements mandated by the Affordable Care Act. In December 2017, Congress repealed the tax penalty for an individual's failure to maintain Affordable Care Act-mandated health insurance, commonly known as the "individual mandate", as part of legislation enacted in 2017, informally titled the Tax Cuts and Jobs Act of 2017 (Tax Act). In addition, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the Affordable Care Act's mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminated the health insurer tax. On June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argue the Affordable Care Act is unconstitutional in its entirety because the "individual mandate" was repealed by Congress.

In addition, there have been a number of health reform initiatives that have impacted the Affordable Care Act. For example, the Bipartisan Budget Act of 2018 (BBA), among other things, amended the Affordable Care Act, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole". In December 2018, CMS published a final rule permitting further collections and payments to and from certain Affordable Care Act qualified health plans and health insurance issuers under the Affordable Care Act risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. On August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 (IRA) 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, President Obama signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select

[Table of Contents](#)

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, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

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. At the federal level, the Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. In addition, in July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue to advance these principles. Further, the IRA, among other things (i) directs HHS to negotiate the price of certain high-expenditure, single-source drugs and biologics covered under Medicare and (ii) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions will take effect progressively starting in fiscal year 2023. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations, although the Medicare drug price negotiation program is currently subject to legal challenges. In response to the Biden administration's October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the CMS Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. Further, on December 7, 2023, the Biden administration announced an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act. 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. 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

[Table of Contents](#)

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 may process personal or sensitive data. Accordingly, we are, or may 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.

[Table of Contents](#)

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, and allows for a new cause of action for certain data breaches. In addition, the California Privacy Rights Act of 2020 (CPRA), effective January 1, 2023, expanded the CCPA by, among other things, giving California residents the ability to limit use of certain sensitive personal data, establishing restrictions on personal data retention, expanding the types of data breaches that are subject to the CCPA's private right of action, and establishing a new California Privacy Protection Agency to implement and enforce the CCPA. As our business progresses, the CCPA and the CPRA 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—including Virginia, Connecticut, Utah, and Colorado—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, 2024, we had 233 total employees, of which 232 are full-time. Of our full-time employees, 50 hold Ph.D. and/or M.D. degrees, and 189 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) diversity, equity, inclusion and belonging, 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.

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 diversity of thought, background 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

[Table of Contents](#)

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.

Diversity, Equity, Inclusion and Belonging

We are committed to cultivating, fostering, and preserving a culture of diversity, equity, inclusion and belonging (DEIB). We foster an inclusive environment through respect, collaboration, and open communication. We embrace and encourage differences in age, color, disability, ethnicity, family or marital status, gender identity or expression, language, national origin, culture or customs, physical and mental ability, political affiliation, race, religion, sexual orientation, socio-economic status, veteran status, and other characteristics that make our employees unique. We also embrace differences in experience and background, and welcome diversity of opinions and thought when making decisions.

As of March 1, 2024, our employees were self-reportedly 51% women. Of our Director-level and above employees, 47% were self-reportedly women.

In addition, as of March 1, 2024, 67% of all employees were self-reportedly ethnic or racial minorities in the U.S., with 49% Asian, 2% Black or African American, 8% Hispanic or Latino and 8% of other minority groups or two or more races. Of our Director-level and above employees, 48% were self-reportedly ethnic or racial minorities in the U.S., with 31% Asian, 5% Black or African American, 4% Hispanic or Latino and 8% of other minority groups or two or more races.

Although we are proud of our efforts to attract the best talent from the broadest pool of talent, we continue to focus on broadening our outreach to underrepresented groups by posting our open positions on top job boards to seek diverse, qualified candidates. We have and will continue to conduct unconscious bias training for interviewers and hiring managers. Our recruiters and hiring managers have active talent recruitment strategies, including the use of diverse slates.

Our DEIB 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 inclusive 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 diversity and inclusion.

To champion our efforts in this area, we established a governance structure and formed a DEIB Committee which is comprised of employees of various levels, departments and backgrounds. The DEIB Committee formalized a DEIB mission statement and also advanced a DEIB policy that sets forth our commitment to the importance of DEIB and the responsibility of our employees to adhere to our policy, including by treating others with dignity and respect at all times. Pursuant to our DEIB policy, all employees are also encouraged to attend and complete annual diversity awareness training to enhance their knowledge to fulfill this responsibility. The DEIB 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 included 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 equitably within a reasonable range, taking into consideration factors such as role; market data; internal equity; 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 equity analysis which we believe demonstrates that our compensation practices and structure are equitable.

We plan to continue to seek feedback from the DEIB Committee, and all our employees to help us achieve our full potential.

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 2023, we recruited over 29 new employees. Our average time to hire was less than 90 days and over 95% of candidates accepted our offers.

[Table of Contents](#)

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. For instance, we have an annual required manager training that allows managers to learn and practice fundamental management skills to enable them to be more effective managers. 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 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, 2023, we reported a net loss of \$327.3 million. As of December 31, 2023, we had an accumulated deficit of \$1.6 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 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, 2023, we had \$448.7 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. 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, 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.

[Table of Contents](#)

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.

Under current law, 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 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. 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. For instance, it will take additional time and expense to transfer any product manufacturing to CF1, which may be further delayed if we are unable to meet regulatory conditions.

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.

[Table of Contents](#)

We are also advancing product candidates against unexplored targets and with new technology. For example, in our TRAVERSE trial we are advancing ALLO-316 against a target, CD70. ALLO-316 may have limited efficacy, even accounting for the selection of patients with CD70 positive tumors, or have off-target toxicities. Since CD70 is found on activated T and other immune cells, ALLO-316 may also cause fratricide resulting in the loss of ALLO-316 cells, either during the ALLO-316 manufacturing process or after ALLO-316 is 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 CRS, 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 MRD. As part of this trial, under Investigational Device Exemption (IDE), we plan to use an investigational assay developed by Foresight Diagnostics to determine if a patient is MRD positive. 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. 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 or is not timely performed on patient samples, it could negatively impact the rate of enrollment or the clinical results of the ALPHA3 trial. 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 regulatory agencies 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 incorporates a companion diagnostic. 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 EMA 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 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. 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 and our BCMA program candidates are 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 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.

[Table of Contents](#)

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.

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, serious infections, prolonged cytopenia and hypogammaglobulinemia, hemophagocytic lymphohistiocytosis/macrophage activation syndrome (HLH/MAS) 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 fludarabine, cyclophosphamide and ALLO-647, that may cause serious adverse events. For instance, because the regimen will cause a transient 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 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 may not agree that sufficient mitigating procedures are included in our protocols to address such side effects, and FDA 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 oncology manufacturing process includes gene engineering by using lentivirus and TALEN 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. In addition, we have

[Table of Contents](#)

observed liver enzyme elevations, including one adverse event – autoimmune hepatitis – that qualified as a dose-limiting toxicity in our TRAVERSE trial.

We may also combine the use of our product candidates with other investigational 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 foreign regulatory authorities will interpret the results as we do, and more trials could be required before we submit our product candidates for approval. To the extent that the results of the trials are not satisfactory to the FDA or 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.

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 may not be consistent with the Phase 1 results. Furthermore, because patients in ALPHA3 will only have MRD after front-line treatment, and not radiographically measurable disease as was required for patients treated in our Phase 1 trials, 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.

[Table of Contents](#)

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 to commence additional clinical trials on the timelines we expect, and even if we are able to, the FDA may not permit us to proceed.

We plan to submit INDs or IND amendments for additional product candidates or indications in the future. We cannot be sure that submission of an IND or IND amendment will result in the FDA 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 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 all 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 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;
- delays in reaching a consensus with regulatory agencies on study design;
- delays in reaching agreement on acceptable terms with prospective contract research organizations (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 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

[Table of Contents](#)

finding that presents uncertain or unreasonable risk to clinical trial participants; a negative finding from an inspection of our clinical study operations or study sites; developments on trials conducted by competitors for related technology that raises FDA concerns about risk to patients of the technology broadly; or if the FDA finds 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 GCP requirements or applicable 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; and
- 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;
- 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, in order to transition manufacturing of certain of our product candidates from our CDMO to our manufacturing facility, we will be required to meet certain regulatory conditions, such as establishing comparability with the product candidates manufactured at our CDMO, and our inability to meet such conditions would result in investment of additional resources, a delay in using our manufacturing facility for production and extend our clinical trial timelines. Similar conditions may apply if we make manufacturing or formulation changes to our product candidates. 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 delaying, suspending 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

[Table of Contents](#)

detrimental impact on the efficacy of the treatment. 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 ALPHA2 CLL cohort, ALPHA3 and TRAVERSE trials, we may face enrollment challenges, including an unwillingness of sites 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 clinical trials due to the previous clinical hold, and will depend on many factors, including:

- the patient eligibility criteria defined in the protocol;
- 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 IVD assay in the TRAVERSE trial to screen for patients with CD70+ tumors and will utilize an MRD assay in the ALPHA3 trial to screen for patients who are MRD positive, both of which are restricting or will restrict 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 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.

[Table of Contents](#)

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 cancer treatment, 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, 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 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 impact our ability to enroll patients with R/R multiple myeloma or LBCL 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 we are targeting, as well as the subset of patients with these cancers 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. 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, or may not be amenable to treatment with our product candidates.

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 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 and solid tumors. 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 approval. Similar conditions may apply if we make process changes to our product candidates, as

[Table of Contents](#)

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 ALLO-501A, 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 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 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.

[Table of Contents](#)

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;
- differing standards and privacy requirements for the conduct of clinical trials;
- 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 Overland Pharmaceuticals (CY) Inc., 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

[Table of Contents](#)

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 Executive Vice President, 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. The value to employees of stock options and RSU awards that vest over time 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.

Our reduction in force undertaken to extend our cash runway and focus more of our capital resources on our prioritized research and development programs might not achieve our intended outcome.

In January 2024, our board of directors approved a reduction in force affecting approximately 22% of our workforce, in order to preserve cash and prioritize investment in our core clinical programs. The reduction in force may result in unintended consequences and costs, such as the loss of institutional knowledge and expertise, attrition beyond the intended number of employees, decreased morale among our remaining employees, and the risk that we may not achieve the anticipated benefits of the reduction in force. In addition, while positions have been eliminated, certain functions necessary to our operations remain, and we might not successfully distribute the duties and obligations of our terminated employees among our remaining employees. The reduction in workforce could also make it difficult for us to pursue, or prevent us from pursuing, new opportunities and initiatives due to insufficient personnel, or require us to incur additional and unanticipated costs to hire new personnel to pursue such opportunities or initiatives. If we are unable to realize the anticipated benefits from the reduction in force, or if we experience significant adverse consequences from the reduction in force, our business, financial condition and results of operations may be materially adversely affected.

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;

[Table of Contents](#)

- 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 Collectis, 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 Collectis, Servier, Notch, Antion, our strategic collaboration with Foresight Diagnostics, and our joint venture with Overland Pharmaceuticals (CY) Inc. 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;

[Table of Contents](#)

- 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 Overland Pharmaceuticals (CY) Inc. 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 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.

In the ordinary course of our business, we collect, process, receive, store, use, generate, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, processing) 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). We rely upon certain third parties, such as CROs and CDMOs, to process our proprietary, confidential and sensitive information. We may also share or receive sensitive information with our partners, 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 we (or a third party upon whom we rely) experience a security incident or are perceived to have experienced a security incident, we may also experience adverse consequences.

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 upon which we rely. 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 upon which we rely, 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 upon which we rely 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 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.

[Table of Contents](#)

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-party service providers 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 and 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 the third-party information technology systems that support us and our services. 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.

Any of the previously identified or similar threats could cause a security incident or other interruption. A security incident or other interruption could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive information. A security incident or other interruption could disrupt our ability (and that of third parties upon whom we rely) to manufacture or deliver our product candidates.

We may expend significant resources, or modify our business activities and operations, including our clinical trial activities, in an effort to protect against security incidents. 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.

Although we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. We have experienced attempts to compromise our information technology systems or otherwise cause a security incident, but, to our knowledge, such attempts have been unsuccessful. In addition, from time to time, our vendors inform us of security incidents. To date, our review of such incidents as reported to us did not reveal material information being lost, Allogene-specific security vulnerabilities or provide any useful information or insight into our systems or environment. However, we may not have all information related to such incidents and future incidents could have an adverse impact on our business.

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 upon which we rely). We may, however, be unable to detect and remediate vulnerabilities in our information technology systems because such threats and techniques change frequently, are often sophisticated in nature, and may not be detected until after a security incident has occurred, meaning that such vulnerabilities could be exploited. Unremediated high risk or critical vulnerabilities pose material risks to our business. Further, we may experience delays in developing and deploying remedial measures designed to address any such identified vulnerabilities. We may 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.

Applicable data protection laws, privacy policies, data protection obligations and public company disclosure obligations may require us to notify relevant stakeholders, including affected individuals, regulators and investors, of certain security incidents. Such disclosures are costly, and the disclosures or the failure to comply with such requirements could lead to adverse consequences. If we (or a third party upon whom we rely) experience a security incident or are perceived to have experienced a security incident, we may also 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

[Table of Contents](#)

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 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 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 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 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. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

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 are subject to stringent and evolving privacy laws, regulations and standards as well as policies, contracts and other obligations related to data privacy and security. Our 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, or may 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

[Table of Contents](#)

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, as amended by the California Privacy Rights Act of 2020 (CPRA) (collectively, 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 of up to \$7,500 per intentional violation and allows private litigants affected by certain data breaches to recover significant statutory damages. Although there are limited exemptions for clinical trial data under the CCPA, as our business progresses, the CCPA may become applicable and 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. While many of these state laws, like the CCPA, also exempt some data processed in the context of clinical trials, these developments and others like them will further complicate compliance efforts, and increase legal risk and compliance costs for us and the third parties upon whom we rely.

Outside the United States, there are an increasing number of laws, regulations and industry standards concerning governing 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) may apply to our operations and 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 may 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. Other jurisdictions may adopt similarly stringent interpretations of their 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

[Table of Contents](#)

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.

In addition, privacy advocates and industry groups have proposed, and may 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. If any of our privacy notices or related materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, 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.

Our obligations related to data privacy and security are quickly changing, becoming increasingly stringent fashion, 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-party collaborators, service providers, contractors, consultants or other 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 on which we rely fail, or are perceived to have failed, to address or comply with obligations related to data privacy and security obligations, 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 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;

[Table of Contents](#)

- 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 that 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. 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, 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 regulatory authorities have limited experience with development of allogeneic T cell therapies for cancer; 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.

Collectis' 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. Collectis 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. This technology may also not be shown to be effective in clinical studies that Collectis, we or other licensees of Collectis 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

[Table of Contents](#)

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, Collectis 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 Collectis' TALEN gene-editing technology to inactivate a gene coding for TCR α , 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 Collectis 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 Collectis, through our agreement with Servier, for exclusive rights to UCART19, ALLO-501 and ALLO-501A. Any other gene-editing technology used to research and develop product candidates directed at targets not covered by our existing agreements with Collectis and Servier will require significant investment and time for advancement. In addition, the Collectis gene-editing technology may fail to produce viable product candidates. Moreover, both Servier and Collectis may terminate our respective agreements in the event of a material breach of the agreements, or upon certain insolvency events. Collectis has challenged and may in the future challenge certain performance by Servier, such as its development of products licensed under the Collectis-Servier Agreement in ALL, and any failure by those parties to resolve such matters may have an adverse impact on us. If our agreements were terminated or we required other gene editing technology, such a license or technology may not be available to us on reasonable terms, or at all, and advancing other gene editing technology would require significant resources.

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

On September 15, 2022, Servier sent a notice of discontinuation (Discontinuation) of its involvement in the development of all CD19 Products pursuant to the Servier Agreement. Despite there being no obligation under the terms of the Servier Agreement to do so, Servier believes that we had to exercise the Ex-US Option within a limited timeframe that passed. Servier also communicated to us that it believes it does not have to contribute to development costs 90 days from its notice of discontinuation, pending our exercise of the Ex-US Option. We disagree with these assertions relating to both the maintenance of the Ex-US Option as well as contribution to development costs during our consideration of the Ex-US Option. Any failure of Servier to fulfill its obligations may be harmful to us.

Servier also licenses certain rights to the CD19 Products from Collectis and sublicenses those rights to us. Collectis has challenged certain performance by Servier and has also challenged the ability of Servier to grant a world-wide sublicense pursuant to our Ex-US Option. Servier's Discontinuation and any subsequent actions may further strain our relationship with Servier, as well as the relationships between Servier and Collectis, and between us and Collectis. Any failure to resolve Collectis challenges could impact our agreement with Servier and could have a significant adverse impact on our business, financial condition and prospects.

Additionally, in December 2022, Servier sent us a notice for material breach due to our purported refusal to allow an audit of certain manufacturing costs under our cost share arrangement. While we do not believe Servier has such an audit right, we submitted to a review of our manufacturing costs of CD19 Products to recover outstanding manufacturing costs owed by Servier to us. In July 2023, Servier sent us a second notice for material breach alleging that we overcharged Servier based on Servier and its accounting firm's review of costs eligible for cost-sharing under the Servier Agreement. We disagree with the material breach allegations and we are disputing such allegations. Absent a resolution between the parties, disputed matters may be resolved in arbitration as specified in the Servier Agreement. While we intend to vigorously pursue our rights and remedies to dispute Servier's allegations and enforce our contractual rights, any legal outcome is inherently uncertain, will add to our costs and divert management time, and could result in a termination of the Servier Agreement which would have a significant adverse impact on our business, financial condition, and prospects.

Under the Servier Agreement, Servier sublicenses to us certain rights it has licensed from Collectis relating to Collectis' TALEN gene editing technology (Collectis-Servier Primary License). In its Form 20-F filed with the SEC, Collectis has asserted that it believes that Servier has not complied with its performance obligations under the Collectis-Servier Primary License, which Collectis believes may involve material breaches of the Collectis-Servier Primary License. There is a risk that Collectis may terminate the Collectis-Servier Primary License. The Servier Agreement provides us with certain rights to obtain a direct license with Collectis in the event the Collectis-Servier Primary License is terminated, however, there can be no assurance that we will be able to obtain such a direct license and failure to do so 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.

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, 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 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 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.

[Table of Contents](#)

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 any 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 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 product candidates, we may continue to use CDMOs from time to time to manufacture product candidates in the United States while we manage all other aspects of the supply, including planning, CDMO oversight, disposition and distribution logistics. For example, in the past, Servier was responsible for UCART19 manufacturing, and experienced UCART19 supply issues that limited its ability to recruit new patients. There can be no assurance that we will not experience supply or manufacturing issues in the future.

[Table of Contents](#)

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 February 2024 Catalent, Inc. and Novo Holdings announced that they have entered into a merger agreement under which Novo Holdings will acquire Catalent. The merger is expected to close towards the end of 2024, and shortly thereafter Novo Holdings intends to sell three Catalent fill-finish sites and related assets acquired in the merger to Novo Nordisk. ALLO-647 is manufactured at one of these sites, and there is a risk that the pendency of the merger and/or the merger itself could impact our ability to utilize the Catalent site for manufacturing ALLO-647. If we are unable to manufacture ALLO-647 at Catalent, we would be required to identify, qualify and establish an alternative manufacturing site and we may be unable to do so in a timely manner, if at all, which could significantly delay our clinical development timelines.

We have built our own manufacturing facility for cell products (CF1) and are in the process of transitioning the manufacture of certain product candidates to our manufacturing facility. Manufacturing product candidates in our own facility requires that we meet certain regulatory conditions, which may delay or extend our clinical trial timelines. As we transition more manufacturing to 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.

