
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549**

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2024

OR

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

For the transition period from _____ to _____

Commission File Number: 001-38693

Allogene Therapeutics, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware

82-3562771

(State or other jurisdiction of
incorporation or organization)

(I.R.S. Employer
Identification No.)

210 East Grand Avenue, South San Francisco, California 94080

(Address of principal executive offices including zip code)

Registrant's telephone number, including area code: (650) 457-2700

N/A

(Former name, former address and former fiscal year, if changed since last report)

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, \$0.001 par value per share	ALLO	The Nasdaq Stock Market LLC

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, 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"/>	Smaller reporting company	<input 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 is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

As of May 9, 2024, the registrant had 170,853,379 shares of common stock, \$0.001 par value per share, outstanding.

Table of Contents

		<u>Page no.</u>
PART I: FINANCIAL INFORMATION		
Item 1.	Financial Statements	1
	Condensed Consolidated Balance Sheets	1
	Condensed Consolidated Statements of Operations and Comprehensive Loss	2
	Condensed Consolidated Statements of Stockholders' Equity	3
	Condensed Consolidated Statements of Cash Flows	4
	Notes to Condensed Consolidated Financial Statements	5
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	22
Item 3.	Quantitative and Qualitative Disclosures About Market Risk	32
Item 4.	Controls and Procedures	33
PART II: OTHER INFORMATION		
Item 1.	Legal Proceedings	35
Item 1A.	Risk Factors	35
Item 2.	Unregistered Sales of Equity Securities and Use of Proceeds	80
Item 3.	Defaults Upon Senior Securities	80
Item 4.	Mine Safety Disclosures	80
Item 5.	Other Information	80
Item 6.	Exhibits	81
	Signatures	82

PART I: FINANCIAL INFORMATION

Item 1. Financial Statements

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

	March 31, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	\$ 51,039	\$ 83,155
Short-term investments	333,821	365,542
Prepaid expenses and other current assets	10,504	10,418
Total current assets	395,364	459,115
Long-term investments	12,405	—
Operating lease right-of-use asset	64,483	63,703
Property and equipment, net	95,931	99,478
Restricted cash	10,292	10,292
Other long-term assets	5,159	6,604
Equity method investments	2,716	3,645
Total assets	<u>\$ 586,350</u>	<u>\$ 642,837</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 5,779	\$ 5,897
Accrued and other current liabilities	25,029	31,096
Deferred revenue	86	86
Total current liabilities	30,894	37,079
Lease liability, noncurrent	88,916	88,346
Other long-term liabilities	5,173	5,179
Total liabilities	<u>124,983</u>	<u>130,604</u>
Commitments and Contingencies (Notes 6 and 7)		
Stockholders' equity:		
Preferred stock, \$0.001 par value: 10,000,000 shares authorized as of March 31, 2024 and December 31, 2023; no shares were issued and outstanding as of March 31, 2024 and December 31, 2023	—	—
Common stock, \$0.001 par value: 400,000,000 shares authorized as of March 31, 2024 and December 31, 2023; 170,452,967 and 168,642,238 shares issued and outstanding as of March 31, 2024 and December 31, 2023, respectively	170	169
Additional paid-in capital	2,089,357	2,075,252
Accumulated deficit	(1,627,233)	(1,562,233)
Accumulated other comprehensive loss	(927)	(955)
Total stockholders' equity	461,367	512,233
Total liabilities and stockholders' equity	<u>\$ 586,350</u>	<u>\$ 642,837</u>

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

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

	Three Months Ended March 31,	
	2024	2023
Collaboration revenue - related party	\$ 22	\$ 30
Operating expenses:		
Research and development	52,259	80,238
General and administrative	17,267	18,884
Total operating expenses	69,526	99,122
Loss from operations	(69,504)	(99,092)
Other income (expense), net:		
Interest and other income, net	5,433	2,059
Other expenses	(929)	(2,935)
Total other income (expense), net	4,504	(876)
Net loss	(65,000)	(99,968)
Other comprehensive loss:		
Net unrealized gain on available-for-sale investments	28	3,992
Net comprehensive loss	\$ (64,972)	\$ (95,976)
Net loss per share, basic and diluted	\$ (0.38)	\$ (0.69)
Weighted-average number of shares used in computing net loss per share, basic and diluted	169,128,362	144,563,829

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

ALLOGENE THERAPEUTICS, INC.
Condensed Consolidated Statements of Stockholders' Equity
(Unaudited)
(In thousands, except share amounts)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
	Shares	Amount				
Balance - December 31, 2023	168,642,238	\$ 169	\$ 2,075,252	\$ (1,562,233)	\$ (955)	\$ 512,233
Issuance of common stock upon exercise of stock options and vesting of RSUs	1,551,729	1	793	—	—	794
Vesting of early exercised common stock	—	—	532	—	—	532
Stock-based compensation	—	—	11,924	—	—	11,924
Employee stock purchase plan	259,000	—	856	—	—	856
Net loss	—	—	—	(65,000)	—	(65,000)
Net unrealized gain on available-for-sale investments	—	—	—	—	28	28
Balance - March 31, 2024	170,452,967	\$ 170	\$ 2,089,357	\$ (1,627,233)	\$ (927)	\$ 461,367

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
	Shares	Amount				
Balance - December 31, 2022	144,438,304	\$ 144	\$ 1,911,632	\$ (1,234,968)	\$ (9,926)	\$ 666,882
Issuance of common stock upon exercise of stock options and vesting of RSUs	942,276	1	(1)	—	—	—
Vesting of early exercised common stock	—	—	603	—	—	603
Stock-based compensation	—	—	18,770	—	—	18,770
Employee stock purchase plan	359,753	1	1,730	—	—	1,731
Net loss	—	—	—	(99,968)	—	(99,968)
Net unrealized gain on available-for-sale investments	—	—	—	—	3,992	3,992
Balance - March 31, 2023	145,740,333	\$ 146	\$ 1,932,734	\$ (1,334,936)	\$ (5,934)	\$ 592,010

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

ALLOGENE THERAPEUTICS, INC.
Condensed Consolidated Statements of Cash Flows
(Unaudited)
(In thousands)

	Three Months Ended March 31,	
	2024	2023
Cash flows from operating activities:		
Net loss	\$ (65,000)	\$ (99,968)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	11,924	18,770
Depreciation and amortization	3,555	3,507
Net amortization/accretion on investment securities	(2,797)	508
Non-cash rent expense	(55)	207
Non-cash collaboration revenue - related party	(14)	(20)
Share of loss from equity method investments	929	2,935
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(86)	1,263
Other long-term assets	1,445	45
Accounts payable	(118)	1,057
Accrued and other current liabilities	(5,690)	5,686
Deferred revenue	—	(3)
Other long-term liabilities	8	(626)
Net cash used in operating activities	<u>(55,899)</u>	<u>(66,639)</u>
Cash flows from investing activities:		
Purchases of property and equipment	(8)	(1,035)
Proceeds from sales of investments	—	5,623
Proceeds from maturities of investments	103,272	143,441
Purchase of investments	(81,131)	(35,094)
Net cash provided by investing activities	<u>22,133</u>	<u>112,935</u>
Cash flows from financing activities:		
Proceeds from issuance of common stock upon exercise of stock options	794	—
Proceeds from issuance of common stock under the employee stock purchase plan	856	1,731
Net cash provided by financing activities	<u>1,650</u>	<u>1,731</u>
Net change in cash and cash equivalents and restricted cash	(32,116)	48,027
Cash and cash equivalents and restricted cash — beginning of period	93,447	72,196
Cash and cash equivalents and restricted cash — end of period	<u>\$ 61,331</u>	<u>\$ 120,223</u>
Non-cash operating activities:		
Right-of-use asset obtained in exchange for lease liability	\$ 2,409	\$ —
Non-cash deferred revenue and other long-term liabilities	\$ 3,079	\$ 3,137
Supplemental disclosure:		
Cash paid for amounts included in the measurement of lease liabilities	\$ (3,068)	\$ (2,965)

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

ALLOGENE THERAPEUTICS, INC.
Notes to Condensed Consolidated Financial Statements

1. Description of Business

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

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 and cash equivalents and investments of \$ 397.3 million as of March 31, 2024. Since inception through March 31, 2024, the Company has incurred cumulative net losses of \$1,627.2 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 accompanying unaudited condensed consolidated financial statements are filed with the Securities and Exchange Commission (SEC).

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (GAAP) for interim financial information and pursuant to Form 10-Q and Article 10 of Regulation S-X of the SEC. Accordingly, they do not include all of the information and footnotes required by GAAP for complete consolidated financial statements. In the Company’s opinion, all adjustments (consisting only of normal recurring adjustments) considered necessary for a fair presentation of the results of operations and cash flows for the periods presented have been included. The condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary, Allogene Therapeutics, B.V. The subsidiary was dissolved on January 3, 2024.

The condensed consolidated balance sheet as of March 31, 2024, the condensed consolidated statements of operations and comprehensive loss for the three months ended March 31, 2024 and 2023, the condensed consolidated statements of stockholders’ equity as of March 31, 2024 and 2023, the condensed consolidated statements of cash flows for the three months ended March 31, 2024 and 2023, and the financial data and other financial information disclosed in the notes to the condensed consolidated financial statements are unaudited. The results of operations for the three months ended March 31, 2024 are not necessarily indicative of the results to be expected for the year ending December 31, 2024, or for any other future annual or interim period. These condensed consolidated financial statements should be read in conjunction with the Company’s audited financial statements and related notes for the year ended December 31, 2023, included in the Company’s Annual Report on Form 10-K filed with the SEC on March 14, 2024.

Use of Estimates

The preparation of condensed 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 condensed consolidated financial statements and the reported amounts of expenses during the reporting period. Significant estimates and assumptions made in the accompanying condensed consolidated financial statements include but are not limited to the fair value of common stock, the fair value of stock options, the fair value of investments, income tax uncertainties, 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.

Significant Accounting Policies

There have been no significant changes to the accounting policies during the three months ended March 31, 2024, as compared to the significant accounting policies described in Note 1 of the "Notes to Financial Statements" in the Company's audited financial statements included in its Annual Report.

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 condensed consolidated financial statements.

Recent Accounting Pronouncements Not Yet Adopted

The Company continues to monitor new accounting pronouncements issued by the FASB and does not believe any accounting pronouncements issued through the date of this report will have a material impact on the Company's condensed consolidated financial statements.

3. Fair Value Measurements

The Company measures and reports its cash equivalents, restricted cash, and investments at fair value.

Money market funds are measured at fair value on a recurring basis using quoted prices and are classified as Level 1. Investments are measured at fair value based on inputs other than quoted prices that are derived from observable market data and are classified as Level 2 inputs, except for investments in U.S. treasury securities which are classified as Level 1.

There were no Level 3 assets or liabilities as of March 31, 2024 and as of December 31, 2023.

Financial assets subject to fair value measurements on a recurring basis and the level of inputs used in such measurements by major security type as of March 31, 2024 and as of December 31, 2023 are presented in the following tables:

	March 31, 2024			
	Level 1	Level 2	Level 3	Fair Value
	(In thousands)			
Financial Assets:				
Money market funds (1)	\$ 45,019	\$ —	\$ —	\$ 45,019
Commercial paper	—	4,879	—	4,879
Corporate bonds	—	109,071	—	109,071
U.S. treasury securities	203,676	—	—	203,676
U.S. agency securities	—	28,600	—	28,600
Total financial assets	<u>\$ 248,695</u>	<u>\$ 142,550</u>	<u>\$ —</u>	<u>\$ 391,245</u>

	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 condensed consolidated balance sheets.

4. Financial Instruments

The fair value and amortized cost of cash equivalents and available-for-sale securities by major security type as of March 31, 2024 and as of December 31, 2023 are presented in the following tables:

	March 31, 2024			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
	(In thousands)			
Money market funds	\$ 45,019	\$ —	\$ —	\$ 45,019
Commercial paper	4,886	—	(7)	4,879
Corporate bonds	109,188	31	(148)	109,071
U.S. treasury securities	203,894	2	(220)	203,676
U.S. agency securities	28,741	2	(143)	28,600
Total cash equivalents and investments	<u>\$ 391,728</u>	<u>\$ 35</u>	<u>\$ (518)</u>	<u>\$ 391,245</u>

Classified as:

Cash equivalents	\$ 45,019
Short-term investments	333,821
Long-term investments	12,405
Total cash equivalents and investments	<u>\$ 391,245</u>

	December 31, 2023				
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value	
	(In thousands)				
Money market funds	\$ 78,536	\$ —	\$ —	\$ 78,536	
Corporate bonds	97,265	113	(212)	97,166	
U.S. treasury securities	229,563	132	(179)	229,516	
U.S. agency securities	39,225	—	(365)	38,860	
Total cash equivalents and investments	\$ 444,589	\$ 245	\$ (756)	\$ 444,078	
Classified as:					
Cash equivalents				\$ 78,536	
Short-term investments				365,542	
Long-term investments				—	
Total cash equivalents and investments				\$ 444,078	

As of March 31, 2024, the remaining contractual maturities of available-for-sale securities were less than 2 years. Realized losses on available-for-sale securities for the three months ended March 31, 2024 and 2023 were zero and \$1.0 million, respectively. As of March 31, 2024, 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 March 31, 2024 and December 31, 2023, securities with a fair value of \$29.4 million and \$48.4 million, respectively, were in a continuous net unrealized loss position for more than 12 months. To date, the Company has not recorded any impairment charges on available-for-sale securities.