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 may have questions regarding any replacement contractor. This may require new testing and regulatory interactions. In addition, a new manufacturer would have to be educated in, or develop substantially equivalent processes for, production of our products after receipt of FDA questions, if any.
- Our third-party manufacturers might be unable to timely formulate and manufacture our product or produce the quantity and quality required to meet our clinical and commercial needs, if any.
- Contract manufacturers may not be able to execute our manufacturing procedures appropriately.
- 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 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.
- 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 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.

[Table of Contents](#)

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 have and are facing 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 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

[Table of Contents](#)

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 our joint venture with Overland Pharmaceuticals (CY) Inc. in China and may do so again in the future. 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 regulatory approval process is lengthy and time-consuming, and we may experience significant delays in the clinical development and regulatory approval of our product candidates.

The research, testing, manufacturing, labeling, approval, selling, import, export, marketing, and distribution of drug products, including biologics, are subject to extensive regulation by the FDA and other regulatory authorities in the United States. We are not permitted to market any biological drug product in the United States until we receive approval of a BLA from the FDA. We have not previously submitted a BLA to the FDA, or similar approval filings to comparable foreign authorities. A BLA 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 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.

We expect the novel nature of our product candidates to create further challenges in obtaining regulatory approval. For example, the FDA has 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 may have difficulty accepting. The FDA may also require a panel of experts, referred to as an Advisory Committee, to deliberate on the adequacy of the safety and efficacy data to support licensure. The opinion of the Advisory Committee, although not binding, may have a significant impact on our ability to obtain licensure of the product candidates based on the completed clinical trials, as the FDA often adheres to the Advisory Committee's recommendations. 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;
- 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;

[Table of Contents](#)

- 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 IRBs for the institutions in which such trials are being conducted or by the FDA or other 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 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's 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 EU 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 believe our product candidates may receive a similar recommendation.

[Table of Contents](#)

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 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 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 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 ALPHA2 (CLL) and ALPHA3 trials, the FDA 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 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 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 grants accelerated approval for our product candidates, as a condition for accelerated approval, the FDA 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 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 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 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 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 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 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 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 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 or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval; and

[Table of Contents](#)

- 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 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 the FDA create additional regulatory uncertainty for us 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 though part one of the ALPHA3 trail. 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.

If we, or our collaborators, are required by the FDA, or similar 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 before, or concurrent with, approval of the therapeutic product and before a product can be commercialized. The approval of a companion diagnostic as part of the therapeutic product's labeling limits the use of the therapeutic product to only those patients who are determined to have MRD that the companion diagnostic was developed to detect.

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. Foresight Diagnostics intends to file an IDE with the FDA seeking approval of PhasEd-Seq as a companion diagnostic. There can be no assurance that Foresight Diagnostic will timely file its IDE, or that the FDA will approve Foresight Diagnostics' IDE, which could significantly delay the start of our ALPHA3 trial.

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 as a companion diagnostic test. A delay or failure by

[Table of Contents](#)

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 ALLO-715 and cema-cel and fast track designation for ALLO-605 and ALLO-316. 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

[Table of Contents](#)

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 Allogene Overland, a joint venture established by us and Overland Pharmaceuticals (CY) Inc. 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.

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 regulatory authorities;
- limitations or warnings contained in the labeling approved by the FDA;
- 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;

[Table of Contents](#)

- 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. While we have internal efforts directed at ESG matters and preparations for any increased required future disclosures, we may be perceived to be not acting responsibly in connection with these matters, which could negatively impact us. Moreover, the SEC has recently proposed, and may continue to propose, certain mandated ESG reporting requirements, such as the SEC's proposed rules designed to enhance and standardize climate-related disclosures, which, if finally approved, would 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. In addition, we currently do not report our environmental emissions, and lack of reporting could result in certain investors declining to invest in our common stock.

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.

[Table of Contents](#)

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 Collectis. 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 Collectis 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 Collectis 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, Collectis has challenged and may in the future challenge certain performance by Servier, such as its development of products licensed under the Collectis-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, Servier has sent us a notice for material breach alleging that we overcharged them for costs eligible for cost-sharing under our license agreement with them. In addition, the parties are disputing the impact of Servier's discontinuation of ex-US development on the parties' rights and obligations under the license agreement. If we are unable to resolve our dispute with Servier, or if other disputes 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. We also have an exclusive worldwide license from Collectis 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;

[Table of Contents](#)

- 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 or that at any time contained 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 going forward 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 Allogene Overland or its affiliates in certain developing countries, and we cannot be certain that we or Allogene Overland 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

[Table of Contents](#)

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 infringe their patents or are otherwise employing their proprietary technology without authorization and may sue us. 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. 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 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 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 candidates 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.

[Table of Contents](#)

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

[Table of Contents](#)

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 Allogene Overland 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 Allogene Overland 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;

[Table of Contents](#)

- 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 target markets;
- our ability to successfully treat additional types of cancers or at different stages;
- 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

[Table of Contents](#)

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.

We have identified a material weakness in our internal control over financial reporting. This material weakness could continue to adversely affect our ability to report our results of operations and financial condition accurately and in a timely manner.

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.

As described elsewhere in this Annual Report, we have identified a material weakness in our internal control over financial reporting. As a result of this material weakness, our management has concluded that our internal control over financial reporting was not effective as of December 31, 2023. For a discussion of management's consideration of the material weakness identified, see Part II, Item 9A: Controls and Procedures included in this Annual Report.

To respond to this material weakness, we plan to devote significant effort and resources to the remediation and improvement of our internal control over financial reporting. While we have processes to identify and appropriately apply applicable accounting requirements, we plan to enhance these processes to better evaluate our research and understanding of the nuances of the complex accounting standards that apply to our financial statements. Our plans at this time include retaining third-party subject matter experts with significant relevant experience to help with accounting treatment of significant non-routine transactions. The elements of our remediation plan can only be accomplished over time, and we can offer no assurance that these initiatives will ultimately have the intended effects.

Any failure to maintain such internal control could adversely impact our ability to report our financial position and results from operations on a timely and accurate basis. If our financial statements are not accurate, investors may not have a complete understanding of our operations. Likewise, if our financial statements are not filed on a timely basis, we could be subject to sanctions or investigations by the stock exchange on which our common stock is listed, the SEC or other regulatory authorities. In either case, a material adverse effect on our business could be the result of ineffective internal controls. Ineffective internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our stock.

We can give no assurance that the measures we plan to take in the future will remediate the material weakness identified or that any additional material weaknesses or restatements of financial results will not arise in the future due to a failure to implement and maintain adequate internal control over financial reporting or circumvention of these controls. In addition, even if we are successful in strengthening our controls and procedures, in the future those controls and procedures may not be adequate to prevent or identify irregularities or errors or to facilitate the fair presentation of our financial statements.

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.

[Table of Contents](#)

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.

[Table of Contents](#)

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 cybersecurity 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; 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, 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.

[Table of Contents](#)

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 and mitigation of risks from cybersecurity threats. Members of the Audit Committee receive scheduled 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 Executive Director/Head of IT. Our Director of IT Security has over 13 years of experience leading IT security and has certifications including CISSP and CCSP. Our Executive Director IT Data Management, Analytics and Integration has over 20 years of experience in IT, data engineering, and data analytics.

Our Director 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 Executive Director of IT Data Management, Analytics and Integration 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 Director of IT Security, Data Management, Analytics and Integration, and General Counsel. Director of IT Security, Data Management, Analytics and Integration, 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.

[Table of Contents](#)

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”.

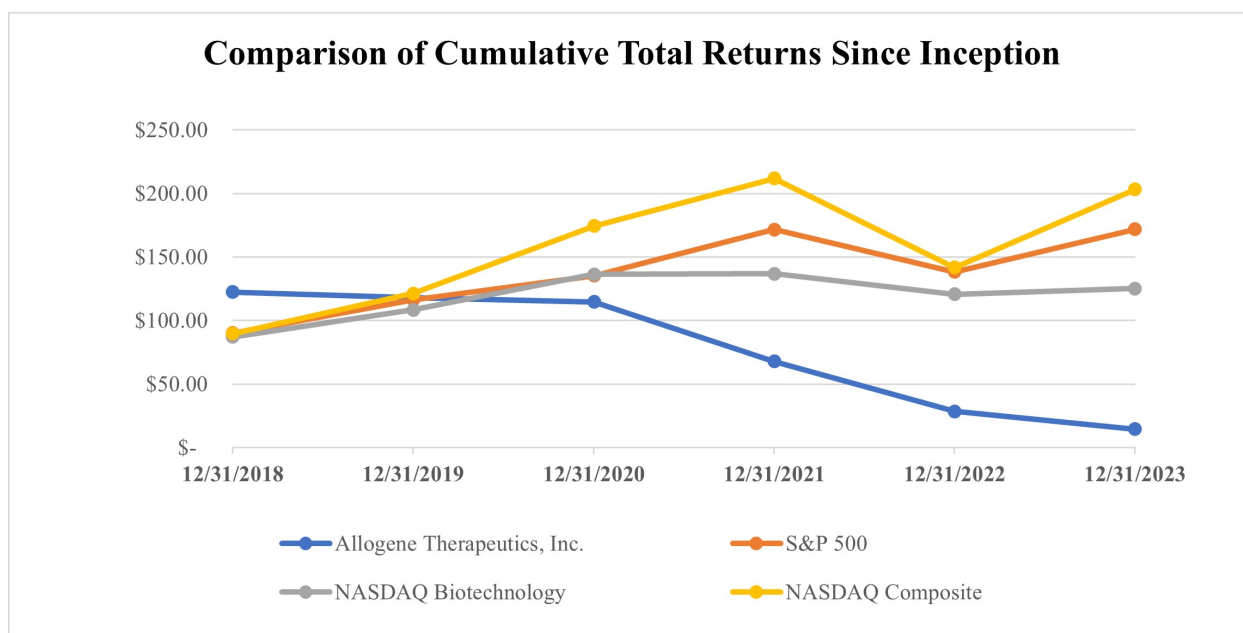
Holders of Common Stock

As of March 14, 2024, there were approximately 68 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 October 11, 2018 (the date our common stock commenced trading on The Nasdaq Global Select Market) through December 31, 2023, 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 | | | | | | |
|-----------------------------|------------------------------------|------------|------------|------------|------------|------------|------------|
| | 10/11/2018 | 12/31/2018 | 12/31/2019 | 12/31/2020 | 12/31/2021 | 12/31/2022 | 12/31/2023 |
| Allogene Therapeutics, Inc. | \$ 100.00 | \$ 122.41 | \$ 118.09 | \$ 114.73 | \$ 67.82 | \$ 28.59 | \$ 14.59 |
| S&P 500 | \$ 100.00 | \$ 90.28 | \$ 116.35 | \$ 135.26 | \$ 171.64 | \$ 138.27 | \$ 171.77 |
| Nasdaq Biotechnology | \$ 100.00 | \$ 87.25 | \$ 108.54 | \$ 136.42 | \$ 135.56 | \$ 120.77 | \$ 125.28 |
| Nasdaq Composite | \$ 100.00 | \$ 89.81 | \$ 121.45 | \$ 174.45 | \$ 211.76 | \$ 141.67 | \$ 203.18 |

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

[Table of Contents](#)

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 disease. Earlier this year, however, we announced our 2024 Platform Vision under which we are now focusing on four core programs.

We are currently focused on developing cemacabtagene ansegedleucel (cema-cel, previously ALLO-501A) in large B-cell lymphoma (LBCL) and chronic lymphocytic leukemia (CLL). We plan to initiate a pivotal Phase 2 clinical trial (ALPHA3) in mid-2024 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. 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 230 patients who achieve a complete response or partial response to 1L therapy, but who are MRD positive. The patients will be randomized to either consolidation with cema-cel or the current standard of care, which is observation. The design, with a primary endpoint of event free survival (EFS), will initially include two lymphodepletion arms (one with standard fludarabine and cyclophosphamide plus ALLO-647 and one with standard fludarabine and cyclophosphamide but without ALLO-647). One lymphodepletion arm will be discontinued following a planned interim analysis in mid-2025 designed to select the most appropriate regimen for this patient population. 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 initiated the Phase 1b cohort of our ALPHA2 trial to evaluate cema-cel following lymphodepletion with fludarabine/cyclophosphamide and ALLO-647 in patients with relapsed/refractory chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL). This cohort will include up to 40 patients, and we expect to release initial data by year-end 2024.

We are enrolling 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 American Association of Cancer Research (AACR) Annual Meeting in April 2023. We have implemented a protocol

[Table of Contents](#)

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. The next update from this trial is planned for a medical forum in the second quarter of 2024 and will discuss the algorithm. A more robust data update from the ongoing trial with the updated protocol is planned for later in 2024.

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. Initiation of this Phase 1 trial with ALLO-329 is expected in early 2025.

We are developing an anti-CD52 monoclonal antibody, ALLO-647, which is a proprietary component of our 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. We plan to select the lymphodepletion regimen with which we will complete enrollment in the study (Part B) in the first half of 2025.

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

On January 4, 2024, our board of directors approved a reduction in our workforce of approximately 22% of our employees in connection with our pipeline prioritization and clinical development strategy.

Since inception, we have had significant operating losses. Our net loss was \$327.3 million for the year ended December 31, 2023. As of December 31, 2023, we had an accumulated deficit of \$1.6 billion. As of December 31, 2023, we had \$448.7 million in cash and cash equivalents and investments and we expect our cash runway to fund operations into 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 Research and Development and License Agreements

Asset Contribution Agreement with Pfizer

In April 2018, we entered into an Asset Contribution Agreement (Pfizer Agreement) with Pfizer pursuant to which we acquired certain assets and assumed certain liabilities from Pfizer, including agreements with Collectis and Servier as described below, and other intellectual property for the development and administration of CAR T cells for the treatment of cancer. See Note 6 to our consolidated financial statements included elsewhere in this Annual Report for further description of the Pfizer Agreement.

Research Collaboration and License Agreement with Collectis

In June 2014, Pfizer entered into a Research Collaboration and License Agreement with Collectis. In April 2018, Pfizer assigned the agreement to us pursuant to the Pfizer Agreement. In March 2019, we terminated the agreement with Collectis and entered into a new license agreement with Collectis. See Note 6 to our consolidated financial statements included elsewhere in this Annual Report for further descriptions of the prior agreement with Collectis and the new license agreement with Collectis.

Exclusive License and Collaboration Agreement with Servier

In October 2015, Pfizer entered into an Exclusive License and Collaboration Agreement (Servier Agreement) with Servier 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.

On September 15, 2022, Servier sent a notice of discontinuation (Discontinuation) of its involvement in the development of all licensed products directed against CD19, including UCART19, ALLO-501 and cema-cel (collectively,

[Table of Contents](#)

CD19 Products), pursuant to the Servier Agreement. Servier's Discontinuation provides us with the right to elect a license to the CD19 Products outside of the United States (Ex-US Option) and does not otherwise affect our current exclusive license for the development and commercialization of CD19 Products in the United States. Upon any exercise of the Ex-US Option by us, our potential milestone payments with respect to ALLO-501A would increase for any first dosing in Phase 2, first dosing in Phase 3 and regulatory approval by €46 million in the aggregate. In addition, upon any such exercise of the Ex-US Option, Servier's obligation to reimburse us for 40% of the development costs for CD19 Products would cease. However, Servier has disputed the implications of the Discontinuation, namely whether development cost contributions continue and the timeframe during which we have the right to elect a license to CD19 Products outside of the United States. Moreover, in December 2022, Servier sent us a notice for material breach due to our purported refusal to allow an audit of certain manufacturing costs under our cost share arrangement. While we do not believe Servier has such an audit right, we submitted to a review of our manufacturing costs of CD19 Products to recover outstanding manufacturing costs owed by Servier to us. In July 2023, Servier sent us a second notice for material breach alleging that we overcharged Servier based on Servier and its accounting firm's review of costs eligible for cost-sharing under the Servier Agreement. We disagree with the material breach allegations and we are disputing such allegations. For more information, see "Risk Factors—*Servier's discontinuation of its involvement in the development of CD19 Products and Servier's disputes with us and Collectis may have adverse consequences.*"

See Note 6 to our consolidated financial statements included elsewhere in this Annual Report for further description of the Servier Agreement.

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.

The Notch Agreement includes a research collaboration to conduct research and pre-clinical development activities to generate engineered cells directed to our exclusive targets, which will be conducted in accordance with an agreed research plan and budget under the oversight of a joint development committee. In connection with the execution of the Notch Agreement, we made an upfront payment to Notch of \$10.0 million. In addition, we made a \$5.0 million investment in Notch's series seed convertible preferred stock, resulting in us having a 25% ownership interest in Notch's outstanding capital stock on a fully diluted basis immediately following the investment. In February 2021, we made an additional \$15.9 million investment in Notch's Series A preferred stock. In October 2021, we made an additional \$1.8 million investment in Notch's common stock. Immediately following this transaction, our share in Notch was 23.0% on a voting interest basis. See Note 6 to our consolidated financial statements included elsewhere in this Annual Report for further description of the Notch Agreement.

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, dated as of November 1, 2019. 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, we will be entitled to receive a percentage of upfront and/or milestone payments associated therewith up to a set cap, and will be entitled to a low, single-digit royalty on net sales of products containing a Released Target. In addition, with respect to our previous equity investments in Notch, the Amended Notch Agreement grants us certain anti-dilution protections up to certain limits for certain pre-IPO equity financings.

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. See Note 6 to our consolidated financial statements included elsewhere in this Annual Report for further description of the agreement with MD Anderson.

License Agreement with Allogene Overland Biopharm (CY) Limited

On December 14, 2020, we entered into a License Agreement with Allogene Overland Biopharm (CY) Limited (Allogene Overland), a joint venture established by us and Overland Pharmaceuticals (CY) Inc. (Overland), pursuant to a Share

[Table of Contents](#)

Purchase Agreement, dated December 14, 2020, 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). 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. See Note 6 to our consolidated financial statements included elsewhere in this Annual Report for further description of the License Agreement and Share Purchase Agreement with Allogene Overland.

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 million investment in Antion's preferred shares and the acquisition of warrants to purchase an additional \$3 million of Antion's preferred shares. See Note 6 to our consolidated financial statements included elsewhere in this Annual Report for further description of the Antion Agreement and the July 2023 amendment.

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 planned 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 the 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 an MRD assay for use as an in vitro diagnostic with cema-cel.

Components of Results of Operations

Revenues

As of December 31, 2023, our revenue has been exclusively generated from our collaboration and license agreement with Allogene Overland Biopharm (PRC) Co., Limited. See Notes 1 and 6 to our consolidated financial statements appearing elsewhere in this Annual Report for more information related to our recognition of revenue and the Allogene Overland 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, 2023 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;

[Table of Contents](#)

- 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.

We have reimbursed Servier for 60% of the costs associated with the prior development of UCART19, including for the long-term follow-up of patients in the CALM and PALL clinical trials of UCART19. We believe Servier is required to reimburse us for 40% of the costs associated with the development of ALLO-501 and cema-cel.

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 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.

We do not track most of our external research and development expenses by programs or product candidates because most of our external research and development expenses could be used for different programs or product candidates.

[Table of Contents](#)

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.