As of March 31, 2024 and December 31, 2023, the Company recognized \$ 1.7 million of accrued interest receivable from available-for-sale securities within prepaid expenses and other current assets on the condensed consolidated balance sheets.

5. Balance Sheet Components

Property and Equipment, Net

Property and Equipment consist of the following:

	March 31, 2024	December 31, 2023
	(In thousands)	
Leasehold improvements	108,621	108,621
Laboratory equipment	33,162	33,157
Computer equipment and purchased software	4,663	4,663
Furniture and fixtures	4,124	4,121
Total	150,570	150,562
Less: accumulated depreciation	(54,639)	(51,084)
Total property and equipment, net	\$ 95,931	\$ 99,478

Accrued and Other Current Liabilities

On January 4, 2024, the Company's Board of Directors approved a reduction in the Company's workforce of approximately 22% of the Company's employees in connection with the Company's pipeline prioritization and clinical development strategy. The reduction in workforce was substantially completed by the end of January 2024. During the three months ended March 31, 2024, the Company paid approximately \$2.6 million for severance and other employee benefits. As of March 31, 2024, \$0.4 million of the severance and other employee benefits accrual was included in accrued and other current liabilities on the condensed consolidated balance sheet.

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 because the Company does not presently hold commercial rights in 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 three months ended March 31, 2024 or 2023.

Pfizer is also eligible to receive, on a product-by-product and country-by-country basis, royalties in single-digit percentages on annual net sales for products covered by the Pfizer Agreement. The Company's royalty obligation with respect to a given product in a given country begins upon the first sale of such product in such country and ends on the later of (i) expiration of the last claim of any applicable patent or (ii) 12 years from the first sale of such product in such country.

Research Collaboration and License Agreement with Cellectis

As part of the Pfizer Agreement, Pfizer assigned to the Company a Research Collaboration and License Agreement (the Original Cellectis Agreement) with Cellectis S.A. (Cellectis). On March 8, 2019, the Company entered into a License Agreement (the Cellectis Agreement) with Cellectis. In connection with the execution of the Cellectis Agreement, on March 8, 2019, the Company and Cellectis also entered into a letter agreement (the Letter Agreement), pursuant to which the Company and Cellectis agreed to terminate the Original Cellectis Agreement. The Original Cellectis Agreement included a research collaboration to conduct discovery and pre-clinical development activities to generate CAR T cells directed at targets selected by each party, which was completed in June 2018.

Pursuant to the Cellectis Agreement, Cellectis granted to the Company an exclusive, worldwide, royalty-bearing license, on a target-by-target basis, with sublicensing rights under certain conditions, under certain of Cellectis's intellectual property, including its TALEN and electroporation technology, to make, use, sell, import, and otherwise exploit and commercialize CAR T products directed at certain targets, including BCMA, CD70, Claudin 18.2, DLL3 and FLT3 (the Allogene Targets), for human oncologic therapeutic, diagnostic, prophylactic and prognostic purposes. In addition, certain Cellectis intellectual property rights granted by Cellectis to the Company and to Servier pursuant to the Exclusive License and Collaboration Agreement by and between Servier and Pfizer, dated October 30, 2016, which Pfizer assigned to the Company in April 2018, will survive the termination of the Original Cellectis Agreement.

Pursuant to the Cellectis Agreement, the Company granted Cellectis a non-exclusive, worldwide, royalty-free, perpetual and irrevocable license, with sublicensing rights under certain conditions, under certain of the Company's intellectual property, to make, use, sell, import and otherwise commercialize CAR T products directed at certain targets (the Cellectis Targets).

The Cellectis Agreement provides for development and sales milestone payments by the Company of up to \$ 185.0 million per product that is directed against an Allogene Target, with aggregate potential development and sales milestone payments totaling up to \$2.8 billion. Cellectis is also eligible to receive tiered royalties on annual worldwide net sales of any products that are commercialized by the Company that contain or incorporate, are made using or are claimed or covered by, Cellectis intellectual property licensed to the Company under the Cellectis Agreement (the Allogene Products), at rates in the high single-digit percentages. Such royalties may be reduced, on a licensed product-by-licensed product and country-by-country basis, for generic entry and for payments due under licenses of third party patents. Pursuant to the Cellectis Agreement, and subject to certain exceptions, the Company is required to indemnify Cellectis against all third party claims related to the development, manufacturing, commercialization or use of any Allogene Product or arising out of the Company's material breach of the representations, warranties or covenants set forth in the Cellectis Agreement, and Cellectis is required, subject to certain exceptions, to indemnify the Company against all third party claims related to the development, manufacturing,

commercialization or use of CAR T products directed at Cellectis Targets or arising out of Cellectis's material breach of the representations, warranties or covenants set forth in the Cellectis Agreement.

The royalties are payable, on a licensed-product-by-licensed-product and country-by-country basis, until the later of (i) the expiration of the last to expire of the licensed patents covering such product; (ii) the loss of regulatory exclusivity afforded such product in such country, and (iii) the tenth anniversary of the date of the first commercial sale of such product in such country; however, in no event shall such royalties be payable, with respect to a particular licensed product, past the twentieth anniversary of the first commercial sale for such product.

Depending on the Cellectis Target, the Company has a right of first refusal or right of first negotiation to purchase or license from Cellectis rights to develop and commercialize products against such Cellectis Targets.

Under the Cellectis Agreement, the Company has certain diligence obligations to progress the development of CAR T product candidates and to commercialize one CAR T product per Allogene Target in one major market country where the Company has received regulatory approval. If the Company materially breaches any of its diligence obligations and fails to cure within 90 days, then with respect to certain targets, such target will cease to be an Allogene Target and instead will become a Cellectis Target.

Unless earlier terminated in accordance with its terms, the Cellectis Agreement will expire on a product-by-product and country-by-country basis, upon expiration of all royalty payment obligations with respect to such licensed product in such country. The Company has the right to terminate the Cellectis Agreement at will upon 60 days' prior written notice, either in its entirety or on a target-by-target basis. Either party may terminate the Cellectis Agreement, in its entirety or on a target-by-target basis, upon 90 days' prior written notice in the event of the other party's uncured material breach. The Cellectis Agreement may also be terminated by the Company upon written notice at any time in the event that Cellectis becomes bankrupt or insolvent or upon written notice within 60 days of a consummation of a change of control of Cellectis.

All costs the Company incurred in connection with this agreement were recognized as research and development expenses in the condensed consolidated statements of operations. For the three months ended March 31, 2024 and 2023, no clinical development milestones were achieved.

Exclusive License Agreement with Servier

As part of the Pfizer Agreement, Pfizer assigned to the Company an Exclusive License Agreement (the 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

[Table of Contents](#)

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 (\$76.1 million), respectively. The foregoing milestones are subject to certain adjustments if the Company obtains rights for certain products outside of the United States.

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 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. The Company subsequently submitted to a review of the Company's manufacturing costs of CD19 Products and 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. In May 2024, the Company entered into an Amendment and Settlement Agreement with Servier (the Servier Amendment). Under the Servier Amendment, among other things, Servier waived any right to receive a refund for past costs under the cost-sharing, and the parties provided mutual releases for all current disputes and any and all claims either party has or has ever had relating to such disputes. See Note 13. Subsequent Events for a description of the Servier Amendment.

For the three months ended March 31, 2024 and 2023, the Company recorded zero and \$0.2 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 March 31, 2024 and December 31, 2023, no amounts due from Servier were recorded in the condensed consolidated balance sheets.

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. 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 March 31, 2024, 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 \$ 7.25 million upon achieving certain agreed research milestones, up to \$ 4.0 million per exclusive target upon achieving certain pre-clinical development milestones, and up to \$283.0 million per exclusive target and cell type (i.e., T cell or NK cell) upon achieving certain clinical, regulatory and commercial milestones. Notch is also entitled to receive tiered royalties in the mid to high single digit range on Allogene's sales of licensed products, subject to certain reductions, for a term, on a country-by-country and product-by-product basis, commencing on first commercial sale of such product in such country and continuing until the latest of (i) the date upon which there is no valid claim of the licensed patents in such country of sale that covers such product, (ii) the expiration of applicable data or other regulatory exclusivity in such country of sale or (iii) a defined period from the first commercial sale of such product in such country.

The terms of the Notch Agreement will continue on a product-by-product and country-by-country basis until Allogene's payment obligations with respect to such product in such country have expired. Following such expiration, Allogene's license with respect to such product and country shall be perpetual, irrevocable, fully paid up and royalty-free. Allogene may terminate the Collaboration Agreement in whole or on a product-by-product basis upon ninety days' prior written notice to Notch. Either party may also terminate the Collaboration Agreement with written notice upon material breach by the other party, if such breach has not been cured within a defined period of receiving such notice, or in the event of the other party's insolvency.

On January 25, 2024, the Company entered into an Amended and Restated Collaboration and License Agreement (the Amended Notch Agreement) with Notch. The Amended Notch Agreement amends and restates the Notch Agreement. Under the Amended Notch Agreement, the Company has relinquished its exclusive rights to all original CAR targets (the Released Targets) except for one CAR target, and has agreed to limit its option right to only one additional CAR target. If the option is exercised, the Company will have a minimum funding commitment for the overall development program. If Notch subsequently out-licenses any of the Released Targets, the Company will be entitled to receive a percentage of upfront and/or milestone payments associated therewith up to a set cap of \$30.0 million, and will be entitled to a low, single-digit royalty on net sales of products containing a Released Target. In addition, with respect to the Company's previous equity investment in Notch, the Amended Notch Agreement grants the Company certain anti-dilution protections up to certain limits for certain pre-IPO equity financings. As of March 31, 2024, no Released Targets were out-licensed by Notch.

For the three months ended March 31, 2024 and 2023, the Company recorded zero and \$1.0 million, respectively, in collaboration costs as research and development expenses. No milestones were achieved by Notch for the three months ended March 31, 2024 and 2023.

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 three months ended March 31, 2024 and 2023, the Company recorded less than \$ 0.1 million and \$0.4 million, respectively, in collaboration costs as research and development expenses.

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

On December 14, 2020, the Company entered into a 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, 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).

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 March 31, 2024, 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.

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 delivery of 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 March 31, 2024 and December 31, 2023. The Company does not have the power to direct the activities which most significantly affect Allogene Overland's economic performance. Accordingly, 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 March 31, 2024 and December 31, 2023 was zero (see Note 8).

For the three months ended March 31, 2024 and 2023, the Company recognized less than \$ 0.1 million of collaboration revenue. For the three months ended March 31, 2024 and 2023, 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.

In connection with the execution of the Antion Collaboration and License Agreement, the Company made an upfront payment to Antion of \$ 3.5 million in return for a license to access Antion's technology in order to conduct research pursuant to the agreement. The upfront payment was fully recognized as research and development expense as the license had no foreseeable alternative future use. In addition, the Company made a \$3.0 million investment in Antion's preferred stock. The Company accounts for its investment in Antion's preferred stock as an equity investment measured at cost less any impairment. In connection with this investment, a Company representative was appointed to Antion's Board of Directors.

In July 2023, the Company and Antion entered into an amendment to the Antion Collaboration and License Agreement. Under the terms of this amendment, Antion's exclusivity obligation relating to the collaboration was terminated; however, Antion agreed to certain restrictions on its ability to pursue products directed against specific targets. Also, in lieu of the Company's prior obligation to make a \$3.0 million investment in Antion following the completion of certain milestones, the Company agreed to make a \$2.0 million investment in Antion's preferred stock and acquired warrants to purchase an additional \$ 3.0 million of Antion's preferred stock.

Under the Antion Collaboration and License Agreement, Antion will be eligible to receive up to \$ 35.3 million for four products upon achievement of certain development and regulatory milestones. For each additional product, Antion will be eligible to receive \$2.0 million upon achievement of a regulatory milestone. Antion is also entitled to receive a low single-digit royalty on the Company's sales of licensed products, subject to certain reductions.

For the three months ended March 31, 2024, the Company recorded zero research and development expenses related to collaboration costs. For the three months ended March 31, 2023, the Company recorded \$0.5 million in research and development expenses related to collaboration costs. As of March 31, 2024 and December 31, 2023, no research and development expenses were recorded in accrued and other liabilities. As of March 31, 2024 and December 31, 2023, the Company's total equity investment in Antion was zero.

Strategic Collaboration Agreement with Foresight Diagnostics

On January 3, 2024, the Company entered into a Strategic Collaboration Agreement with Foresight Diagnostics, Inc. (Foresight Diagnostics) (the Foresight Agreement). Pursuant to the Foresight Agreement, the parties have agreed to collaborate on a non-exclusive basis in the development of Foresight Diagnostics' minimal residual disease (MRD) assay based on their PhasED-Seq Circulating Tumor DNA Platform as an in vitro diagnostic to identify the MRD+ patient population to be enrolled in the Company's 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 its MRD assay for use as an in vitro diagnostic with cema-cel. The Company has agreed to fund approximately \$26.2 million in MRD assay development costs, milestone payments for regulatory submissions and assay utilization to process clinical samples.

For the three months ended March 31, 2024, the Company recorded \$ 0.5 million of research and development expenses related to clinical trials start readiness milestone. As of March 31, 2024 and December 31, 2023, zero and \$0.7 million of research and development expenses, respectively, were recorded in accrued and other liabilities.

7. Commitments and Contingencies

Leases

In August 2018, the Company entered into an operating lease agreement (HQ Lease) for office and laboratory space which consists of approximately 68,000 square feet located in South San Francisco, California. The lease term was 127 months beginning August 2018 through February 2029 with an option to extend the term for seven years which was not reasonably assured of exercise. The Company has made certain tenant improvements, including the addition of laboratory space, and has received \$5.0 million of tenant improvement allowances through December 31, 2020. The rent payments began on March 1, 2019 after an abatement period. In December 2021, the Company amended its lease agreement to lease an additional 47,566 square feet of office and laboratory space in South San Francisco, California, as part of the same building as the Company's current headquarters. The lease term commenced in April 2022 and is for a period of 120 months. The rent payments for the expansion premises began in August 2022 after an abatement period. The lease term for the existing premises was also extended and the lease for both the existing and expansion premises will expire on March 31, 2032 with an option to extend the term for eight years which is not reasonably assured of exercise.

In October 2018, the Company entered into an operating lease agreement for office and laboratory space which consists of 14,943 square feet located in South San Francisco, California. The lease term was 124 months beginning November 2018 through February 2029, with an option to extend the term for another seven years which was not reasonably assured of exercise. The Company has made certain tenant improvements, including the upgrading of current office and laboratory space with a lease incentive allowance of \$0.8 million. Rent payments began in November 2018. In December 2021, the Company amended its lease agreement to extend the term of the lease to be co-terminus with the HQ Lease. The lease term will expire March 31, 2032 with an option to extend the term for eight years which is not reasonably assured of exercise.

In February 2019, the Company entered into a lease agreement for approximately 118,000 square feet of space to develop a cell therapy manufacturing facility in Newark, California. The lease term is 188 months and began in November 2020. Upon certain conditions, the Company has two ten-year options to extend the lease, both of which are not reasonably assured of exercise. The Company has received \$ 3.0 million of tenant improvement allowances for costs related to the design and construction of certain Company improvements.

In February 2023, the Company entered into a sublease with Bellco Capital Advisors Inc. (Bellco) for 2,218 square feet of office space in Los Angeles, California. The sublease term is 115 months, subject to certain early termination rights. The sublease commenced on January 1, 2024.

The Company maintains letters of credit for the benefit of landlords which is disclosed as restricted cash in the condensed consolidated balance sheets. Restricted cash related to letters of credit due to landlords was \$6.0 million as of March 31, 2024 and December 31, 2023.

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

	March 31, 2024	December 31, 2023
Operating lease liabilities		
Current portion included in accrued and other current liabilities	\$ 6,930	\$ 6,775
Long-term portion of lease liabilities	88,916	88,346
Total operating lease liabilities	\$ 95,846	\$ 95,121

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

	Three Months Ended March 31,	
	2024	2023
Operating lease cost	\$ 3,020	\$ 3,181
Variable lease cost	867	691
Total lease costs	\$ 3,887	\$ 3,872

Cash paid for amounts included in the measurement of lease liabilities for the three months ended March 31, 2024 was \$ 3.1 million and was included in net cash used in operating activities in the Company's condensed consolidated statements of cash flows.

The undiscounted future non-cancellable lease payments under the Company's operating leases as of March 31, 2024 were as follows:

Year ending December 31:	(in thousands)
2024 (remaining 9 months)	\$ 9,436
2025	12,920
2026	13,163
2027	13,612
2028	14,076
2029 and thereafter	65,385
Total undiscounted lease payments	128,592
Less: Present value adjustment	(32,746)
Total	\$ 95,846

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 6.24%. As of March 31, 2024, the weighted average remaining lease term for our operating leases is 8.82 years.

Other Commitments

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 condensed consolidated balance sheets as of March 31, 2024 and December 31, 2023.

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 March 31, 2024.

The Company enters into contracts in the normal course of business that includes arrangements with clinical research organizations, vendors for preclinical research and vendors for manufacturing. These agreements generally allow for cancellation with notice. As of March 31, 2024, the Company had non-cancellable purchase commitments of \$0.9 million.

8. Equity Method Investments

Notch Therapeutics

In conjunction with the execution of the Notch Agreement (see Note 6), the Company also entered into a Share Purchase Agreement with the Company acquiring shares of Notch's Series Seed convertible preferred stock for a total investment cost of \$5.1 million which includes transaction costs of \$0.1 million, resulting in a 25% ownership interest in Notch. In February 2021, the Company made a \$ 15.9 million investment in Notch's Series A preferred stock. Immediately following this transaction, the Company's share in Notch was 20.7% on a voting interest basis. In October 2021, the Company made an additional \$1.8 million investment in Notch's common stock. Immediately following this transaction, the Company's share in Notch was 23.0% on a voting interest basis.

The Company's total equity investment in Notch as of March 31, 2024 and December 31, 2023 was \$ 2.7 million and \$3.6 million, respectively, and the Company accounted for the investment using the equity method of accounting. For the three months ended March 31, 2024 and 2023, the Company recognized its share of Notch's net loss of \$0.9 million and \$1.7 million, respectively, under the other expenses caption within the condensed consolidated statements of operations.

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

The Company's total equity investment in Allogene Overland as of March 31, 2024 and December 31, 2023 was zero and the Company accounted for the investment using equity method of accounting. For the three months ended March 31, 2024 and 2023, the Company recognized its share of Allogene Overland's net loss of zero and \$1.2 million, respectively, under the other expenses caption within the condensed consolidated statement of operations.

9. Stock-Based Compensation

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 March 31, 2024, there were 9,738,364 shares reserved by the Company under the 2018 Plan for the future issuance of equity awards.

Stock Option Exchange Program

On June 21, 2022, the Company commenced an offer to exchange certain eligible options held by eligible employees of the Company for new options (the Exchange Offer). The Exchange Offer expired on July 19, 2022. Pursuant to the Exchange Offer, 199 eligible holders elected to exchange, and the Company accepted for cancellation, eligible options to purchase an aggregate of 3,666,600 shares of the Company's common stock, representing approximately 93.5% of the total shares of common stock underlying the eligible options. On July 19, 2022, immediately following the expiration of the Exchange Offer, the Company granted new options to purchase 3,666,600 shares of common stock, pursuant to the terms of the Exchange Offer and the 2018 Plan. The exercise price of the new options granted pursuant to the Exchange Offer was \$13.31 per share, which was the closing price of the common stock on the Nasdaq Global Select Market on the grant date of the new options. The new options are subject to a new three-year vesting schedule, vesting in equal annual installments over the vesting term. Each new option has a maximum term of seven years.

The exchange of stock options was treated as a modification for accounting purposes. The incremental expense of \$ 5.2 million for the modified options was calculated using a lattice option pricing model. The incremental expense and the unamortized expense remaining on the exchanged options as of the modification date are being recognized over the new three-year service period.

Stock Option Activity

The following summarizes option activity under the 2018 Plan:

	Outstanding Options				Weighted-Average Remaining Contract Term (in years)	Aggregate Intrinsic Value (in thousands)		
	Number of Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contract Term (in years)					
			(in years)	(in thousands)				
Balance, December 31, 2023	21,812,946	\$ 9.93	7.53	\$ 662				
Options granted	4,259,396	3.22	9.50					
Options exercised	(350,118)	2.27		\$ 584				
Options forfeited	(1,696,808)	10.68						
Balance, March 31, 2024	<u>24,025,416</u>	\$ 8.80	7.80	\$ 7,516				
Exercisable, March 31, 2024	<u>17,689,533</u>	\$ 9.97	7.43	\$ 2,262				
Vested and expected to vest, March 31, 2024	<u>24,025,416</u>	\$ 8.80	7.80	\$ 7,516				

The aggregate intrinsic values of options 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 March 31, 2024. For the three months ended March 31, 2024, the estimated weighted-average grant-date fair value of employee options granted was \$2.15 per share. As of March 31, 2024, there was \$54.0 million of unrecognized stock-based compensation related to unvested stock options, which is expected to be recognized over a weighted-average period of 2.4 years.

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:

	Three Months Ended March 31,	
	2024	2023
Expected term in years	5.85 - 6.06	6.03 - 6.07
Expected volatility	73.50%	73.85%
Expected risk-free interest rate	3.94% - 4.22%	3.45% - 4.10%
Expected dividend	0%	0%

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.

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, 2023	12,180,471	\$ 6.68	2.00	\$ 39,099	
Granted	4,046,261	4.44	1.85		
Vested	(1,170,889)	9.82			
Forfeited	(1,446,452)	8.78			
Unvested March 31, 2024	<u>13,609,391</u>	\$ 5.52	1.98	\$ 60,834	
Vested and expected to vest, March 31, 2024	<u>13,609,391</u>	\$ 5.52	1.98	\$ 60,834	

As of March 31, 2024, there was \$52.4 million of unrecognized stock-based compensation related to unvested restricted stock units, which is expected to be recognized over a weighted-average period of 2.4 years.

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 Plan. These awards are subject to the holders' continuous service to the Company through each applicable vesting event. Through March 31, 2024, the Company believes that the achievement of the requisite performance conditions for these awards are not probable. As a result, no compensation expense has been recognized related to the performance-based restricted stock units in the quarters ended March 31, 2024 and March 31, 2023. The Company recognized \$0.7 million and \$0.1 million in stock-based compensation expense related to the restricted stock units with a market condition in the quarters ended March 31, 2024 and 2023, respectively.

Stock-based compensation expense

For the quarters ended March 31, 2024 and 2023, the Company recorded \$ 11.9 million and \$18.8 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 condensed consolidated statements of operations and comprehensive loss.

10. Related Party Transactions

Collaboration Revenue and Equity Method Investment

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 three months ended March 31, 2024 and 2023, the Company recognized less than \$0.1 million of collaboration revenue under this arrangement.

[Table of Contents](#)

For the three months ended March 31, 2024 and 2023, the Company recorded zero and \$1.2 million, respectively, of its share of Allogene Overland's net loss as other expenses (see Note 8).

Sublease Agreement

In December 2018, the Company entered into a sublease with Bellco Capital LLC for 1,293 square feet of office space in Los Angeles, California for a three year term. On April 1, 2020, Bellco assumed all rights, title, interests and obligations under the sublease from Bellco Capital LLC. In November 2021, the sublease was extended to June 30, 2025. The sublease was amended, effective in July 2022, to move to a nearby location, with office space of 737 square feet. The Company's executive chairman, Arie Beldegrun, M.D., FACS, is a trustee of the Beldegrun Family Trust, which controls Bellco. In 2023, the Company exercised its early termination right under the sublease agreement and the sublease was terminated effective December 31, 2023.

In February 2023, the Company entered into a new sublease agreement with Bellco for 2,218 square feet of office space in Los Angeles, California. The sublease term is 115 months, subject to certain early termination rights. The sublease commenced on January 1, 2024. The total right of use asset and associated lease liability recorded related to this related party lease was \$2.4 million as of March 31, 2024. For the three months ended March 31, 2024, the Company recorded \$0.1 million of rent expense related to this lease.

Consulting Agreements

In June 2018, the Company entered into a services agreement with Two River Consulting, LLC (Two River), a firm affiliated with the Company's President and Chief Executive Officer, the Company's Executive Chair of the board of directors, and a director of the Company to provide various managerial, clinical development, administrative, accounting and financial services to the Company. In December 2023, the service agreement between the Company and Two River was terminated. The costs incurred for services provided under this agreement were \$0.1 million for the three months ended March 31, 2023.

In August 2018, the Company entered into a consulting agreement with Bellco Capital LLC. Pursuant to the consulting agreement, Bellco Capital LLC 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 Capital LLC \$40,217 per month in arrears commencing January 2022. The Company may also, at its discretion, pay Bellco Capital LLC an annual performance award in an amount up to 60% of the aggregate compensation payable to Bellco Capital LLC in a calendar year. The Company also reimburses Bellco Capital LLC for out of pocket expenses incurred in performing the services. The costs incurred for services provided, bonus, and out-of-pocket expenses incurred under this consulting agreement were \$0.2 million for the three months ended March 31, 2024 and 2023.

11. Income Taxes

The Company has a history of losses and expects to record a loss in 2024. The Company continues to maintain a full valuation allowance against its net deferred tax assets.