We expect our general and administrative expenses to increase over the next several years to support our continued research and development activities, manufacturing activities, potential commercialization of our product candidates and operating as a public company. These increases are anticipated to include increased costs related to the hiring of additional personnel, developing commercial infrastructure, fees to outside consultants, lawyers and accountants, and costs associated with being a public company such as expenses related to services associated with maintaining compliance with Nasdaq listing rules and SEC requirements, complying with and advancing environmental, social and governance matters, and insurance and investor relations costs.

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.

Other Income (Expenses)

Other income (expenses) consists 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 investment.

Results of Operations

Comparison of the Years Ended December 31, 2023, 2022 and 2021

The following sets forth our results of operations for the years ended December 31, 2023, 2022, and 2021 (in thousands):

| | Year Ended December 31, | | | Change | |
|---------------------------------------|-------------------------|---------------|---------------|--------------|--------------|
| | 2023 | 2022 | 2021 | 2023 vs 2022 | 2022 vs 2021 |
| | | (As Restated) | (As Restated) | | |
| Collaboration revenue - related party | \$ 95 | \$ 156 | \$ 114,089 | \$ (61) | \$ (113,933) |
| Operating expenses: | | | | | |
| Research and development | 242,914 | 256,387 | 220,176 | (13,473) | 36,211 |
| General and administrative | 71,673 | 79,305 | 74,105 | (7,632) | 5,200 |
| Impairment of long-lived asset | 13,245 | — | — | 13,245 | — |
| Total operating expenses | 327,832 | 335,692 | 294,281 | (7,860) | 41,411 |
| Loss from operations | (327,737) | (335,536) | (180,192) | 7,799 | (155,344) |
| Other income (expense), net: | | | | | |
| Interest and other income, net | 18,307 | 4,566 | 1,714 | 13,741 | 2,852 |
| Other expenses | (17,835) | (9,444) | (3,573) | (8,391) | (5,871) |
| Total other income (expense), net | 472 | (4,878) | (1,859) | 5,350 | (3,019) |
| Net loss | \$ (327,265) | \$ (340,414) | \$ (182,051) | \$ 13,149 | \$ (158,363) |

Collaboration revenue - related party

[Table of Contents](#)

Collaboration revenue was \$0.1 million and \$0.2 million for the years ended December 31, 2023 and 2022, respectively. Revenue recognized in the years ended December 31, 2023 and 2022 was mainly due to participation in the joint steering committee performance obligation related to the License Agreement entered into with Allogene Overland on December 14, 2020.

Collaboration revenue was \$0.2 million and \$114.1 million for the years ended December 31, 2022 and 2021, respectively. The decrease of \$113.9 million was due to the revenue recognized related to the license of intellectual property and delivery of the know-how, which was delivered in the first quarter of 2021, under the License Agreement entered into with Allogene Overland in December 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, | | | Change | |
|---|-------------------------|------------|------------|---------------|---------------|
| | 2023 | 2022 | 2021 | 2023 vs. 2022 | 2022 vs. 2021 |
| Personnel | \$ 112,457 | \$ 129,604 | \$ 112,903 | \$ (17,147) | \$ 16,701 |
| Development costs | 74,644 | 71,293 | 69,025 | 3,351 | 2,268 |
| Facilities and depreciation | 44,684 | 43,457 | 29,300 | 1,227 | 14,157 |
| Other | 11,129 | 12,033 | 8,948 | (904) | 3,085 |
| Total research and development expenses | 242,914 | 256,387 | 220,176 | (13,473) | 36,211 |

Our research and development expenses included \$119.0 million of internal expense and \$123.9 million of external expenses for the year ended December 31, 2023. Our research and development expenses included \$133.6 million of internal expenses and \$122.8 million of external expenses for the year ended December 31, 2022.

Research and development expenses were \$242.9 million and \$256.4 million for the years ended December 31, 2023 and 2022, respectively. The net decrease of \$13.5 million was primarily due to a decrease in personnel related costs of \$17.1 million, of which \$13.5 million was decreased stock-based compensation expense, offset by an increase in external costs related to the advancement of our product candidates of \$3.4 million due to the timing of process development activities and manufacturing runs.

Research and development expenses were \$256.4 million and \$220.2 million for the years ended December 31, 2022 and 2021, respectively. The net increase of \$36.2 million was primarily due to an increase in building rent and facilities costs of \$14.2 million, an increase in personnel related costs of \$16.7 million, of which \$3.5 million was increased stock-based compensation expense, and an increase in external costs relating to the advancement of our product candidates of \$2.3 million due to the timing of process development activities and manufacturing runs.

General and Administrative Expenses

General and administrative expenses were \$71.7 million and \$79.3 million for the years ended December 31, 2023 and 2022, respectively. The net decrease of \$7.6 million was primarily due to a decrease in personnel related costs of \$5.7 million, of which \$4.1 million was decreased stock-based compensation expense, and a decrease in expenses related to corporate communications of \$1.8 million.

General and administrative expenses were \$79.3 million and \$74.1 million for the years ended December 31, 2022 and 2021, respectively. The net increase of \$5.2 million was primarily due to an increase in personnel related costs of \$3.4 million, an increase in expenses related to corporate communications of \$2.8 million, partially offset by a \$1.5 million decrease in business and consulting fees.

Impairment of long-lived asset

In December 2023, we made a decision to sublease one of our leased buildings in South San Francisco. We vacated and ceased occupancy of this building in December 2023 and currently we are actively marketing the leased building for sublease. We determined that the change in how this property is being used could indicate impairment and recorded long-lived asset impairment loss based on the performed impairment analysis.

Interest and Other Income, Net

[Table of Contents](#)

Interest and other income, net was \$18.3 million and \$4.6 million for the years ended December 31, 2023 and 2022, respectively. The \$13.7 million increase was primarily due to higher yields and a corresponding increase in the interest earned on our cash, cash equivalents and investments.

Interest and other income, net was \$4.6 million and \$1.7 million for the years ended December 31, 2022 and 2021, respectively. The \$2.9 million increase was due to higher yields and a corresponding increase in the interest earned on our cash, cash equivalents and investments.

Other expenses

Other expenses were \$17.8 million and \$9.4 million for the years ended December 31, 2023 and 2022, respectively. The \$8.4 million increase was primarily due to impairment loss of \$7.0 million related to our equity method investment and equity investment recorded for the year ended December 31, 2023.

Other expenses were \$9.4 million and \$3.6 million for the years ended December 31, 2022 and 2021, respectively. The \$5.9 million increase was primarily due to higher share of net losses in our equity method investments.

Quarterly Discussion and Analysis

The following discussion should be read in conjunction with our accompanying restated unaudited interim condensed consolidated financial statements disclosed in Part II. Item 8. Financial Statements and Supplementary Data, Note 15 "Selected Quarterly Financial Data (Unaudited)", of this Annual Report.

The following sets forth our results of operations for the three months ended March 31, 2023 and 2022 (in thousands):

| | Three Months Ended March 31, | | Change | |
|--|-------------------------------------|----------------------|-----------------|---------------|
| | 2023 | 2022 | \$ | % |
| | (As Restated) | (As Restated) | | |
| Collaboration revenue - related party | \$ 30 | \$ 39 | \$ (9) | (23)% |
| Operating expenses: | | | | |
| Research and development | 80,238 | 60,156 | 20,082 | 33 % |
| General and administrative | 18,884 | 19,897 | (1,013) | (5)% |
| Total operating expenses | 99,122 | 80,053 | 19,069 | 24 % |
| Loss from operations | (99,092) | (80,014) | (19,078) | 24 % |
| Other income (expense), net: | | | | |
| Interest and other income, net | 2,059 | 492 | 1,567 | 318 % |
| Other income (expenses), net | (2,936) | 914 | (3,850) | (421)% |
| Total other income (expense), net | (877) | 1,406 | (2,283) | (162)% |
| Net loss | (99,969) | (78,608) | (21,361) | 27 % |

Collaboration revenue - related party

Collaboration revenue recognized for the three months ended March 31, 2023 and 2022 was mainly due to participation in the joint steering committee performance obligation related to the License Agreement entered into with Allogene Overland 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:

| | Three Months Ended March 31, | | |
|--|-------------------------------------|---------------|---------------|
| | 2023 | 2022 | Change |
| Personnel | \$ 34,173 | \$ 33,079 | \$ 1,094 |
| Development costs | 31,261 | 14,323 | 16,938 |
| Facilities and depreciation | 11,193 | 10,070 | 1,123 |
| Other | 3,611 | 2,684 | 927 |
| Total research and development expenses | 80,238 | 60,156 | 20,082 |

Our research and development expenses included \$35.2 million of internal expenses and \$45.0 million of external expenses for the three months ended March 31, 2023. Our research and development expenses included \$33.9 million of internal expenses and \$26.2 million of external expenses for the three months ended March 31, 2022.

Research and development expenses were \$80.2 million and \$60.1 million for the three months ended March 31, 2023 and 2022, respectively. The increase of \$20.1 million was driven primarily by an increase in external costs relating to the advancement of our product candidates due to the timing of development activities and manufacturing runs of \$16.9 million and an increase in facilities costs and depreciation expense of \$1.1 million.

General and Administrative Expense

General and administrative expenses were \$18.9 million and \$19.9 million for the three months ended March 31, 2023 and 2022, respectively. The decrease of \$1.0 million was primarily due to an decrease in personnel related costs.

Interest and Other Income, Net

Interest and other income, net was \$2.1 million and \$0.5 million for the three months ended March 31, 2023 and 2022, respectively. The increase of \$1.6 million was primarily due to higher yields and a corresponding increase in the interest earned on our cash, cash equivalents and investments.

Other income (expenses), Net

Other expenses were \$2.9 million for the three months ended March 31, 2023 and other income was \$0.9 million for the three months ended March 31, 2022. The increase in other expenses of \$3.8 million was primarily due to higher share of net losses in our equity method investments.

The following sets forth our results of operations for the three and six months ended June 30, 2023 and 2022 (in thousands):

| | Three Months Ended June 30, | | Change | Six Months Ended June 30, | | Change |
|--|------------------------------------|----------------------|---------------|----------------------------------|----------------------|-----------------|
| | 2023 | 2022 | \$ | 2023 | 2022 | \$ |
| | (As Restated) | (As Restated) | | (As Restated) | (As Restated) | |
| Collaboration revenue - related party | \$ 22 | \$ 64 | \$ (42) | \$ 52 | \$ 103 | \$ (51) |
| Operating expenses: | | | | | | |
| Research and development | 62,038 | 57,171 | 4,867 | 142,276 | 117,327 | 24,949 |
| General and administrative | 18,524 | 19,509 | (985) | 37,408 | 39,406 | (1,998) |
| Total operating expenses | 80,562 | 76,680 | 3,882 | 179,684 | 156,733 | 22,951 |
| Loss from operations | (80,540) | (76,616) | (3,924) | (179,632) | (156,630) | (23,002) |
| Other income (expense), net: | | | | | | |
| Interest and other income, net | 3,778 | 315 | 3,463 | 5,837 | 807 | 5,030 |
| Other expenses | (2,470) | (3,990) | 1,520 | (5,406) | (3,076) | (2,330) |
| Total other income (expense), net | 1,308 | (3,675) | 4,983 | 431 | (2,269) | 2,700 |
| Net loss | (79,232) | (80,291) | 1,059 | (179,201) | (158,899) | (20,302) |

Collaboration revenue - related party

Collaboration revenue recognized for the three and six months ended June 30, 2023 and 2022 was mainly due to participation in the joint steering committee performance obligation related to the License Agreement entered into with Allogene Overland on December 14, 2020.

Research and Development Expenses

[Table of Contents](#)

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

| | Three Months Ended June 30, | | | Six Months Ended June 30, | | |
|---|-----------------------------|-----------|------------|---------------------------|-----------|------------|
| | 2023 | 2022 | Change | 2023 | 2022 | Change |
| Personnel | \$ 29,574 | \$ 34,926 | \$ (5,352) | \$ 63,748 | \$ 68,005 | \$ (4,257) |
| Development costs | 18,218 | 8,078 | 10,140 | 49,479 | 22,401 | 27,078 |
| Facilities and depreciation | 11,457 | 11,039 | 418 | 22,650 | 21,110 | 1,540 |
| Other | 2,789 | 3,128 | (339) | 6,399 | 5,811 | 588 |
| Total research and development expenses | 62,038 | 57,171 | 4,867 | 142,276 | 117,327 | 24,949 |

Our research and development expenses included \$31.1 million of internal expenses and \$30.9 million of external expenses for the three months ended June 30, 2023. Our research and development expenses included \$36.1 million of internal expenses and \$21.1 million of external expenses for the three months ended June 30, 2022.

Research and development expenses were \$62.0 million and \$57.2 million for the three months ended June 30, 2023 and 2022, respectively. The increase of \$4.9 million was driven primarily by a decrease in Servier cost recoveries of \$11.0 million, offset by a decrease in personnel related costs of \$5.4 million and a decrease in external costs relating to the advancement of our product candidates due to the timing of development activities and manufacturing runs of \$0.9 million.

Our research and development expenses included \$66.3 million of internal expenses and \$75.9 million of external expenses for the six months ended June 30, 2023. Our research and development expenses included \$70.1 million of internal expenses and \$47.2 million of external expenses for the six months ended June 30, 2022.

Research and development expenses were \$142.3 million and \$117.3 million for the six months ended June 30, 2023 and 2022, respectively. The increase of \$24.9 million was driven primarily by a decrease in Servier cost recoveries of \$16.1 million and an increase in external costs relating to the advancement of our product candidates due to the timing of development activities and manufacturing runs of \$11.0 million, offset by a decrease in personnel related costs of \$4.3 million.

General and Administrative Expense

General and administrative expenses were \$18.5 million and \$19.5 million for the three months ended June 30, 2023 and 2022, respectively. The decrease of \$1.0 million was primarily due to a decrease in personnel related costs of \$0.4 million and a decrease in expenses related to corporate communications and outside services of \$0.3 million.

General and administrative expenses were \$37.4 million and \$39.4 million for the six months ended June 30, 2023 and 2022, respectively. The decrease of \$2.0 million was primarily due to a decrease in personnel related costs of \$1.4 million and a decrease in expenses related to corporate communications and outside services of \$0.6 million.

Interest and Other Income, Net

Interest and other income, net was \$3.8 million and \$0.3 million for the three months ended June 30, 2023 and 2022, respectively. The increase of \$3.5 million was primarily due to higher yields and a corresponding increase in the interest earned on our cash, cash equivalents and investments.

Interest and other income, net was \$5.8 million and \$0.8 million for the six months ended June 30, 2023 and 2022, respectively. The increase of \$5.0 million was primarily due to higher yields and a corresponding increase in the interest earned on our cash, cash equivalents and investments.

Other expenses

Other expenses were \$2.5 million and \$4.0 million for the three months ended June 30, 2023 and 2022, respectively. The decrease of \$1.5 million was primarily due to lower share of net losses in our equity method investments.

Other expenses were \$5.4 million and \$3.1 million for the six months ended June 30, 2023 and 2022, respectively. The increase of \$2.3 million was primarily due to higher share of net losses in our equity method investments.

The following sets forth our results of operations for the three and nine months ended September 30, 2023 and 2022 (in thousands):

[Table of Contents](#)

| | Three Months Ended September 30, | | Change | Nine Months Ended September 30, | | Change |
|---------------------------------------|----------------------------------|---------------|----------|---------------------------------|---------------|---------|
| | 2023 | 2022 | | 2023 | 2022 | |
| | (As Restated) | (As Restated) | \$ | (As Restated) | (As Restated) | \$ |
| Collaboration revenue - related party | \$ 22 | \$ 27 | \$ (5) | \$ 74 | \$ 130 | \$ (56) |
| Operating expenses: | | | | | | |
| Research and development | 45,977 | 63,641 | (17,664) | 188,253 | 180,968 | 7,285 |
| General and administrative | 17,041 | 18,897 | (1,856) | 54,449 | 58,303 | (3,854) |
| Total operating expenses | 63,018 | 82,538 | (19,520) | 242,702 | 239,271 | 3,431 |
| Loss from operations | (62,996) | (82,511) | 19,515 | (242,628) | (239,141) | (3,487) |
| Other income (expense), net: | | | | | | |
| Interest and other income, net | 6,205 | 1,002 | 5,203 | 12,042 | 1,809 | 10,233 |
| Other expenses | (5,496) | (2,733) | (2,763) | (10,902) | (5,809) | (5,093) |
| Total other income (expense), net | 709 | (1,731) | 2,440 | 1,140 | (4,000) | 5,140 |
| Net loss | (62,287) | (84,242) | 21,955 | (241,488) | (243,141) | 1,653 |

Collaboration revenue - related party

Collaboration revenue recognized for the three and nine months ended September 30, 2023 and 2022 was mainly due to participation in the joint steering committee performance obligation related to the License Agreement entered into with Allogene Overland 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:

| | Three Months Ended September 30, | | | Nine Months Ended September 30, | | |
|---|----------------------------------|-----------|------------|---------------------------------|------------|-------------|
| | 2023 | 2022 | Change | 2023 | 2022 | Change |
| Personnel | \$ 26,170 | \$ 32,748 | \$ (6,578) | \$ 89,917 | \$ 100,753 | \$ (10,836) |
| Development costs | 6,494 | 16,799 | (10,305) | 55,973 | 39,200 | 16,773 |
| Facilities and depreciation | 11,104 | 11,349 | (245) | 33,754 | 32,459 | 1,295 |
| Other | 2,209 | 2,745 | (536) | 8,609 | 8,556 | 53 |
| Total research and development expenses | 45,977 | 63,641 | (17,664) | 188,253 | 180,968 | 7,285 |

Our research and development expenses included \$28.1 million of internal expenses and \$17.9 million of external expenses for the three months ended September 30, 2023. Our research and development expenses included \$33.6 million of internal expenses and \$30.0 million of external expenses for the three months ended September 30, 2022.

Research and development expenses were \$46.0 million and \$63.6 million for the three months ended September 30, 2023 and 2022, respectively. The decrease of \$17.7 million was driven primarily by a decrease in external costs relating to the advancement of our product candidates due to the timing of development activities and manufacturing runs of \$10.3 million and a decrease in personnel related costs of \$6.6 million, of which \$4.3 million was stock-based compensation expense.

Our research and development expenses included \$94.5 million of internal expenses and \$93.8 million of external expenses for the nine months ended September 30, 2023. Our research and development expenses included \$103.8 million of internal expenses and \$77.2 million of external expenses for the nine months ended September 30, 2022.

Research and development expenses were \$188.3 million and \$181.0 million for the nine months ended September 30, 2023 and 2022, respectively. The increase of \$7.3 million was driven primarily by a decrease in Servier cost recoveries of \$19.7 million and an increase in facilities costs of \$1.3 million, offset by a decrease in personnel related costs of \$10.8 million, of which \$12.4 million was a decrease in stock-based compensation expense, and a decrease in external costs relating to the advancement of our product candidates due to the timing of development activities and manufacturing runs of \$2.9 million.

General and Administrative Expense

General and administrative expenses were \$17.0 million and \$18.9 million for the three months ended September 30, 2023 and 2022, respectively. The decrease of \$1.9 million was primarily due to a decrease in personnel related costs of \$2.1 million, of which \$1.5 million was stock-based compensation expense.

[Table of Contents](#)

General and administrative expenses were \$54.4 million and \$58.3 million for the nine months ended September 30, 2023 and 2022, respectively. The decrease of \$3.9 million was primarily due to a decrease in personnel related costs of \$3.6 million, of which \$3.3 million was stock-based compensation expense.