12. Net Loss Per Share

The following outstanding potentially dilutive shares have been excluded from the calculation of diluted net loss per share for the period presented due to their anti-dilutive effect:

	March 31,	
	2024	2023
Stock options to purchase common stock	24,025,416	23,548,486
Restricted stock units subject to vesting	13,609,391	13,587,470
Expected shares to be purchased under Employee Stock Purchase Plan	1,077,525	1,234,606
Early exercised stock options subject to future vesting	—	105,743
Total	38,712,332	38,476,305

13. Subsequent Events

Servier Amendment and Settlement Agreement

On May 10, 2024, the Company and Servier entered into the Servier Amendment which settles all existing disputes (as described in Note 6) between the Company and Servier relating to each party's performance under the Servier Agreement. The Servier Amendment also restructures the parties' relationship on the following terms:

- (1) The Company's licensed territory was expanded to include the European Union and the United Kingdom. The Company was also granted an option to further extend its licensed territory to include China and Japan upon the objective showing of sufficient resources to develop licensed products in those countries, which could be met through the Company entering into a strategic partnership covering those countries. Additionally, the Company agreed to waive certain of its rights under the Servier Agreement to elect a conversion of its license to the CD19 Products to a worldwide license.
- (2) Under the Servier Agreement, Servier sublicenses to the Company certain rights which Servier licenses from Cellectis pursuant to a first development and commercialization agreement, dated February 7, 2014, by and between Cellectis and Servier (as amended, the Servier-Cellectis Agreement). All of the Company's future milestone payments (regulatory and sales) under the Servier Agreement are modified to be the same as, and to coincide with, Servier's milestone payments to Cellectis that are required under the Servier-Cellectis Agreement. As amended by the Servier Amendment, the Servier Agreement provides for aggregate potential payments by the Company to Servier of up to €75.0 million, of which €60.0 million remains, upon successful completion of various regulatory milestones in the United States, European Union and the United Kingdom for the initial indication of each licensed product, with additional payments of €55.0 million due for each subsequent indication, and aggregate potential payments by the Company to Servier of up to €80.0 million upon achievement of certain net sales milestones for each licensed product. Should Servier's rights and obligations under the Servier-Cellectis Agreement be assigned to the Company, these milestone payments would terminate, and the Company would assume Servier's milestone payment obligation to Cellectis. In the absence of any such assignment, Servier will remain responsible for making milestone payments that may be due to Cellectis under the Servier-Cellectis Agreement.
- (3) The Company agreed to transfer € 20.0 million into an escrow account in connection with a potential future milestone payment, which is included in the remaining €60.0 million in milestone payments referenced above. Such milestone payment will be triggered, if at all, upon the occurrence of one of these events: (1) the Company doses the first subject in its first phase 3 clinical study for a CD19 CAR-T product that is a licensed product under the Servier Agreement, (2) the Company submits a phase 2 clinical study for a licensed product to the U.S. Food and Drug Administration or the European Medicines Agency, and such phase 2 clinical study is accepted for regulatory approval as a pivotal study, or (3) a final and definitive decision of a tribunal or court finding that under the Servier-Cellectis Agreement the milestone has occurred and the €20.0 million payment is due to Cellectis.
- (4) The Company agreed to pay to Servier royalties on annual net sales of any licensed products that are commercialized by the Company that is directed at CD19. Such royalties include tiered royalties on annual net sales in the United States and a flat royalty on annual net sales in territories outside the United States. The United States royalty rates are in a range from the low tens to the mid teen percentages, and the ex-U.S. royalty rate is 10%. Such royalties may be reduced for interchangeable drug entry, expiration of patent rights and amounts paid pursuant to licenses of third-party patents. This royalty obligation begins upon the first commercial sale of such product in a given country and ends after the later of a defined number of years or the expiration of the last to expire licensed patent covering the product in such country. The net effect of the Servier Amendment is that the Company's royalty rate in the United States for the first half of the first tier of net sales was increased by a low single digit percentage. Should Servier's rights and obligations under the Servier-Cellectis Agreement be assigned to the Company, each tier of royalty rates in the United States to Servier would be reduced by 10%, the ex-U.S. royalties to Servier would terminate, and the Company would assume Servier's royalty obligations to Cellectis. In the absence of any such assignment, Servier will remain responsible for making royalty payments that may be due to Cellectis under the Servier-Cellectis Agreement.
- (5) Requires that the Company reconcile its net sales reports required to be delivered to Servier under the Servier Agreement at the end of each calendar year to the amount of net sales that would have been applicable if such net sales were calculated in accordance with International Financial Reporting Standards and requires that any shortfall or overpayment, as applicable, be paid by the Company to Servier or credited to the Company by Servier, as applicable.
- (6) The parties agreed that co-development performed by the Company and Servier under the Servier Agreement, including all development performed by Servier and for product candidates that the Company was co-developing with Servier (for which specified development costs were split with Allogene responsible for 60% and Servier responsible for 40%),

[Table of Contents](#)

including the CD19 Products, ceased as of December 15, 2022, and that all development costs incurred by either party after that date shall be borne solely by such party.

- (7) As soon as practicable after the date of the Servier Amendment but in any event prior to the end of July 2024, the parties will also agree to a transition plan, including transition timing and allocation of costs, to either transfer the sponsorship of the Servier's long-term follow-up study of patients previously exposed to its UCART19V1 product candidate from Servier to the Company or consolidate the patients in this study into another Company-sponsored long-term follow-up study.
- (8) The parties agreed to waive any and all outstanding claims that were asserted relating to alleged violations of the Servier Agreement, including all claims that such party was entitled to various payments or refunds from the other party under the Servier Agreement, and any and all claims that either party now has or may have in the future related to such outstanding claims, and mutual releases with respect to such claims were granted.

California Institute for Regenerative Medicine Grant

On April 26 2024, the Company was awarded a \$ 15.0 million grant from the California Institute for Regenerative Medicine (CIRM) to support the clinical development of ALLO-316, an AlloCAR T™ investigational product targeting CD70 in development for the treatment of advanced or metastatic renal cell carcinoma (RCC). The grant was awarded in accordance with the CIRM Grants Administration Policy for Clinical Stage Projects which may require the grant to be repaid by the Company.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

You should read the following discussion of our financial condition and results of operations in conjunction with our unaudited condensed consolidated financial statements and the related notes and other financial information included elsewhere in this Quarterly Report on Form 10-Q (Quarterly Report) and the audited financial statements and notes thereto as of and for the year ended December 31, 2023 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our Annual Report on Form 10-K for the year ended December 31, 2023 (Annual Report), which was filed with the Securities and Exchange Commission (SEC) on March 14, 2024. Unless the context requires otherwise, references in this Quarterly Report to the "Company", "Allogene," "we," "us" and "our" refer to Allogene Therapeutics, Inc., and references to "Servier" collectively refer to Les Laboratoires Servier SAS and Institut de Recherches Internationales Servier SAS.

In addition to historical financial information, this discussion contains forward-looking statements based upon current expectations that involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth in the section titled "Risk Factors" under Part II, Item 1A below. In some cases, you can identify forward-looking statements by terminology such as "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potentially," "predict," "should," "will" or the negative of these terms or other similar expressions.

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 Quarterly 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.

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.

[Table of Contents](#)

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 240 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. The efficacy analysis is expected to occur in 2026 and will include the Independent Data Safety Monitoring Board (IDSMB) interim efficacy analysis in the first half of 2026 and the data readout of the primary analysis is expected in the second half of 2026 with a biologics license application (BLA) submission targeted for 2027. In view of the potential of the earlier line ALPHA3 trial, we have deprioritized the third line (3L) LBCL ALPHA2 and EXPAND trials.

We have 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 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. We plan to file an investigational new drug (IND) application in the first quarter of 2025. We expect to initiate the Phase 1 trial with ALLO-329 in early 2025 and have proof-of-concept by year-end 2025. 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.

We estimate that the expansion of our license for the CD19 Products to the European Union and United Kingdom will substantially increase our market opportunity in 1L consolidation LBCL and R/R/ CLL from more than \$6.0 billion in the U.S.

alone to more than \$9.5 billion across the U.S., European Union and United Kingdom, in turn increasing the potential future revenue opportunity for cema-cel by more than 50%.

Since inception, we have had significant operating losses. Our net loss was \$65.0 million for the three months ended March 31, 2024. As of March 31, 2024, we had an accumulated deficit of \$1.6 billion. As of March 31, 2024, we had \$397.3 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 the Pfizer Agreement with Pfizer pursuant to which we acquired certain assets and assumed certain liabilities from Pfizer, including agreements with Cellectis 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 condensed consolidated financial statements included elsewhere in this report for further description of the Pfizer Agreement.

Research Collaboration and License Agreement with Cellectis

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

Exclusive License Agreement with Servier

In October 2015, Pfizer entered into the 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.

In May 2024 we entered into the Servier Amendment with Servier under which the parties settled disputes relating to each party's performance under the Servier Agreement. The parties agreed to waive any and all outstanding claims that were asserted relating to alleged violations of the Servier Agreement, including all claims that such party was entitled to various payments or refunds from the other party under the Servier Agreement, and mutual releases with respect to such claims were granted.

Additionally, the Servier Amendment expanded our territory under the Servier Agreement to include the European Union and the United Kingdom, and provides for an option to further expand our territory to include China and Japan upon the objective showing of sufficient resources to develop licensed products in those countries, which could be met through us entering into a strategic partnership covering those countries. Additionally, we agreed to waive certain of its rights under the Servier Agreement to elect a conversion of its license to the CD19 Products to a worldwide license.

Additionally, under the Servier Amendment all of our future milestone payments (regulatory and sales) under the Servier Agreement are modified to be the same as, and to coincide with, Servier's milestone payments to Cellectis under the Servier-Cellectis Agreement. As amended by the Servier Amendment, the Servier Agreement provides for aggregate potential payments by us to Servier of up to €75 million, of which €60 million remains, upon successful completion of various regulatory milestones in the United States, European Union and the United Kingdom for the initial indication of each licensed product, with additional payments of €55 million due for each subsequent indication, and aggregate potential payments by us to Servier of up to €80 million upon achievement of certain net sales milestones for each licensed product. Should Servier's rights and obligations under the Servier-Cellectis Agreement be assigned to us, these milestone payments would terminate, and we would assume Servier's milestone payment obligation to Cellectis. In the absence of any such assignment, Servier will remain responsible for making milestone payments that may be due to Cellectis under the Servier-Cellectis Agreement.

As part of the settlement, we agreed to transfer €20 million into an escrow account in connection with a potential future milestone payment, which is included in the remaining €60 million in milestone payments referenced above. The

[Table of Contents](#)

milestone payment will be triggered, if at all, upon the occurrence of one of these events: (1) we dose the first subject in its first phase 3 clinical study for a CD19 CAR-T product that is a licensed product under the Servier Agreement, (2) we submit a phase 2 clinical study for a licensed product to the U.S. Food and Drug Administration or the European Medicines Agency, and such phase 2 clinical study is accepted for regulatory approval as a pivotal study, or (3) a final and definitive decision of a tribunal or court finding that under the corresponding milestone under the Servier-Collectis Agreement has occurred and the €20 million payment is due to Collectis.

The royalties under the Servier Agreement were also amended. The amended royalties include tiered royalties on annual net sales in the United States and a flat royalty on annual net sales in territories outside the United States. The United States royalty rates are in a range from the low tens to the mid teen percentages, and the ex-U.S. royalty rate is 10%. Such royalties may be reduced for interchangeable drug entry, expiration of patent rights and amounts paid pursuant to licenses of third-party patents. This royalty obligation begins upon the first commercial sale of such product in a given country and ends after the later of a defined number of years or the expiration of the last to expire licensed patent covering the product in such country. The net effect of the Servier Amendment is that our royalty rate in the United States for the first half of the first tier of net sales was increased by a low single digit percentage. Should Servier's rights and obligations under Servier-Collectis Agreement be assigned to us, each tier of royalty rates in the United States to Servier would be reduced by 10%, the ex-U.S. royalties to Servier would terminate, and we would assume Servier's royalty obligations to Collectis. In the absence of any such assignment, Servier will remain responsible for making royalty payments that may be due to Collectis under Servier-Collectis Agreement.

For more information, see "Risk Factors— Servier's discontinuation of its involvement in the development of CD19 Products and Servier's disputes with Collectis, or future disputes with us, may have adverse consequences."

See Notes 6 and 13 to our condensed consolidated financial statements included elsewhere in this report for further description of the Servier Agreement and the Servier Amendment.

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.

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

See Note 6 to our condensed consolidated financial statements included elsewhere in this report for further description of the Notch Agreement.

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 condensed consolidated financial statements included elsewhere in this 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) (the License Agreement), a joint venture established by us and Overland Pharmaceuticals (CY) Inc. (Overland), pursuant to a 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 (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 condensed consolidated financial statements included elsewhere in this 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 condensed consolidated financial statements included elsewhere in this 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 ansegeldeucel, 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. See Note 6 to our condensed consolidated financial statements included elsewhere in this report for further description of the Foresight Agreement.

Components of Results of Operations

Revenues

As of March 31, 2024, our revenue has been exclusively generated from the License Agreement with Allogene Overland Biopharm (PRC) Co., Limited. See Note 6 to our financial statements appearing elsewhere in this Quarterly Report for more information related to our recognition of revenue and the License Agreement.

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

Operating Expenses

Research and Development

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

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

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

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.

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

Other Expenses

Other expenses consist of non-operating expenses, including our share of equity investments' net losses for the period.

Results of Operations

Comparison of the Three Months Ended March 31, 2024 and 2023

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

	Three Months Ended March 31,		Change	
	2024	2023	\$	%
Collaboration revenue - related party	\$ 22	\$ 30	\$ (8)	(27) %
Operating expenses:				
Research and development	52,259	80,238	(27,979)	(35) %
General and administrative	17,267	18,884	(1,617)	(9) %
Total operating expenses	69,526	99,122	(29,596)	(30) %
Loss from operations	(69,504)	(99,092)	29,588	(30) %
Other income (expense), net:				
Interest and other income, net	5,433	2,059	3,374	164 %
Other expenses	(929)	(2,935)	2,006	(68) %
Total other income (expense), net	4,504	(876)	5,380	(614) %
Net Loss	\$ (65,000)	\$ (99,968)	\$ 34,968	(35) %

Collaboration revenue - related party

Collaboration revenue recognized for the three months ended March 31, 2024 and 2023 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,		Change
	2024	2023	
Personnel	\$ 22,752	\$ 34,173	\$ (11,421)
Development costs	16,705	31,261	(14,556)
Facilities and depreciation	10,502	11,193	(691)
Other	2,300	3,611	(1,311)
Total research and development expenses	52,259	80,238	(27,979)

Our research and development expenses included \$25.5 million of internal expenses and \$26.8 million of external expenses for the three months ended March 31, 2024. Our research and development expenses included \$35.2 million of internal expenses and \$45.1 million of external expenses for the three months ended March 31, 2023.

Research and development expenses were \$52.3 million and \$80.2 million for the three months ended March 31, 2024 and 2023, respectively. The decrease of \$28.0 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 \$14.6 million and a decrease in personnel related costs of \$11.4 million, including \$6.1 million related to a decrease in stock-based compensation expense.

General and Administrative Expenses

General and administrative expenses were \$17.3 million and \$18.9 million for the three months ended March 31, 2024 and 2023, respectively. The decrease of \$1.6 million was primarily due to a decrease in personnel related costs of \$1.7 million, including \$0.8 million related to a decrease in stock-based compensation expense.

Interest and Other Income, Net

Interest and other income, net was \$5.4 million and \$2.1 million for the three months ended March 31, 2024 and 2023, respectively. The increase of \$3.4 million 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 \$0.9 million and \$2.9 million for the three months ended March 31, 2024 and 2023, respectively. The decrease in other expenses of \$2.0 million was primarily due to a decrease in the share of net losses in our equity method investments.

Liquidity and Capital Resources

To date, we have incurred significant net losses and negative cash flows from operations. As of March 31, 2024, we had \$397.3 million in cash and cash equivalents and investments. We anticipate that the aggregate of our current cash and cash equivalents and investments available for operations will be sufficient to fund our operations for at least 12 months from the date this Quarterly Report 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 three months ended March 31, 2024, we did not sell any shares of common stock in ATM offerings. 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 March 2024, we filed a sales agreement prospectus within a registration statement on Form S-3, registering the offering, issuance and sale of up to \$250.0 million of our common stock in ATM offerings.

Cash Flows

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

	Three Months Ended March 31,	
	2024	2023
	(In thousands)	
Net cash (used in) provided by:		
Operating activities	\$ (55,899)	\$ (66,639)
Investing activities	22,133	112,935
Financing activities	1,650	1,731
Net increase (decrease) in cash and cash equivalents and restricted cash	\$ (32,116)	\$ 48,027

Operating Activities

During the three months ended March 31, 2024, cash used in operating activities of \$55.9 million was attributable to a net loss of \$65.0 million, a decrease of \$4.4 million in our net operating assets and liabilities, partially offset by non-cash charges of \$13.5 million. The non-cash charges consisted primarily of stock-based compensation expense of \$11.9 million, depreciation of \$3.6 million, our share of equity investments' net losses for the period of \$0.9 million, offset by net amortization and accretion on investment securities of \$2.8 million. The change in operating assets and liabilities was primarily due to a \$5.7 million decrease in accrued and other current liabilities, offset by a \$1.4 million decrease in other long-term assets.

During the three months ended March 31, 2023, cash used in operating activities of \$66.6 million was attributable to a net loss of \$100.0 million, partially offset by non-cash charges of \$25.9 million and an increase of \$7.4 million in our net operating assets and liabilities. The non-cash charges consisted primarily of stock-based compensation expense of \$18.8 million, depreciation of \$3.5 million, our share of equity investments' net losses for the period of \$2.9 million, net amortization and accretion on investment securities of \$0.5 million, and non-cash rent expense of \$0.2 million. The change in operating

assets and liabilities was primarily due to a \$5.7 million increase in accrued and other current liabilities, a \$1.3 million decrease in prepaid expenses and other current assets, and a \$1.1 million increase in accounts payable, offset by a \$0.6 million decrease in other long-term liabilities.

Investing Activities

During the three months ended March 31, 2024, net cash provided by investing activities of \$22.1 million was related to cash provided by investment maturities of \$103.3 million, offset by cash used in the purchase of investments of \$81.1 million.

During the three months ended March 31, 2023, net cash provided by investing activities of \$112.9 million was related to cash provided by investment maturities of \$143.4 million and cash provided by proceeds from sales of investments of \$5.6 million, offset by cash used in the purchase of investments of \$35.1 million and cash used in the purchase of property and equipment of \$1.0 million.

Financing Activities

During the three months ended March 31, 2024, cash provided by financing activities of \$1.7 million was related to \$0.9 million of cash provided by the sale of common stock through our employee stock purchase plan and \$0.8 million of cash provided by the issuance of common stock upon exercise of stock options.

During the three months ended March 31, 2023, cash provided by financing activities of \$1.7 million was related to cash provided by the sale of common stock through our employee stock purchase plan.

Material Cash Commitments and Requirements

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.

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 March 31, 2024, we were unable to estimate the timing or likelihood of achieving the milestones or making future product sales. For additional information regarding our agreements, see Note 6 to our condensed consolidated financial statements included elsewhere in this 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 condensed consolidated financial statements included elsewhere in this 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

[Table of Contents](#)

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 March 31, 2024, the Company had non-cancellable purchase commitments of \$0.9 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 Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our condensed consolidated financial statements, which have been prepared in accordance with United States generally accepted accounting principles. The preparation of these condensed 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 condensed consolidated financial statements, as well as the reported expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

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

There have been no significant changes in our critical accounting policies and estimates as compared to the critical accounting policies and estimates disclosed in the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in our Annual Report.

Recent Accounting Pronouncements

There have been no new accounting pronouncements issued or effective that are expected to have a material impact on our unaudited condensed consolidated financial statements.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are exposed to market risks in the ordinary course of our business. These risks primarily relate to interest rate fluctuations.

Interest Rate Risk

Our cash and cash equivalents and investments of \$397.3 million as of March 31, 2024 consist of bank deposits, money market funds and available-for-sale securities. Such interest-earning instruments carry a degree of interest rate risk; however, historical fluctuations in interest income have not been significant for us. A 10% change in the interest rates in effect on March 31, 2024 would not have had a material effect on the fair market value of our cash equivalents and available-for-sale securities.

Foreign 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 condensed consolidated financial statements. As of March 31, 2024, we had no receivables and \$0.5 million of current liabilities denominated in foreign currency.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

As of March 31, 2024, management, with the participation of our Chief Executive Officer and Chief Financial Officer, performed an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended (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 March 31, 2024, our disclosure controls and procedures were not effective at a reasonable assurance level.

As described in Company's Annual Report filed with the SEC on March 14, 2024, we re-evaluated our prior accounting for shares received in the License Agreement and Share Purchase Agreement entered into on December 14, 2020, with Allogene Overland. Upon reassessment, we 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. We 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.

Status of Remediation of Material Weakness

To remediate this material weakness, during the three months ended March 31, 2024, we continue to improve the operation of our controls over financial reporting with respect to the technical accounting analysis of significant non-routine transactions, which includes engaging third-party subject matter experts with significant relevant experience. While we believe that these efforts will improve our internal control over financial reporting, the implementation of our remediation is ongoing and 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.

While the foregoing measures are intended to effectively remediate the material weakness described in this Item 4, 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 condensed consolidated financial statements are prepared in accordance with GAAP.

Changes in Internal Control over Financial Reporting

Other than as discussed under the "Status of Remediation of Material Weakness" heading, no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the three months ended March 31, 2024 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II-OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, we may become involved in legal proceedings relating to claims arising from the ordinary course of business. Our management believes that there are currently no claims or actions pending against us, the ultimate disposition of which could have a material adverse effect on our results of operations, financial condition or cash flows.

Item 1A. Risk Factors

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" and should be carefully considered, together with other information in this Quarterly Report and our other filings with the SEC 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 or equivalent foreign applications, to commence additional clinical trials on the timelines we expect, and even if we are able to, the FDA or comparable foreign regulatory authorities, 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 contract development and manufacturing organizations (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.
- 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 Cellectis, or future disputes with us, 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, or comparable foreign authorities, may disagree with our regulatory plan and we may fail to obtain regulatory approval of our CAR T cell product candidates.
- If we, or our collaborators, are required by the FDA, or comparable foreign regulatory authorities, to obtain approval (or clearance, or certification) of a companion diagnostic device in connection with approval of one of our product candidates, and we, or our collaborators, do not obtain, or face delays in obtaining, approval (or clearance, or certification) of a companion diagnostic device, we will not be able to commercialize the product candidate, and our ability to generate revenue will be materially impaired.

Risks Related to Our Intellectual Property

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

Risks Related to Ownership of Our Common Stock

- 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.

RISK FACTORS

An investment in shares of our common stock involves a high degree of risk. You should carefully consider the following risk factors, as well as the other information in this report, before deciding whether to purchase, hold or sell shares of our common stock. The occurrence of any of the following risks could harm our business, financial condition, results of operations and/or growth prospects or cause our actual results to differ materially from those contained in forward-looking statements we have made in this report and those we may make from time to time. You should consider all of the risk factors described below when evaluating our business. The risk factors set forth below that are marked with an asterisk () contain changes to the similarly titled risk factors included in, or did not appear as separate risk factors in, Item 1A of our Annual Report, which was filed with the SEC on March 14, 2024.*

Risks Related to Our Financial Position and Capital Needs

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

We are a clinical-stage biopharmaceutical company and investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval and become commercially viable. We are advancing an allogeneic CAR T platform of primarily early-stage product candidates and have no products approved for commercial sale and have not generated any revenue from product sales to date, and we will continue to incur significant research and development and other expenses related to our ongoing operations. To date, we have devoted substantially all of our resources to organizing and staffing our company, business planning, raising capital, securing related intellectual property rights, building our product manufacturing infrastructure, including a dedicated good manufacturing practices (GMP) manufacturing facility, manufacturing our clinical product candidates and conducting discovery, research and development activities for our programs. As a result, we are not profitable and have incurred net losses in each period since our inception. For the year ended December 31, 2023, we reported a net loss of \$327.3 million. For the three months ended March 31, 2024, we reported a net loss of \$65.0 million. As of March 31, 2024, 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 U.S. Food and Drug Administration (FDA) placed our clinical trials on hold in October 2021, which suspended our clinical programs prior to resolution of the hold in January 2022. Even if we succeed in advancing our clinical trials and commercializing one or more of our product candidates, we will continue to incur substantial research and development and other expenditures to develop and market additional product candidates. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital.

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

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

As of March 31, 2024, we had \$397.3 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, contract research organizations (CROs), clinical trial sites and other contractors and consultants, could be subject to business disruptions, including those caused by earthquakes, power shortages, telecommunications failures, cybersecurity attacks, water shortages, floods, hurricanes, tsunamis, typhoons, fires, extreme weather conditions, medical epidemics or pandemics, wars and other geopolitical conflicts (such as Russia's military action against Ukraine and the Israel–Hamas conflict), bank failures, adverse legislative actions and other natural or man-made disasters or business interruptions, for which we are predominantly self-insured. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses.

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

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

Adverse developments that affect financial institutions, such as events involving liquidity that are rumored or actual, have in the past and may in the future lead to bank failures and market-wide liquidity problems. For example, on March 10, 2023, Silicon Valley Bank (SVB) was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation (FDIC) as receiver. Similarly, on March 12, 2023, Signature Bank and Silvergate Capital Corp. were each swept into receivership. In addition, on May 1, 2023, the FDIC seized First Republic Bank and sold its assets to JPMorgan Chase & Co. It is uncertain whether the U.S. Department of Treasury, FDIC and Federal Reserve Board will provide access to uninsured funds in the future in the event of the closure of other banks or financial institutions, or that they would do so in a timely fashion. We maintain the majority of our cash and cash equivalents in accounts at banking institutions in the United States that we believe are of high quality. Cash held in these accounts often exceed the FDIC insurance limits. If such banking institutions were to fail, we could lose all or a portion of amounts held in excess of such insurance limitations. In the event of failure of any of the financial institutions where we maintain our cash and cash equivalents, there can be no assurance that we would be able to access uninsured funds in a timely manner or at all. Any inability to access or delay in accessing these funds could adversely affect our business and financial position.

Although we assess our banking relationships as we believe necessary or appropriate, our access to cash in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that affect the financial institutions with which we have banking relationships. These factors could include, among others, events such as liquidity constraints or failures, the ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, disruptions or instability in the financial services industry or financial markets, or

[Table of Contents](#)

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 initial public offering (IPO) in October 2018 and private placements and other transactions that have occurred since our incorporation, we may have experienced an "ownership change". We may also experience ownership changes in the future as a result of subsequent shifts in our stock ownership. We anticipate incurring significant additional net losses for the foreseeable future, and our ability to utilize net operating loss carryforwards associated with any such losses to offset future taxable income may be limited to the extent we incur future ownership changes. In addition, at the state level, there may be periods during which the use of net operating loss carryforwards is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. 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 our own manufacturing facility for cell products (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 cytokine release syndrome (CRS), immune effector cell-associated neurotoxicity syndrome (ICANS), and/or immune effector cell-associated hemophagocytic lymphohistiocytosis-like syndrome (IEC-HS), which can be life-threatening and results in death. These events have been observed in our clinical trials and have resulted in pausing enrollment or requiring protocol amendments. For example, in our ongoing ALLO-316 TRAVERSE trial, we implemented risk mitigation measures for IEC-HS, which delayed and increased the cost of conducting the clinical trial.