Interest and Other Income, Net

Interest and other income, net was \$6.2 million and \$1.0 million for the three months ended September 30, 2023 and 2022, respectively. The increase of \$5.2 million was primarily due to higher yields and a corresponding increase in the interest earned on our cash, cash equivalents and investments.

Interest and other income, net was \$12.0 million and \$1.8 million for the nine months ended September 30, 2023 and 2022, respectively. The increase of \$10.2 million was primarily due to higher yields and a corresponding increase in the interest earned on our cash, cash equivalents and investments.

Other expenses

Other expenses were \$5.5 million and \$2.7 million for the three months ended September 30, 2023 and 2022, respectively. The increase of \$2.8 million was primarily due to impairment loss related to our equity method investment recorded for the three months ended September 30, 2023.

Other expenses were \$10.9 million and \$5.8 million for the nine months ended September 30, 2023 and 2022, respectively. The increase of \$5.1 million was primarily due to higher share of net losses and impairment of our equity method investments.

Liquidity and Capital Resources

To date, we have incurred significant net losses and negative cash flows from operations. As of December 31, 2023, we had \$448.7 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, and upfront cash payment of \$40.0 million received in December 2020 pursuant to our License Agreement with Allogene Overland. 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 year ended December 31, 2023, we 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.

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

[Table of Contents](#)

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

| | Year Ended December 31, | | |
|---|-------------------------|---------------------|-------------------|
| | 2023 | 2022 | 2021 |
| | (in thousands) | | |
| Net cash (used in) provided by: | | | |
| Operating activities | \$ (237,733) | \$ (220,519) | \$ (184,812) |
| Investing activities | 163,289 | 106,159 | 163,655 |
| Financing activities | 95,695 | 2,950 | 11,963 |
| Net increase (decrease) in cash, cash equivalents and restricted cash | <u>\$ 21,251</u> | <u>\$ (111,410)</u> | <u>\$ (9,194)</u> |

Operating Activities

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 \$104.8 million and a net change of \$15.3 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, share of losses from equity method investments of \$10.7 million, impairment of long-lived assets of \$13.2 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 \$0.6 million. The net change in operating assets and liabilities was primarily due to a \$7.5 million decrease in accounts payable, a \$6.8 million decrease in accrued and other current liabilities, a \$1.5 million increase in other long-term assets, and a \$0.6 million decrease in other long-term liabilities, offset by a \$1.1 million decrease in prepaid expenses and other current assets.

During the year ended December 31, 2022, cash used in operating activities of \$220.5 million was attributable to a net loss of \$340.4 million, substantially offset by non-cash charges of \$116.0 million and a net change of \$3.9 million in our net operating assets and liabilities. The non-cash charges consisted primarily of stock-based compensation of \$83.6 million, depreciation and amortization of \$14.3 million, share of losses from equity method investments of \$12.9 million, net amortization and accretion on investment securities of \$2.9 million, and non-cash rent expense of \$2.4 million. The net change in operating assets and liabilities was primarily due to a \$4.9 million increase in accounts payable, a \$2.5 million decrease in prepaid expense and other current assets, and a \$1.7 million increase in accrued and other current liabilities, offset by an increase in other long-term assets of \$3.3 million and a decrease in other long-term liabilities of \$1.9 million.

During the year ended December 31, 2021, cash used in operating activities of \$184.8 million was attributable to a net loss of \$182.1 million, a net change of \$31.9 million in our net operating assets and liabilities substantially offset by non-cash charges of \$29.2 million. The non-cash charges consisted primarily of stock-based compensation of \$80.8 million, non-cash collaboration revenue from related party of \$75.7 million, depreciation and amortization of \$10.5 million, net amortization and accretion on investment securities of \$7.0 million, share of losses from equity method investments of 4.1 million, and non-cash rent expense of \$2.6 million. The net change in operating assets and liabilities was primarily due to a \$38.3 million decrease in deferred revenue within current liabilities, a \$0.8 million decrease in accounts payable, and a \$0.6 million increase in other long-term assets, offset by a \$3.7 million increase in accrued and other current liabilities, a \$3.2 million decrease in prepaid expenses and other current assets and a \$0.9 million increase in other long-term liabilities.

Investing Activities

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, offset by the purchase of investments of \$438.6 million and purchases of property and equipment of \$1.5 million.

During the year ended December 31, 2022, net cash provided by investing activities of \$106.2 million was related to cash inflows from maturities of investments of \$359.5 million, offset by the purchase of investments of \$248.1 million and purchases of property and equipment of \$5.2 million.

During the year ended December 31, 2021, net cash used in investing activities of \$163.7 million was related to cash inflows from maturities of investments of \$728.4 million, offset by the purchase of investments of \$525.6 million, purchases of property and equipment of \$21.4 million, and purchase of stock in equity method investment of \$17.7 million.

Financing Activities

[Table of Contents](#)

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

During the year ended December 31, 2022, net cash provided by financing activities of \$3.0 million was related to proceeds from the employee stock purchase plan of \$2.5 million and proceeds from the issuance of common stock upon the exercise of stock options of \$0.5 million.

During the year ended December 31, 2021, net cash provided by financing activities of \$12.0 million was related to proceeds from the issuance of common stock upon the exercise of stock options of \$8.3 million and proceeds from the employee stock purchase plan of \$3.6 million.

Contractual Obligations and Commitments

Material Cash Commitments and Requirements

Our commitments primarily consist of obligations under our agreements with Pfizer, Cellectis, Servier and Notch. 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, 2023, 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.

Additionally, we have entered into agreements with third-party contract manufacturers for the manufacture and processing of certain of our product candidates for clinical testing purposes, and we have entered and will enter into other contracts in the normal course of business with contract research organizations for clinical trials and other vendors for other services and products for operating purposes. These agreements generally provide for termination or cancellation, other than for costs already incurred. As of December 31, 2023, we had non-cancellable purchase commitments of \$2.1 million.

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 obligated to make further payments to MD Anderson each year upon the anniversary of the agreement effective date through the duration of the agreement term. 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, revenue recognition, research and development expenses, stock-based compensation and leases 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. We have not experienced any material differences between accrued costs and actual costs incurred since our inception.

Revenue Recognition

Our revenue is 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.

We analyze our 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, we first determine 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 we determine should be accounted for under ASC 606, we assess which activities in our collaboration agreements are performance obligations that should be accounted for separately and determine 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. We consider a performance obligation satisfied once we have 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 we expect to collect in exchange for our products is an estimate and may be fixed or variable. We constrain the estimated variable consideration when we assess it is probable that a significant reversal

[Table of Contents](#)

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 we 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

We expense research and development costs as incurred. Acquired intangible assets are expensed as research and development costs if, at the time of payment, the technology is under development; is not approved by the FDA or other regulatory agencies for marketing; has not reached technical feasibility; or otherwise has no foreseeable alternative future use.

Research and development expenses also include costs incurred for internal and sponsored and collaborative research and development activities. Research and development costs consist of salaries and benefits, including associated stock-based compensation, and laboratory supplies and facility costs, as well as fees paid to other entities that conduct certain research and development activities on our behalf. Costs associated with co-development activities performed under the various license and collaboration agreements, including milestones achieved, are included in research and development expenses.

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. 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.

The Black-Scholes option-pricing model and the lattice option pricing model require the use of subjective assumptions to determine the fair value of stock-based awards. These assumptions include:

- *Expected term*— The expected term represents the period that stock-based awards are expected to be outstanding. The expected term for option grants is determined using the simplified method. 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*— We use 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, in addition to some consideration to our own stock price volatility. We continue to utilize comparable public companies as part of this process as we do not have sufficient trading history for our common stock. We will continue to apply this process until a sufficient amount of historical information regarding the volatility of our own stock price becomes available.
- *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*—We have never paid dividends on our common stock and have no plans to pay dividends on our common stock. Therefore, we used an expected dividend yield of zero.
- *Expected exercise barrier*—The modified options in accordance with the Stock Option Exchange Program 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. For additional information regarding our Stock Option Exchange Program, see Note 10 to our consolidated financial statements included elsewhere in this Annual Report.

For the years ended December 31, 2023, 2022 and 2021, stock-based compensation was \$66.0 million, \$83.6 million and \$80.8 million, respectively. As of December 31, 2023 and 2022, we had \$108.7 million and \$153.6 million, respectively, of total unrecognized stock-based compensation.

Leases

[Table of Contents](#)

We early adopted Accounting Standards Update (ASU) No. 2016-02, Leases as of January 1, 2018. For our long-term operating leases, we recognized right-of-use assets and lease liabilities on our consolidated balance sheet. The lease liabilities are determined as the present value of future lease payments using an estimated rate of interest that we would have to pay to borrow equivalent funds on a collateralized basis at the lease commencement date. The right-of-use assets are based on the liability adjusted for any prepaid or deferred rent. For each lease, 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.

We elected to exclude from our 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 our long-term real estate leases.

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 \$448.7 million as of December 31, 2023, 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, 2023 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, 2023, we had no receivables and \$0.6 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, 2023 and 2022

| | |
|--|-----|
| Report of Independent Registered Public Accounting Firm (PCAOB ID: 42) | 101 |
| Consolidated Financial Statements: | |
| Consolidated Balance Sheets | 102 |
| Consolidated Statements of Operations and Comprehensive Loss | 103 |
| Consolidated Statements of Stockholders' Equity | 104 |
| Consolidated Statements of Cash Flows | 105 |
| Notes to Consolidated Financial Statements | 106 |

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, 2023 and 2022, the related consolidated statements of operations and comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2023 and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2023 and 2022, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2023, in conformity with U.S. generally accepted accounting principles.

Restatement of Financial Statements

As discussed in Note 1 to the consolidated financial statements, the 2022 and 2021 consolidated financial statements have been restated to correct misstatements.

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

Critical audit matters are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. We determined that there are no critical audit matters.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2018.
San Mateo, California
March 14, 2024

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

| | <u>December 31, 2023</u> | <u>December 31, 2022</u> (As Restated) |
|---|------------------------------|---|
| Assets | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 83,155 | \$ 61,904 |
| Short-term investments | 365,542 | 455,416 |
| Prepaid expenses and other current assets | 10,418 | 11,504 |
| Total current assets | 459,115 | 528,824 |
| Long-term investments | — | 59,151 |
| Operating lease right-of-use asset | 63,703 | 83,592 |
| Property and equipment, net | 99,478 | 112,839 |
| Restricted cash | 10,292 | 10,292 |
| Other long-term assets | 6,604 | 9,564 |
| Equity method investments | 3,645 | 17,317 |
| Total assets | <u>\$ 642,837</u> | <u>\$ 821,579</u> |
| Liabilities and stockholders' equity | | |
| Current liabilities: | | |
| Accounts payable | \$ 5,897 | \$ 13,890 |
| Accrued and other current liabilities | 31,096 | 39,743 |
| Deferred revenue | 86 | 95 |
| Total current liabilities | 37,079 | 53,728 |
| Lease liability, noncurrent | 88,346 | 95,122 |
| Other long-term liabilities | 5,179 | 5,847 |
| Total liabilities | <u>130,604</u> | <u>154,697</u> |
| Commitments and Contingencies (Notes 6 and 7) | | |
| Stockholders' equity: | | |
| Preferred stock, \$0.001 par value: 10,000,000 authorized as of December 31, 2023 and December 31, 2022; no shares were issued and outstanding as of December 31, 2023 and December 31, 2022 | — | — |
| Common stock, \$0.001 par value: 400,000,000 shares authorized as of December 31, 2023 and December 31, 2022; 168,642,238 and 144,438,304 shares issued and outstanding as of December 31, 2023 and December 31, 2022, respectively | 169 | 144 |
| Additional paid-in capital | 2,075,252 | 1,911,632 |
| Accumulated deficit | (1,562,233) | (1,234,968) |
| Accumulated other comprehensive loss | (955) | (9,926) |
| Total stockholders' equity | 512,233 | 666,882 |
| Total liabilities and stockholders' equity | <u>\$ 642,837</u> | <u>\$ 821,579</u> |

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, | | |
|---|-------------------------|---------------|---------------|
| | 2023 | 2022 | 2021 |
| | | (As restated) | (As restated) |
| Collaboration revenue - related party | \$ 95 | \$ 156 | \$ 114,089 |
| Operating expenses: | | | |
| Research and development | 242,914 | 256,387 | 220,176 |
| General and administrative | 71,673 | 79,305 | 74,105 |
| Impairment of long-lived asset | 13,245 | — | — |
| Total operating expenses | 327,832 | 335,692 | 294,281 |
| Loss from operations | (327,737) | (335,536) | (180,192) |
| Other income (expense), net: | | | |
| Interest and other income, net | 18,307 | 4,566 | 1,714 |
| Other expenses | (17,835) | (9,444) | (3,573) |
| Total other income (expense), net | 472 | (4,878) | (1,859) |
| Net loss | (327,265) | (340,414) | (182,051) |
| Other comprehensive income: | | | |
| Net unrealized gain (loss) on available-for-sale investments | 8,971 | (7,359) | (2,835) |
| Net comprehensive loss | \$ (318,294) | \$ (347,773) | \$ (184,886) |
| Net loss per share, basic and diluted | \$ (2.09) | \$ (2.38) | \$ (1.34) |
| Weighted-average number of shares used in computing net loss per share, basic and diluted | 156,931,778 | 143,147,165 | 135,820,386 |

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, 2020 (As Restated) | 140,474,305 | 140 | 1,725,552 | (712,503) | 268 | 1,013,457 |
| Issuance of common stock upon exercise of stock options and vesting of RSUs | 1,961,554 | 2 | 8,344 | — | — | 8,346 |
| Vesting of early exercised common stock | — | — | 3,848 | — | — | 3,848 |
| Stock-based compensation | — | — | 80,818 | — | — | 80,818 |
| Employee stock purchase plan | 187,206 | — | 3,617 | — | — | 3,617 |
| Net loss (As Restated) | — | — | — | (182,051) | — | (182,051) |
| Net unrealized loss on available-for-sale investments | — | — | — | — | (2,835) | (2,835) |
| Balance — December 31, 2021 (As Restated) | 142,623,065 | 142 | 1,822,179 | (894,554) | (2,567) | 925,200 |
| Issuance of common stock upon exercise of stock options and vesting of RSUs | 1,453,624 | 2 | 487 | — | — | 489 |
| Vesting of early exercised common stock | — | — | 2,905 | — | — | 2,905 |
| Stock-based compensation | — | — | 83,600 | — | — | 83,600 |
| Employee stock purchase plan | 361,615 | — | 2,461 | — | — | 2,461 |
| Net loss (As Restated) | — | — | — | (340,414) | — | (340,414) |
| Net unrealized loss on available-for-sale investments | — | — | — | — | (7,359) | (7,359) |
| 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 | — | — | — | (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 |

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, | | |
|--|-------------------------|---------------|---------------|
| | 2023 | 2022 | 2021 |
| | | (As Restated) | (As Restated) |
| Cash flows from operating activities: | | | |
| Net loss | \$ (327,265) | \$ (340,414) | \$ (182,051) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | | |
| Stock-based compensation | 65,951 | 83,600 | 80,818 |
| Depreciation and amortization | 14,199 | 14,295 | 10,454 |
| Net amortization/accretion on investment securities | (6,809) | 2,891 | 6,955 |
| Impairment of long-lived asset | 13,245 | — | — |
| Impairment of equity investment and equity method investment | 7,000 | — | — |
| Non-cash rent expense | 642 | 2,433 | 2,611 |
| Non-cash collaboration revenue - related party | (63) | (104) | (75,740) |
| Share of loss from equity method investments | 10,672 | 12,883 | 4,090 |
| Changes in operating assets and liabilities: | | | |
| Prepaid expenses and other current assets | 1,086 | 2,517 | 3,199 |
| Other long-term assets | (1,455) | (3,334) | (646) |
| Accounts payable | (7,502) | 4,868 | (767) |
| Accrued and other current liabilities | (6,820) | 1,749 | 3,652 |
| Deferred revenue | (3) | (21) | (38,297) |
| Other long-term liabilities | (611) | (1,882) | 910 |
| Net cash used in operating activities | (237,733) | (220,519) | (184,812) |
| Cash flows from investing activities: | | | |
| Purchases of property and equipment | (1,516) | (5,191) | (21,446) |
| Purchase of stock in equity method investment | — | — | (17,710) |
| Proceeds from sales of investments | 5,623 | — | — |
| Proceeds from maturities of investments | 597,811 | 359,459 | 728,394 |
| Purchase of investments | (438,629) | (248,109) | (525,583) |
| Net cash provided by (used in) investing activities | 163,289 | 106,159 | 163,655 |
| Cash flows from financing activities: | | | |
| Proceeds from issuance of common stock from ATM offering, net of commissions and issuance costs | 91,112 | — | — |
| Proceeds from issuance of common stock and upon exercise of stock options | 2,087 | 489 | 8,346 |
| Proceeds from issuance of common stock under the employee stock purchase plan | 2,496 | 2,461 | 3,617 |
| Net cash provided by financing activities | 95,695 | 2,950 | 11,963 |
| Net increase (decrease) in cash, cash equivalents and restricted cash | 21,251 | (111,410) | (9,194) |
| Cash, cash equivalents and restricted cash — beginning of period | 72,196 | 183,606 | 192,800 |
| Cash, cash equivalents and restricted cash — end of period | \$ 93,447 | \$ 72,196 | \$ 183,606 |
| Non-cash operating, investing and financing activities: | | | |
| Right-of-use asset obtained in exchange for lease liability | \$ — | \$ 31,361 | \$ 20,079 |
| Property and equipment purchases in accounts payable and accrued and other current liabilities | \$ — | \$ 678 | \$ 1,725 |
| Capitalized cloud computing costs included in accounts payable and accrued and other current liabilities | \$ — | \$ 415 | \$ — |
| Non-cash deferred revenue and other long-term liabilities | \$ 3,094 | \$ 3,157 | \$ 3,260 |
| Supplemental disclosure: | | | |
| Cash paid for amounts included in the measurement of lease liabilities | \$ (12,049) | \$ (9,540) | \$ (6,013) |
| Cash received for amounts related to tenant improvement allowances from lessors | \$ — | \$ 325 | \$ 1,111 |

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. The Company is developing a pipeline of off-the-shelf T cell product candidates that are designed to target and kill cancer cells.

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, 2020, the Company sold an aggregate of 848,663 shares of common stock in ATM offerings resulting in net proceeds of \$26.2 million. 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.

In June 2020, the Company sold 13,457,447 shares of its common stock, which included 1,755,319 shares sold pursuant to the full exercise of the underwriters' option to purchase additional shares, in an underwritten public offering at a price of \$47.00 per share, which resulted in gross proceeds of approximately \$632.5 million. Net proceeds to the Company after deducting the underwriting discounts and commissions and other expenses were approximately \$595.7 million.

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 \$448.7 million as of December 31, 2023. Since inception through December 31, 2023, the Company has incurred cumulative net losses of \$1,562.2 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. All material intercompany balances and transactions have been eliminated during consolidation.

Restatement of financial statements

As described further in Note 6 and Note 8, on December 14, 2020, the Company entered into an Exclusive License Agreement (License Agreement) with Allogene Overland Biopharm (CY) Limited (Allogene Overland), a joint venture established by the Company and Overland Pharmaceuticals (CY) Inc. (Overland) pursuant to a Share Purchase Agreement

[Table of Contents](#)

(Share Purchase Agreement), dated December 14, 2020, for the purpose of developing, manufacturing and commercializing certain allogeneic CAR T cell therapies for patients in greater China, Taiwan, South Korea and Singapore, which resulted in the Company acquiring shares of Allogene Overland's Seed Preferred Stock (Seed Preferred Shares) representing a 49% ownership interest in exchange for entering into a License Agreement.