In our ALPHA3 trial, we are advancing cema-cel for the treatment of patients with LBCL who have completed R-CHOP and have attained a remission, but who still test positive for minimal residual disease (MRD). As part of this trial, under Investigational Device Exemption (IDE), we 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 comparable foreign regulatory authorities and the criteria these regulators use to determine the safety and efficacy of a product candidate are determined according to the type, complexity, novelty and intended use and market of the potential products. The regulatory approval process for novel product candidates such as ours can be more complex and consequently more expensive and take longer than for other, better known or extensively studied pharmaceutical or other product candidates. For example, the regulatory approval process for cema-cel based on our ALPHA3 trial is more complex because it 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 European Commission and FDA for existing autologous CAR T therapies, such as Kymriah and Yescarta, may not be indicative of what these regulators may require for approval of our therapies. Also, the use of healthy donor material in our allogeneic CAR T product candidates may create product variability challenges for us, and we do not yet fully understand the impact of donor variability on clinical outcomes.

More generally, approvals by any regulatory agency may not be indicative of what any other regulatory agency may require for approval or what such regulatory agencies may require for approval in connection with new product candidates. Moreover, our product candidates may not perform successfully in clinical trials or may be associated with adverse events that distinguish them from the autologous CAR T therapies that have previously been approved. For instance, allogeneic product candidates may result in graft-versus-host disease (GvHD) or chromosomal abnormalities not experienced with autologous products. Additionally, any Phase 2 trial results, such as in the ALPHA3 trial, may not be representative of Phase 1 results, which were based on limited patients and a patient population in an advanced stage or LBCL. 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 B-cell maturation antigen (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'

[Table of Contents](#)

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.

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

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

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

Future undesirable or unacceptable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign regulatory authorities. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. Approved autologous CAR T therapies and those under development have shown frequent rates of CRS, neurotoxicity, 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

[Table of Contents](#)

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 our Annual Report.

As we treat and re-treat more patients with our product candidates in our clinical trials, new less common side effects may also emerge or increased incidence of previously observed side effects may occur. There is a risk that the FDA or other comparable foreign regulatory authorities may not agree that sufficient mitigating procedures are included in our protocols to address such side effects, and FDA or other comparable foreign regulatory authorities may impose a clinical hold as it evaluates risks associated with such side effects and/or as we work with the agency to implement protocol amendments to appropriately manage such side effects. For instance, we observed a chromosomal abnormality that led to a previous clinical hold on our clinical trials. While our investigation concluded that the chromosomal abnormality had no clinical significance and was unrelated to our manufacturing process, our 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 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.

[Table of Contents](#)

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

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

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

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

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

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

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

In addition, we have an open IND for ALLO-647, which is being used as part of lymphodepletion in 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 CROs and clinical study sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical study sites;
- delays in obtaining required IRB approval or approval of other ancillary regulatory committees at each clinical study site;
- imposition of a temporary or permanent clinical hold by regulatory agencies for a number of reasons, including after review of an IND application or amendment, or equivalent application or amendment; as a result of a new safety finding that presents uncertain or unreasonable risk to clinical trial participants; a negative finding from an inspection of our clinical study operations or study sites; developments on trials conducted by competitors for related technology that raises FDA or other comparable foreign regulatory authority concerns about risk to patients of the technology broadly; or if the FDA or other comparable foreign regulatory authorities find that the investigational protocol or plan is clearly deficient to meet its stated objectives;
- delays in recruiting suitable patients to participate in our clinical studies;
- difficulty collaborating with patient groups and investigators;
- failure by our CROs, other third parties or us to adhere to clinical study requirements;
- failure to perform in accordance with the FDA's good clinical practices (GCP) requirements or equivalent regulatory guidelines in other countries;
- delays or failures in the transfer of manufacturing processes to any CDMO or our own manufacturing facility or any other development or commercialization partner for the manufacture of product candidates;
- delays in having patients complete participation in a study or return for post-treatment follow-up;
- patients dropping out of a study;
- occurrence of adverse events associated with the product candidate that are viewed to outweigh its potential benefits;
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols;
- changes in the standard of care on which a clinical development plan was based, which may require new or additional trials;
- the cost of clinical studies of our product candidates being greater than we anticipate;
- clinical studies of our product candidates producing negative or inconclusive results, which may result in our deciding, or regulators requiring us, to conduct additional clinical studies or abandon product development programs;
- delays or failure to secure supply agreements with suitable raw material suppliers, or any failures by suppliers to meet our quantity or quality requirements for necessary raw materials; and

[Table of Contents](#)

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

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

We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. For example, as we progress the 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;

[Table of Contents](#)

- the competition from approved products in the same or other lines of therapy and and/or disease indications and from product candidates in other clinical trials; and
- the risk that patients enrolled in clinical trials will drop out of the trials before the infusion of our product candidates or trial completion.

Since we only need to conduct a limited number of manufacturing runs to generate clinical supply, the diversity of our supply is limited during clinical trials. As a result, some patients may have antibodies to certain donor specific antigens at titers that could negatively impact the activity of our product candidates and which would render the patients ineligible for treatment. Furthermore, cellular mechanisms of allogeneic tissue rejection may limit the efficacy of our products. In addition, we have introduced an *in vitro* companion diagnostic (IVD) assay in the TRAVERSE trial to screen for patients with CD70+ tumors and 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 or our partners make to the assay(s) during development may reduce the pace of enrollment or may lead to alterations in the expected benefit risk profile as compared to results collected prior to the change. The diagnostic assay itself may not perform as expected due to identifiable or obscure factors. It is also possible that we may not be aware of such underperformance of the assay which could lead to incorrect conclusions. This could, in turn, impact enrollment and interpretation of the clinical trial results.

Our clinical trials will also compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. For example, our collaboration with Foresight Diagnostics is nonexclusive. As a result, there is a risk that Foresight Diagnostics might work with our competitors to enable a competing clinical trial involving the same MRD positive patient population that we plan to enroll in ALPHA3, which would reduce the number of patients who are available to participate in ALPHA3, and potentially delay completion of ALPHA3. Since the number of qualified clinical investigators is limited, some of our clinical trial sites are also being used by some of our competitors, which may reduce the number of patients who are available for our clinical trials in that clinical trial site.

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

Moreover, because our product candidates represent a departure from more commonly used methods for 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 relapsed/refractory (R/R) multiple myeloma, as described under the section entitled "Business—Competition" included in our 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 or other comparable foreign regulatory authority approval. Similar conditions may apply if we make process changes to our product candidates, as we plan to do for our BCMA program. In addition, any process or raw material change could introduce unacceptable product variability and impact our ability to manufacture on a consistent and reproducible basis. Ultimately, any failure or delays in manufacturing and qualification of our product candidates at our CDMO or at our own manufacturing facility could delay our clinical trials.

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

The manufacture of biopharmaceutical products is complex and requires significant expertise, including the development of advanced manufacturing techniques and process controls. Manufacturers of cell therapy products often encounter difficulties in production, particularly in validating initial production and ensuring the absence of contamination. Other problems can include difficulties with production costs and yields, quality control, including stability of the product, operator error, shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. The application of new regulatory guidelines or parameters, such as those related to release testing, may also

[Table of Contents](#)

adversely affect our ability to manufacture our product candidates. Furthermore, if contaminants are discovered in our supply of product candidates or in the manufacturing facilities, such supply may have to be discarded and our manufacturing facility may need to be closed for an extended period of time to investigate and remedy the contamination. We cannot assure you that any stability or other issues relating to the manufacture of our product candidates will not occur in the future.

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

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

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

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

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

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

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

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

- differing regulatory requirements in foreign countries;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- 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 product candidates for use in limited circumstances. For additional information regarding our competition, see the section entitled "Business—Competition" included in our 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 or upon the achievement of certain key strategic goals. The value to employees of stock options and RSU awards that vest over time or upon achieving goals have been significantly affected by movements in our stock price that are beyond our control and may at any time be insufficient to counteract more lucrative offers from other companies. We completed an option exchange program in July 2022 to alleviate the significant number of employee options that were underwater at that time. Our stock price has significantly declined since the option exchange program and a significant number of our employee options remain underwater and may not provide the intended incentive for employees to remain at our company. Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us on short notice. Although we have employment agreements with our key employees, these employment agreements provide for at-will employment, which means that any of our employees could leave our employment at any time, with or without notice. We do not maintain "key person" insurance policies on the lives of these individuals or the lives of any of our other employees. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level and senior managers as well as junior, mid-level and senior scientific and medical personnel.

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;
- 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.

[Table of Contents](#)

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

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

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

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

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

We actively evaluate various strategic transactions on an ongoing basis. We may acquire other businesses, products or technologies as well as pursue joint ventures or investments in complementary businesses. The success of our strategic transactions, including our acquisition of CAR T cell assets from Pfizer, licenses with Cellectis, Servier, Notch, Antion, our strategic collaboration with Foresight Diagnostics, and our joint venture with 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;
- disagreements regarding each party's contractual rights and obligations under our partnership agreements;
- costs and uncertainties related to managing disputes with any strategic partners;
- increases in our expenses and reductions in our cash available for operations and other uses;
- inability of our strategic partners to access suitable capital;
- disruption in or termination of our relationships with collaborators or suppliers as a result of such a transaction; and
- possible write-offs or impairment charges relating to acquired businesses or joint ventures.

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

Additionally, foreign acquisitions and joint ventures are subject to additional risks, including those related to integration of operations across different cultures and languages, currency risks, potentially adverse tax consequences of overseas operations and the particular economic, political and regulatory risks associated with specific countries. For instance, our joint venture with 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 with whom we work, are or were compromised or the security, confidentiality, integrity or availability of our information technology, software, services, networks, communications or data is compromised, limited or fails, we could experience a material adverse impact.*

In the ordinary course of our business, we and the third parties with whom we work collect, process, receive, store, use, generate, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, process) proprietary, confidential and sensitive information, including personal data (including health information), intellectual property, trade secrets, information we collect about patients in connection with clinical trials, and proprietary business information owned or controlled by ourselves or other parties (collectively, sensitive information). We work with 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 with whom we work) 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 with whom we work. Such threats are prevalent and are increasing in their frequency, sophistication and intensity, and have become increasingly difficult to detect. These threats come from a variety of sources, including traditional computer "hackers," "hacktivists," organized criminal threat actors, threat actors, personnel (such as through theft or misuse), sophisticated nation-states, and nation-state-supported actors. Some actors now engage and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we, and the third parties with whom we work, may be vulnerable to a heightened risk of these attacks, including retaliatory cyber-attacks, that could materially disrupt our systems and operations, supply chain, and ability to produce and distribute our product candidates. We and the third parties with whom we work are subject to a variety of evolving threats, including but not limited to social-engineering attacks (including through deep fakes, which may be increasingly more difficult to identify as fake, and phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service credential stuffing attacks, credential harvesting, adware, ransomware, supply chain attacks, personnel misconduct or error, attacks enhanced or facilitated by AI, and other similar threats. Our information technology systems and data may also be subject to failure or disruption from software bugs, server malfunction, software or hardware failures, loss of data or other information technology assets, telecommunications failures, natural disasters such as earthquakes, fires, and floods, and other similar issues.

In particular, severe ransomware attacks are becoming increasingly prevalent and severe and can lead to significant interruptions, delays, or outages in our operations, disruptions to our clinical trials, loss of data (including data related to clinical trials), significant expense to restore data or systems, reputational loss and the diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments. In addition, our reliance on third-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.

[Table of Contents](#)

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 with whom we work) 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 with whom we work). 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 they may be exploited and could result in a security incident. 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, or to implement other requirements, such as providing credit monitoring. Such disclosures and compliance with such requirements are costly, and the disclosures or the failure to comply with such requirements could lead to adverse consequences. If we (or a third party with whom we work) 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 publicity, loss of investor or partner confidence in the effectiveness of our cybersecurity measures, diversion of management's attention, governmental investigations, lawsuits, and the expenditure of significant capital and other resources.

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

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

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

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

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

Disruptions at the FDA and other agencies or other comparable foreign regulatory authorities may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. 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 and the third parties with whom we work 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 (or the third parties with whom we work) actual or perceived failure to comply with such obligations could lead to enforcement or litigation (including class claims) and mass arbitration demands, fines or penalties, a disruption of clinical trials or commercialization of products, reputational harm, or other adverse business effects.*

In the ordinary course of business, we process sensitive information. Accordingly, we are, 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 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

[Table of Contents](#)

transmission of individually identifiable health information. Among other things, HITECH, through its implementing regulations, makes certain of HIPAA's privacy and security standards directly applicable to business associates, defined as a person or organization, other than a member of a covered entity's workforce, that creates, receives, maintains or transmits protected health information for or on behalf of a covered entity for a function or activity regulated by HIPAA as well as their covered subcontractors.