In 2023, the Company re-evaluated its application of ASC Topic 606, *Revenue from Contracts with Customers (ASC 606)* and ASC Topic 323, *Investments - Equity Method and Joint ventures (ASC 323)* to its License Agreement and Share Purchase Agreement with Allogene Overland. Upon reassessment, the Company has determined the 49% of Allogene Overland's outstanding Seed Preferred Shares received as a partial consideration for the License Agreement should be initially measured at fair value of \$79.0 million rather than the zero carryover basis originally attributed to the Seed Preferred Shares. The initial transaction price to determine revenue related to the License Agreement was revised to include the fair value of the Seed Preferred Shares of \$79.0 million and was allocated to the identified performance obligations based on their estimated standalone selling price. Additional revisions were made in the year ended December 31, 2020 whereby, on the date when the Seed Preferred Shares were received, the Company recorded as "Other expenses" in its consolidated statements of operations and comprehensive loss the basis difference of \$67.5 million between the fair value of the Seed Preferred Shares of \$79.0 million and the amount of the Company's underlying equity in net assets of Allogene Overland of \$11.5 million and reduced the carrying value of the Seed Preferred Shares to \$11.5 million. In the year ended December 31, 2021, the collaboration revenue increased by \$75.6 million and the remaining transaction price of \$3.4 million will impact subsequent future periods when related performance obligations are satisfied. Further, the Company recorded its share of net losses of Allogene Overland in each reporting period and reduced the carrying value of the Seed Preferred Shares. Refer to the Impact of restatement section below which describes detailed impact of the restatement for all the periods presented.

The error resulted in an understatement of collaboration revenue and other expenses in the consolidated statements of operations and comprehensive loss for the years ended December 31, 2022, 2021 and 2020, and an understatement of deferred revenue and equity method investment in the consolidated balance sheets as of December 31, 2022 and 2021. These annual periods were restated in the Amendment No. 1 to the Annual Report on Form 10-K/A for the year ended December 31, 2022 filed with the Securities and Exchange Commission (the SEC) on March 14, 2024.

The consolidated financial statements (as restated) also include adjustments to correct certain other previously identified misstatements relating to prior periods that the Company had determined to be immaterial, both individually and in aggregate, with a decrease in other expenses of \$0.7 million for the year ended December 31, 2021 and an increase in other expenses of \$2.0 million for the year ended December 31, 2022 in the consolidated statements of operations and comprehensive loss.

Impact of restatement

See below for reconciliation from the previously reported to the restated amounts in the consolidated statements of operations and comprehensive loss for the years ended December 31, 2022 and 2021, and in the consolidated balance sheets as of December 31, 2022. The previously reported amounts were derived from the Company's Annual Report on Form 10-K for the year ended December 31, 2022 filed with the SEC on February 28, 2023 (Original Report). These amounts are labeled as "As Previously Reported" in the tables below. The amounts labeled "Restatement Adjustment" represent the effects of this restatement described above.

The following presents a reconciliation of the impacted financial statement line items as previously reported to the restated amounts as of December 31, 2022, and for the years ended December 31, 2022 and 2021 (in thousands, except share and per share data):

| | December 31, 2022 | | |
|--|-------------------------------|-------------------------------|--------------------|
| | As previously Reported | Restatement Adjustment | As Restated |
| Consolidated Balance Sheets | | | |
| Equity method investment | \$ 12,817 | \$ 4,500 | \$ 17,317 |
| Total assets | 817,079 | 4,500 | 821,579 |
| Deferred revenue | 885 | (790) | 95 |
| Total current liabilities | 54,518 | (790) | 53,728 |
| Other long-term liabilities | 1,569 | 4,278 | 5,847 |
| Total liabilities | 151,209 | 3,488 | 154,697 |
| Accumulated deficit | (1,235,980) | 1,012 | (1,234,968) |
| Total stockholders' equity | 665,870 | 1,012 | 666,882 |
| Total liabilities and stockholders' equity | 817,079 | 4,500 | 821,579 |

Table of Contents

| Consolidated Statements of Operations and Comprehensive Loss | Year ended December 31, 2022 | | | Year ended December 31, 2021 | | |
|---|------------------------------|------------------------|------------------|------------------------------|------------------------|------------------|
| | As Previously Reported | Restatement Adjustment | As Restated | As Previously Reported | Restatement Adjustment | As Restated |
| Collaboration revenue - related party | \$ 243 | \$ (87) | \$ 156 | \$ 38,489 | \$ 75,600 | \$ 114,089 |
| Operating expenses: | | | | | | |
| Research and development | 256,387 | — | 256,387 | 220,176 | — | 220,176 |
| General and administrative | 79,305 | — | 79,305 | 74,105 | — | 74,105 |
| Total operating expenses | 335,692 | — | 335,692 | 294,281 | — | 294,281 |
| Loss from operations | (335,449) | (87) | (335,536) | (255,792) | 75,600 | (180,192) |
| Other income (expense), net: | | | | | | |
| Interest and other income, net | 4,566 | — | 4,566 | 1,714 | — | 1,714 |
| Other expenses | (1,749) | (7,695) | (9,444) | (2,927) | (646) | (3,573) |
| Total other income (expense), net | 2,817 | (7,695) | (4,878) | (1,213) | (646) | (1,859) |
| Net loss | (332,632) | (7,782) | (340,414) | (257,005) | 74,954 | (182,051) |
| Other comprehensive income: | | | | | | |
| Net unrealized (loss) gain on available-for-sale investments, net of tax | (7,359) | — | (7,359) | (2,835) | — | (2,835) |
| Net comprehensive loss | (339,991) | (7,782) | (347,773) | (259,840) | 74,954 | (184,886) |
| Net loss per share, basic and diluted | (2.32) | | (2.38) | (1.89) | | (1.34) |
| Weighted-average number of shares used in computing net loss per share, basic and diluted | 143,147,165 | | 143,147,165 | 135,820,386 | | 135,820,386 |

| Consolidated Statements of Stockholders' Equity | Year ended December 31, 2022 | | | Year ended December 31, 2021 | | |
|---|------------------------------|------------------------|----------------|------------------------------|------------------------|----------------|
| | As Previously Reported | Restatement Adjustment | As Restated | As Previously Reported | Restatement Adjustment | As Restated |
| Net Loss | \$ (332,632) | \$ (7,782) | \$ (340,414) | \$ (257,005) | \$ 74,954 | \$ (182,051) |
| Accumulated Deficit | (1,235,980) | 1,012 | (1,234,968) | (903,348) | 8,794 | (894,554) |
| Total stockholders' equity | 665,870 | 1,012 | 666,882 | 916,406 | 8,794 | 925,200 |

| Consolidated Statements of Cash Flow | Year ended December 31, 2022 | | | Year ended December 31, 2021 | | |
|--|------------------------------|------------------------|------------------|------------------------------|------------------------|------------------|
| | As Previously Reported | Restatement Adjustment | As Restated | As Previously Reported | Restatement Adjustment | As Restated |
| Net Loss | \$ (332,632) | \$ (7,782) | \$ (340,414) | \$ (257,005) | \$ 74,954 | \$ (182,051) |
| Non-cash collaboration revenue - related party | — | (104) | (104) | — | (75,740) | (75,740) |
| Share of losses from equity method investments | 5,188 | 7,695 | 12,883 | 3,444 | 646 | 4,090 |
| Changes in operating assets and liabilities: | | | | | | |
| Deferred revenue | 462 | (483) | (21) | (38,569) | 272 | (38,297) |
| Other long-term liabilities | (2,556) | 674 | (1,882) | 1,042 | (132) | 910 |
| Net cash used in operating activities | (220,519) | — | (220,519) | (184,812) | — | (184,812) |

The remainder of the notes to the Company's consolidated financial statements have been updated and restated, as applicable, to reflect the impacts from the restatement discussed above.

Included in Note 15 of these consolidated financial statements is the impact of restatement on previously issued (i) unaudited condensed balance sheets as of March 31, 2023 and 2022, June 30, 2023 and 2022 and September 30, 2023 and 2022, (ii) unaudited condensed statements of operations and comprehensive loss for the three months ended March 31, 2023 and 2022, three and six months ended June 30, 2023 and 2022, and three and nine months ended September 30, 2023 and 2022, (iii) unaudited condensed statements of cash flows for the three months ended March 31, 2023 and 2022, six months ended June 30, 2023 and 2022 and nine months ended September 30, 2023 and 2022, in each of the Quarterly Reports on Form 10-Q for the quarterly periods ended March 31, 2023, June 30, 2023 and September 30, 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

[Table of Contents](#)

limited to the fair value of common stock, the fair value of stock options, the fair value of investments, income tax uncertainties, 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, 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, 2023 and 2022, 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.

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

[Table of Contents](#)

not it will be required to sell any available-for-sale securities before recovery of its amortized cost basis. Realized gains and losses and declines in fair value judged to be other than temporary, if any, on available-for-sale securities are included in interest and other income, net. The cost of investments sold is based on the specific-identification method. Interest income on investments 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 sheet 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 adopted Accounting Standards Update ("ASU") No. 2018-15, *Intangibles – Goodwill and other – Internal-Use Software (Subtopic 350-40)* on January 1, 2020 on a prospective basis. 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 sheet. Capitalized implementation costs from cloud computing arrangements are amortized over the term of the cloud-based service arrangement.

Leases

The Company early adopted ASU No. 2016-2, *Leases* on January 1, 2018. 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.

[Table of Contents](#)

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 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. The Company has not experienced any material differences between accrued costs and actual costs incurred since its inception.

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.

[Table of Contents](#)

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, 2023, 2022 and 2021 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 loss of \$13.2 million for the year ended December 31, 2023 (see Note 5). There were no long-lived assets impairment losses recorded for the years ended December 31, 2022 and December 31, 2021.

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

[Table of Contents](#)

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

There have been no new accounting pronouncements issued or effective that are expected to have a material impact on the Company's consolidated financial statements.

Recent Accounting Pronouncements Not Yet Adopted

In September 2023, the FASB issued Accounting Standard Update No. 2023-09, *Income taxes (Topic 740), Improvement to income tax disclosures*, which requires to disclose some additional information in the consolidated financial statements. This standard is effective for fiscal years beginning after December 15, 2024, with early adoption permitted. The Company is currently evaluating the impact of the new guidance on its consolidated financial statements.

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.

[Table of Contents](#)

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 at December 31, 2023 or 2022.

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 | <u>\$ 308,052</u> | <u>\$ 136,026</u> | <u>\$ —</u> | <u>\$ 444,078</u> |

¹ Included within cash and cash equivalents on the Company's consolidated balance sheet

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, 2022 are presented in the following table:

| | December 31, 2022 | | | |
|---------------------------------|--------------------------|-------------------|----------------|-------------------|
| | Level 1 | Level 2 | Level 3 | Fair Value |
| | (in thousands) | | | |
| Financial Assets: | | | | |
| Money market funds ¹ | \$ 10,679 | \$ — | \$ — | \$ 10,679 |
| Commercial paper | — | 4,954 | — | 4,954 |
| Corporate bonds | — | 153,256 | — | 153,256 |
| U.S. treasury securities | 318,022 | — | — | 318,022 |
| U.S. agency securities | — | 39,416 | — | 39,416 |
| Total financial assets | <u>\$ 328,701</u> | <u>\$ 197,626</u> | <u>\$ —</u> | <u>\$ 526,327</u> |

¹ Included within cash and cash equivalents on the Company's consolidated balance sheet

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, 2023 or 2022.

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, 2023 are presented in the following table:

| 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 | <u>\$ 444,589</u> | <u>\$ 245</u> | <u>\$ (756)</u> | <u>\$ 444,078</u> |
| Classified as: | | | | |
| Cash equivalents | | | | \$ 78,536 |
| Short-term investments | | | | 365,542 |
| Long-term investments | | | | — |
| Total cash equivalents, and investments | | | | <u>\$ 444,078</u> |

The fair value and amortized cost of cash equivalents and available-for-sale securities by major security type as of December 31, 2022 are presented in the following table:

| December 31, 2022 | | | | |
|---|---------------------------|-----------------------------|------------------------------|-------------------|
| | Amortized Cost | Unrealized Gains | Unrealized Losses | Fair Value |
| (in thousands) | | | | |
| Money market funds | \$ 10,679 | \$ — | \$ — | \$ 10,679 |
| Commercial paper | 4,956 | — | (2) | 4,954 |
| Corporate bonds | 156,019 | 25 | (2,788) | 153,256 |
| U.S. treasury securities | 323,077 | 5 | (5,060) | 318,022 |
| U.S. agency securities | 41,078 | — | (1,662) | 39,416 |
| Total cash equivalents and investments | <u>\$ 535,809</u> | <u>\$ 30</u> | <u>\$ (9,512)</u> | <u>\$ 526,327</u> |
| Classified as: | | | | |
| Cash equivalents | | | | \$ 11,760 |
| Short-term investments | | | | 455,416 |
| Long-term investments | | | | 59,151 |
| Total cash equivalents, and investments | | | | <u>\$ 526,327</u> |

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.

[Table of Contents](#)

The fair values of available-for-sale debt investments by contractual maturity as of December 31, 2023 and 2022 were as follows:

| | December 31, | |
|---|-------------------|-------------------|
| | 2023 | 2022 |
| | (in thousands) | |
| Due in 1 year or less | \$ 365,542 | \$ 456,497 |
| Due in 1 - 2 years | — | 59,151 |
| Due in 3 years | — | — |
| Instruments not due at a single maturity date | 78,536 | 10,679 |
| Total cash equivalents and investments | <u>\$ 444,078</u> | <u>\$ 526,327</u> |

As of December 31, 2023 and 2022, the remaining contractual maturities of available-for-sale securities were one year and less. Realized losses on available-for-sale securities for the year ended December 31, 2023 were \$1.0 million. There were no significant realized losses on available-for-sale securities for the years ended December 31, 2022 and 2021. As of December 31, 2023 and 2022, 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 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, 2023 and 2022, securities with a fair value of \$48.4 million and \$329.4 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.

As of December 31, 2023 and 2022, the Company recognized \$1.7 million and \$1.8 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, | |
|---|------------------|-------------------|
| | 2023 | 2022 |
| | (in thousands) | |
| Leasehold improvements | \$ 108,621 | \$ 108,550 |
| Laboratory equipment | 33,157 | 32,601 |
| Computer equipment and purchased software | 4,663 | 4,533 |
| Furniture and fixtures | 4,121 | 4,012 |
| Construction in progress | — | 28 |
| Total | 150,562 | 149,724 |
| Less: accumulated depreciation | (51,084) | (36,885) |
| Total property and equipment, net | <u>\$ 99,478</u> | <u>\$ 112,839</u> |

Depreciation expense for the years ended December 31, 2023, 2022 and 2021 was \$14.2 million, \$14.3 million and \$10.5 million, respectively. Disposals of property and equipment were less than \$0.1 million for the years ended December 31, 2023 and 2022. Disposals of property and equipment were zero for the year ended December 31, 2021.

To date, the Company has not recorded any impairment loss on its Property and Equipment. The Company continues to monitor its long-lived assets, including Property and Equipment, for events or changes in circumstances which indicate that the carrying amount of its long-lived assets may not be recoverable.

In December 2023, 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 in December 2023 and currently the Company is actively marketing the leased building for sublease. The Company determined that the change in how this property is being used could indicate impairment. The Company has determined it operates in a single operating segment and has one reportable segment. The Company identified two asset groups for purposes of long-lived asset impairment assessment: to be sublet property and

[Table of Contents](#)

remaining operating segment. The Company concluded that the carrying value of the sublet property asset group was not recoverable and the estimated fair value of this asset group was below its carrying value. The lower fair value of the sublet property asset group was mainly due to the lower estimated sublease income compared to the lease payments in accordance with the initial operating lease agreement and higher discount rate. The Company applied a discounted cash flow method to estimate fair value of its right-of-use asset. It represents level 3 non-recurring fair value measurement. Based on this analysis, the Company concluded the fair value of the right-of-use asset of \$13.8 million was lower than its net book value of \$27.0 million. 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%. The Company recognized pre-tax long-lived asset impairment charge of \$13.2 million on the right-of-use asset.

Accrued Liabilities

Accrued liabilities consist of the following:

| | December 31, | |
|---|-----------------------|------------------|
| | 2023 | 2022 |
| | (in thousands) | |
| Accrued compensation and related benefits | \$ 12,665 | \$ 17,935 |
| Accrued research and development expenses | 9,315 | 11,790 |
| Accrued lease liability | 6,775 | 6,002 |
| Unvested shares liability | 532 | 1,898 |
| Other | 1,809 | 2,118 |
| Total accrued and other current liabilities | <u>\$ 31,096</u> | <u>\$ 39,743</u> |

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, provided that the Company is not obligated to pay a milestone for regulatory approval in the European Union for an anti-CD19 allogeneic CAR T cell product, to the extent Servier has commercial rights to such territory. 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, 2023, 2022 and 2021.

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

[Table of Contents](#)

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 Collectis Agreement, Collectis 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 Collectis' 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 Collectis intellectual property rights granted by Collectis 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 Collectis Agreement.

Pursuant to the Collectis Agreement, the Company granted Collectis 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 Collectis Targets).

The Collectis 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. Collectis 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, Collectis intellectual property licensed to the Company under the Collectis 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 Collectis Agreement, and subject to certain exceptions, the Company is required to indemnify Collectis against all thirdparty 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 Collectis Agreement, and Collectis 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 Collectis Targets or arising out of Collectis' material breach of the representations, warranties or covenants set forth in the Collectis 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 Collectis Target, the Company has a right of first refusal or right of first negotiation to purchase or license from Collectis rights to develop and commercialize products against such Collectis Targets.

Under the Collectis 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 Collectis Target.

Unless earlier terminated in accordance with its terms, the Collectis 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 Collectis 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 Collectis 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 Collectis Agreement may also be terminated by the Company upon written notice at any time in the event that Collectis becomes bankrupt or insolvent or upon written notice within 60 days of a consummation of a change of control of Collectis.

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, 2023 and 2022, zero clinical development milestones were achieved. For the year ended December 31, 2021, \$10.0 million of costs were incurred related to the achievement of clinical development milestones under this agreement.

License and Collaboration Agreement with Servier

As part of the Pfizer Agreement, Pfizer assigned to the Company 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, 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 Servier Agreement, the Company has an exclusive license to develop, manufacture and commercialize UCART19, ALLO-501 and ALLO-501A 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.

Under the Servier Agreement, the Company is required to use commercially reasonable efforts to develop and obtain marketing approval in the United States in the field of anti-tumor adoptive immunotherapy for at least one product directed against CD19, and Servier is required to use commercially reasonable efforts to develop and obtain marketing approval in the European Union, and one other country in a group of specified countries outside of the European Union and the United States, in the field of anti-tumor adoptive immunotherapy for at least one allogeneic adaptive T cell product directed against a certain Company-selected target.

For product candidates that the Company is co-developing with Servier, including UCART19, ALLO-501 and ALLO-501A, the Company is responsible for 60% of the specified development costs and Servier is responsible for the remaining 40% of the specified development costs under the applicable global research and development plan. Subject to certain restrictions, each party has the right to conduct activities that are specific to its territory outside the global research and development plan at such party's sole expense. In addition, each party is solely responsible for commercialization activities in its territory at such party's sole expense.

The Company is required to make milestone payments to Servier upon successful completion of regulatory and sales milestones. The Servier Agreement provides for aggregate potential payments by the Company to Servier of up to \$137.5 million upon successful completion of various regulatory milestones, and aggregate potential payments by the Company to Servier of up to \$78.0 million upon successful completion of various sales milestones. Similarly, Servier is required to make milestone payments upon successful completion of regulatory and sales milestones for products directed at the Allogene-target covered by the Servier Agreement that achieves such milestones. The total potential payments that Servier is obligated to make to the Company under the Servier Agreement upon successful completion of regulatory and sales milestones are \$42.0 million and €70.5 million (\$77.8 million), respectively. The foregoing milestones are subject to certain adjustments if the Company obtains rights for certain products outside of the United States upon Servier's election not to pursue such rights.

Each party is also eligible to receive tiered royalties on annual net sales in countries within the paying party's respective territory of any licensed products that are commercialized by such party that are directed at the targets licensed by such party under the Servier Agreement. The royalty rates are in a range from the low tens to the high teen percentages. Such royalties may be reduced for interchangeable drug entry, expiration of patent rights and amounts paid pursuant to licenses of third-party patents. The royalty obligation for each party with respect to a given licensed product in a given country in each party's respective territory (the Servier Royalty Term) begins upon the first commercial sale of such product in such country and ends after a defined number of years.

Unless earlier terminated in accordance with the Servier Agreement, the Servier Agreement will continue, on a licensed product-by-licensed product and country-by-country basis, until the Servier Royalty Term with respect to the sale of such licensed product in such country expires.

On September 15, 2022, Servier sent a notice of discontinuation (Discontinuation) of its involvement in the development of all licensed products directed against CD19, including UCART19, ALLO-501 and ALLO-501A (collectively, CD19 Products), pursuant to the Servier Agreement. Servier's Discontinuation provides the Company with the right to elect a license to the CD19 Products outside of the United States (Ex-US Option) and does not otherwise affect the Company's current exclusive license for the development and commercialization of CD19 Products in the United States. However, Servier has

[Table of Contents](#)

disputed the implications of the Discontinuation, namely whether development cost contributions continue and the timeframe during which the Company has the right to elect a license to CD19 Products outside of the United States.

In December 2022, Servier sent the Company a notice for material breach due to the Company's purported refusal to allow an audit of certain manufacturing costs under the cost share arrangement. While the Company does not believe Servier has such an audit right, the Company submitted to a review of the Company's manufacturing costs of CD19 Products to recover outstanding manufacturing costs owed by Servier to the Company. In July 2023, Servier sent the Company a second notice for material breach alleging that the Company overcharged Servier based on Servier and its accounting firm's review of costs eligible for cost-sharing under the Servier Agreement. The Company disagrees with the material breach allegations and the Company is disputing such allegations. Absent a resolution between the parties, disputed matters may be resolved in arbitration as specified in the Servier Agreement.

For the years ended December 31, 2023, 2022 and 2021, the Company recorded zero, \$19.9 million, and \$17.1 million, respectively, of net cost recoveries under the cost-sharing terms of the Servier Agreement as a reduction to research and development expenses. As of December 31, 2023 and 2022, amounts due from Servier of zero and \$1.5 million, respectively, were recorded in other current assets in the accompanying consolidated balance sheets. For the year ended December 31, 2022, \$8.0 million in costs were incurred related to the achievement of a clinical development milestone under the Servier Agreement. Zero clinical development milestones were achieved for the years ended December 31, 2023 and 2021.

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. 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. The Company recognized a research and development expense of \$10 million during the year ended December 31, 2019 as the license had no foreseeable alternative future use. 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 serves 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 23.0% on a voting interest basis. The Company did not have a controlling interest in Notch as of December 31, 2023, and continued to account for its investment in Notch as an equity method investment.

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.

[Table of Contents](#)

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.

For the years ended December 31, 2023, 2022, and 2021, the Company recorded \$1.8 million, \$3.8 million, and \$4.3 million, respectively, in collaboration costs as research and development expenses. For the year ended December 31, 2021, \$0.3 million in costs were incurred related to the achievement of a research milestone under this agreement. Zero milestones were achieved for the years ended December 31, 2023 and 2022. For the year ended December 31, 2023, the Company recorded \$3.0 million in other expenses as impairment loss on its equity method investment in Notch. Zero impairment loss was recorded for the years ended December 31, 2022 and 2021.

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 obligated to make further payments to MD Anderson each year upon the anniversary of the agreement effective date through the duration of the agreement term. 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, 2023, 2022, and 2021, the Company recorded \$0.9 million, \$1.4 million, and \$1.0 million, respectively, in collaboration costs under this agreement as research and development expenses.

Joint Venture and License Agreement with Allogene Overland Biopharm (CY) Limited (As Restated)

On December 14, 2020, the Company entered into the License Agreement with Allogene Overland, a joint venture established by the Company and Overland, pursuant to the Share Purchase Agreement, 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. As of December 31, 2023, the Company and Overland are the sole equity holders in Allogene Overland. The Company received \$40 million from Allogene Overland as partial consideration for the License Agreement.

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, 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.

[Table of Contents](#)

Promises that the Company concluded were distinct performance obligations in the License Agreement 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 Allogene Overland. 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.

The Company has determined that Allogene Overland is a variable interest entity as of December 31, 2023 and 2022, respectively. The Company does not have the power to direct the activities which most significantly affect Allogene Overland's economic performance. Accordingly, for the years ended December 31, 2023 and 2022, the Company did not consolidate Allogene Overland because the Company determined that it was not the primary beneficiary. The Company's total equity investment in Allogene Overland as of December 31, 2023 and 2022 was zero and \$4.5 million, respectively (see Note 8).

For the years ended December 31, 2023, 2022 and 2021, the Company recognized \$0.1 million, \$0.2 million and \$114.1 million, respectively, of collaboration revenue, primarily related to support services and the delivery of a performance obligation consisting of a license of intellectual property and related know-how which was delivered in the first quarter of 2021. For the year ended December 31, 2022, the Company recorded \$0.7 million of net cost recoveries under the terms of the license agreement as a reduction to research and development expenses. For the years ended December 31, 2023 and 2021, the Company recorded zero net cost recoveries.

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.

[Table of Contents](#)

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. The Company accounts for the fair value of the new investment of \$1.0 million as an equity investment and the remaining \$1.0 million was recorded as research and development expense.

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, 2023 and 2022, the Company recorded \$1.8 million and \$5.0 million, respectively, in research and development expenses related to the upfront payment and collaboration costs. For the years ended December 31, 2023 and 2022, the Company recorded \$0.4 million and zero, respectively, in research and development expenses related to the achievement of a milestone under the Antion Collaboration and License Agreement. For the year ended December 31, 2023 and 2022, the Company recorded \$4.0 million and zero, respectively, in other expenses as impairment loss on its equity investment in Antion.

As of December 31, 2023 and 2022, research and development expenses recorded in accrued and other liabilities relating to Antion were zero and \$0.5 million, respectively. As of December 31, 2023 and 2022, the Company's total equity investment in Antion was zero and \$3.0 million, respectively, and is recognized in other long-term assets in the consolidated balance sheets.

Note 7. Commitments and Contingencies

Leases

In August 2018, the Company entered into an operating lease agreement (HQ Lease) for new 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 7 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 up to December 31, 2023. 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 8 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 7 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 March 31, 2032 with an option to extend the term for 8 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

[Table of Contents](#)

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.

The Company maintains letters of credit for the benefit of landlords which is disclosed as restricted cash in the consolidated balance sheet. Restricted cash related to letters of credit due to landlords was \$6.0 million as of December 31, 2023 and 2022.

The balance sheet classification of our lease liabilities were as follows (in thousands):

| | December 31, 2023 | December 31, 2022 |
|---|-------------------|-------------------|
| Operating lease liabilities | | |
| Current portion included in accrued and other current liabilities | \$ 6,775 | \$ 6,002 |
| Long-term portion of lease liabilities | 88,346 | 95,122 |
| Total operating lease liabilities | <u>\$ 95,121</u> | <u>\$ 101,124</u> |

The components of lease costs for operating leases, which were recognized in operating expenses, were as follows (in thousands):

| | Year Ended December 31, | | |
|----------------------|-------------------------|------------------|-----------------|
| | 2023 | 2022 | 2021 |
| Operating lease cost | \$ 12,711 | \$ 11,664 | \$ 7,513 |
| Variable lease cost | 3,102 | 2,139 | 1,629 |
| Total lease costs | <u>\$ 15,813</u> | <u>\$ 13,803</u> | <u>\$ 9,142</u> |

Cash paid for amounts included in the measurement of lease liabilities for the year ended December 31, 2023 was \$12.0 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, 2023 is as follows:

| Year ending December 31: | (in thousands) |
|-----------------------------------|------------------|
| 2024 | \$ 12,447 |
| 2025 | 12,627 |
| 2026 | 12,819 |
| 2027 | 13,257 |
| 2028 and thereafter | 77,234 |
| Total undiscounted lease payments | 128,384 |
| Less: Present value adjustment | (33,263) |
| Total | <u>\$ 95,121</u> |

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 6.22%. As of December 31, 2023, the weighted average remaining lease term for our operating leases is 9.03 years.

The Company did not incur any significant rent expense for short-term leases for the years ended December 31, 2023, 2022 and 2021, 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 \$0.6 million as of December 31, 2023 and 2022.

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, 2023 and 2022.

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, 2023.

Purchase Commitments

In the normal course of business, the Company enters into various purchase commitments with third-party contract manufacturers for the manufacture and processing of our product candidates and related raw materials, and the Company has entered into other contracts in the normal course of business with contract research organizations for clinical trials and other vendors for other services and products for operating purposes. These agreements generally provide for termination or cancellation, other than for costs already incurred. As of December 31, 2023, the Company had non-cancellable purchase commitments of \$2.1 million.

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 Method Investments (As Restated)

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.

The Company's total equity investment in Notch as of December 31, 2023 and 2022 was \$3.6 million and \$12.8 million, respectively, and the Company accounted for the investment using the equity method of accounting. During the years ended December 31, 2023, 2022 and 2021, the Company recognized its share of Notch's net loss of \$6.2 million, \$7.2 million

[Table of Contents](#)

and \$2.7 million, respectively, under the other expenses caption within the consolidated statement of operations. For the year ended December 31, 2023, the Company recorded \$3.0 million in other expenses as impairment loss on its equity method investment in Notch. Zero impairment loss was recorded for the years ended December 31, 2022 and 2021.

Allogene Overland Biopharm (CY) Limited

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 Stock representing a 49% ownership interest in exchange for entering into a License Agreement.

The Company's total equity investment in Allogene Overland as of December 31, 2023 and 2022 was zero and \$4.5 million, respectively, and the Company accounted for the investment using the equity method of accounting. During the years ended December 31, 2023, 2022 and 2021, the Company recognized its share of Allogene Overland's net loss of \$4.5 million, \$5.7 million, and \$1.3 million, respectively, under the other expenses 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, 2023 and 2022.

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 168,642,238 and 144,438,304 shares were issued and outstanding at December 31, 2023 and 2022, 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, 2023 and 2022, 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, 2023 and 2022, there were 6,468,650 and 12,932,861 shares reserved by the Company under the 2018 Plan for the future issuance of equity awards.

Stock Option Exchange program

[Table of Contents](#)

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 (in years) | Aggregate Intrinsic Value (in thousands) |
| Balance, December 31, 2022 | 17,569,575 | \$ 12.90 | 7.73 | \$ 6,658 |
| Options granted | 10,315,270 | 4.94 | | |
| Options exercised | (850,396) | 2.45 | | \$ 2,334 |
| Options forfeited | (5,221,503) | 11.31 | | |
| Balance, December 31, 2023 | <u>21,812,946</u> | \$ 9.93 | 7.53 | \$ 662 |
| Exercisable, December 31, 2023 | 18,687,724 | \$ 9.98 | 7.56 | \$ 639 |
| Vested and expected to vest, December 31, 2023 | <u>21,812,946</u> | \$ 9.93 | 7.53 | \$ 662 |

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, 2023. The aggregate intrinsic value of options exercised during the years ended December 31, 2023, 2022 and 2021 was \$2.3 million, \$1.9 million and \$21.9 million, respectively. During the years ended December 31, 2023, 2022 and 2021, the estimated weighted-average grant-date fair value of employee options granted was \$3.33 per share, \$9.97 per share and \$18.79 per share, respectively. As of December 31, 2023 and 2022, there was \$58.1 million and \$83.2 million, respectively, of unrecognized stock-based compensation related to unvested stock options, which is expected to be recognized over a weighted-average period of 2.42 years and 2.70 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, | |
|----------------------------------|--------------------------------|------------------|
| | 2023 | 2022 |
| Fair value of common stock | \$2.72 - \$7.23 | \$7.08 - \$17.28 |
| Expected term in years | 5.27 - 6.08 | 5.25 - 6.08 |
| Expected volatility | 73.18% - 74.10% | 70.82% - 73.39% |
| Expected risk-free interest rate | 3.45% - 4.61% | 1.61% - 4.12% |
| Expected dividend | 0% | 0% |

[Table of Contents](#)

The fair value of the new options granted under the Option Exchange program was estimated at the date of grant using a lattice option pricing model with the following assumptions: expected volatility of 73.74%, expected risk-free rate of 3.06%, expected dividends of 0% and expected exercise barrier of 2.57.

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 grants before October 2018 when the Company was private and there was no public market for the Company’s common stock, the fair value of the Company’s common stock underlying share-based awards was estimated on each grant date by the Company’s Board of Directors. In order to determine the fair value of the Company’s common stock underlying option grants, the Company’s Board of Directors considered, among other things, valuations of the Company’s common stock prepared by an unrelated third-party valuation firm in accordance with the guidance provided by the American Institute of Certified Public Accountants Practice Guide, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*. 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— The Company uses 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. The Company will continue to apply this process until a sufficient amount of historical information regarding the volatility of its own stock price becomes available.

Risk-free interest rate—The risk-free interest rate is based on the U.S. Treasury 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.

For the years ended December 31, 2023, 2022 and 2021, total stock-based compensation expense related to stock options was \$34.4 million, \$42.2 million and \$38.2 million, respectively.

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 (in years) | Aggregate Intrinsic Value (in thousands) |
| Unvested December 31, 2022 | 5,493,406 | \$ 16.86 | 1.54 | \$ 34,554 |
| Granted | 12,119,645 | 4.55 | 1.79 | |
| Vested | (1,905,294) | 17.47 | | |
| Forfeited | (3,527,286) | 9.39 | | |
| Unvested December 31, 2023 | <u>12,180,471</u> | \$ 6.68 | 2.00 | \$ 39,099 |
| Vested and expected to vest, December 31, 2023 | <u>12,180,471</u> | \$ 6.68 | 2.00 | \$ 39,099 |

For the year ended December 31, 2023, the Company granted 3,264,750 performance-based restricted stock units and 2,189,125 restricted stock units with a market condition to certain executive officers and other employees pursuant to the 2018

[Table of Contents](#)

Plan. These awards are subject to the holders' continuous service to the Company through each applicable vesting event. Through December 31, 2023, 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, 2023. The Company recognized \$2.2 million in stock-based compensation expense related to the restricted units with a market condition for the year ended December 31, 2023.

For the years ended December 31, 2023, 2022 and 2021, total stock-based compensation expense related to restricted stock units, performance based restricted stock units and restricted stock units with a market condition was \$28.5 million, \$34.3 million and \$26.6 million, respectively. For the years ended December 31, 2023, 2022 and 2021, 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 \$33.3 million, \$32.8 million and \$18.5 million, respectively. As of December 31, 2023 and 2022, there was \$50.7 million and \$70.5 million, respectively, of unrecognized stock-based compensation which is expected to be recognized over a weighted average period of 2.36 years and 2.55 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, 2023 and 2022, the number of shares authorized under the ESPP for employee purchases increased by 1,444,383 and 1,426,230 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, | |
|--------------------------|-------------------------|-----------------|
| | 2023 | 2022 |
| Expected term (in years) | 0.50 – 2.00 | 0.50 – 2.00 |
| Volatility | 67.32% - 85.05% | 74.20% - 85.63% |
| Risk-free interest rate | 4.05%-5.35% | 0.86% - 3.88% |
| Dividend yield | — | — |

For the years ended December 31, 2023, 2022 and 2021, total stock-based compensation expense related to ESPP was \$3.1 million, \$3.6 million and \$2.3 million, respectively.

Founders' Stock

In 2018, the Company's founders agreed to modify their common shares outstanding to include vesting provisions that require continued service to the Company in order to vest in those shares. Stock-based compensation expense is recognized for shares of founders' stock as vesting conditions are met. In relation to the modification, 24,230,750 shares of founders' stock remained unvested at the modification date in April 2018. For the years ended December 31, 2022, and 2021, \$3.4 million and \$13.7 million of stock-based compensation expense was recognized related to the vesting of 1,514,424, and 6,057,695 shares, respectively, of founders' stock. At December 31, 2022, there was no unrecognized stock-based compensation expense. The weighted-average fair value at grant date for founders' stock was \$2.27 per share.

Stock-based compensation expense

[Table of Contents](#)

For the years ended December 31, 2023, 2022 and 2021, the Company recorded \$66.0 million, \$83.6 million and \$80.8 million, respectively, of stock-based compensation expense related to stock options, restricted stock units, employee stock purchase plans and vesting of the founders' common stock as research and development and general and administrative expense in its consolidated statements of operations and comprehensive loss.

Early Exercised Options

The Company allows certain of its employees and its directors to exercise options granted under the Prior 2018 Plan and the 2018 Plan prior to vesting. The shares related to early exercised stock options are subject to the Company's lapsing repurchase right upon termination of employment or service on the Company's Board of Directors at the lesser of the original purchase price or fair market value at the time of repurchase. In order to vest, the holders are required to provide continued service to the Company. The proceeds are initially recorded in accrued and other liabilities and other long-term liabilities for the noncurrent portion. The proceeds are reclassified to paid-in capital as the repurchase right lapses. During the years ended December 31, 2023 and 2022, no options were early exercised. As of December 31, 2023 and 2022, there was \$0.5 million and \$1.9 million, respectively, recorded in accrued and other liabilities and zero and \$0.6 million, respectively, recorded in other long-term liabilities related to shares held by employees and directors that were subject to repurchase. The underlying shares are shown as outstanding in the consolidated financial statements since the exercise date but the shares which are subject to future vesting conditions are not included in the calculation of earnings per share.

Note 11. Related Party Transactions

Pfizer Inc.

PF Equity Holdings 2 B.V. held 22,032,040 shares of Common Stock based on the Schedule 13D/A filed on September 17, 2021 with the SEC. According to the Schedule 13D/A filing, PF Equity Holdings 2 B.V. is a wholly-owned subsidiary of Pfizer formed for the purpose of holding certain assets owned or controlled by Pfizer or its direct or indirect subsidiaries. Based on a Form 4 filed on April 4, 2022 by PF Equity Holdings 2 B.V., Pfizer held the 22,032,040 shares as of March 31, 2022.

Collaboration Revenue and Equity Method Investment (As Restated)

In December 2020, the Company entered into the License Agreement with Allogene Overland, 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. During the years ended December 31, 2023, 2022 and 2021, the Company recognized \$0.1 million, \$0.2 million and \$114.1 million, respectively, of collaboration revenue under this arrangement.