In the past few years, numerous U.S. states have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal data. As applicable, such rights may include the right to access, correct, or delete certain personal data, and to opt-out of certain data processing activities, such as targeted advertising, profiling, and automated decision-making. The exercise of these rights may impact our business and ability to provide our products and services. Certain states also impose stricter requirements for processing certain personal data, including sensitive information, such as conducting data privacy impact assessments. These state laws allow for statutory fines for noncompliance. For example, the California Consumer Privacy Act of 2018 (CCPA), applies to personal data of consumers, business representatives, and employees who are California residents, and requires covered companies to provide specific disclosures in privacy notices and honor requests of such individuals to exercise certain privacy rights. The CCPA provides for fines of up to \$7,500 per intentional violation and allows private litigants affected by certain data breaches to recover significant statutory damages. The CCPA and other comprehensive U.S. state privacy laws exempt some data processed in the context of clinical trials, but these developments may further complicate compliance efforts, and increase legal risk and compliance costs for us, the third parties with whom we work. Such laws may significantly impact our business activities, exemplifying the vulnerability of our business to evolving regulatory environment related to personal data and protected health information. Similar laws are being considered in other states, as well as at the federal and local levels, and we expect more states to pass similar laws in the future.

Outside the United States, 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 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. The United States is also increasingly scrutinizing certain data transfers and may also impose certain data localization requirements, particularly if we transfer personal data to, or process personal data of residents of, high risk or sanctioned jurisdictions.

[Table of Contents](#)

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

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

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

Regardless of the merits or eventual outcome, liability claims may result in:

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

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

Risks Related to the Development of Our Product Candidates

Our engineered allogeneic T cell product candidates represent a novel approach to cancer treatment 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 comparable foreign 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.

Cellectis' TALEN technology, which we use in our oncology programs, and Arbor's CRISPR technology, which we use in our AID program, both involve relatively new approaches to gene editing, using sequence-specific DNA-cutting enzymes, or nucleases, to perform precise and stable modifications in the DNA of living-cells and organisms, and we have very little experience with Arbor's CRISPR technology. Cellectis and Arbor have not created nucleases for all gene sequences that we may seek to target, and they may not agree to or have difficulty creating nucleases for other gene sequences that we may seek to target, which could limit the usefulness of this technology. This technology may also not be shown to be effective in clinical studies that Cellectis, we or other licensees of Cellectis technology or Arbor's CRISPR technology may conduct, or may be associated with safety issues that may negatively affect our development programs. For instance, gene-editing may create unintended changes to the DNA such as a non-target site gene-editing, a large deletion, or a DNA translocation, any of which could lead to oncogenesis. In our ALPHA2 trial, we observed a chromosomal abnormality, and the FDA placed our clinical trials on hold following this observation. While our investigation concluded that gene editing was not responsible for the chromosomal abnormality and the hold was resolved, we may discover future abnormalities caused by gene editing or other factors that would impact our development plans. The gene editing of our product candidates may also not be successful in limiting the risk of GvHD or premature rejection by the patient.

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

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

A critical aspect to manufacturing allogeneic T cell product candidates involves gene editing the healthy donor T cells in an effort to avoid GvHD and to limit the patient's immune system from attacking the allogeneic T cells. GvHD results when allogeneic T cells start recognizing the patient's normal tissue as foreign. For our oncology product candidates, we use Cellectis' TALEN gene-editing technology to inactivate a gene coding for 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 Cellectis for exclusive rights to use TALEN technology for 15 select cancer targets, including BCMA, FLT3, CD70, DLL3, Claudin 18.2 and other targets included in our pipeline. We also rely on Cellectis, through our agreement with Servier, for exclusive rights to UCART19, ALLO-501 and cema-cel. Any other gene-editing technology used to research and develop product candidates directed at targets not covered by our existing agreements with Cellectis and Servier will require significant investment and time for advancement. In addition, the Cellectis gene-editing technology may fail to produce viable product candidates. Moreover, both Servier and Cellectis may terminate our respective agreements in the event of a material breach of the agreements, or upon certain insolvency events. Cellectis has challenged and may in the future challenge certain performance by Servier, such as its development of products licensed under the Cellectis-Servier Agreement in 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 Cellectis, or future disputes with us, may have adverse consequences.*

On September 15, 2022, Servier sent a notice of discontinuation (Discontinuation) of its involvement in the development of CD19, including the CD19 Products pursuant to the Servier Agreement. 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. We subsequently agreed to a review of our manufacturing costs of CD19 Products. 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.

In May 2024 we entered into the Servier Amendment which we believe resolves all current disputes with Servier including those raised in Servier's December 2022 and July 2023 correspondence, and which includes mutual waivers and releases with respect to such disputes. In addition, under the Servier Amendment Servier agreed to expand our licensed territory under the Servier Agreement to include the European Union and the United Kingdom, and granted us an option, under certain circumstances, to expand the territory further to include China (including Hong Kong) and Japan. Although we have resolved all current disputes with Servier, there can be no assurance that we will not have future disputes with Servier regarding our respective rights and obligations under our agreements and any future dispute could jeopardize our CD19 Products license, the loss of which would have a significant adverse impact on our business, financial condition, and prospects.

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

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

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

In the prior CALM and PALL trials, a commercially available monoclonal antibody, alemtuzumab, that binds CD52 was used. Alemtuzumab is known to have risk of causing certain adverse events. In 2020, within the context of a procedure based on Article 20 of Regulation 726/2004 (EMA Regulation), the EMA completed a pharmacovigilance review of alemtuzumab in the context of the treatment of multiple sclerosis following reports of immune-mediated conditions and problems affecting the heart and blood vessels, including fatal cases. The EMA recommended that alemtuzumab should not be used in patients with certain heart, circulation or bleeding disorders or in patients who have autoimmune disorders other than multiple sclerosis. The EMA also recommended that alemtuzumab only be given in a hospital with ready access to intensive care facilities and specialists who can manage serious adverse reactions. The use of our anti-CD52 antibody may result in the same or similar adverse events as alemtuzumab, and we have chosen to administer our product candidates at trial centers experienced at managing patients with advanced malignancies as well as toxicities associated with immunomodulatory therapies, which significantly limits the sites that are eligible to participate in our clinical trials. If the EMA or other regulatory agencies further limit the use of alemtuzumab or anti-CD52 antibodies, our clinical program would be adversely affected.

To secure our own readily available source of anti-CD52 antibody, we are developing our own monoclonal anti-CD52 antibody, ALLO-647, which we use in 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

[Table of Contents](#)

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 our Annual Report for information on safety events.

If we are unable to successfully develop and manufacture ALLO-647 in the timeframe we anticipate, or at all, such as if regulatory authorities do not agree with our selected dose or approve of the use of ALLO-647 in combination with our allogeneic T cell product candidates, our clinical trial timelines and ability to commercialize 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 not and will not be our employees and, except for remedies available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our ongoing preclinical, clinical and nonclinical programs. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical studies or other drug development activities, which could affect their performance on our behalf. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to complete development of, obtain regulatory approval of or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.

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

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

While we utilize CF1 for clinical manufacturing of our 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

[Table of Contents](#)

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.

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 CF1 and are in the process of transitioning the manufacturing 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 or other comparable foreign regulatory authorities may have questions regarding any replacement contractor. This may require new testing and regulatory interactions. In addition, a new manufacturer would have to be educated in, or develop substantially equivalent processes for, production of our products after receipt of FDA or other comparable foreign regulatory authorities questions, if any.
- Our third-party manufacturers might be unable to timely formulate and manufacture our product or produce the quantity and quality required to meet our clinical and commercial needs, if any.
- Contract manufacturers may not be able to execute our manufacturing procedures appropriately.
- Contract manufacturers may be subject to adverse legislative actions.
- Manufacturers are subject to ongoing periodic unannounced inspection by the FDA, the Drug Enforcement Administration and corresponding state agencies or other comparable foreign regulatory authorities to ensure strict compliance with cGMP and other government regulations and corresponding foreign standards. We do not have control over third-party manufacturers' compliance with these regulations and standards.
- We may not own, or may have to share, the intellectual property rights to any improvements made by our third-party manufacturers in the manufacturing process for our products.
- Our future contract manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store and distribute our products.
- Our third-party manufacturers could breach or terminate their agreement with us.

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

[Table of Contents](#)

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

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

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

We have strict specifications for donor material, which include specifications required by regulatory authorities. If we are unable to identify and obtain donor material that satisfy specifications, agree with regulatory authorities on appropriate specifications, or address variability in donor T cells, there may be inconsistencies in the product candidates we produce or we may be unable to initiate or continue clinical trials on the timelines we expect, which could harm our reputation and adversely impact our business and prospects.

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

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

Our product candidates require many specialty raw materials, including viral vectors that deliver the CAR sequence and electroporation technology, some of which are manufactured by small companies with limited resources and experience to support a commercial product, and the suppliers may not be able to deliver raw materials to our specifications. We do not have contracts with many of the suppliers, and we may not be able to contract with them on acceptable terms, or at all. As a result of logistical challenges and recent inflation, we may experience higher costs or delays in receiving, or fail to secure entirely, key raw materials to support clinical or commercial manufacturing. Certain raw materials also require third-party testing, and some of the testing service companies may not have capacity or be able to conduct the testing that we request.

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

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

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

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

Our research and development activities involve the controlled use of potentially hazardous substances, including chemical and biological materials. We and our suppliers are subject to federal, state and local laws and regulations in the United States governing the use, manufacture, storage, handling and disposal of medical and hazardous materials, and there is a risk of contamination or injury resulting from medical or hazardous materials. For instance, we have had and may continue to have environmental notice of violations at our manufacturing facility. As a result of any such contamination or injury, we may incur liability or local, city, state or federal authorities may curtail the use of these materials and interrupt our business operations. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. We do not have any insurance for liabilities arising from medical or hazardous materials. In addition, we have previously shipped certain materials to 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 and other comparable foreign regulatory approval processes are lengthy and time-consuming, and we may experience significant delays in the clinical development and regulatory approval of our product candidates.*

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

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

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

- obtaining regulatory authorization to begin a trial, if applicable, including regulatory approval of any companion diagnostic, if applicable;
- the availability of financial resources to commence and complete the planned trials;
- reaching agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- developing and implementing processes and procedures with collaborators relating to the collection and transfer of patient samples and the timely performance of a companion diagnostic on such samples;
- obtaining approval at each clinical trial site by an independent IRB or a positive opinion from an Ethics Committee;

- obtaining regulatory and other approvals to modify the conduct of a clinical trial;
- recruiting suitable patients to participate in a trial;
- delays by a collaboration partner in running a companion diagnostic on patient samples;
- having patients complete a trial, including having patients enrolled in clinical trials dropping out of the trial prior to treatment, or return for post-treatment follow-up;
- clinical trial sites deviating from trial protocol or dropping out of a trial;
- addressing any patient safety concerns that arise during the course of a trial;
- adding new clinical trial sites; or
- manufacturing sufficient quantities of qualified materials under cGMPs, releasing product in accordance with specifications, and delivering product candidates for use in clinical trials.

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

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

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

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

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

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

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

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

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

The general approach for FDA or comparable foreign regulatory authorities approval of a new biologic or drug is for the sponsor to provide dispositive data from two well-controlled, Phase 3 clinical studies of the relevant biologic or drug in the relevant patient population. Phase 3 clinical studies typically involve hundreds of patients, have significant costs and take years to complete. We expect ongoing FDA, EMA, or comparable foreign regulatory authorities feedback on our trials, some of which may lead to changes in the trials, which could cause future delays to our trials. In addition, even if we believe the results are sufficiently compelling, such as for the ALPHA2 (CLL) and ALPHA3 trials, the FDA, EMA, or comparable foreign regulatory authorities could ultimately require longer-term follow-up results, additional data from our clinical trials or additional trials that could delay or prevent our first BLA submission. The FDA, EMA, or comparable foreign regulatory authorities may require that we conduct a comparative trial against an approved therapy including potentially an approved autologous T cell therapy, which would significantly delay our development timelines and require substantially more resources. In addition, the FDA, EMA, or comparable foreign regulatory authorities may only allow us to evaluate patients that have failed or who are ineligible for autologous therapy, which are extremely difficult patients to treat and patients with advanced and aggressive cancer, and our product candidates may fail to improve outcomes for such patients.

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

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

- the inability to resolve any future clinical hold;
- the FDA, EMA, or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA, EMA, or comparable foreign regulatory authorities that our product candidates are safe and effective for any of their proposed indications;

[Table of Contents](#)

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

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

As we are concurrently developing ALLO-647 to be used as part of the lymphodepletion regimen for our allogeneic CAR T cell product candidates, mapping a co-development path for dual approval of ALLO-647 and any of our CAR T cell product candidates and coordinating concurrent review with different divisions of competent regulatory authorities. As an example, the 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 through part one of the ALPHA3 trial. Some clinical trial sites may elect not to participate, and we cannot be certain when or whether we will be able to successfully enroll the ALPHA3 trial in a timely manner or that the outcome of this study will support FDA approval of both cema-cel and ALLO-647. Any delays to ALLO-647 approval could delay any approval or commercialization of our allogeneic CAR T cell product candidates. We anticipate that the EMA, or comparable foreign regulatory authorities will impose equivalent obligations as part of the marketing authorization process in their territory.