For the year ended December 31, 2023, 2022 and 2021, the Company recorded zero, \$0.7 million and \$0.2 million, respectively, of net cost recoveries under the terms of the license agreement as a reduction to research and development expenses. For the years ended December 31, 2023, 2022 and 2021, the Company recorded \$4.5 million, \$5.7 million and \$1.3 million, respectively, of its share of Allogene Overland's net loss as other expenses (see Note 8).

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. The costs incurred for services provided under this agreement were \$0.3 million, \$0.7 million and \$0.6 million for the years ended December 31, 2023, 2022 and 2021, respectively. In December 2023, the service agreement between the Company and Two River was terminated.

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. Beldegrun, 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

[Table of Contents](#)

the services. The costs incurred for services provided, bonus and out-of-pocket expenses incurred under this consulting agreement were \$0.9 million, \$0.8 million and \$0.7 million for the years ended December 31, 2023, 2022 and 2021, respectively.

As of December 31, 2023 and 2022, amounts due to Bellco of \$0.2 million and \$0.3 million, respectively, were 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 for 1,293 square feet of office space in Los Angeles, California for a three year term. On April 1, 2020, Bellco Capital Advisors Inc. 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 chair, Arie Belldegrun, M.D., FACS, is a trustee of the Belldegrun Family Trust, which controls Bellco Capital Advisors Inc. The total right of use asset and associated liability recorded related to this related party lease was \$0.1 million and \$0.2 million at December 31, 2023 and 2022, respectively.

In February 2023, the Company subleased an additional 2,030 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 is expected to commence January 1, 2024. The Company paid approximately \$0.2 million towards the monthly base rent due for the first month of the sublease term and its share of the security deposit. The total estimated amount of base rent is \$2.9 million, subject to rent abatement. The Company also expects to contribute to certain tenant improvements to the space totaling to its share of the total tenant contribution.

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 \$2.5 million, \$2.3 million and \$1.8 million for the years ended December 31, 2023, 2022 and 2021, 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.

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, | | |
|---------------------------------------|-------------------------|---------------|---------------|
| | 2023 | 2022 | 2021 |
| | | (As Restated) | (As Restated) |
| | (in thousands) | | |
| Tax benefit at federal statutory rate | \$ (68,725) | \$ (71,487) | \$ (38,231) |
| State taxes, net of federal benefit | (21,610) | (40,642) | 8,731 |
| Stock-based compensation | 11,132 | 8,619 | 4,534 |
| Research tax credits | (3,873) | (4,274) | (2,942) |
| Change in valuation allowance | 82,526 | 106,111 | 27,889 |
| Other | 550 | 1,673 | 19 |
| Benefit for incomes taxes | <u>\$ —</u> | <u>\$ —</u> | <u>\$ —</u> |

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.

[Table of Contents](#)

Significant components of our deferred tax assets and liabilities are as follows:

| | Year Ended December 31, | | |
|---------------------------------------|--------------------------------|-----------------|-----------------|
| | 2023 | 2022 | 2021 |
| | | (As Restated) | (As Restated) |
| | (in thousands) | | |
| Deferred tax assets: | | | |
| Net operating loss carryforwards | \$ 211,124 | \$ 174,222 | \$ 144,133 |
| Tax credit carryforwards | 32,826 | 24,517 | 15,595 |
| Intangibles | 14,524 | 16,966 | 14,092 |
| Accrued expenses | 3,039 | 4,227 | 3,091 |
| Lease liabilities | 26,358 | 28,298 | 15,724 |
| Stock based compensation | 25,350 | 25,731 | 14,693 |
| Investments | 28,735 | 26,291 | 15,849 |
| Capitalized R&D | 73,492 | 41,273 | — |
| Other | 2,189 | 1,741 | 1,076 |
| Total deferred tax assets | 417,637 | 343,266 | 224,253 |
| Deferred tax liabilities: | | | |
| Fixed assets | — | — | (250) |
| Right of use leased assets | (17,652) | (23,392) | (12,478) |
| Other | (301) | (244) | (68) |
| Total deferred tax liabilities | (17,953) | (23,636) | (12,796) |
| Net deferred tax assets | 399,684 | 319,630 | 211,457 |
| Valuation allowance | (399,684) | (319,630) | (211,457) |
| 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 \$80.1 million, \$108.2 million and \$28.5 million during the years ended December 31, 2023, 2022 and 2021, 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, 2023:

| | Amount | Expiration |
|--|----------------|-------------------|
| | (in thousands) | |
| Net operating losses, federal | \$ 707,797 | Indefinite |
| Net operating losses, federal | \$ 2 | 2037 |
| Net operating losses, state | \$ 895,132 | 2037-2043 |
| Tax credits, federal | \$ 26,383 | 2038-2043 |
| Tax credits, state | \$ 20,856 | 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.

In December 2019, the FASB issued Accounting Standards Update No. 2019-12, Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes (ASU 2019-12), which simplifies the accounting for income taxes, eliminates certain exceptions within ASC 740, Income Taxes, and clarifies certain aspects of the current guidance to promote consistency among reporting entities. This guidance was effective for the Company in the first quarter of 2021 on a prospective basis, and early adoption was permitted. The Company early adopted this standard as of January 1, 2020 on a prospective basis in

[Table of Contents](#)

accordance with ASC 250, Accounting Changes and Error Corrections. The adoption resulted in the Company no longer needing to determine the tax effect from unrealized gains on available for sale securities, which previously had been disclosed in the consolidated statement of operations as a benefit from income taxes. The impact of the adoption is that the benefit from income taxes in the consolidated statement of operations and comprehensive loss is zero. For the years ended December 31, 2023, 2022 and 2021, the Company recorded a tax benefit of zero.

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, | | |
|--|------------------|------------------|-----------------|
| | 2023 | 2022 | 2021 |
| | (in thousands) | | |
| Balance at beginning of the year: | \$ 14,570 | \$ 9,798 | \$ 6,161 |
| Additions based on tax positions related to current year | 4,325 | 4,772 | 3,637 |
| 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 | <u>\$ 18,895</u> | <u>\$ 14,570</u> | <u>\$ 9,798</u> |

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, 2023, 2022 and 2021, 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, | | |
|--|-------------------------|---------------|---------------|
| | 2023 | 2022 | 2021 |
| | | (As Restated) | (As Restated) |
| Numerator: | | | |
| Net loss | \$ (327,265) | \$ (340,414) | \$ (182,051) |
| Denominator: | | | |
| Weighted average common shares outstanding | 156,931,778 | 143,147,165 | 135,820,386 |
| Net loss per share, basic and diluted | \$ (2.09) | \$ (2.38) | \$ (1.34) |

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, | | |
|--|-------------------------|-------------------|-------------------|
| | 2023 | 2022 | 2021 |
| Stock options to purchase common stock | 21,812,946 | 17,569,575 | 10,239,167 |
| Restricted stock units subject to vesting | 12,180,471 | 5,493,406 | 4,261,108 |
| Expected shares purchased under Employee Stock Purchase Plan | 2,168,264 | 1,092,314 | 474,966 |
| Founder shares subject to future vesting | — | — | 1,514,424 |
| Early exercised stock options subject to future vesting | 29,180 | 138,841 | 720,321 |
| Total | <u>36,190,861</u> | <u>24,294,136</u> | <u>17,209,986</u> |

Note 15. Selected Quarterly Financial Data (Unaudited)

The following tables present selected quarterly financial data for 2023 and 2022 (in thousands, except share and per share data):

| Condensed Consolidated Balance Sheets | March 31, 2023 | | | March 31, 2022 | | |
|---|------------------------|------------------------|----------------|------------------------|------------------------|----------------|
| | As Previously Reported | Restatement Adjustment | As Restated | As Previously Reported | Restatement Adjustment | As Restated |
| Assets | | | | | | |
| Current assets: | | | | | | |
| Cash and cash equivalents | \$ 109,931 | \$ — | \$ 109,931 | \$ 84,514 | \$ — | \$ 84,514 |
| Short-term investments | 361,293 | — | 361,293 | 364,536 | — | 364,536 |
| Prepaid expenses and other current assets | 10,241 | — | 10,241 | 20,694 | — | 20,694 |
| Total current assets | 481,465 | — | 481,465 | 469,744 | — | 469,744 |
| Long-term investments | 42,788 | — | 42,788 | 284,093 | — | 284,093 |
| Operating lease right-of-use asset | 81,964 | — | 81,964 | 57,057 | — | 57,057 |
| Property and equipment, net | 109,849 | — | 109,849 | 120,200 | — | 120,200 |
| Restricted cash | 10,292 | — | 10,292 | 10,292 | — | 10,292 |
| Other long-term assets | 9,389 | — | 9,389 | 9,042 | — | 9,042 |
| Equity method investments | 11,124 | 3,257 | 14,381 | 14,204 | 13,459 | 27,663 |
| Total assets | 746,871 | 3,257 | 750,128 | 964,632 | 13,459 | 978,091 |
| Liabilities and stockholders' equity | | | | | | |
| Current liabilities: | | | | | | |
| Accounts payable | 14,688 | — | 14,688 | 8,708 | — | 8,708 |
| Accrued and other current liabilities | 44,624 | — | 44,624 | 27,763 | — | 27,763 |
| Deferred revenue | 273 | (187) | 86 | 406 | (259) | 147 |
| Total current liabilities | 59,585 | (187) | 59,398 | 36,877 | (259) | 36,618 |
| Lease liability, noncurrent | 93,514 | — | 93,514 | 69,035 | — | 69,035 |
| Other long-term liabilities | 1,510 | 3,695 | 5,205 | 3,490 | 3,681 | 7,171 |
| Total liabilities | 154,609 | 3,509 | 158,118 | 109,402 | 3,421 | 112,823 |
| Stockholders' equity: | | | | | | |
| Preferred stock, \$0.001 par value: 10,000,000 authorized as of March 31, 2023 and March 31, 2022; no shares were issued and outstanding as of March 31, 2023 and March 31, 2022 | — | — | — | — | — | — |
| Common stock, \$0.001 par value: 400,000,000 and 200,000,000 shares authorized as of March 31, 2023 and March 31, 2022, respectively; 145,740,333 and 143,569,902 shares issued and outstanding as of March 31, 2023 and March 31, 2022, respectively | 146 | — | 146 | 143 | — | 143 |
| Additional paid-in capital | 1,932,734 | — | 1,932,734 | 1,847,534 | — | 1,847,534 |
| Accumulated deficit | (1,334,684) | (252) | (1,334,936) | (983,198) | 10,037 | (973,161) |
| Accumulated other comprehensive loss | (5,934) | — | (5,934) | (9,249) | — | (9,249) |
| Total stockholders' equity (deficit) | 592,262 | (252) | 592,010 | 855,230 | 10,037 | 865,267 |
| Total liabilities and stockholders' equity | 746,871 | 3,257 | 750,128 | 964,632 | 13,459 | 978,091 |

[Table of Contents](#)

| Condensed Consolidated Statements of Operations and Comprehensive Loss | Three Months ended March 31, 2023 | | | Three Months ended March 31, 2022 | | |
|---|-----------------------------------|------------------------|-----------------|-----------------------------------|------------------------|-----------------|
| | As Previously Reported | Restatement Adjustment | As Restated | As Previously Reported | Restatement Adjustment | As Restated |
| Collaboration revenue - related party | \$ 52 | \$ (22) | \$ 30 | \$ 61 | \$ (22) | \$ 39 |
| Operating expenses: | | | | | | |
| Research and development | 80,238 | — | 80,238 | 60,156 | — | 60,156 |
| General and administrative | 18,884 | — | 18,884 | 19,897 | — | 19,897 |
| Total operating expenses | 99,122 | — | 99,122 | 80,053 | — | 80,053 |
| Loss from operations | (99,070) | (22) | (99,092) | (79,992) | (22) | (80,014) |
| Other income (expense), net: | | | | | | |
| Interest and other income, net | 2,059 | — | 2,059 | 492 | — | 492 |
| Other expenses | (1,693) | (1,242) | (2,935) | (350) | 1,265 | 915 |
| Total other income (expense), net | 366 | (1,242) | (876) | 142 | 1,265 | 1,407 |
| Net loss | (98,704) | (1,264) | (99,968) | (79,850) | 1,243 | (78,607) |
| Other comprehensive income: | | | | | | |
| Net unrealized (loss) gain on available-for-sale investments, net of tax | 3,992 | — | 3,992 | (6,682) | — | (6,682) |
| Net comprehensive loss | (94,712) | (1,264) | (95,976) | (86,532) | 1,243 | (85,289) |
| Net loss per share, basic and diluted | (0.68) | | (0.69) | (0.56) | | (0.56) |
| Weighted-average number of shares used in computing net loss per share, basic and diluted | 144,563,829 | | 144,563,829 | 141,356,306 | | 141,356,306 |

| Condensed Consolidated Statements of Cash Flow | Three Months ended March 31, 2023 | | | Three Months ended March 31, 2022 | | |
|--|-----------------------------------|------------------------|-----------------|-----------------------------------|------------------------|-----------------|
| | As Previously Reported | Restatement Adjustment | As Restated | As Previously Reported | Restatement Adjustment | As Restated |
| Net Loss | \$ (98,704) | \$ (1,264) | \$ (99,968) | \$ (79,850) | \$ 1,243 | \$ (78,607) |
| Non-cash collaboration revenue - related party | — | (20) | (20) | — | (26) | (26) |
| Share of losses from equity method investments | 1,693 | 1,242 | 2,935 | 3,800 | (1,265) | 2,535 |
| Changes in operating assets and liabilities: | | | | | | |
| Deferred revenue | (612) | 609 | (3) | (17) | 14 | (3) |
| Other long-term liabilities | (59) | (567) | (626) | (635) | 34 | (601) |
| Net cash used in operating activities | (66,639) | — | (66,639) | (68,237) | — | (68,237) |

[Table of Contents](#)

| Condensed Consolidated Balance Sheets | June 30, 2023 | | | June 30, 2022 | | |
|--|------------------------|------------------------|----------------|------------------------|------------------------|----------------|
| | As Previously Reported | Restatement Adjustment | As Restated | As Previously Reported | Restatement Adjustment | As Restated |
| Assets | | | | | | |
| Current assets: | | | | | | |
| Cash and cash equivalents | \$ 154,758 | \$ — | \$ 154,758 | \$ 96,041 | \$ — | \$ 96,041 |
| Short-term investments | 337,204 | — | 337,204 | 394,451 | — | 394,451 |
| Prepaid expenses and other current assets | 10,139 | — | 10,139 | 22,536 | — | 22,536 |
| Total current assets | 502,101 | — | 502,101 | 513,028 | — | 513,028 |
| Long-term investments | 52,586 | — | 52,586 | 195,637 | — | 195,637 |
| Operating lease right-of-use asset | 80,314 | — | 80,314 | 86,837 | — | 86,837 |
| Property and equipment, net | 106,386 | — | 106,386 | 117,216 | — | 117,216 |
| Restricted cash | 10,292 | — | 10,292 | 10,292 | — | 10,292 |
| Other long-term assets | 9,382 | — | 9,382 | 8,938 | — | 8,938 |
| Equity method investments | 9,910 | 2,036 | 11,946 | 15,696 | 7,977 | 23,673 |
| Total assets | 770,971 | 2,036 | 773,007 | 947,644 | 7,977 | 955,621 |
| Liabilities and stockholders' equity | | | | | | |
| Current liabilities: | | | | | | |
| Accounts payable | 10,229 | — | 10,229 | 9,713 | — | 9,713 |
| Accrued and other current liabilities | 44,263 | — | 44,263 | 34,360 | — | 34,360 |
| Deferred revenue | 229 | (143) | 86 | 836 | (732) | 104 |
| Total current liabilities | 54,721 | (143) | 54,578 | 44,909 | (732) | 44,177 |
| Lease liability, noncurrent | 91,821 | — | 91,821 | 98,232 | — | 98,232 |
| Other long-term liabilities | 1,523 | 3,674 | 5,197 | 2,554 | 4,175 | 6,729 |
| Total liabilities | 148,065 | 3,531 | 151,596 | 145,695 | 3,443 | 149,138 |
| Stockholders' equity: | | | | | | |
| Preferred stock, \$0.001 par value: 10,000,000 authorized as of June 30, 2023 and June 30, 2022; no shares were issued and outstanding as of June 30, 2023 and June 30, 2022 | — | — | — | — | — | — |
| Common stock, \$0.001 par value: 400,000,000 shares authorized as of June 30, 2023 and June 30, 2022; 167,133,664 and 143,723,171 shares issued and outstanding as of June 30, 2023 and June 30, 2022, respectively | 167 | — | 167 | 144 | — | 144 |
| Additional paid-in capital | 2,039,263 | — | 2,039,263 | 1,871,262 | — | 1,871,262 |
| Accumulated deficit | (1,412,673) | (1,495) | (1,414,168) | (1,057,985) | 4,534 | (1,053,451) |
| Accumulated other comprehensive loss | (3,851) | — | (3,851) | (11,472) | — | (11,472) |
| Total stockholders' equity (deficit) | 622,906 | (1,495) | 621,411 | 801,949 | 4,534 | 806,483 |
| Total liabilities and stockholders' equity | 770,971 | 2,036 | 773,007 | 947,644 | 7,977 | 955,621 |