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

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

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

of the IVDR. Compliance with these requirements is a prerequisite to be able to affix the CE mark to devices, without which they cannot be marketed or sold in the EEA. To demonstrate compliance with the GSPR laid down in Annex I to the IVDR, and obtain the right to affix the CE mark, IVD manufacturers must conduct a conformity assessment procedure, which varies according to the type of IVD and its classification. Companion diagnostics must undergo a conformity assessment by a Notified Body. If the related medicinal product has, or is in the process of, been authorised through the centralized procedure for the authorization of medicinal products, the notified body will, before it can issue a CE Certificate of Conformity, be required to seek a scientific opinion from the EMA on the suitability of the companion diagnostic for use in relation to the medicinal product concerned. For medicinal products that have or are in the process of authorisation through any other route provided in European Union legislation, the Notified Body must seek the opinion of the national competent authority of an EU Member State. 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. Additionally, Foresight Diagnostics has not sought approval of PhasEd-Seq in the EU, and there can be no assurance that Foresight Diagnostics will be able to do so in a timely manner, or at all, to support approval of cema-cel in the EU.

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 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 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

[Table of Contents](#)

shortened due to congressional action or otherwise, or that the FDA will not consider the subject product candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of the reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

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

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

The use of engineered T cells as a potential cancer treatment is a recent development and may not become broadly accepted by physicians, patients, hospitals, cancer treatment centers and others in the medical community. We expect physicians in the large bone marrow transplant centers to be particularly important to the market acceptance of our products and we may not be able to educate them on the benefits of using our product candidates for many reasons. For example, certain of the product candidates that we will be developing target a cell surface marker that may be present on cancer cells as well as non-cancerous cells. It is possible that our product candidates may kill these non-cancerous cells, which may result in unacceptable side effects, including death. Additional factors will influence whether our product candidates are accepted in the market, including:

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

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

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

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

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

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

The advancement of healthcare reform may negatively impact our ability to sell our product candidates, if approved, profitably.

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

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

There is an increasing focus from certain investors, employees, partners, and other stakeholders concerning ESG matters. 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.*

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

[Table of Contents](#)

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, we previously had a dispute with Servier regarding our respective rights and obligations under the Servier Agreement. In May 2024, we entered into the Servier Amendment with Servier which amended the Servier Agreement and resolved all pending disputes between us and Servier. There can be no assurance that further disputes with Servier will not arise or that we would be able to amicably settle any such further disputes. 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, the European Union and the United Kingdom. We also have an exclusive worldwide license from Cellectis to its TALEN gene-editing technology for the development of allogeneic T cell product candidates directed against 15 different cancer antigens. The Servier Agreement gives us access to TALEN gene-editing technology for all product candidates under the agreement. Certain intellectual property which is covered by these agreements may have been developed with funding from the U.S. government. If so, our rights in this intellectual property may be subject to certain research and other rights of the government.

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

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

Composition of matter patents for biological and pharmaceutical products such as CAR-based product candidates often provide a strong form of intellectual property protection for those types of products, as such patents provide protection without regard to any method of use. We cannot be certain that the claims in our pending patent applications covering compositions of matter of our product candidates will be considered patentable by the United States Patent and Trademark Office (USPTO) or

[Table of Contents](#)

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 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.

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

[Table of Contents](#)

established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities.

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

Competitors may infringe our patents or the patents of our licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that one or more of our patents is not valid or is unenforceable or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated, held unenforceable or interpreted narrowly and could put one or more of our pending patent applications at risk of not issuing. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure.

Interference proceedings provoked by third parties or brought by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our licensors. An unfavorable outcome could result in a loss of our current patent rights and could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Litigation or interference proceedings may result in a decision adverse to our interests and, even if we are successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent, alone or with our licensors, misappropriation of our trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as in the United States.

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

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

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

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

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

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

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

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

If we or one of our licensing partners initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that the patent covering our product candidate, as applicable, is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include IPR, ex parte re-examination and post grant review in the United States, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover and protect our product candidates. The outcome following legal assertions of unpatentability, invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we, our patent counsel and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of unpatentability, invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates. Such a loss of patent protection could have a material adverse impact on our business.

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

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

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

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

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries where 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;
- 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;

[Table of Contents](#)

- 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 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 Quarterly 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 March 31, 2024. For a discussion of management's consideration of the material weakness identified, see Part I Item 4: Controls and Procedures included in this Quarterly 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 continue 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, which 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 are implementing 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.

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

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

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

General Risk Factors

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

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

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

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

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

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

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

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

Servier Amendment

On May 10, 2024, we entered into the Servier Amendment with Servier, pursuant to which the parties settled their disputes relating to each party's performance under the Servier Agreement. The parties agreed to waive any and all outstanding claims that were asserted relating to alleged violations of the Servier Agreement, including all claims that such party was entitled to various payments or refunds from the other party under the Servier Agreement, and any and all claims that either party now has or may have in the future related to such outstanding claims, and mutual releases with respect to such claims were granted.

Additionally, the Servier Amendment expanded our territory under the Servier Agreement to include the European Union and the United Kingdom, and provides for an option to further expand our territory to include China and Japan. Under the Servier Amendment all of our future milestone payments (regulatory and sales) under the Servier Agreement are modified to be the same as, and to coincide with, Servier's milestone payments to Cellectis under the Servier-Cellectis Agreement. The Servier Amendment also modified the royalties payable under the Servier Agreement. See Note 13. Subsequent Events to our condensed consolidated financial statements included elsewhere in this report for further description of the Servier Amendment.

Item 6. Exhibits.

Exhibit number	Description of document
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).
10.1+	Non-employee director compensation policy, as amended.
10.2* ‡	Amended and Restated Collaboration and License Agreement, dated January 17, 2024, by and between the Registrant and Notch Therapeutics Inc. (incorporated by reference to Exhibit 10.18 to the Registrant's Annual Report on Form 10-K, filed with the SEC on March 14, 2024).
10.3*	Strategic Collaboration Agreement, dated January 3, 2024, by and between Foresight Diagnostics, Inc. and the Registrant (incorporated by reference to Exhibit 10.30 to the Registrant's Annual Report on Form 10-K, filed with the SEC on March 14, 2024).
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended.
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended.
32.1	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document - The instance document does not appear in the interactive data file because its XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document.
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
104	The cover page from the Company's Quarterly Report on Form 10-Q has been formatted in Inline XBRL.

+ Indicates management contract or compensatory plan.

* Certain portions of this exhibit (indicated by "[***]") have been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K because it is both not material and is the type of information that the Registrant treats as private or confidential.

‡ Schedules have been omitted pursuant to Item 601(a)(5) of Regulation S-K.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Date: May 13, 2024

By: /s/ David Chang

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

President and Chief Executive Officer
(*Principal Executive Officer*)

Date: May 13, 2024

By: /s/ Geoffrey Parker

Geoffrey Parker

Chief Financial Officer
(*Principal Financial and Accounting Officer*)

ALLOGENE THERAPEUTICS, INC.
NON-EMPLOYEE DIRECTOR COMPENSATION POLICY ADOPTED:
SEPTEMBER 26, 2018
AMENDED: APRIL 16, 2019
AMENDED: SEPTEMBER 17, 2019
AMENDED: SEPTEMBER 13, 2023
AMENDED: March 28, 2024

Each member of the Board of Directors (the “**Board**”) of Allogene Therapeutics, Inc. (the “**Company**”) who is a non-employee director of the Company (each such member, a “**Non- Employee Director**”) will receive the compensation described in this Non-Employee Director Compensation Policy (the “**Director Compensation Policy**”) for his or her Board service following the closing of the initial public offering of the Company’s common stock (the “**IPO**”).

A Non-Employee Director may decline all or any portion of his or her compensation by giving notice to the Company prior to the date cash is to be paid or equity awards are to be granted, as the case may be.

Annual Cash Compensation

Commencing January 1, 2019, each Non-Employee Director will receive the cash compensation set forth below for service on the Board. The annual cash compensation amounts will be payable in equal quarterly installments, in arrears following the end of each quarter in which the service occurred, pro-rated for any partial months of service. All annual cash fees are vested upon payment.

1. Annual Board Service Retainer:
 - a. All Eligible Directors: \$40,000
2. Annual Committee Member Service Retainer:
 - a. Member of the Audit Committee: \$12,500
 - b. Member of the Compensation Committee: \$7,500
 - c. Member of the Nominating and Corporate Governance Committee: \$5,000
 - d. Member of the Research and Development Committee: \$10,000

3. Annual Committee Chair Service Retainer (in lieu of Committee Member Service Retainer)

- a. Chair of the Audit Committee: \$25,000
- b. Chair of the Compensation Committee: \$15,000
- c. Chair of the Nominating and Corporate Governance Committee: \$10,000
- d. Chair of the International and Business Development Oversight Committee: \$100,000
- e. Chair of the Research and Development Committee: \$ 20,000

In addition, the members of the International and Business Development Oversight Committee, excluding the Chair, are eligible to receive compensation of \$3,500 per meeting, and the members of the Research and Development Committee are eligible to receive compensation of \$5,000 per annual Scientific Advisory Board meeting that they attend.

Equity Compensation

Equity awards will be granted under the Company's Amended and Restated 2018 Equity Incentive Plan (the **Plan**"), adopted in connection with the IPO. All stock options granted under this policy will be Nonstatutory Stock Options (as defined in the Plan), with a term of ten years from the date of grant and an exercise price per share equal to 100% of the Fair Market Value (as defined in the Plan) of the underlying common stock of the Company on the date of grant.

(a) Automatic Equity Grants.

(i) **Initial Grant for New Directors.** Without any further action of the Board, each person who, after the IPO, is elected or appointed for the first time to be a Non-Employee Director will automatically, upon the date of his or her initial election or appointment to be a Non-Employee Director (or, if such date is not a market trading day, the first market trading day thereafter), be granted (i) a Nonstatutory Stock Option to purchase shares of common stock of the Company (the "**Initial Option Grant**") and (ii) a restricted stock unit award covering shares of common stock of the Company (the **Initial RSU Grant**"), whereby the Initial Option Grant and Initial RSU Grant shall together have a total grant date value of \$600,000 (with the shares covered by the award rounded down to the nearest whole share). The recipient shall designate the proportionate share between the Initial Option Grant and Initial RSU Grant prior to or on the date of grant. The grant date value will be calculated in accordance with the Black-Scholes option valuation methodology or such other methodology as the Board or the Compensation Committee of the Board may determine prior to the grant of such award. Each Initial Option Grant will vest in a series of 36 successive equal monthly installments over the three-year period measured from

the date of grant. Each Initial RSU Grant will vest in a series of three successive equal annual installments over the three-year period measured from the date of grant.

(ii) **Annual Grant.** Without any further action of the Board, at the close of business on the date of each Annual Meeting following the IPO, each person who is then a Non-Employee Director will automatically be granted (i) a Nonstatutory Stock Option to purchase shares of common stock (the “**Annual Option Grant**”) and (ii) a restricted stock unit award covering shares of common stock of the Company (the “**Annual RSU Grant**”), whereby the Annual Option Grant and Annual RSU Grant shall together have a total grant date value of \$300,000 (with the shares covered by the award rounded down to the nearest whole share). The recipient shall designate the proportionate share between the Annual Option Grant and Annual RSU Grant prior to or on the date of grant. The grant date value will be calculated in accordance with the Black-Scholes option valuation methodology or such other methodology as the Board or the Compensation Committee of the Board may determine prior to the grant of such award. Each Annual Option Grant will vest in a series of 12 successive equal monthly installments over the one-year period measured from the date of grant. Each Annual RSU Grant will vest on the one-year anniversary of the date of grant.

(b) **Vesting; Change in Control.** All vesting is subject to the Non-Employee Director’s “**Continuous Service**” (as defined in the Plan) on each applicable vesting date. Notwithstanding the foregoing vesting schedules, for each Non-Employee Director who remains in Continuous Service with the Company until immediately prior to the closing of a “**Change in Control**” (as defined in the Plan), the shares subject to his or her then-outstanding equity awards that were granted pursuant to this policy will become fully vested immediately prior to the closing of such Change in Control.

(c) **Remaining Terms.** The remaining terms and conditions of each award, including transferability, will be as set forth in the Company’s Director Option Grant Package or Director RSU Grant Package, as applicable, in the forms adopted from time to time by the Board.

Expenses

The Company will reimburse Non-Employee Director for ordinary, necessary and reasonable out-of-pocket travel expenses to cover in-person attendance at and participation in Board and committee meetings; *provided*, that the Non-Employee Director timely submit to the Company appropriate documentation substantiating such expenses in accordance with the Company’s travel and expense policy, as in effect from time to time.

**CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, David Chang, M.D., Ph.D., certify that:

1. I have reviewed this quarterly report on Form 10-Q of Allogene Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 13, 2024

/s/ David Chang

David Chang, M.D., Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

**CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Geoffrey Parker, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Allogene Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 13, 2024

/s/ Geoffrey Parker

Geoffrey Parker
Chief Financial Officer
(Principal Financial and Accounting Officer)

**CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the quarterly report of Allogene Therapeutics, Inc. (the "Company") on Form 10-Q for the quarter ended March 31, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, David Chang, M.D., Ph.D., President and Chief Executive Officer of the Company, and I, Geoffrey Parker, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended (the "Exchange Act"); and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 13, 2024

/s/ David Chang

David Chang, M.D., Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

Date: May 13, 2024

/s/ Geoffrey Parker

Geoffrey Parker
Chief Financial Officer
(Principal Financial and Accounting Officer)

This certification shall not be deemed "filed" for purposes of Section 18 of the Exchange Act or otherwise subject to the liability of Section 18 of the Exchange Act. Such certification shall not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except to the extent that the Company specifically incorporates it by reference.