[Table of Contents](#)

| Condensed Consolidated Statements of Operations and Comprehensive Loss | Three Months ended June 30, 2023 | | | Three Months ended June 30, 2022 | | |
|---|----------------------------------|------------------------|-----------------|----------------------------------|------------------------|-----------------|
| | As Previously Reported | Restatement Adjustment | As Restated | As Previously Reported | Restatement Adjustment | As Restated |
| Collaboration revenue - related party | \$ 44 | \$ (22) | \$ 22 | \$ 86 | \$ (22) | \$ 64 |
| Operating expenses: | | | | | | |
| Research and development | 62,038 | — | 62,038 | 57,171 | — | 57,171 |
| General and administrative | 18,524 | — | 18,524 | 19,509 | — | 19,509 |
| Total operating expenses | 80,562 | — | 80,562 | 76,680 | — | 76,680 |
| Loss from operations | (80,518) | (22) | (80,540) | (76,594) | (22) | (76,616) |
| Other income (expense), net: | | | | | | |
| Interest and other income, net | 3,778 | — | 3,778 | 315 | — | 315 |
| Other expenses | (1,249) | (1,221) | (2,470) | 1,492 | (5,481) | (3,989) |
| Total other income (expense), net | 2,529 | (1,221) | 1,308 | 1,807 | (5,481) | (3,674) |
| Net loss | (77,989) | (1,243) | (79,232) | (74,787) | (5,503) | (80,290) |
| Other comprehensive income: | | | | | | |
| Net unrealized (loss) gain on available-for-sale investments, net of tax | 2,083 | — | 2,083 | (2,223) | — | (2,223) |
| Net comprehensive loss | (75,906) | (1,243) | (77,149) | (77,010) | (5,503) | (82,513) |
| Net loss per share, basic and diluted | (0.53) | | (0.54) | (0.52) | | (0.56) |
| Weighted-average number of shares used in computing net loss per share, basic and diluted | 146,795,826 | | 146,795,826 | 143,385,045 | | 143,385,045 |

| Condensed Consolidated Statements of Operations and Comprehensive Loss | Six Months ended June 30, 2023 | | | Six Months ended June 30, 2022 | | |
|---|--------------------------------|------------------------|------------------|--------------------------------|------------------------|------------------|
| | As Previously Reported | Restatement Adjustment | As Restated | As Previously Reported | Restatement Adjustment | As Restated |
| Collaboration revenue - related party | \$ 96 | \$ (44) | \$ 52 | \$ 147 | \$ (44) | \$ 103 |
| Operating expenses: | | | | | | |
| Research and development | 142,276 | — | 142,276 | 117,327 | — | 117,327 |
| General and administrative | 37,408 | — | 37,408 | 39,406 | — | 39,406 |
| Total operating expenses | 179,684 | — | 179,684 | 156,733 | — | 156,733 |
| Loss from operations | (179,588) | (44) | (179,632) | (156,586) | (44) | (156,630) |
| Other income (expense), net: | | | | | | |
| Interest and other income, net | 5,837 | — | 5,837 | 807 | — | 807 |
| Other expenses | (2,942) | (2,463) | (5,405) | 1,142 | (4,216) | (3,074) |
| Total other income (expense), net | 2,895 | (2,463) | 432 | 1,949 | (4,216) | (2,267) |
| Net loss | (176,693) | (2,507) | (179,200) | (154,637) | (4,260) | (158,897) |
| Other comprehensive income: | | | | | | |
| Net unrealized (loss) gain on available-for-sale investments, net of tax | 6,075 | — | 6,075 | (8,905) | — | (8,905) |
| Net comprehensive loss | (170,618) | (2,507) | (173,125) | (163,542) | (4,260) | (167,802) |
| Net loss per share, basic and diluted | (1.21) | | (1.23) | (1.09) | | (1.12) |
| Weighted-average number of shares used in computing net loss per share, basic and diluted | 145,685,993 | | 145,685,993 | 142,376,280 | | 142,376,280 |

| Condensed Consolidated Statements of Cash Flow | Six Months ended June 30, 2023 | | | Six Months ended June 30, 2022 | | |
|--|--------------------------------|------------------------|------------------|--------------------------------|------------------------|------------------|
| | As Previously Reported | Restatement Adjustment | As Restated | As Previously Reported | Restatement Adjustment | As Restated |
| Net Loss | \$ (176,693) | \$ (2,507) | \$ (179,200) | \$ (154,637) | \$ (4,260) | \$ (158,897) |
| Non-cash collaboration revenue - related party | — | (34) | (34) | — | (69) | (69) |
| Share of losses from equity method investments | 2,907 | 2,463 | 5,370 | 2,309 | 4,216 | 6,525 |
| Changes in operating assets and liabilities: | | | | | | |
| Deferred revenue | (656) | 653 | (3) | 413 | (430) | (17) |
| Other long-term liabilities | (46) | (575) | (621) | (1,571) | 543 | (1,028) |
| Net cash used in operating activities | (128,496) | — | (128,496) | (110,768) | — | (110,768) |

[Table of Contents](#)

| Condensed Consolidated Balance Sheets | September 30, 2023 | | | September 30, 2022 | | |
|---|------------------------|------------------------|----------------|------------------------|------------------------|----------------|
| | As Previously Reported | Restatement Adjustment | As Restated | As Previously Reported | Restatement Adjustment | As Restated |
| Assets | | | | | | |
| Current assets: | | | | | | |
| Cash and cash equivalents | \$ 69,246 | \$ — | \$ 69,246 | \$ 74,357 | \$ — | \$ 74,357 |
| Short-term investments | 396,259 | — | 396,259 | 477,872 | — | 477,872 |
| Prepaid expenses and other current assets | 7,949 | — | 7,949 | 16,832 | — | 16,832 |
| Total current assets | 473,454 | — | 473,454 | 569,061 | — | 569,061 |
| Long-term investments | 32,170 | — | 32,170 | 85,108 | — | 85,108 |
| Operating lease right-of-use asset | 78,643 | — | 78,643 | 85,245 | — | 85,245 |
| Property and equipment, net | 102,826 | — | 102,826 | 114,442 | — | 114,442 |
| Restricted cash | 10,292 | — | 10,292 | 10,292 | — | 10,292 |
| Other long-term assets | 9,576 | — | 9,576 | 9,378 | — | 9,378 |
| Equity method investments | 5,365 | 1,085 | 6,450 | 14,046 | 6,905 | 20,951 |
| Total assets | 712,326 | 1,085 | 713,411 | 887,572 | 6,905 | 894,477 |
| Liabilities and stockholders' equity | | | | | | |
| Current liabilities: | | | | | | |
| Accounts payable | 6,205 | — | 6,205 | 11,045 | — | 11,045 |
| Accrued and other current liabilities | 31,195 | — | 31,195 | 36,938 | — | 36,938 |
| Deferred revenue | 236 | (150) | 86 | 889 | (790) | 99 |
| Total current liabilities | 37,636 | (150) | 37,486 | 48,872 | (790) | 48,082 |
| Lease liability, noncurrent | 90,102 | — | 90,102 | 96,706 | — | 96,706 |
| Other long-term liabilities | 1,486 | 3,702 | 5,188 | 2,033 | 4,255 | 6,288 |
| Total liabilities | 129,224 | 3,552 | 132,776 | 147,611 | 3,465 | 151,076 |
| Stockholders' equity: | | | | | | |
| Preferred stock, \$0.001 par value: 10,000,000 authorized as of September 30, 2023 and September 30, 2022; no shares were issued and outstanding as of September 30, 2023 and September 30, 2022 | — | — | — | — | — | — |
| Common stock, \$0.001 par value: 400,000,000 shares authorized as of September 30, 2023 and September 30, 2022; 168,175,221 and 144,031,588 shares issued and outstanding as of September 30, 2023 and September 30, 2022, respectively | 168 | — | 168 | 144 | — | 144 |
| Additional paid-in capital | 2,059,333 | — | 2,059,333 | 1,893,908 | — | 1,893,908 |
| Accumulated deficit | (1,473,988) | (2,467) | (1,476,455) | (1,141,133) | 3,440 | (1,137,693) |
| Accumulated other comprehensive loss | (2,411) | — | (2,411) | (12,958) | — | (12,958) |
| Total stockholders' equity (deficit) | 583,102 | (2,467) | 580,635 | 739,961 | 3,440 | 743,401 |
| Total liabilities and stockholders' equity | 712,326 | 1,085 | 713,411 | 887,572 | 6,905 | 894,477 |

[Table of Contents](#)

| Condensed Consolidated Statements of Operations and Comprehensive Loss | Three Months ended September 30, 2023 | | | Three Months ended September 30, 2022 | | |
|---|---------------------------------------|------------------------|-----------------|---------------------------------------|------------------------|-----------------|
| | As Previously Reported | Restatement Adjustment | As Restated | As Previously Reported | Restatement Adjustment | As Restated |
| Collaboration revenue - related party | \$ 43 | \$ (21) | \$ 22 | \$ 49 | \$ (22) | \$ 27 |
| Operating expenses: | | | | | | |
| Research and development | 45,977 | — | 45,977 | 63,641 | — | 63,641 |
| General and administrative | 17,041 | — | 17,041 | 18,897 | — | 18,897 |
| Total operating expenses | 63,018 | — | 63,018 | 82,538 | — | 82,538 |
| Loss from operations | (62,975) | (21) | (62,996) | (82,489) | (22) | (82,511) |
| Other income (expense), net: | | | | | | |
| Interest and other income, net | 6,205 | — | 6,205 | 1,002 | — | 1,002 |
| Other expenses | (4,545) | (951) | (5,496) | (1,661) | (1,072) | (2,733) |
| Total other income (expense), net | 1,660 | (951) | 709 | (659) | (1,072) | (1,731) |
| Net loss | (61,315) | (972) | (62,287) | (83,148) | (1,094) | (84,242) |
| Other comprehensive income: | | | | | | |
| Net unrealized (loss) gain on available-for-sale investments, net of tax | 1,440 | — | 1,440 | (1,486) | — | (1,486) |
| Net comprehensive loss | (59,875) | (972) | (60,847) | (84,634) | (1,094) | (85,728) |
| Net loss per share, basic and diluted | (0.37) | | (0.37) | (0.58) | | (0.59) |
| Weighted-average number of shares used in computing net loss per share, basic and diluted | 167,649,010 | | 167,649,010 | 143,661,721 | | 143,661,721 |

| Condensed Consolidated Statements of Operations and Comprehensive Loss | Nine Months ended September 30, 2023 | | | Nine Months ended September 30, 2022 | | |
|---|--------------------------------------|------------------------|------------------|--------------------------------------|------------------------|------------------|
| | As Previously Reported | Restatement Adjustment | As Restated | As Previously Reported | Restatement Adjustment | As Restated |
| Collaboration revenue - related party | \$ 139 | \$ (65) | \$ 74 | \$ 196 | \$ (66) | \$ 130 |
| Operating expenses: | | | | | | |
| Research and development | 188,253 | — | 188,253 | 180,968 | — | 180,968 |
| General and administrative | 54,449 | — | 54,449 | 58,303 | — | 58,303 |
| Total operating expenses | 242,702 | — | 242,702 | 239,271 | — | 239,271 |
| Loss from operations | (242,563) | (65) | (242,628) | (239,075) | (66) | (239,141) |
| Other income (expense), net: | | | | | | |
| Interest and other income, net | 12,042 | — | 12,042 | 1,809 | — | 1,809 |
| Other expenses | (7,487) | (3,414) | (10,901) | (519) | (5,288) | (5,807) |
| Total other income (expense), net | 4,555 | (3,414) | 1,141 | 1,290 | (5,288) | (3,998) |
| Net loss | (238,008) | (3,479) | (241,487) | (237,785) | (5,354) | (243,139) |
| Other comprehensive income: | | | | | | |
| Net unrealized (loss) gain on available-for-sale investments, net of tax | 7,515 | — | 7,515 | (10,391) | — | (10,391) |
| Net comprehensive loss | (230,493) | (3,479) | (233,972) | (248,176) | (5,354) | (253,530) |
| Net loss per share, basic and diluted | (1.55) | | (1.58) | (1.67) | | (1.70) |
| Weighted-average number of shares used in computing net loss per share, basic and diluted | 153,087,449 | | 153,087,449 | 142,809,469 | | 142,809,469 |

| Condensed Consolidated Statements of Cash Flow | Nine Months ended September 30, 2023 | | | Nine Months ended September 30, 2022 | | |
|--|--------------------------------------|------------------------|------------------|--------------------------------------|------------------------|------------------|
| | As Previously Reported | Restatement Adjustment | As Restated | As Previously Reported | Restatement Adjustment | As Restated |
| Net Loss | \$ (238,008) | \$ (3,479) | \$ (241,487) | \$ (237,785) | \$ (5,354) | \$ (243,139) |
| Non-cash collaboration revenue - related party | — | (49) | (49) | — | (87) | (87) |
| Share of losses from equity method investments | 7,452 | 3,414 | 10,866 | 3,959 | 5,288 | 9,247 |
| Changes in operating assets and liabilities: | | | | | | |
| Deferred revenue | (649) | 646 | (3) | 466 | (485) | (19) |
| Other long-term liabilities | (83) | (532) | (615) | (2,092) | 638 | (1,454) |
| Net cash used in operating activities | (184,026) | — | (184,026) | (158,423) | — | (158,423) |

Note 16. Subsequent Events

On January 3, 2024, the Company 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' minimal residual disease (MRD) assay as an in vitro diagnostic to identify the MRD+ patient population to be enrolled in the Company's planned 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 an MRD assay for use as an in vitro diagnostic with cema-cel. The Company has agreed to fund approximately \$26.0 million in MRD assay development costs, milestone payments for regulatory submissions and assay utilization to process clinical samples.

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, dated as of November 1, 2019. 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, the Company will be entitled to receive a percentage of upfront and/or milestone payments associated therewith up to a set cap, 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 investments in Notch, the Amended Notch Agreement grants the Company certain anti-dilution protections up to certain limits for certain pre-IPO equity financings.

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 substantially completed by the end of January 2024. The Company estimates that it will incur charges of approximately \$2.9 million for severance payments and employee benefits, primarily in the first quarter of 2024.

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, 2023, 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 ensure 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, and as a result of the material weakness described below, our Chief Executive Officer and Chief Financial Officer concluded that, as of December 31, 2023, our disclosure controls and procedures were not 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, and as a result of the material weakness described below, management has concluded that our internal control over financial reporting was not effective as of December 31, 2023.

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.

Material Weaknesses

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 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

[Table of Contents](#)

We have identified and begun to implement steps, as further described below, designed to remediate the foregoing material weakness. We will not consider the material weakness remediated until our controls are operational for a sufficient period of time and tested, enabling management to conclude that the controls are operating effectively.

To remediate this material weakness, we are in the process of improving the operation of our controls related to the technical accounting analysis of significant non-routine transactions which includes engaging third-party subject matter experts with significant relevant experience.

While the foregoing measures are intended to effectively remediate the material weakness described in this Item 9A, it is possible that additional remediation steps will be necessary. As such, as we continue to evaluate and implement our plan to remediate the material weakness, our management may decide to take additional measures to address the material weakness or modify the remediation steps described above. Until this material weakness is remediated, we plan to continue to perform additional analyses and other procedures to help ensure that our consolidated financial statements are prepared in accordance with GAAP.

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 no changes in our internal control over financial reporting that occurred during the most recently completed fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

None.

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

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 2024 Annual Meeting of Stockholders to be filed with the SEC on or before April 29, 2024 (our Proxy Statement) and is incorporated in this Annual Report by reference.

Our Board of Directors consists of the following members:

Elizabeth Barrett, 61, 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., 74, 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 Belco 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 Bonderman, 81, has served as a member of our Board since April 2018. He is a Founding Partner and Chairman of TPG, a global alternative asset firm, established in 1992. Mr. Bonderman currently serves on the board of directors of TPG, Inc., a public company. He has previously served on the boards of many public companies, some of which include: RyanAir Holdings, plc and Continental Airlines, for both of which he was Chairman, Ducati Motor Holding, S.p.A, China International Capital Corporation Limited, Co-Star Group, Inc., General Motors Company, Kite Pharma, Inc., Oxford Health Plans, Inc., Paradyne Networks, Inc., Seagate Technology Holdings plc, TPG Pace Tech Opportunities Corp., TPG Pace Solutions Corp., TPG Pace Energy Holdings Corp., TPG Pace Holdings, Inc., TPG Pace Beneficial Finance Corp., and Univision Holdings, Inc. Throughout Mr. Bonderman’s career, he has served as a director on numerous other public, private, advisory, academic and charitable boards. Mr. Bonderman received a Bachelor of Arts degree from the University of Washington, cum laude, and a J.D. from Harvard Law School, magna cum laude, where he was a member of the Harvard Law Review and Sheldon Fellow.

David Chang, M.D., Ph.D., 64, 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,

[Table of Contents](#)

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, 61, 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., 77, 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, 47, 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., 62, 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, 66, 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

[Table of Contents](#)

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., 75, 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, 52, 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., 74, 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:

Timothy Moore, 62, has served as our Executive Vice President, Chief Technical Officer since April 24, 2023. Previously, Mr. Moore served as the Chief Operating Officer of Instil Bio from September 2022 to December 2022, President and Chief Operating Officer at PACT Pharma, Inc. from April 2020 to July 2022, and as the President and Chief Technology Officer at PACT from October 2019 to April 2020. Prior to PACT, Mr. Moore served as Executive Vice President, Technical Operations of Kite Pharma, or Kite, a Gilead Company, from March 2016 to September 2019. Prior to Kite, he spent more than 12 years at Genentech, a Roche Company, most recently as Senior Vice President, Head of Global Technical Operations – Biologics and as a member of the Genentech Executive Committee. He holds a B.S. in Chemical Engineering from Tulsa University and an M.S. from Northwestern University.

Zachary Roberts, M.D., Ph.D., 46, 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

[Table of Contents](#)

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, 59, 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 Better Therapeutics and 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, 61, 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.

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. We will promptly disclose on our website (i) the nature of any amendment to the policy 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 policy 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. |
| 10.8+ | Employment Agreement 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). |

Table of Contents

- 10.9+ [Consulting Agreement, dated April 29, 2023, by and between the Registrant and Alison Moore, Ph.D. \(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 3, 2023\).](#)
- 10.10+ [First Amendment to Consulting Agreement, dated December 16, 2023, by and between the Registrant and Alison Moore, Ph.D.](#)
- 10.11+ [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\).](#)
- 10.12+ [Employment Letter of Agreement, dated April 18, 2023, by and between the Registrant and Timothy Moore \(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 May 3, 2023\).](#)
- 10.13+ [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\).](#)
- 10.14+ [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\).](#)
- 10.15* [License Agreement, dated March 8, 2019, between the Registrant and Collectis 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\).](#)
- 10.16† [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 \(incorporated by reference to Exhibit 10.7 to the Registrant's Registration Statement on Form S-1, as amended \(File No. 333-227333\), filed with the SEC on September 17, 2018\).](#)
- 10.17† [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\).](#)
- 10.18* [Amended and Restated Collaboration and License Agreement, dated January 17, 2024, by and between the Registrant and Notch Therapeutics Inc.](#)
- 10.19 [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\).](#)
- 10.20 [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\).](#)
- 10.21 [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\).](#)
- 10.22 [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\).](#)
- 10.23 [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\).](#)
- 10.24 [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\).](#)
- 10.25 [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\).](#)

Table of Contents

| | |
|---------|--|
| 10.26*† | 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). |
| 10.27*† | 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). |
| 10.28* | 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). |
| 10.29* | Shareholders' 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 10.25 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). |
| 10.30* | Strategic Collaboration Agreement, dated January 3, 2024, by and between Foresight Diagnostics, Inc. and the Registrant |
| 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 |
| 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. |

+ Indicates management contract or compensatory plan.

† Confidential treatment has been granted with respect to certain portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission

* 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 14, 2024.

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.

[Table of Contents](#)

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.

| <u>Signature</u> | <u>Title</u> | <u>Date</u> |
|---|--|----------------|
| <u>/s/ David Chang, M.D., Ph.D.</u> David Chang, M.D., Ph.D. | President, Chief Executive Officer and Member of the Board of Directors <i>(Principal Executive Officer)</i> | March 14, 2024 |
| <u>/s/ Geoffrey Parker</u> Geoffrey Parker | Chief Financial Officer <i>(Principal Financial and Accounting Officer)</i> | March 14, 2024 |
| <u>/s/ Arie Beldegrun, M.D., FACS</u> Arie Beldegrun, M.D., FACS | Executive Chair of the Board of Directors | March 14, 2024 |
| <u>/s/ Elizabeth Barrett</u> Elizabeth Barrett | Member of the Board of Directors | March 14, 2024 |
| <u>/s/ David Bonderman</u> David Bonderman | Member of the Board of Directors | March 14, 2024 |
| <u>/s/ John DeYoung</u> John DeYoung | Member of the Board of Directors | March 14, 2024 |
| <u>/s/ Franz Humer, Ph.D.</u> Franz Humer, Ph.D. | Member of the Board of Directors | March 14, 2024 |
| <u>/s/ Joshua Kazam</u> Joshua Kazam | Member of the Board of Directors | March 14, 2024 |
| <u>/s/ Stephen Mayo, Ph.D.</u> Stephen Mayo, Ph.D. | Member of the Board of Directors | March 14, 2024 |
| <u>/s/ Deborah Messemer</u> Deborah Messemer | Member of the Board of Directors | March 14, 2024 |
| <u>/s/ Vicki Sato, Ph.D.</u> Vicki Sato, Ph.D. | Member of the Board of Directors | March 14, 2024 |
| <u>/s/ Todd Sisitsky</u> Todd Sisitsky | Member of the Board of Directors | March 14, 2024 |
| <u>/s/ Owen Witte, M.D.</u> Owen Witte, M.D. | Member of the Board of Directors | March 14, 2024 |